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**REPORT OF THE VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE REVISION OF  
BSE STANDARDS AND THE IMPACT OF THIS REVISION ON THE OFFICIAL STATUS  
RECOGNITION**

**21, 23, 28, 29, 30 June, and 1 July 2021**

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A virtual meeting of the OIE *ad hoc* Group on the revision of bovine spongiform encephalopathy (BSE) standards and its impact on the official status recognition (the Group) was held on 21, 23, 28, 29, 30 June, and 1 July 2021 to conduct an assessment of the impact of BSE revised provisions on the Members having an officially recognised BSE risk status by the OIE. The Group also addressed selected Members' comments referred by the Terrestrial Animal Health Standards Commission (Code Commission) during its review of the revised draft Chapters 11.4. and 1.8. at its February 2021 meeting.

This is a continuation of the work initiated by the *ad hoc* Group on BSE risk assessment which met in July<sup>1</sup> and November 2018<sup>2</sup>, the *ad hoc* Group on BSE surveillance which met in October 2018<sup>3</sup>, and the two *ad hoc* Groups on BSE risk assessment and surveillance which met in March 2019<sup>4</sup> and June 2020<sup>5</sup>.

## **1. Opening**

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, welcomed the Group on behalf of Dr Monique Eloit, Director General of the OIE.

Dr Stone commended the Group for the significant achievements made to date on the revision of BSE standards and their contribution to this work in the previous meetings and thanked the experts for their time, commitment, and involvement in the standard-setting process. Dr Stone welcomed Drs Baptiste Dungu and Bernardo Todeschini, respectively representing the Scientific Commission and the Code Commission at this meeting. Dr Stone reminded the Group that the purpose of the meeting was not to reassess the status of Members, but to determine if the issues that prevented a Member from gaining a negligible exposure assessment at the time when the official risk status was initially granted have been resolved since then based on the information submitted via the annual reconfirmations. A negligible exposure assessment was not previously required for the overall assessment of negligible or controlled risk, but it will be required following the revision of the standard. Following an inquiry from the Group regarding the potential impact of the revised BSE provisions on Members, Dr Stone clarified that the revised provisions have been developed based on scientific evidence to help Members to adapt and enhance their risk assessment and surveillance systems. He reiterated that the objective of this meeting was to assess the potential impact of the ongoing revision of the BSE standards on the official status recognition and to provide every opportunity for successful maintenance of Members' BSE risk status after the foreseen adoption of the new BSE standards in May 2022.

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<sup>1</sup> The July 2018 report of the meeting of the OIE *ad hoc* group on BSE risk assessment can be found [here](#):

<sup>2</sup> The November 2018 report of the meeting of the OIE *ad hoc* group on BSE risk assessment can be found [here](#):

<sup>3</sup> The October 2018 report of the meeting of the OIE *ad hoc* group on BSE surveillance can be found [here](#):

<sup>4</sup> The March 2019 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance can be found [here](#):

<sup>5</sup> The June 2020 report of the meeting of the OIE *ad hoc* group on BSE risk assessment and surveillance can be found [here](#):

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

Dr Neo Mapitse, Head of the OIE Status Department, provided a brief overview of the ToR and tentative daily agenda of the meeting. Finally, Dr Mapitse introduced the OIE Secretariat supporting the work of the Group and Dr Yoenten Phuentshok, participating as an observer, who recently joined the Status Department.

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

The Group was chaired by Dr Noel Murray and Dr Lesley van Helden acted as rapporteur, with the support of the OIE 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 Members already having an officially recognised BSE risk status**

According to the current provisions of Article 11.4.2. point 1. b) of the *Terrestrial Code*, an exposure assessment should be conducted if a risk factor is identified at the entry assessment. Consistent with this provision, some Members were granted an official BSE risk status based on a negligible risk of entry despite a non-negligible exposure assessment. The revised BSE provisions would 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. This requirement may have an impact on the BSE risk status of some Members already having an official status recognised by the OIE.

The OIE Status Department proposed an approach to assess the impact of the revised provisions on the recognised BSE risk status. This approach was endorsed by both the joint *ad hoc* Group on BSE risk assessment and surveillance at its March 2019 meeting, and by the Scientific Commission at its September 2019 meeting. The proposed approach had as objectives: a) to identify Members with a non-negligible exposure assessment at the time of official status recognition, b) to identify the issue(s) at the time of recognition that did not allow for a negligible exposure assessment, and c) to identify if the issue(s) had been addressed since the time of recognition.

Based on the above-mentioned approach, 18 out of 61 Members or zones having a BSE risk status were identified with a non-negligible exposure assessment at the time of official recognition: 14 out of 18 with negligible BSE risk status and four with controlled 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 for seven Members or zones having a negligible BSE risk status, and for one Member having a controlled BSE risk status. The Group recommended that these eight Members or zones submit additional information when reconfirming their BSE risk status in November 2021 to prevent any issue on their maintenance of BSE risk status once the new standards are adopted.

The Group also assessed a further seven Members having a negligible BSE risk status, and two Members and one zone having a controlled BSE risk status. For the Members having a negligible BSE risk status, the Group concluded that based on the information available in the dossiers submitted when their BSE risk status was initially recognised and the information provided annually to reconfirm their BSE risk status, their exposure assessments could still be considered negligible, and these Members would not be impacted by the new standards once they are adopted. For the Members and a zone having a controlled BSE risk status, the Group concluded that based on the information available in the dossiers submitted when their BSE risk status was initially recognised and the information provided annually to reconfirm their BSE risk status, their controlled BSE risk status would not be impacted by the new standards once they are adopted.

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

The Group took note of the recommendations made by the 2019 *ad hoc* Group on BSE risk assessment and surveillance, which were endorsed by the Scientific Commission at its 2019 September meeting, on the relevant information that Members will need to provide to show evidence of compliance with the revised Articles 11.4.3. and 11.4.4. of the *Terrestrial Code* to be retained on the list of countries or zones with negligible or controlled BSE risk status.

The Group highlighted that the main issue of the current annual reconfirmation form is the lack of consistency with the current questionnaire. In addition, the OIE Status Department pointed out that the lack of specificity and consistency between both annual reconfirmation form and questionnaire created confusion for Members on what relevant information to provide when reconfirming their BSE risk status. Moreover, the Group discussed the level of detail needed in the information to be provided by Members to comply with the revised standards and specifically under Point 2 of Article 11.4.18. related to surveillance.

Considering the above-mentioned topics, and guided by the revised standards, the Group drafted and agreed a proposed annual reconfirmation form. In addition, the Group suggested that Members be requested to provide an updated risk assessment when selected for comprehensive review by the Scientific Commission.

#### 5. Revision of the plan to obtain the ‘period for which the risk of recycling of BSE agents in the cattle population can be considered to be negligible’ for all Members with a BSE risk status

The Group acknowledged 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. Hence, provisions for trade of commodities are different for animals born within that period than for those born before. The Group made reference to the revised Article 11.4.10 “*Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk*” to emphasise the importance of making this information publicly available for trade purposes.

Based on an approach proposed by the OIE to determine this period for Members having a negligible or controlled BSE risk status, the Group concluded that this period would be calculated as the eight years preceding the year of official recognition of a negligible BSE risk status. However, for those Members having a controlled BSE risk status, the Group concluded that this period could not be determined and suggested that these Members submit evidence that could determine this period after the adoption of the new standards.

The Group acknowledged that it will be the OIE’s responsibility to determine a transparent way to make the information publicly available.

#### 6. Consideration of Member comments on the draft revised Chapter 11.4.

The Group considered selected Members’ comments on the draft revised Chapter 11.4 referred by the Code Commission during its February 2021 meeting.

##### a) Draft Article 11.4.2. General criteria for the determination of the BSE risk of a country, zone or compartment

The Group discussed a Member’s proposal to add ‘*sheep and goats*’ in the commodities that should be considered in the entry assessment under Point 1.a.i. The Group acknowledged the scientific evidence cited by the Member on the emergence of classical BSE from atypical/Nor98 scrapie in small ruminants<sup>6</sup>. The Group was of the opinion that although the evidence provided represents a hazard of interest, the revised standards account for mitigation strategies to avoid the exposure of cattle to ruminant-derived protein

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<sup>6</sup> Huor, A., Espinosa, J. C., Vidal, E., Cassard, H., Douet, J. Y., Lugan, S., Aron, N., Marín-Moreno, A., Lorenzo, P., Aguilar-Calvo, P., Badiola, J., Bolea, R., Pumarola, M., Benestad, S. L., Orge, L., Thackray, A. M., Bujdoso, R., Torres, J. M., & Andreoletti, O. (2019). The emergence of classical BSE from atypical/Nor98 scrapie. *Proceedings of the National Academy of Sciences of the United States of America*, 116(52), 26853–26862. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6936354/>

irrespective of the source of that ruminant-derived protein. Therefore, the Group considered that no further amendments to the revised provisions were needed. In addition, the Group reminded Members that in the exposure assessment, the revised provisions focus on ensuring that cattle are not exposed to ruminant-derived protein meal based on the livestock industry practices or mitigation measures.

With reference to Point 1.d., the Group considered the Code Commission's request to advise whether a description for other transmission pathways should be included in this point. The Group stressed that the transmission pathway referred to in this Article is the principal pathway accounting for the vast majority, if not all, of BSE transmission in cattle. Therefore, the Group considered it unnecessary to include further amendments in this Article.

The Group agreed with a Member's proposal to add the provision 'Indicate the period of time for which it can be considered that the risk of BSE agents being recycled in the cattle population has been negligible' under Point 1.d of the revised Article 11.4.2. The Group noted that this provision was already included in the questionnaire under Point 4.d. of the revised Article 1.8.5 and considered that it should also be included under Point 1.d of the revised Article 11.4.2.

**b) Draft Article 11.4.16bis. Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices**

The Group discussed a Member's request seeking clarification on the parameters for temperature, time and pressure to safely produce tallow derivatives under Point 3. The Group stated they could not specify any particular parameter because there is a wide variation in the conditions under which these products are produced, based on the evidence available in literature. The Group noted that these conditions have been accepted over the years in the current BSE Chapter, and in the absence of no new scientific evidence, suggested to maintain the text as it is.

The Group suggested a minor amendment in Point 3 of this Article to improve clarity.

## **7. Finalisation and adoption of the report**

The Group reviewed the draft report and agreed to circulate it electronically for comments before the final adoption.

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.../Appendices

Appendix I

**VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE REVISION OF BSE STANDARDS  
AND THE IMPACT OF THIS REVISION ON THE OFFICIAL STATUS RECOGNITION**

**21, 23, 28, 29, 30 June, and 1 July 2021**

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**Terms of reference**

**Purpose**

The purpose of this *ad hoc* Group (the Group) is to conduct an assessment of the impact of BSE revised provisions on the Members with a currently officially recognised status, and to provide independent analysis and advice to the OIE in response to the comments received from the Members regarding the revised draft Chapters 11.4 and 1.8 for the recognition and maintenance of BSE risk status as well as the recommendations for international trade.

The Group is convened under the authority of and reports to the OIE Director General.

**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 Chapter 11.4, Bovine spongiform encephalopathy (BSE). Since July 2018, the OIE has convened five *ad hoc* Groups on bovine spongiform encephalopathy (BSE) to complete the revision of the BSE standards: two *ad hoc* Groups on risk assessment (July 2018 and November 2018), one *ad hoc* Group on surveillance (October 2018), and two joint *ad hoc* Groups on risk assessment and surveillance (March 2019 and June 2020). During its September 2019 meeting, the Code Commission reviewed the reports of the first four *ad hoc* Group meetings and the opinion of the Scientific Commission regarding the revised draft chapter, and circulated the revised chapter for comments for the first time.

During its June 2020 meeting (second joint meeting), the Group reviewed the amendments made by the Code Commission at its February 2020 meeting on Chapter 11.4 upon circulation with Members for comments, and 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. The report of the second joint meeting by the Group was reviewed by the Code Commission at its September 2020 meeting, and the revised Chapters were circulated for second time for Members' comments. The Code Commission, at its February 2021 meeting, reviewed the comments received from Members on the revised Chapters and requested further expert advice on some comments.

Following the revision of BSE standards, an assessment of the impact of the revised provisions on currently officially recognized Members needs to be conducted to identify issues that can potentially affect their status. In a similar way, the requirements for maintenance of BSE risk status have to be in line with the revised provisions; therefore, the draft form for annual reconfirmation of BSE risk status also needs to be reviewed and finalised.

**Pre-requisites**

Group members should:

- Sign the OIE 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. Conduct the assessment of the impact that the revised BSE provisions may have on the status of Members currently officially recognised with a BSE risk status.

Propose the next steps to follow for each Member considering the information in the summary sheets prepared by the OIE Secretariat and any other relevant additional information. The purpose is to assist Members to comply with the revised BSE provisions as soon as possible to prevent suspensions in the future.

2. Revise and endorse the draft annual reconfirmation form for maintenance of BSE risk status.

Revise and endorse the draft annual reconfirmation form developed for maintenance of BSE risk status based on the conclusions of the *ad hoc* Group on the revision of BSE standards on risk assessment and surveillance that met in March 2019, which were endorsed by the Scientific Commission in September 2019.

3. Revise and endorse the plan to obtain and publish the ‘period for which the risk of recycling of BSE agents in the cattle population can be considered to be negligible’ for all Members with a BSE risk status.

4. Address the Members’ comments to the revision of Chapter 11.4.:

- a. Draft Article 11.4.16bis. (Recommendations for importation of tallow derivatives)

- \*Provide opinion on the requirements (temperature, time and pressure) of the methods used safely produce tallow derivatives.

- b. Draft Article 11.4.2. (The BSE risk of the cattle population of a country, zone or compartment)

- Consider the proposal of a Member in point 1 (a)(i) to add ‘sheep and goats’ in the commodities that should be considered in the entry assessment taking into consideration point 2 of Article 11.4.1.
- Consider the proposal of a Member to delete ‘through the feeding of ruminant-derived protein meal, with indigenous cases arising’ in point 1 (d).

5. Further revise Chapter 1.8. (the BSE questionnaire):

Address any remaining matters emerging from the revision of Chapter 11.4., ensuring full consistency between the questionnaire and the draft Chapter 11.4.

Point marked with an \* will be discussed if time permits.

**Deliverables**

The Group is expected to produce a detailed report with the outcome for each of the activities listed above. Should the *ad hoc* 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.

**Reporting / Timeline**

The OIE will circulate the draft report no more than seven days after the virtual meeting (not later than 8 July 2021) and the Group will finalise its report within the following week (deadline: 15 July 2021).

Appendix II

**VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE REVISION OF BSE STANDARDS  
AND THE IMPACT OF THIS REVISION ON THE OFFICIAL STATUS RECOGNITION**

**21, 23, 28, 29, 30 June, and 1 July 2021**

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**Agenda**

1. Opening.
2. Adoption of the agenda and appointment of chairperson and rapporteur.
3. Assessment of the impact that the revised BSE provisions may have on the Members already having an officially recognised BSE risk status
4. Revision of the draft annual reconfirmation for maintenance of BSE risk status.
5. Revision of the plan to obtain the ‘period for which the risk of recycling of BSE agents in the cattle population can be considered to be negligible’ for all Members with a BSE risk status.
6. Consideration of Member comments on the draft revised Chapter 11.4.
7. Finalisation and adoption of the report

Appendix III**VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE REVISION OF BSE STANDARDS  
AND THE IMPACT OF THIS REVISION ON THE OFFICIAL STATUS RECOGNITION****21, 23, 28, 29, 30 June, and 1 July 2021**

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**Lit of participants****Members**

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Appendix IV

**Proposal Form for the annual reconfirmation of  
bovine spongiform encephalopathy (BSE) risk status of OIE Members**

QUESTION		YES	NO
1.	Have any cases of classical BSE occurred in the past 12 months in indigenous cattle born within the last 8 years?		
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.	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. that are likely to have an impact on preventing cattle from being fed ruminant-derived protein meal?		
5.	Have there been any changes to BSE specific mitigation measures in the last 12 months as described under Point 1.b.ii of Article 11.4.2. that are likely to have an impact on preventing cattle from being fed ruminant-derived protein meal?		
6.	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?		
	a) Has the likelihood that the classic BSE agent has been introduced into the country or zone through the importation of the following commodities in accordance with the requirements at least as strict as those in Chapter 11.4. during the past 12 months remained negligible:		
	i. Cattle?		
		N/A	
	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	
	b) Has the likelihood of cattle being exposed to BSE either through imported commodities or as a result of the presence of BSE agents in the indigenous cattle population of the country or zone continued to be negligible during the past 12 months as a result of:		
	i. Livestock industry practices that have prevented cattle from being fed ruminant derived protein meal as described under Point 1.b.i of Article 11.4.2.?		
	ii. Specific risk mitigation measures that have prevented cattle from being fed ruminant derived protein meal as described in Point 1.b.ii of Article 11.4.2.?		
7.	If cattle were likely to have been exposed to the BSE agents during the past 12 months, was the likelihood of cattle becoming infected following exposure to the BSE agents negligible as described under Point 1.c of Article 11.4.2.?		

8.	If cattle were likely to have become infected with the BSE agents during the past 12 months, is the likelihood that the BSE agents will be subsequently recycled in the cattle population negligible as described under Point 1.c of Article 11.4.2.?		
9.	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 in 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 9.

\*\* 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		