



**ELECTRONIC CONSULTATION OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION
OF MEMBERS¹
Paris, 27 October and 24 November 2017**

The OIE *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) Risk Status Evaluation of Members (hereafter the Group) was consulted electronically on 27 October and on 24 November 2017.

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

Dr Noel Murray was appointed Chair and Dr Lucie Carrouée-Pook acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

2. Evaluation of applications from Members for the official recognition of their negligible BSE risk status

2.1. Nicaragua

Nicaragua was recognised as having a controlled risk status for BSE in May 2012.

In May 2017, Nicaragua submitted a dossier seeking its recognition as a country presenting a negligible BSE risk status.

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

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

▪ *Risk assessment for entry of the BSE agent*

The Group noted that regulations were in place to prohibit importations of meat-and-bone meal (MBM) or greaves intended to be used for feeding to ruminants from countries affected by transmissible spongiform encephalopathies (TSEs). While imports of MBM or greaves from TSE affected countries for other purposes were not specifically prohibited by regulations, based on the subsequent clarification provided by Nicaragua, the Group acknowledged that MBM or greaves of ruminant origin had not been imported into Nicaragua within the past eight years for any purpose.

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 February 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/>

With regard to importations of feedstuff containing MBM or greaves, the Group noted that only pre-packed, retail ready pet food containing MBM was imported into Nicaragua from countries with a negligible or controlled BSE risk status as well as from three countries with an undetermined BSE risk status. The Group noted that under a Ministerial Agreement from 2004, “feed could be imported provided it was either for use by animals not susceptible to BSE or if it was certified that it was not made using ruminant proteins”. In 2011, a further Ministerial Agreement stated that import requirements for animal feedstuffs were to be based on the OIE standards according to the BSE risk status of the exporting country and that it was only permitted to import feed containing MBM if it was intended to be used for feeding mono-gastric animals. Finally, from the additional information provided, the Group noted that since this year imports of feed for mono-gastric animals are prohibited from countries with an undetermined BSE risk status.

The Group noted that Nicaragua conducted a risk analysis and on-site visits to assess the compliance of the exporting countries with an undetermined risk status with the requirements of Chapter 11.4 of the *Terrestrial Code* in view of the importations of pet food containing MBM. In light of Chapter 5.3 of the *Terrestrial Code* describing the principle of equivalence to the measures described in disease-specific chapters, the Group determined that this approach was acceptable.

With respect to importations of live cattle, the Group noted that imports into Nicaragua from three neighbouring undetermined BSE risk countries were recorded until 2015. Further imports from such countries were subsequently banned from 2016, in accordance with a new Ministerial Agreement. The Group examined the sanitary requirements applicable since November 2011 and concluded that they were compliant with the requirements of Article 11.4.9. of the *Terrestrial Code*. However the Group determined that they had been enforced for less than seven years.

With regard to imports of products of bovine origin, the Group noted that various meat and meat products of bovine origin (including viscera, offal, tallow) which are not listed as safe commodities in Article 11.4.1. of the *Terrestrial Code*, were imported from countries having a negligible, controlled or undetermined risk status for BSE. The dossier indicated that for imports from undetermined BSE-risk countries, Nicaragua conducted a risk analysis and on-site visits to assess compliance of the exporting countries with the requirements of Chapter 11.4. of the *Terrestrial Code*. The Group reiterated that in light of Chapter 5.3. of the *Terrestrial Code*, this approach was acceptable. However, the Group noted that the actual sanitary requirements applicable to these importations as well as a more precise description of the products of bovine origin imported (e.g. nature of the viscera and bones) were not provided.

Overall, the Group considered that the conclusion of the entry assessment was that the risk that the BSE agent could have entered Nicaragua during the interval covered by the assessment, although very low, could not be considered negligible.

- *Risk of recycling and amplification of the BSE agent*

The Group noted that, since 2004, the list of tissues defined as specified risk material (SRM) consisted of the tonsils and the distal ileum of cattle of any age, together with the brain, eyes, spinal cord, and dorsal root ganglia of cattle older than 30 months old, as well as the skull and vertebral column from slaughtered cattle older than 30 months. The Group noted that this definition of SRM, which is consistent with Article 11.4.14. of the *Terrestrial Code*, was further extended by an Administrative Resolution in 2016 to include fallen stock and non-ambulatory animals in abattoirs. The Group acknowledged that the extended list exceeded the material listed in Article 11.4.14. of the *Terrestrial Code*.

The Group noted that about 80% of the cattle were slaughtered in six industrial slaughterhouses and the remaining 20% were slaughtered in municipal slaughterhouses.

The Group acknowledged that in industrial slaughterhouses, protocols for the removal, segregation, identification and destruction of SRM through incineration have been implemented and supervised by government inspectors from the Official Meat Inspection Service (IPSA) since 2004. The Group also took note that offal from municipal slaughterhouses may be used for local human consumption. The Group acknowledged that other wastes from municipal slaughterhouses, as clarified in response to a follow-up question, is disposed of in a municipal dump. Animals that die on farm are either burnt or buried. All non-ambulatory and condemned animals that arise in industrial abattoirs are incinerated on-site with the ash subsequently buried.

Based on the information provided, the Group also noted that live cattle imported for slaughter were processed in one of the six industrial scale slaughterhouses. Cattle imported for breeding may have been subsequently slaughtered in one of these facilities where their SRM would have been removed segregated and destroyed as previously outlined. An unspecified number of breeding cattle would also have been slaughtered in municipal abattoirs with any waste being consumed by the low income population or disposed of in municipal dumps.

Overall, the Group determined that SRM from all industrial abattoirs as well as all waste not intended for human consumption from municipal abattoirs, including fallen stock, non-ambulatory and condemned animals were excluded from materials sent for rendering and that oversight verifying the exclusion of these materials was provided by the Official Meat Inspection Service (IPSA).

The Group acknowledged that since 2001, non-SRM ruminant waste materials, which are rendered, have been processed under high temperature and pressure (133°C, for at least 20 minutes with a minimum absolute pressure of 3 bars). This is in compliance with the procedures for the reduction of BSE infectivity in MBM as outlined in Article 11.4.19. of the *Terrestrial Code*. In addition, the Group noted that no rendering plants processed materials or waste from external sources, but only materials or waste from industrial slaughterhouses, which all destroy SRM by incineration.

The Group acknowledged that legislation prohibiting the feeding of cattle with feed of bovine origin has been in force since 2001, followed by an enhanced ruminant-to-ruminant feed ban in 2011. This legislation was subsequently amended in 2016 to a cattle-to-ruminant ban. However, in the additional information provided, Nicaragua clarified that by-products of other ruminants than cattle were not processed in Nicaragua, and the ban had still the same practical effect as a ruminant-to-ruminant feed ban.

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

- *Appropriate level of control and audit of the feed ban*

The Group reviewed the information provided by Nicaragua on inspection oversight conducted by government inspectors in rendering plants processing ruminant material or mixed species containing ruminant material and in ruminant feed mills within the past eight years (2009-2016).

The Group noted that microscopy is used to detect bone fragments as a check for cross-contamination in feed mills. The Group pointed out that microscopy could only differentiate between materials derived from terrestrial animals and that originating from aquatic animals. While Nicaragua's feed ban prohibits cattle MBM from being fed to all ruminants, based on the information provided for the preceding eight years and considering that alternative tests such as PCR are not used to distinguish between species, in practice, and although not supported by a specific regulatory framework, the corrective actions that have been implemented as a result of

any positive microscopic findings in samples of feed for livestock are consistent with those taken under a more extensive terrestrial animals to ruminants feed ban. The establishment of separate production lines and the establishment of single conveyors for the application of MBM in the mixer were implemented from 2011, less than eight years ago. Where separate production lines could not be established, the use of MBM in the feed mill was suspended or the authorisation of the feed mill withdrawn.

Considering that correctives actions were implemented as a result of the presence of any positive microscopic findings, the Group concluded, that a de facto ban on feeding ruminants with terrestrial animal proteins has been implemented in Nicaragua for the preceding eight years.

The Group noted that the use of PCR as an alternative or additional test for checking for potential cross-contamination of cattle feed with MBM of ruminant origin may be advisable as it would increase the specificity of the diagnostic process. However, the Group was of the opinion that a de facto terrestrial animals to ruminant feed ban, if consistently implemented, provided sufficient guarantees of appropriate level of control and audit of the feed ban. Nevertheless, the Group noted a potential issue concerning the sustainability of this approach (implementation of a de facto terrestrial animals to ruminant feed ban) as the lack of legal basis exposed the administration to possible litigations and enforcement difficulties.

The Group assessed in detail the fact that the legislation to separate production lines of ruminant and monogastric feed in feed mills has only been in force since 2011 (i.e. less than 8 years) and the sustainability of a de facto terrestrial animals to ruminant feed ban in the absence of supporting legal regulations. However, the Group ultimately concluded that Nicaragua provided convincing evidence that the various layers of mitigating measures had been implemented for more than 8 years, in light of Article 5.3.2. of the *Terrestrial Code* which defines the principle of “equivalence of sanitary measures”, according to which “significantly different systems and measures may achieve equivalent animal and human health protection”. Overall, the Group concluded that an appropriate level of control and audit of the proper implementation of the feed ban had been in force for at least eight years (cf section f).

b) *Surveillance according to Articles 11.4.20. - 11.4.22.*

The Group noted that the surveillance undertaken over the seven year period from 2010 to 2016 exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*. Based on the information provided in the dossier, 470,362 surveillance points were collected, compared to a minimal requirement of 150,000 for an adult cattle population of 2,400,000 over two years of age.

The Group acknowledged that Nicaragua’s surveillance programme for BSE targeted all surveillance streams, however, it was noted that clinical suspects was the most represented stream. Overall, clinical suspects contributed 99.8% of the surveillance points collected over the period 2010-2016. This high number of clinical suspects was justified by Nicaragua by the occurrence of "derrenque" in cattle in the dry season, a condition due to toxic plants producing alkaloids (pyramid flower: *melochia pyramidata*, *Lantana camara*). The Group pointed out that, both official and private veterinarians should be aware of the clinical symptoms caused by this common intoxication and should therefore try to distinguish them from any eventuality that could give rise to a suspected BSE case.

Importantly, the Group recommended that Nicaragua should consider increasing the number of samples collected through other surveillance streams.

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

▪ *Awareness programme*

The Group noted that an awareness program on BSE was initiated in 1996 and was formalised throughout the country in 2004. The Group appreciated that this programme appeared to be both comprehensive and broad in scope, covering all relevant sectors, and acknowledged that it was supported by a range of materials including presentations, newsletters, murals, calendars, and leaflets. The Group concluded that this awareness programme met the requirements of the *Terrestrial Code*.

▪ *Compulsory notification and investigation*

The Group noted that BSE has been declared to be a notifiable disease under relevant legislation since 1998. The Group appreciated that the compulsory notification of cattle displaying clinical symptoms suggestive of BSE was supported by training and awareness programmes, a 24-hour free hotline, financial compensation (although details were not provided) and sanctions under the law for failing to report. The Group therefore concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

▪ *Laboratory examination*

The Group noted that within the last seven years BSE diagnosis was conducted in the Central Veterinary Diagnostics and Food Microbiology Laboratory (LCDVM) based on histopathology and immunohistochemistry. Immunohistochemistry was performed on suspicious samples arising from histopathology and on a random selection of non-suspicious histopathological samples. The Group pointed out that according to Chapter 2.4.5. of the *Terrestrial Manual*, histopathology was no longer a diagnostic method of choice for the investigation of clinical suspects or the screening of healthy populations but could “be used in some situations”.

The Group recommended that Nicaragua undertake all tests for BSE using methods recommended by the *Terrestrial Manual*: i.e. immunohistochemistry (or rapid tests for the active surveillance streams).

The Group acknowledged that the LCDVM operated under ISO17025. However, the Group pointed out that immunohistochemistry as performed at the LCDVM has not been validated to date and that the LCDVM has not been accredited for the diagnosis of BSE, although a request for accreditation for BSE diagnosis is planned to be made in 2018.

Overall, and consistent with previous positive evaluations of the negligible BSE risk status of countries using histopathology, the Group concluded that the laboratory examination for BSE carried out in Nicaragua could be considered to be compliant with the *Terrestrial Manual* for at least the preceding seven years.

The Group suggested that the Biological Standards Commission review Chapter 2.4.5 of the *Terrestrial Manual* and clarify whether testing by histopathology, a method known to be of limited sensitivity, was acceptable and, if so, under what circumstances. Should histopathology be no longer considered to be acceptable for the purpose of surveillance by the Biological Standards Commission, the Scientific Commission for Animal Diseases may need to ensure, through the review of the annual reconfirmations for BSE, that all countries currently recognised as having negligible risk status transition to performing BSE testing with methods recommended by the *Terrestrial Manual*.

d) BSE history in the country

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

e) Compliance with the questionnaire in Article 1.6.5.

The Group agreed that the dossier submitted was mostly compliant with the format of the questionnaire of Article 1.6.5. of the *Terrestrial Code* for Member Countries. However, the Group pointed out that the extensive number of appendixes (42) led to significant challenges in undertaking an evaluation of this application. Furthermore, it is noteworthy that the answers provided for a number of questions in the original dossier seeking recognition of negligible BSE risk status were inadequate. This resulted in additional questions being raised with Nicaragua on several occasions seeking a more detailed explanation together with appropriate supporting evidence.

f) Conclusions

It has to be noted that whilst the majority of the Group was confident that an appropriate level of control and audit of the proper implementation of the feed ban had been in force for at least eight years, two experts expressed concerns over the fact that the legislation to separate production lines of ruminant and monogastric feed in feed mills has only been in force since 2011 (i.e. less than 8 years) and one expert expressed concerns over the sustainability of a *de facto* terrestrial animals to ruminant feed ban in the absence of supporting legal regulations. However, the Group ultimately concluded that Nicaragua provided convincing evidence that the various layers of mitigating measures had been implemented for more than 8 years, in light of Article 5.3.2. of the *Terrestrial Code* which defines the principle of “equivalence of sanitary measures”. A consensus was reached and the Group determined that an appropriate level of control and audit of the proper implementation of the feed ban had been in force for at least eight years. Importantly, in order to ensure the continuous implementation of appropriate mitigating measures, the Group recommended that future submissions for annual reconfirmation of Nicaragua’s negligible BSE risk status should be comprehensively reviewed by the Scientific Commission for Animal Diseases (see section Recommended status).

▪ *Recommended status*

Considering the information submitted in the dossier and Nicaragua’s answers to the questions raised, the Group concluded that the application was compliant with the requirements of Article 11.4.3. and with the questionnaire in Article 1.6.5. of the *Terrestrial Code*. The Group therefore recommended that Nicaragua be recognised as a ‘negligible BSE risk’ country.

However, the Group advised that Nicaragua should:

- continue to remove and exclude SRM, including fallen stock, condemned and non-ambulatory animals from raw waste material that is rendered for the production of MBM;
- continue to ensure that all non-SRM ruminant waste materials that are rendered are processed under high temperature and pressure (133°C, for at least 20 minutes with a minimum absolute pressure of 3 bars);
- consider using an alternative or additional method to check for potential cross contamination in feedstuffs such as PCR that is more specific than microscopy as it enables taxonomic identification to be undertaken, unless Nicaragua decides to align its legal basis with the current *de facto* terrestrial animals to ruminants feed ban;
- increase the number of samples collected through surveillance streams other than clinical suspects;
- perform all testing for BSE using methods recommended by the *Terrestrial Manual* (i.e. immunohistochemistry -or rapid tests-);
- consider obtaining accreditation and establishing a quality assurance system for the diagnostic methods used to detect BSE infected animals.

In order to assess the progress made along these recommendations, as well as to monitor the continuous implementation of the feed ban and subsequent corrective actions, and to check the continuous removal of SRM, the Group recommended that future annual reconfirmations of Nicaragua's negligible risk status should provide the above-mentioned information and be comprehensively reviewed by the Scientific Commission for Animal Diseases.

2.2. Other Member request

The Group assessed another request from a Member for the recognition of its BSE negligible risk status. The Group concluded that this Member did not meet the requirements of the *Terrestrial Code* and the dossier was referred back to the corresponding Member.

3. Finalisation and adoption of the draft report

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

.../Appendices

**Terms of Reference and working procedure
for evaluating dossiers for official recognition of BSE risk status
2017 – Electronic consultation**

1. Prerequisites

All experts should:

- a) Sign off the OIE Undertaking on Confidentiality of information, if not done previously;
- b) Complete the Declaration of Interests Form and forward it to the OIE at their earliest convenience, and at least two weeks before the teleconference.

2. To prepare the BSE *ad hoc* Group teleconference

Upon reception of an application from a Member Country, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the relevant questionnaire, main sections of the questionnaire, regular notification to the OIE, payment of the fee, PVS report, etc.). If an information gap is identified, the SD requests additional information to the country. When needed, the SD undertakes translation into English of the dossier or main parts of it.

The SD sends the working documents to the experts of the *ad hoc* Group (AHG), including the dossiers received from applicant countries **at least 1 month before the AHG meeting**. Translations may be forwarded later.

The SD suggests the nomination of a chair and rapporteur, for the Group's consideration. The chair will lead the electronic discussion and the rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossier.

All experts should:

- a) Evaluate and study in detail the dossiers provided by the OIE;
- b) Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- c) Summarise the dossiers according to the *Terrestrial Animal Health Code (Terrestrial Code)* requirements, using the form provided by SD (Appendix A);
- d) Draft the questions, whenever the analysis of the dossiers raises questions which need to be clarified or "completed" by the applicant Member Countries.
- e) Send the completed form for each dossier and the possible questions to the SD, **10 days before the teleconference**.
- f) The SD compiles the forms and the questions to be forwarded to the applicant Member Countries before the teleconference.

The experts can request support from the SD at any time.

The SD will consider the available PVS report and share with the experts any concern. As they are bound by the OIE rules on confidentiality of information, the experts may request the OIE PVS reports if not obsolete or confidential. They may also take into account any other information available in the public domain that is considered pertinent for the evaluation of dossiers.

3. During the BSE *ad hoc* Group teleconference

During the teleconference, the Chair is requested to lead the discussion. All experts should:

- a) Mention any potential conflict of interest and if relevant, withdraw him/herself from the discussion;
- b) Contribute to the discussion.

The Group may determine that additional information should be requested to the applicant countries before an informed conclusion can be drawn.

4. After the BSE *ad hoc* Group teleconference

If the Group decides during the teleconference that additional information should be requested to the applicant countries, via the SD, the responses are sent by email to the Group by the SD. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all Group members on the additional information received are taken into consideration.

The SD with the support of the rapporteur provides a draft report no more than seven days after the teleconference (no later than 31 October 2017) and circulates it to the AHG. The AHG finalises the report within the following week (indicative deadline: 7 November 2017).

The Chair may determine that a second teleconference is needed for the Group to further discuss before finalising the report.

It is recommended that the report follows a structure based on the list of requirements of the *Terrestrial Code* followed by a discussion, the conclusion and the recommendation(s) to the Scientific Commission (Appendix B). The report should state clearly the conclusions of the AHG and its recommendations to the Scientific Commission for Animal Diseases (Scientific Commission). The rationale of each observation and recommendation should be described to facilitate understanding by the Scientific Commission and communication between the OIE and the applicant Member Country.

The SD circulates the final version of the report to the Group once endorsed by the Scientific Commission.

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ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION
OF MEMBERS**

Paris, 27 October and 24 November 2017

Agenda

1. Adoption of the agenda and appointment of chairperson and rapporteur
2. Evaluation of applications from Member Countries for official recognition of BSE negligible risk status
 - 2.1. Nicaragua
 - 2.2. Other Member Country request
3. Finalisation and adoption of report

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