



**REPORT OF THE MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY¹
Paris, 23-25 August 2016**

A meeting of the *ad hoc* Group on bovine spongiform encephalopathy (BSE) (hereafter the Group) was held at the OIE Headquarters from 23 to 25 August 2016.

1. Opening

Dr Monique Eloit, Director General of the OIE, welcomed and thanked the experts for their commitment towards the OIE and for personal and professional time invested in this *ad hoc* Group.

Dr Eloit highlighted that in line with the objectives of the OIE 6th strategic plan, the procedure for the election process of the members of the Specialist Commissions and the appointment of experts to Working Groups and *ad hoc* Groups were being reviewed. The new procedure would be submitted to the approval of the OIE Council in September 2016 before it is presented to the World Assembly of OIE Delegates for adoption.

Dr Eloit emphasised that the revised procedure for the selection of OIE's experts aims at enhancing the transparency of the way in which experts are selected as well as at further reinforcing OIE's capacity to develop evidence-based international standards.

Dr Laure Weber-Vintzel, Head of Status Department, clarified that a previous BSE *ad hoc* Group had revised Chapter 11.4. of the *Terrestrial Animal Health Code (Terrestrial Code)*, in 2014. However, the corresponding draft chapter was not adopted by the World Assembly during the 83rd General Session due to the limited time Member Countries were given for its revision. Nevertheless, Member Countries agreed at this time to insert a sentence specifying that atypical BSE was excluded for the purpose of official disease status recognition. She advised that both the current adopted chapter and the draft chapter elaborated by the *ad hoc* Group in 2014 be used as a basis for discussion.

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

Dr Armando Giovannini was appointed Chair and Dr Noel Murray appointed rapporteur. The Group endorsed the proposed agenda.

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

3. Review and update of the existing chapter on BSE in the *Terrestrial Code*

3.1. Revision of the draft chapter (Articles 11.4.1. to 11.4.19.)

The Group thoroughly reviewed the amended BSE chapter drafted in 2014 by the BSE *ad hoc* Group.

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 2016 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/>

The Group agreed that only cattle, cattle-derived products and by-products trade represent a risk for the spread of BSE and therefore agreed to refer the trade recommendations to only cattle and not to “ruminants”.

The origin of BSE is indeed still largely unknown. Hypotheses on BSE origin include cattle infected with atypical BSE or sheep and goats infected with scrapie. Thus, the feeding of meat-and-bone or greaves derived from small ruminants cannot be excluded as a potential route of introduction of BSE into a cattle population. Therefore, the Group was of the opinion that the provisions concerning the feed ban and meat-and-bone meal or greaves should apply to the ruminant population in general rather than to the cattle population. Changes were made accordingly all along the chapter.

o Article 11.4.1. General provisions

During the 83rd General Session the World Assembly decided to only amend Article 11.4.1. by including the following sentence: “For the purpose of official BSE risk status recognition, BSE excludes ‘atypical BSE’”. The Group unanimously supported the opinion that official recognition of BSE risk status should only focus on the occurrence of classical BSE. However, as Articles 11.4.3. - Negligible BSE risk and 11.4.4. - Controlled BSE risk were to be revised, the Group considered that this preliminary statement in the General Provisions was no longer necessary.

The Group decided to create two new articles. The first to include a case definition for classical and atypical BSE. The second dedicated to safe commodities.

o Article 11.4.1bis. Case definition

The Group considered the case definitions for classical and atypical BSE proposed by Member Countries, the recently adopted chapter on BSE of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* (Chapter 2.4.5.), and the case definition approach used in other adopted chapters of the *Terrestrial Code*.

The Group discussed clinical and epidemiological criteria relevant for the BSE case definitions.

BSE is an invariably fatal disease neurological prion infection of adult cattle. However, for clarity the Group decided not to include the age of the affected cattle in the case definition and to further specify this parameter in the section of the chapter dedicated to surveillance.

At the time of writing, atypical BSE is generally considered to occur spontaneously. As shown by the data collected by the European Commission (Figure 1), the occurrence of atypical BSE in the European Union (EU) appears to be independent of feed controls. However, further scientific evidence would be needed to formally exclude contaminated feed as a potential source of infection for atypical BSE. On the other hand, classical BSE is mainly transmitted through contaminated feed. Overall, the Group considered that clinical and epidemiological criteria should be considered during the investigation of a BSE outbreak but without laboratory confirmation would not allow for the discrimination of classical and atypical BSE.

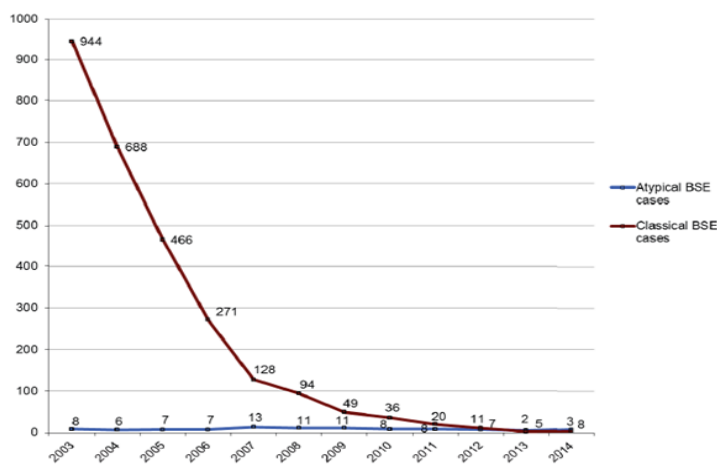


Figure 1. Evolution of the number of confirmed classical and atypical BSE cases in the EU 28 from 2003 to 2014
 Source: European Commission (2014) (http://ec.europa.eu/food/safety/docs/biosafety_food-borne-disease_tse_ms-annual-report_2014.pdf)

The Group acknowledged that species other than cattle (e.g. goats) can be naturally infected with the BSE agent, however, in the presence of an effective ruminant-to-ruminant feed ban, these species are not considered to be epidemiologically significant. For the purpose of the *Terrestrial Code*, the Group recommended restricting the list of BSE susceptible species to cattle (*Bos taurus* and *B. indicus*).

The Group pointed out that laboratory criteria were the sole basis for the differentiation of classical and atypical BSE. The Group advised that a stepwise approach should be followed for the laboratory confirmation of the infection, aiming, first, at confirming BSE, and, secondly, at distinguishing atypical and classical BSE. With regard to the laboratory tests to be performed, the Group decided to cross-reference the *Terrestrial Manual* and noted that currently only the Western immunoblot banding was recognised for the laboratory discrimination of classical and atypical BSE.

- Article 11.4.1ter. Safe commodities

The Group reviewed and endorsed the existing list of safe commodities and dedicated a sole article to safe commodities, for consistency with other chapters of the *Terrestrial Code*.

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

The current Article 11.4.2. specifies that an exposure assessment should be conducted if the entry assessment identifies a non-negligible risk of the entry of BSE into a country, zone or compartment. Considering the potential risk of recycling and amplification of atypical BSE (which is considered to occur spontaneously in all cattle populations), the Group was of opinion that an exposure assessment should be performed regardless of the outcome of the entry assessment. It was noted that in the context of official status recognition, such a change in the provisions for the exposure assessment would mean that Member Countries that may have been previously recognised as having a negligible BSE risk on the basis of an entry assessment only would now have to complement this assessment with an exposure assessment when reconfirming their official risk status (a transition period may be needed).

With regard to point 3 of Article 11.4.2., the Group specified that the notification of all cattle showing clinical signs consistent with BSE should be made to the Veterinary Authority and all cases should be subsequently investigated.

- Article 11.4.3 - Negligible BSE risk

Point 3a.: The Group clarified that the occurrence of atypical BSE would not affect the negligible risk status, provided it the animal has been completely destroyed. A reference to the case definition for atypical BSE provided in Article 14.4.1. was included.

The Group clarified why a period of seven years should apply to the provisions related to surveillance and risk assessment while a period of eight years was relevant for the provisions applicable to feed ban and prevention of cross contamination. The incubation period for classical BSE is seven years (95th percentile of the incubation period). It is therefore advisable to consider an eight-year period for the feed ban since once it is implemented, an additional year is considered necessary to ensure the complete elimination of any remaining potentially contaminated feed.

Point 3b.: The Group agreed that Point 3b. of Article 11.4.3. addressing the occurrence of indigenous cases should only apply to classical BSE.

The Group questioned the provisions applicable to birth cohort animals in case of the identification of an indigenous case of classical BSE prescribed in Point 3b. iv. of Article 11.4.3. and whether any additional gain in risk reduction following the complete destruction of all cohort animals could be justified.

Some experts were of the opinion that provided measures including a feed ban and the removal and destruction of tissues listed in Article 11.4.14. had been and continue to be effectively implemented, any potential risks associated with cohort animals would be effectively eliminated so that the complete destruction of the whole cohort would not be warranted. However, the Group considered unpublished surveillance data from the European Union for the period 2008-2015. Overall, seven birth cohort animals from a total of 10,000 tested were positive. For that time period, this represented the second highest ratio of BSE cases confirmed in any of the surveillance sub-populations (fallen stock, emergency slaughtered, clinical signs at ante-mortem inspection, healthy slaughter, BSE eradication and BSE suspects).

The Group considered then the option of slaughter and testing cohort animals, and destroying the positive ones, rather than destroying the entire birth cohort, as prescribed in Point 3b. iii. The added-value of testing cohort animals as compared to destruction without testing would be to provide a broad indication of the effectiveness of control measures. While an isolated case may not necessarily reflect a breach in national level control measures, more than one infected animals in a given cohort might be indicative of shortfalls in the herd concerned. While recognising that this would indeed be of interest for the purpose of surveillance, some experts pointed out that it may have little impact on risk mitigation as it may be possible to miss animals at an earlier stage in their incubation period when they are unlikely to be positive to a test but still harbor infectivity in some tissues. While acknowledging that the levels of infectivity would be very low (below the detection threshold), the Group was of the opinion that, for the purpose of international trade, due to the presumably higher probability that some cohort animals associated with a confirmed BSE case could be infected, birth cohort animals should be destroyed and provisions of Point 3b.iv. of Article 11.4.3. should remain unchanged. On the other hand, for the purpose of monitoring the effectiveness of control measures, countries with an official BSE risk status may decide to test cohort animals. The Group therefore recommended including this aspect in the BSE surveillance streams and in the questionnaire on BSE for status recognition provided in Article 1.6.5.

- Article 11.4.4. - Controlled BSE risk

Similarly to Article 11.4.3. and for the sake of clarity, a reference to the case definition for atypical BSE provided in the General Provisions was included in Point 3a. of Article 11.4.4.

The Group discussed the consequences of the occurrence of an indigenous case of classical BSE detected in cattle born more than 11 years ago on the negligible BSE risk status. The Group recommended that the negligible risk status should be withdrawn but advised that a country's BSE risk status could be reclassified as controlled without delay, provided that the OIE assesses and endorses compliance with all requirements of Article 11.4.4, including the outcome of an updated risk assessment (entry and exposure).

- Article 11.4.6. - Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

The Group clarified that provisions of Article 11.4.6. for the importation of bovine commodities from countries posing a negligible BSE risk were not applicable to commodities listed as safe commodities (Article 11.4.1.) and to commodities for which recommendations were prescribed in other articles of this chapter (*i.e.* Articles 11.4.7., 11.4.10., and from 11.4.13. to 11.4.18.).

- Article 11.4.7. - Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case of 'classical' BSE

The Group agreed that the recommendations provided in Article 11.4.7. should apply to the occurrence of classical BSE in cattle.

- Article 11.4.9.- Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk

The Group concurred with the modification proposed by the previous *ad hoc* Group.

- Article 11.4.10. - Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

The Group clarified that the occurrence of indigenous BSE case(s) in countries with a negligible BSE risk relates to classical BSE (Point 3). The Group stressed the importance of the provisions in the current Code chapter recommending that cattle from which the fresh meat and meat products are destined for export should be born after the implementation of an effective feed ban. The Group advised that each country would have to determine the date at which the implementation of its feed ban can be considered effective based on adequate audit and monitoring.

Considering that atypical BSE may have a zoonotic potential and in order to protect public health, the Group proposed a recommendation aiming at ensuring that the imported meat and meat products were not contaminated with tissues listed in the newly proposed point 4 of Article 11.4.14.

- Article 11.4.12. - Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

The Group removed Point 2b. related to “*nervous and lymphatic tissues exposed during the deboning process*”, as it was considered a safe commodity according to Article 11.4.1ter. which lists deboned skeletal muscle.

- Article 11.4.14. - Recommendations on commodities that should not be traded

Point1: The Group reviewed EFSA’s data² on the total infectivity of clinical case of BSE which estimates the infectivity of tonsil to be < 0.01% of the total amount of infectivity represented by the different tissues of a clinical case. The EFSA report cites the level of infectivity in tonsils to be 10^{-6.5} CoID₅₀/g, which is in the same order of magnitude as that for the peripheral nervous system (PNS). Such levels of infectivity are extremely low, so low in fact, that it would be biologically implausible to ingest a sufficient amount of tissue from an infected animal to pose a credible risk. This has been widely accepted for the PNS as it is not classified as a high risk tissue (SRM). As a result, it is reasonable to conclude that the risk posed by tonsillar tissue is negligible. The Group therefore recommended removing the restriction applicable to tonsils.

Point 4: Considering the body of evidence related to zoonotic potential of atypical BSE, the Group concurred with the proposal made by the previous *ad hoc* Group that included brains, eyes, spinal cord and skull of older animals as the tissues that may pose a risk to public health and therefore should not be traded regardless of the BSE risk status of a country. Indeed, intracerebral inoculation studies suggested that low molecular weight type of atypical bovine spongiform encephalopathy (L-type BSE) may be more virulent than classical BSE for infecting primates (incubation periods were shorter than for classical BSE)³ and histology and biochemistry studies showed that primates infected

² Source: EFSA, Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins, EFSA Journal 2011;9 (1):1947 (<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.1947/epdf>)

³ Baron T, Biacabe AG, Rouland S, Verdier JM and Mestre-Francés N, 2008. Transmission of atypical BSE to *Microcebus murinus*, a non-human primate: development of clinical symptoms and tissue distribution of PrPres. Proceedings Prion 2008 Conference. Madrid, 8-10 October 2008, 16.

with L-type BSE and MM2-cortical-type sporadic Creutzfeldt-Jakob disease (MM2 sCJD) patients exhibited similar lesion profiles⁴. Furthermore, experiments demonstrated the transmissibility of L-BSE to macaques by the oral route⁵. Finally, available collective data indicate that atypical BSE shares a similar tissue distribution to classical BSE cases with the exception of lymphoid or gastrointestinal tissues⁶. The Group agreed that this justified the definition of a limited list of most infectious tissues for countries with negligible BSE risk status in Article 11.4.14.

The Group discussed the age limit to be considered for the removal of those high risk tissues originating from a country, zone or compartment defined in Article 11.4.3. Most frequently atypical BSE occurs in cattle older than 8 years (≥ 96 months). However, based on retrospective BSE typing data from the European Commission⁷, out of 112 atypical BSE cases, three cases were 6 years of age at the time of testing and another three cases were 7 years of age. Among these 112 atypical cases, the youngest animal was 75 months of age.

Although the Group agreed that overall the occurrence of cases of atypical BSE younger than 96 months was uncommon, it was of the opinion that these younger animals should be taken into consideration when setting the age limit for the purpose of trade of cattle products.

Some in the Group were of the opinion that the age limit could be based on these data (and should then be 6 years - 72 months) while others stressed that these data were based on a limited sample and that any inference should be drawn with caution (i.e. the youngest case identified in this sample might not represent the lowest possible age limit for an atypical BSE case). They therefore recommended that, in view of the precautionary principle, the age limit should be five years (60 months). In addition, they noted that, five years was also a practical threshold to determine the age of a cattle through dentition (the incisors in cattle are fully erupted by the age of five years). As, the Group did not reach a consensus on that matter, it was decided to seek the opinion of the Scientific Commission.

The Group also noted that in some countries, those high risk commodities may be used for human consumption and unanimously stressed the public health risk that may be associated with that practice.

- Article 11.4.15. - Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

In order to address the risk that may be associated with atypical BSE in countries with a negligible BSE risk, the Group recommended that the skull from cattle over 60/72 months of age should be excluded. The provision to require *ante-* and *post-mortem* inspection was also added.

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

The Group specified that tallow should not have been prepared using tissues listed in Article 11.4.14.

⁴ Comoy E, Richt J, Durand V, Freire S, Correia E, Hamir A, Ruchoux MM, Brown P and Deslys JP, 2009. Transmission of bovine-passaged TME prion strain to macaque. Proceedings Prion 2009 Conference. Thessaloniki. 23-25 September 2009, 46.

⁵ Comoy E, 2010. Transmission studies in primates. Workshop on the epidemiology of human and animal TSEs. 30 April 2010, Torino, Italy. In: Food safety assurance and veterinary public health - volume 6 - Foodborne viruses and prions and their significance for public health. Eds Smulders, F.J.M., Noerrung, B. and Budka, H. Wageningen Academic Publishers The Netherlands, 2013. p. 296.

⁶ Source: EFSA, Scientific report on a Protocol for further laboratory investigations into the distribution of infectivity of Atypical BSE, *EFSA Journal*, 2014; **12**(7): 3798 (<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3798/epdf>)

⁷ Source: European Commission, Report on the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathies (TSEs) in the EU in 2014 (http://ec.europa.eu/food/safety/docs/biosafety_food-borne-disease_tse_ms-annual-report_2014.pdf)

- Article 11.4.17. - Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices and Article 11.4.18. - Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The Group was of the opinion that tallow derivatives and dicalcium phosphate should originate from products compliant with the requirements of the relevant articles of this chapter.

3.2. Revision of the provisions of the draft chapter on surveillance (Articles 11.4.20. to 11.4.22.)

The Group discussed the need for a revision of the provisions for BSE surveillance because some of the modelling assumptions underpinning it and some of the default data used to feed the model may be outdated.

Surveillance to detect classical BSE: The Group took note of the goals of BSE surveillance listed in Article 11.4.20. and agreed that BSE surveillance provisions should not aim at detecting atypical BSE cases despite the inevitable detection of some cases during the course of surveillance for classical BSE. Given that the expected incidence of atypical BSE, based on extensive data from the EU (Figure 1), has been established (i.e. expected to be similar to the incidence of sporadic Creutzfeldt-Jakob Disease in humans (one case per million)), the Group pointed out that the detection of cases of atypical BSE is likely to be a reflection of the level of intensity of surveillance for classical BSE. The data from Europe together with observations elsewhere (Brazil, Canada, Japan and the United States of America) support the contention that atypical BSE is likely to arise spontaneously in all cattle populations at a very low rate.

New approach: The previous Group had proposed a new approach to estimate the level of the infection in the population. In that proposal, the probability of a positive test result (either classical or atypical BSE) was calculated for each age class and for the four surveillance streams (routine slaughter, fallen stock, casualty slaughter, and clinical suspect) based on a set of data from EU countries. The ratio of the probability of a positive test result to the overall probability of a positive test result was used to calculate the surveillance point value of an animal belonging to that specific age class and surveillance stream. Compared to the current surveillance point values, the proposed points place a greater weight on cattle older than seven years. As a consequence, those Member Countries that based their surveillance on younger animals may no longer comply with the surveillance requirements for the status maintenance.

Concerns were raised that the model proposed by the previous *ad hoc* Group placed too much emphasis on the increasing age of BSE cases. Increasingly older cases of classic BSE are more than likely a reflection of the effectiveness of control measures, as they reflect the tail of an extended incubation period. Ascribing considerably more weight (points) to older animals could lead to distortions in surveillance where the intensity of testing animals less than seven years of age could be curtailed. Given that an important goal of BSE surveillance continues to be monitoring its evolution (including detection of (re-)mergence) and the effectiveness of the feed ban, the existing approach might also remain valid.

Surveillance streams: The Group discussed simplifying the current four surveillance streams into two categories by considering: (i) “healthy slaughter” (i.e. routine slaughter), (ii) “at risk animals” (by merging the three current streams: fallen stock, casualty slaughter, and clinical suspect). While this approach would require the recalculation of surveillance point, this can be performed easily and transparently within the modelling framework provided by BSurvE. The Group acknowledged that it would reduce the weight of animals in the “clinical suspect” category, but considered that it would have merits as concerns were raised that some countries may be classifying more cattle as clinical suspects than could be reasonably expected. In addition, allocating animals into clinical suspects, casualty slaughter and fallen stock subpopulations can be an artificial construct, particularly in those circumstances where cattle are raised in more extensive conditions. In such cases cattle are unlikely to be

regularly scrutinised so that an animal that may have symptoms consistent with BSE may be missed only to be first seen as recumbent or found dead. Such animals under the current approach would be ascribed much less value (points) than if observed as a clinical suspect. Combining clinical suspects, casualty slaughter and fallen stock into a single “risk” subpopulation provides a more reasonable and balanced approach that takes proper account of cattle rearing practices and opportunities for observation without compromising the integrity of the surveillance system.

The Group discussed a proposal that animals from the same birth cohort as an identified classical BSE case could provide a potentially new surveillance stream or, alternatively, could be included in the above-mentioned surveillance stream of “at risk animals”.

Designed prevalence – Type A vs Type B surveillance: The Group also discussed whether the two current types of surveillance (Type A and Type B) should be maintained or if a simpler approach may be warranted with a single design prevalence.

Considering the collective goals of BSE surveillance as outlined in article 11.4.20., the Group was of the opinion that a design prevalence of one case per 50,000 would be sufficient to meet them. As a result, the Group recommended that the design prevalence for BSE surveillance should be that of Type B.

Next steps: The Group did not reach a consensus on the proposal from the previous Group and agreed that further work was required using updated data as well as revisiting previous assumptions. Results from the model described above as well as those from an updated BSurvE model would be compared and reviewed by the Group as soon as they are available and recommendations would be proposed for the revision of the provisions for BSE surveillance.

The Group drew the attention on the potential impact of the revisions of the surveillance provisions (i.e. surveillance points’ values, surveillance streams, design prevalence) on Member Countries BSE risk status. If the requirements for surveillance were to be revised, the Group emphasised that it would be essential to allow for a transition period, so that countries having an official BSE risk status would be able to adapt their sampling strategy while maintaining their status.

3.3. Revision of the provisions of the draft chapter on risk assessment (Articles 11.4.23. to 11.4.29.)

The Group noted that the provisions on risk assessment (Articles 11.4.23. to 11.4.29.) were largely redundant with the questionnaire on BSE provided in Article 1.6.5. for Member Countries to apply for recognition of status and stressed that it was essential to ensure consistency and cross-referencing between these articles and Article 11.4.2.

The Group did not undertake a detailed review of the Articles related to risk assessment (11.4.23. to 11.4.29.). However, the Group proposed the following revisions:

- Article 11.4.23. - BSE risk assessment: introduction

Regarding the entry assessment, the Group specified that point 1 b should refer to live cattle and not to live animals.

- Article 11.4.27.- The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin

To take into consideration the risk that may be associated with small ruminants, the Group clarified that if potentially infected ruminants (*i.e.* not only infected cattle) or contaminated materials were rendered, there would be a risk that the resulting meat-and-bone meal could retain BSE infectivity.

- Article 11.4.28. - The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

To be concise, the assumptions 1 to 4 were removed as the Group agreed this narrative was not essential for the purpose of assessing the rendering processes.

Consistent with the recommendation of the previous Group, the Group was of the opinion that the BSE agent cannot be qualified as “*present at much higher titer*” in reticulo-endothelial tissue. In addition, the Group followed the advice of the Code Commission not to use the terminology “specified risk material” as it might be interpreted differently by different Member Countries and made references to Article 11.4.14. which defines a precise list of material.

4. Consideration on whether or not chronic wasting disease of cervids should be included in the OIE list

The Group was reminded that only the criteria for the inclusion of diseases, infections and infestations in the OIE list defined in Chapter 1.2 of the *Terrestrial Code* should be taken into consideration for listing/delisting any disease.

Dr Marija Popovic, representative of the OIE World Animal Health Information and Analysis Department, presented the most recent developments of the epidemiological situation of chronic wasting disease (CWD) in cervids. While endemic cases had previously only been reported in North America, three cases of CWD have been notified in Norway in 2016. The origin of these cases has not yet been elucidated.

The Group evaluated CWD against the criteria listed in Article 1.2.2.

1. *First criteria: “International spread of the agent (via live animals or their products, vectors or fomites) has been proven.”*

In 2001 and 2004, cases of CWD were reported in the Republic of Korea due to the import of elks infected with CWD from North America. This illustrates the potential for international spread of CWD via the trade of live animals.

2. *Second criteria: “at least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.”*

According to the information made available to the Group, some countries implement an active surveillance program for CWD. However, in the absence of detailed information on these surveillance programmes, the Group felt it was difficult to assess if these countries should be regarded as free based on the provisions of Chapter 1.4.

The Group took note of an EFSA scientific opinion on the results of an EU survey for CWD in cervids⁸. This survey was carried out in 2006-2010. Approximately 13,000 samples were collected in 21 EU Member States and Norway. No CWD positive results were found. However, EFSA concluded that the absence of positive cases in that survey could not exclude the presence of CWD infected animals.

The Group was informed that an updated EFSA’s scientific opinion on CWD should be published in two phases, the first phase by the end of 2016 and the second phase by the end of 2017. The Group recommended that a literature review should be carried out to further assess demonstration of freedom for CWD by some Member Countries and advised waiting for EFSA’s opinion on this matter.

3. *Third criteria: “Reliable means of detection and diagnosis exist and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations.”*

The Group noted that there is no accredited commercially available test available to diagnose the presence of the disease in live animals. The identification of the agent relies on post mortem testing. However, the Group felt that a more in depth review of scientific evidence would be necessary to properly assess this issue.

⁸ EFSA, Scientific Opinion on the results of the EU survey for Chronic Wasting Disease (CWD) in cervids. EFSA Journal 2010;8(10):1861 (<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1861/epdf>)

4. Fourth criteria

- 4a) *“Natural transmission to humans has been proven, and human infection is associated with severe consequences”*

To the best knowledge of the Group, there is no demonstrated evidence of transmission of the CWD agent to humans.

OR

- 4b. *“The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.”*

It was clarified that according to OIE terminology, cervids should be considered as wildlife, and the impact of CWD should be assessed against criteria 4.c.

OR

- 4c. *“The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population.”*

The Group questioned at what level the impact on the health of wildlife should be considered “significant”. The Group agreed that the disease can cause significant mortality at the farm or local level but does not have a significant impact at either the national or regional level at this stage. A significant concern in North America is associated with potential spill-over into the densely populated wild caribou (reindeer) herds as CWD continues its relentless spread. If this were to occur it is likely there would be significant impacts at a regional level. The Group recommended that a literature review be performed to further analyse this criteria.

In conclusion:

The Group acknowledged the potential for CWD’s international spread but felt that there were gaps in the Group’s knowledge on CWD, especially regarding the demonstration of freedom (criteria 2), the means of detection and diagnosis and the case definition (criteria 3), and the impact on the health of wildlife (criteria 4c). The Group recommended that a literature review should be conducted and subject matter and wildlife experts contacted to further assess these criteria before elaborating any recommendation regarding the relevance of CWD’s inclusion in the OIE list.

5. Finalisation and adoption of the draft report

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

.../Appendices

**MEETING OF THE OIE AD HOC GROUP ON
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)
Paris, 23-25 August 2016**

Agenda

1. Opening
 2. Adoption of the agenda and appointment of chairperson and rapporteur
 3. Review and update of the existing chapter on BSE in the Terrestrial Code
 - 3.1. Revision of the draft chapter (Articles 11.4.1. to 11.4.19.)
 - 3.2. Revision of the provisions of the draft chapter on surveillance (Articles 11.4.20. to 11.4.22.)
 - 3.3. Revision of the provisions of the draft chapter on risk assessment (Articles 11.4.23. to 11.4.29.)
 4. Consideration on whether or not chronic wasting disease of cervids should be included in the OIE list
 5. Finalisation and adoption of the draft report
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**REPORT OF THE MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY**

Paris, 23-25 August 2016

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