



**REPORT OF THE MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT¹**

Paris, 3-5 July 2018

The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment (hereafter the Group) met from 3 to 5 July 2018 at the OIE Headquarters to provide independent analysis and advice to the OIE on the risk-based provisions applicable to the categorisation of BSE risk status as well as on the recommendations for international trade.

1. Opening

Dr Monique Eloit, Director General of the OIE, welcomed the Group convened to revise the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)* Chapter 11.4. on BSE, in particular the provisions pertaining to the categorisation of official BSE risk status, which may no longer be appropriate to the current BSE risk, and may not reflect the latest scientific evidence. She emphasised that the revision of the BSE standards was considered a priority for the OIE and its Members. She insisted that whilst BSE might be a sensitive and political issue, the Group's proposals should only be scientifically driven.

Dr Eloit indicated this Group would probably meet several times to complete its mandate. She also noted that this Group will articulate with another BSE *ad hoc* Group which will focus on BSE surveillance, and some experts might participate in the two Groups.

The World Assembly of OIE Delegates will be updated on the progress of these Groups at the next OIE General Session.

Dr Laure Weber-Vintzel, Head of Status Department, reminded the Group about the confidentiality undertaking that they have signed, and about the importance of properly managing conflicts of interest.

Dr Baptiste Dungu, representative of the Scientific Commission for Animal Diseases, and Dr Masatsugu Okita, representative of the Terrestrial Animal Health Standards Commission, indicated the support of the Commissions they represent to Dr Eloit's point regarding the need to refine the BSE standards based on an adequate risk assessment which would not discriminate against any OIE regions.

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

Dr Noel Murray was appointed Chair and Dr Stephen Cobb acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda for the meeting.

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

¹ Note: This *ad hoc* Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2018 report of the Scientific Commission for Animal Diseases because this report provides its considerations and comments. It is available at: <http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/scientific-commission-reports/meetings-reports/>

3. Main directions proposed for a revised BSE risk-based approach

The main directions proposed by the Group regarding a risk-based approach for categorising BSE risk status of a country or *zone* are outlined below with further details provided in section 4 of this report.

Consistent with the recommendations in Chapter 2.1. of the *Terrestrial Code* and the OIE Handbook on Import Risk Analysis for Animals and Animal Products (Volume 1, 2010), the categorisation of BSE risk status should be determined from a comprehensive risk assessment composed of four steps: entry assessment, exposure assessment, consequence assessment, and risk estimation.

The current provisions for the official recognition of BSE risk status primarily place the emphasis on determination of whether or not a country has implemented appropriate measures, particularly through a feed ban, to mitigate against the risk factors associated with the recycling and amplification of the BSE agent. This pathway proved appropriate for countries that have reported indigenous cases of classical BSE in their cattle populations and for those whose import history indicated that there was a non-negligible likelihood that the BSE agent may have been introduced. However, the Group acknowledged that the impact of local husbandry and farming practices on the likelihood of the BSE agent being recycled were insufficiently taken into account. This is particularly relevant for those countries whose cattle populations are reared either predominantly or exclusively under extensive pastoral systems, or where there is practically no animal rendering production. The Group therefore emphasised the need to recognise that there are two pathways whereby the BSE risk status of the cattle population (*Bos taurus* and *Bos indicus*) of a country or *zone* can be considered to pose a negligible risk. One from a negligible likelihood of a cattle population being exposed to the BSE agent due to the local husbandry and farming practices (e.g., extensive pastoral systems), and the other from the implementation of appropriate measures to mitigate risk factors for recycling and amplification of the BSE agent. The Group recommended to explicitly incorporate these two pathways for achieving a BSE negligible risk status, together with the risk-based provisions defining these distinct scenarios, in the *Terrestrial Code*.

The impact of the occurrence of one or more indigenous cases of classical BSE in cattle born after a ruminant-to-ruminant feed ban on the BSE risk status of countries or *zones* recognised as posing a negligible BSE risk should be assessed on the basis of an epidemiological investigation and an updated risk assessment.

Demonstration of compliance with the requirements for negligible BSE risk status, but for an insufficient period of time, would result in a controlled BSE risk status categorisation. This would represent an intermediate step for countries or *zones* to ultimately achieve negligible BSE risk status.

To minimise inconsistencies, duplications should be avoided in the *Terrestrial Code*. Chapter 11.4. should focus on defining the broad requirements applicable to the official recognition of BSE risk status, whereas Chapter 1.8. (the 'BSE questionnaire') should provide a complementary tool for Members to demonstrate that they fulfil the requirements laid out in Chapter 11.4.

Both the BSE questionnaire and the annual reconfirmation form for official recognition of a BSE risk status should be thoroughly reviewed alongside the changes hereby proposed to Chapter 11.4.

The Group emphasised that training by the OIE on the procedures and requirements for the official recognition of the BSE risk status of a country or *zone* would be beneficial for Members once the revised provisions come into force.

4. Revision of Chapter 11.4.

When revising Chapter 11.4., the Group considered the revisions proposed by the OIE *ad hoc* groups on BSE in 2014 and 2016 as well as Members' comments on the 2014 proposals, and gave careful regard to the specific issues listed in the Terms of Reference.

4.1. Article 11.4.1. General provisions, case definition and safe commodities

a) *Atypical BSE*

The Group considered how atypical BSE should be addressed in the *Terrestrial Code*. Since atypical BSE is "*believed to occur spontaneously in all cattle populations*", the Group questioned whether BSE would fulfil the second criteria for the inclusion of a disease in the OIE list specified in Article 1.2.2. of the *Terrestrial Code* as it would be implausible for any country with cattle to claim freedom

from atypical BSE. Nevertheless, if BSE was to remain a listed disease, then consistent with the approach retained by previous OIE *ad hoc* Groups on BSE and endorsed by the OIE World Assembly in 2015, the occurrence of atypical BSE should not be considered for the purpose of official BSE risk status recognition, and that this should be clearly stated in Article 11.4.2. rather than in Article 11.4.1. Importantly, the Group determined that despite classical BSE is the only BSE strain recognised as being transmitted via feed and considered for the purpose of OIE official BSE risk status recognition, the possible recycling and amplification of all BSE agents, including that of atypical BSE, must be considered in the exposure assessment (Article 11.4.2.b.) when assessing the risk of exposure.

b) Articles 11.4.1, 11.4.1.bis, and 11.4.1.ter

The Group reviewed the draft Articles 11.4.1., 11.4.1.bis, and 11.4.1.ter (General provisions, Case definition, and Safe commodities, respectively) proposed by the 2014 and 2016 BSE *ad hoc* Groups. Overall, the Group concurred with the proposed provisions, and edits were suggested to improve clarity.

BSE primarily affects cattle. While natural cases of BSE were reported many years ago in household cats, several ruminant and feline species in zoos, and two goats in commercial herds, these species are not considered to be epidemiologically significant, particularly in the presence of an ongoing ruminant-to-ruminant feed ban². Similarly, although sheep can be experimentally infected by oral challenge and can transmit BSE under usual husbandry conditions, there is no evidence that BSE has become established in the commercial sheep population³.

4.2. Article 11.4.2. The BSE risk status of the cattle population of a country, zone or compartment

a) Scope (country, zone, compartment)

The Group discussed the relevance of defining a BSE risk status at the level of a *zone* or *compartment*.

The official recognition of BSE risk status by the OIE only applies to countries and *zones* (Article 1.6.1. of the *Terrestrial Code*). Regarding *compartments*, their BSE risk status may be claimed by Members on the basis of a self-declaration and their recognition should be based on bilateral negotiations between trading partners.

The Group noted that since legislation supporting a feed ban was likely to be national in scope, monitoring its implementation at the level of a *zone* or *compartment* would likely be challenging. The need for an animal identification and traceability system that underpins the establishment of a *zone* or *compartment* was highlighted. The Group also noted that only a few *zones* have been officially recognised to date, and that some of these were defined “artificially” to exclude portions of the territory of a country where the youngest indigenous BSE case was born less than 11 years ago.

Nevertheless, the Group determined that provisions for the definition of BSE risk status at the level of a *zone* or *compartment* should remain in the *Terrestrial Code* to provide sufficient flexibility to Members in defining a BSE strategy that would best accommodate their specific situation as well as ensuring consistency with the provisions for other diseases in the *Terrestrial Code*.

b) Risk assessment

The Group noted that it was specified in the introduction of point 1 of Article 11.4.2. that the risk assessment should be reviewed annually. The Group agreed with this recommendation, but advised that it should be captured in Articles 11.4.3. and 11.4.4. within the provisions for the maintenance of a BSE risk status.

² Simmons M, Ru G, Casalone C, et al. DISCONTTOOLS: Identifying gaps in controlling bovine spongiform encephalopathy. *Transbound Emerg Dis.* 2018; 65(Suppl. 1):9–21. DOI: 10.1111/tbed.12671 and Sugurdson CJ and Miller M. Other animal prion diseases. *Br Med Bull* 2003; 66(1):199-212. DOI: 10.1093/bb/dg66.199

³ Stack M, Jeffrey M, Gubbins S., et al. Monitoring for bovine spongiform encephalopathy in sheep in Great Britain, 1998-2004. *J Gen Virol.* 2006; 87(Pt 7), 2099–2107. DOI: 10.1099/vir.0.81254-0

The Group stressed that factors to be taken into consideration in the entry and the exposure assessments listed in Article 11.4.2. were duplicated -without being fully harmonised- in Articles 11.4.23. to 11.4.29. and in Chapter 1.8. Duplications within the *Terrestrial Code* increase the likelihood of inconsistencies. The Group recommended to delete the details in Article 11.4.2. regarding the factors to be taken into consideration in the entry and the exposure assessments, and to only include them in Chapter 1.8.

Regarding the entry assessment, the Group noted that it included both local factors (points i and ii; i.e., presence/absence of the BSE agent in the indigenous population, and production of MBM or greaves) and factors associated with the introduction of the BSE agent through import (points iii to vii). The Group suggested that, consistent with recommended approaches on risk assessment, including provisions of Chapter 2.1. of the *Terrestrial Code* on Import Risk Analysis and the OIE Handbook on Import Risk Analysis for Animals and Animal Products (Volume 1, 2010), the entry assessment should focus on the likelihood of imported commodities being infected or contaminated with the BSE agent, whilst local factors should be addressed in the exposure assessment. The Group stressed that there are two important outcomes associated with this approach:

- Chapter 1.8. will have to be revised to mirror the proposed changes;
- An exposure assessment will need to be performed regardless of the results of the entry assessment.

With respect to the exposure assessment, the Group clarified that exposure to the atypical BSE agent should be taken into consideration. Indeed, whilst to date there is no evidence that atypical BSE is transmissible, recycling of the atypical BSE agent has not been ruled out and should be avoided as a precautionary measure. The Group noted that this represents another reason why an exposure assessment should be performed regardless of the outcome of the entry assessment.

Consistent with standard OIE methodologies for conducting a risk assessment, the Group proposed that two additional steps (a 'consequence assessment' and a 'risk estimation') should also be undertaken to complete the assessment of the BSE risk.

A consequence assessment estimates the likelihood of cattle becoming infected following exposure to the BSE agent together with the likely extent of any subsequent recycling and amplification of the BSE agent. As an example, in countries where cattle are predominantly reared under an extensive pastoral system, the only plausible exposure pathway to prions would be in those situations where some cattle may be fattened for several months on feed supplements in a so called "terminal feedlot"⁴. Cattle are more likely infected within their first year of life, whereas older animals are likely to be refractory to infection. Even if animals in terminal feedlots were to become infected, considering that they would be slaughtered within months following exposure, they would not have reached a stage in their incubation period when their SRM (those tissues listed in Article 11.4.14) could potentially result in recycling of infectivity if these tissue were then rendered and contaminated ruminant feed. In this example, given the age at the time of exposure and the protracted incubation period of BSE, it would be reasonable to consider negligible the consequences of exposure of yearling or adult cattle to the BSE agent in contaminated feed supplements within one or several months prior to slaughter. As a contrasting example, the consequences of exposure would not be considered negligible for cattle exposed to prion contaminated feed within their first year of life (calves or weaners) when they are more likely to become infected. This is because there is substantial amount of prion infectivity in SRMs of individuals exposed to the BSE agent within their first year of life and that entered the breeding herd and have survived long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in their SRM would begin to rise dramatically. If these SRMs were rendered and subsequently contaminated ruminant feed, which was then fed to cattle, it is highly likely that some level of recycling of infectivity would occur. It is important to note that while a small amount of contaminated feed may be sufficient to transmit BSE, amplification requires significant

⁴ A terminal feedlot is a type of feedlot where all cattle leaving it are sent directly to slaughter and do not re-enter the general cattle population.

recycling. Unless there is widespread, systemic, ongoing exposure to the BSE agent in a cattle population, an epidemic is unlikely to emerge.

The risk estimation step summarizes the results from the entry, exposure, and consequence assessments. For the official recognition of the BSE risk status of a country or a *zone* by the OIE, the risk estimation would have to be assessed by the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members and endorsed by the Scientific Commission for Animal Diseases.

The Group discussed whether there was a need to outline the different steps of the BSE risk assessment in Chapter 11.4. or if these steps could be covered by a cross-reference to Chapter 2.1. of the *Terrestrial Code*. Considering that Chapter 2.1. focuses on import risk analysis, the Group determined it was appropriate to list and define the steps to be undertaken to perform a comprehensive BSE risk assessment in Article 11.4.2.

The Group noted that points 2 to 4 of Article 11.4.2. (i.e., an ongoing awareness programme for BSE, compulsory notification and investigation, and examination of samples carried out in accordance with the *Terrestrial Manual*) were more related to risk mitigation than to risk assessment. Therefore, to improve clarity, the Group recommended Article 11.4.2. should primarily focus on risk assessment and that the provisions related to risk mitigation should be moved to Article 11.4.3.

4.3. Article 11.4.3. Negligible BSE risk

a) *Categories of BSE risk status*

The Group discussed the merits of retaining a categorisation system for a country or zone's BSE risk status as a basis for selecting sanitary measures for particular commodities, versus a purely commodity-based approach whereby the same measures would apply to a particular commodity from all countries or zones irrespective of their specific BSE-related risk factors. Overall, the Group agreed that the level of BSE risk could not be considered similar for all Members and therefore determined that a categorisation should be retained to facilitate trade from countries having a lesser risk of BSE.

As highlighted in Section 3 of this report, the current provisions for the official recognition of BSE risk status primarily place the emphasis on determination of whether or not a country has implemented appropriate measures, particularly through a feed ban, to mitigate against the risk factors associated with the recycling and amplification of the BSE agent. This pathway proved appropriate for countries that have reported indigenous cases of classical BSE in their cattle populations and for those whose import history indicated that there was a non-negligible likelihood that the BSE agent may have been introduced. However, the Group acknowledged that the impact of local husbandry and farming practices on the likelihood of the BSE agent being recycled were insufficiently taken into account. This is particularly relevant for those countries whose cattle populations are reared either predominantly or exclusively under extensive pastoral systems, or where there is practically no animal rendering production.

The Group determined that a negligible BSE risk status could result from either:

- a negligible likelihood of a cattle population being exposed to BSE agent due to the local husbandry and farming practices (e.g., extensive pastoral systems) for more than the 95th percentile of the incubation period (i.e., for at least 8 years);
- the appropriate mitigation of risk factors for recycling and amplification of the BSE agent for the same duration as defined above (i.e., at least 8 years).

The Group recommended that these two pathways for achieving a negligible BSE risk status should be recognised in the *Terrestrial Code* and that provisions adequate to these distinct scenarios should be proposed.

b) Prerequisites for the detection of BSE cases

The Group agreed that regardless of which pathway leads to a categorisation as negligible BSE risk status (i.e., on the basis of husbandry and farming practices, or as a result of the effective application of measures to prevent recycling), requirements for an ongoing awareness programme, compulsory notification and investigation of clinical suspects, as well as a laboratory examination of appropriate samples performed in accordance with the *Terrestrial Manual*, continue to be relevant as they support the identification of BSE cases. The Group recommended that the *ad hoc* Group on BSE surveillance should determine how long these requirements need to have been in place before a BSE risk status can be officially recognised by the OIE (currently 7 years based on the provisions of Articles 11.4.3. and 11.4.4.).

The Group also recommended that the *ad hoc* Group on BSE surveillance should define the surveillance provisions for countries posing a negligible BSE risk as well as the duration for which these provisions should have been applied before an official BSE risk status can be recognised by the OIE.

c) Ruminants not fed with meat-and-bone meal or greaves derived from ruminants

The Group emphasised that, depending on traditional husbandry and farming practices, particularly in countries with extensive pastoral systems, a legislated feed ban enforced by national regulations may not always be necessary to provide assurance that ruminants are not fed with meat-and-bone meal nor greaves derived from ruminants. However, it remains reasonable that, under such circumstances, these countries would be required to demonstrate that neither meat-and-bone meal nor greaves derived from ruminants have been fed to ruminants for at least eight years. In addition, they would need to demonstrate that the consequences of cross contamination, that might occur in a terminal feedlot, would be negligible. Rather than official control and audits, the Group recommended that documented evidence be provided to substantiate any claims made concerning the impact of husbandry and farming practices on mitigating against BSE related risks. This would include a detailed explanation of husbandry and farming practices for both ruminant and non-ruminant species, the demographics of the cattle population and other farmed animal species, the activities to deal with cattle mortalities and slaughterhouse waste, and the existence or lack of rendering facilities and feed mills. Such an approach would allow for more flexibility to accommodate different situations and practices particularly in lower and middle income countries.

d) Occurrence of indigenous cases of classical of BSE

The Group discussed the impact of the occurrence of one or a few indigenous cases of classical BSE on the BSE risk status. In particular, the Group assessed the current requirement that “*if there has been an indigenous case, every indigenous case was born more than 11 years ago*”.

This 11-year period was defined based on unpublished data at the time the corresponding provision in Chapter 11.4. was adopted in May 2006. The Group pointed out the lack of any robust scientific evidence supporting this time period, and recommended that the occurrence of a BSE case (without any specification of a time window) and its potential impact on the overall level of risk should be addressed in the consequence assessment.

The Group agreed that the occurrence of one or a few indigenous cases of classical BSE in animals born after the implementation of a feed ban did not necessarily raise concerns over the ongoing effectiveness of the feed ban. The Group noted the outcome of a detailed investigation described in a recent opinion from the European Food Safety Authority⁵ of 60 classical BSE cases in the European Union (EU) born after the “total⁶” feed ban was enforced from January 2001 (such cases are referred to as BARBs).

⁵ EFSA, Bovine spongiform encephalopathy (BSE) cases born after the total feed ban, *EFSA Journal* (2017) ;15(7):4885 (2017) <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4885>

⁶ Under the total feed ban the feeding of all processed animal proteins (PAPs) was banned from feeding to all farmed animals.

In the context of considerable uncertainty resulting from the timespan between the confirmation of any BSE cases and their potential exposure to the BSE agent within their first year of life, it is extremely unlikely that a specific source of infection can ever be ascertained. In this investigation, feeding material contaminated with the BSE agent could not be excluded as the origin for any of the BARBs, with the apparent exception of one. At the same time, while it was not possible to definitively attribute feed as the cause of any of these cases, it was considered unlikely that they were spontaneous. Considering that it is well known that the BSE agent can remain biologically active for many years, isolated pockets of residual infectivity in a complex network of rendering, feed production, distribution and storage may account for rare, sporadic opportunities of exposure. In fact, it is worth noting that the rate of occurrence of the BARBs in the 11 Member States of the EU from which they were reported has been extremely rare. Collectively, testing over 97 million cattle between 2001 and 2015 led to the detection of just 60 BARBs. Since the year of birth of a BSE case is accepted to be a surrogate indicator of the year when the exposure to the BSE agent occurred, it is informative to consider that the vast majority (90%) of the BARBs were born within the first four years⁷ following the implementation of the reinforced (total) feed ban in the EU in January 2001. The remaining 10% (6) cases were born between 2005 and 2011, with single cases reported from each of these years, except for 2008 when no case arose. Taken together, the results from the EU's ongoing surveillance program confirm that the occurrence of a limited number of BARBs is not indicative of gaps or failures in a feed ban. Rather, they are more than likely to be indicative of isolated, residual pockets of infectivity with extremely limited opportunities of exposure involving one or a few animals that ultimately have negligible consequences in terms of recycling of infectivity, particularly considering the ongoing implementation of a feed ban. Overall, the Group could not conclude that the occurrence of one or a few cases of classical BSE in animals born after a feed ban systematically reveals a breach in the effective enforcement of the feed ban.

The Group stressed that, currently, the occurrence of a single indigenous case of classical BSE born less than 11 years ago automatically leads to the downgrading of a BSE risk status of a country or *zone* from negligible to controlled. The Group emphasised that, based on the rationale outlined in the preceding paragraph, withdrawal of negligible BSE risk status in such circumstances is likely to be disproportionate to the risk associated with the occurrence of one or a few indigenous cases of classical BSE in animals born after a feed ban, particularly where effective mitigating measures have been continuously implemented.

Overall, the Group reaffirmed that the provisions applicable to BSE in the *Terrestrial Code* should be based on a risk assessment. Therefore:

- For the initial recognition of a negligible BSE risk status of a country or a *zone*, the age of the youngest indigenous case of classical BSE should be taken into consideration in the BSE risk assessment (consequence assessment);
- For countries or *zones* recognised as posing a negligible BSE risk status, the occurrence of indigenous case(s) should trigger an investigation and an update of the BSE risk assessment by the Member. The impact on the BSE risk status of the country or the *zone* should then be assessed by the Scientific Commission for Animal Diseases, with the support of the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members, based on the outcome of the corresponding investigation and updated risk assessment. This may lead to resetting the date from which the feed ban can be considered effectively enforced, with possible consequences for the age of animals from which commodities can be traded.

The Group discussed the provisions applicable to birth cohort animals when an indigenous case of classical BSE is identified. The Group acknowledged that tracing birth cohorts can be challenging in practice. In addition, the potential gain in risk reduction following the complete destruction of all cohort animals was assessed. The Group reviewed the surveillance data from the EU from 2001 to 2017, which include a total of 13,037 cases of classical BSE identified through various surveillance streams. The surveillance stream “eradication measures” includes tested animals from birth cohorts, feed cohorts, live offspring, and sire and dams. Overall, 48 cases were identified through this surveillance stream, accounting for 0.4% of all BSE cases identified over the last 16 years. Surveillance data from Great Britain from 1996 to 2008 also showed the occurrence of BSE cases

⁷ A total of 25 cases (41.6%) were born in 2001; 14 cases (23.3%) born in 2002; 8 cases born in 2003; 7 cases (11.6%) born in 2004.

amongst cohorts to be much lower than in other surveillance streams⁸. Based on these findings, together with a consideration of the ongoing application of various sanitary measures to protect public health, principally through the hygienic removal of SRM (those tissues listed in Article 11.4.14) at slaughter, as well as animal health through the ongoing implementation of a feed ban, the Group determined that the complete destruction of all cohort animals would not provide a significant gain in risk reduction. Overall, the Group concluded that as long as measures including a feed ban and the removal and destruction of tissues listed in Article 11.4.14. had been continuously and effectively implemented, and an effective surveillance system for the detection and investigation of cases is in place, any risks associated with cohort animals would be effectively eliminated.

4.4. Article 11.4.4. Controlled BSE risk

If a country or *zone* can demonstrate compliance with the requirements listed in Article 11.4.3., but not yet for the relevant period of time, it would qualify to be recognised as having a controlled BSE risk. As such, controlled BSE risk status provides an intermediate step for Members as they work towards achieving negligible BSE risk status as well as ensuring the sanitary safety of exported commodities.

4.5. Article 11.4.5. Undetermined BSE risk

By default, the cattle population of a country, *zone* or *compartment* not recognised as fulfilling the requirements of negligible or controlled BSE risk would be considered as posing an undetermined BSE risk.

4.6. Articles 11.4.6. to 11.4.19. Requirements for trade

The Group undertook a preliminary evaluation of the requirements for trade listed in Articles 11.4.6. to 11.4.19 and determined that a detailed review of these requirements would be undertaken at its next meeting.

4.7. Articles 11.4.23. to 11.4.29. BSE risk assessment

The Group noted that while Articles 11.4.23 to 11.4.29 set out the requirements for an entry and exposure assessment together with the assumptions, the broad questions to be answered, and the supporting rationale and evidence required for key steps in the risk assessment, these are not fully harmonised with Chapter 1.8. (the ‘BSE questionnaire’) of the *Terrestrial Code*. As a result, there are a number of inconsistencies that potentially create confusion for Members requesting official recognition by the OIE. To address this issue, the Group recommended that Articles 11.4.23 to 11.4.29 be deleted from Chapter 11.4. In this way, and to be consistent with the structure of other Chapters of diseases that have official recognition, Chapter 11.4. would focus on defining the requirements applicable to the official recognition of BSE risk status, whereas Chapter 1.8. would provide a tool in the form of a questionnaire for Members to provide the relevant information and demonstrate how they fulfil the requirements set in Chapter 11.4.

The Group emphasised that Chapter 1.8. will need to be thoroughly reviewed to ensure that it fully reflects the proposed revisions to Chapter 11.4.

5. Preliminary considerations for Chapter 1.8.

The Group undertook a preliminary evaluation of the BSE questionnaire (Chapter 1.8.) and determined that its detailed revision would be undertaken at the next *ad hoc* group meeting.

⁸ Wilesmith JM, Ryan JBM, Arnold ME, et al. Descriptive epidemiological features of cases of bovine spongiform encephalopathy born after July 31, 1996 in Great Britain. *Vet Record* 2010; 167:279-286. DOI: 10.1136/vr.c4552

5.1. Article 1.8.1.

The Group noted that a general description of bovine husbandry and slaughtering practices is requested in the introduction (Article 1.8.1.1.). However, in accordance with the proposed revisions to Articles 11.4.2. and 11.4.3., and as husbandry and farming practices may be a key pillar to support the recognition of a negligible or controlled BSE risk status of a country or *zone*, rather than a general description of these practices, comprehensive details would need to be provided by the applicant Member. The most appropriate place in the questionnaire to request this information would be in the exposure assessment.

5.2. Article 1.8.2. BSE risk status

a) *Entry assessment*

Detailed quantitative information (e.g., volume, statistics, etc.) is currently requested on importations of various imported commodities regardless of whether or not the relevant measures within Chapter 11.4. that ensure their sanitary safety are applied. The Group considered that requesting detailed quantitative information for commodities imported under conditions consistent with the recommendations in the Chapter 11.4 cannot be justified. Rather, the emphasis should be on documenting the details of the measures applied to imported commodities depending on the BSE risk status of the country or *zone* of origin and whether or not they are consistent with or provide an equivalent level of assurance with the recommendations laid out in Chapter 11.4. The rationale and supporting evidence upon which a claim of consistence with Chapter 11.4 or equivalence is being made should be provided. In addition to describing the measures, details would need to be provided on how the Competent Authority verifies compliance with them through supporting legislation, certification, etc. In situations where the measures are not consistent and cannot be considered to provide an equivalent level of assurance, it would be reasonable to request that detailed quantitative information continue to be provided.

b) *Exposure assessment*

Depending on which pathway is relevant for a Member seeking status recognition as having a negligible or controlled BSE risk (husbandry and farming practices, or appropriate risk mitigating measures), the information that needs to be provided for the exposure assessment would differ. Specific details of the amounts and types of information required for each pathway will be developed at the next meeting of the *ad hoc* group.

The Group emphasized that only official inspections (i.e., those undertaken by the Competent Authority) should be considered in the exposure assessment. The Group recommended to review the tables in the questionnaire where audit findings in rendering plants and feed mills are recorded. In particular, clarification is needed on the meaning of the term “supervision” in relation to the number of rendering plants and feed mills inspected under Competent Authority supervision. Also, when referring to infractions in feed mills and rendering plants, the term 'corrective action' should be used instead of 'method of resolution'. Also, inconsistent use of the terms “cattle”, “bovine”, “ruminants” and “by-products” throughout the BSE questionnaire needs to be reviewed.

c) *Consequence assessment and risk estimation*

Consistent with draft Article 11.4.2, explicit sections on consequence assessment and risk estimation will need to be developed and included in the BSE questionnaire.

5.3. Articles 1.8.3 and 1.8.4. Other requirements and BSE surveillance and monitoring systems

The sections on other requirements and BSE surveillance and monitoring systems will be reviewed by the *ad hoc* Group on BSE surveillance.

5.4. Article 1.8.5. BSE history

Evidence regarding the historic presence (or absence) of the BSE agent addressed in Article 1.8.5. of the BSE questionnaire should be included in the exposure assessment (however, the information on cohorts would no longer be relevant in the assessment in light of the revised provisions of Article 11.4.3.).

6. Finalisation and adoption of the draft report

The Group reviewed and amended the draft report. The Group agreed that the report reflected the discussions.

7. Way forward

The Group suggested the *ad hoc* Group on BSE surveillance be convened before this Group meets again to complete its terms of reference.

.../Appendices

MEETING OF THE OIE *AD HOC* GROUP ON BSE RISK ASSESSMENT

Paris, 3 to 5 July 2018

Terms of Reference

Purpose

The purpose of this *ad hoc* Group is to provide independent analysis and advice to OIE on the risk-based provisions applicable to the categorisation of BSE risk status as well as on the subsequent recommendations applicable for international trade.

Functions

This *ad hoc* Group will report to the Director General of the OIE, and approved reports will be considered by the relevant Specialist Commissions (the Scientific Commission or the Terrestrial Animal Health Standards Commissions) when necessary, in accordance with the OIE Basic Texts.

The responsibilities of this *ad hoc* Group will be to review current scientific evidence, provide guidance and draft recommendations on:

1. The assessment of the risk with regard to the BSE agent:
 - i. Assess the need for revising Article 11.4.1. of the *Terrestrial Code*, especially the list of susceptible species of significance for the purpose of the *Terrestrial Code*;
 - ii. Revise Article 11.4.2 of the *Terrestrial Code*;
 - iii. Revise Articles 11.4.23. to 11.4.29. of the *Terrestrial Code*. In addition, considering that BSE risk assessment is addressed in Article 1.6.5 (now Chapter 1.8., Article 1.8.2. points 2 and 3) as well as in Articles 11.4.2. point 1 and 11.4.23. to 11.4.29. of the *Terrestrial Code*, advise as to the best structure to be retained in the *Terrestrial Code* to avoid duplications.
 - iv. Revise and clarify the relationship between the entry and the exposure assessments. In particular, the necessity of performing an exposure assessment if the likelihood of entry of the BSE agent is negligible should be further assessed;
 - v. Re-assess the requirement that no indigenous case of classical BSE should be born less than 11 years ago and whether this should be encompassed in the overall risk assessment.
2. The provisions applicable to the categorisation of BSE risk status (revision of Articles 11.4.3. and 11.4.4. of the *Terrestrial Code*)
 - i. assess the relevance of the current categorisation of BSE risk status (negligible, controlled and undetermined categories of risk). This assessment should encompass the following as well as any additional factors identified as relevant by the Group:
 - the different requirements applicable to the recognition and maintenance of controlled and negligible BSE risks;
 - the prevailing epidemiological situation (countries currently having a controlled risk status and expected application in the future);
 - the impact on risk associated with the duration of the implementation of an effective feed ban and the time elapsed since the birth of the youngest indigenous case of classical BSE;

- relevance of the high level of continuous active surveillance required for maintenance of BSE risk status (N.B. this is common to both *ad hoc* Groups, and therefore interaction between the groups on this aspect is expected);
 - the relevance of a zoning or compartmentalisation approach for the categorisation of BSE risk status, and the corresponding requirements- if considered appropriate.
- ii. If appropriate based on the assessment described in i), the requirements applicable to the current categories of BSE risk status or new categories of BSE risk status and corresponding requirements for risk-based categorisation, with particular attention to:
- Whether the timelines should be reassessed based on current scientific evidence on the epidemiology of the disease;
 - Clarifying the information required to demonstrate the effectiveness of the feed ban;
 - The potential impact of the new requirements/categorisation on the status of countries or *zones* already having an officially recognised BSE risk status.
3. The relevance of the requirements for trade applicable to the different categories BSE risk status (revision of Articles 11.4.6 to 11.4.19 of the *Terrestrial Code*).
 4. The relevance of providing requirements for trade applicable to atypical BSE.
 5. The list of safe commodities if appropriate in light of the recent scientific knowledge (revision of Article 11.4.1. of the *Terrestrial Code*) taking into consideration the recommendations made by the *ad hoc* Group on BSE which met in 2016.
 6. The list of specified risk materials (SRMs) if appropriate in light of the recent scientific knowledge (revision of Article 11.4.14. on recommendations on commodities that should not be traded).
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MEETING OF THE OIE AD HOC GROUP ON BSE RISK ASSESSMENT
Paris, 3 to 5 July 2018

Agenda

1. Opening.
2. Adoption of the agenda and appointment of chairperson and rapporteur.
3. Main directions proposed for a revised BSE risk-based approach
4. Revision of Chapter 11.4.
5. Preliminary considerations on Chapter 1.8.
6. Finalisation and adoption of the draft report
7. Way forward

MEETING OF THE OIE AD HOC GROUP ON BSE RISK ASSESSMENT

Paris, 3 to 5 July 2018

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