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ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION OF MEMBERS[1]
Paris, 25-26 September 2019

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The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk status evaluation of Members (hereafter the Group) was consulted electronically on 25 and 26 September 2019.

1. Opening

On behalf of Dr Monique Eloit, Director General of the OIE, Dr Neo Mapitse, Head of the Status Department, welcomed and thanked the Group for its commitment and the extensive support towards the OIE mandates. He acknowledged the amount of work before, during and after the *ad hoc* Group meeting and the efforts required in reviewing the dossiers and highlighted that the official recognition of disease status was an important activity for the OIE.

Dr Mapitse reminded the Group on the significance and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the forms for undertaking of confidentiality. He underlined the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest (by withdrawing themselves from the discussion/conclusion in case of a potential conflict of interest). No conflicts of interest were declared in this Group.

Dr Mapitse pointed out that whilst the evaluation of the BSE risk status of Members might be a politically sensitive issue, the Group's assessment should be driven by standards, science and evidence-based, and highlighted that the ongoing revision of the BSE Chapter should not impact the evaluation of the dossiers received by the Group. Dr Mapitse also encouraged the Group to capture the rationale supporting its decisions and recommendations in its meeting report for the consideration of Members.

The Group and the OIE welcomed Drs Juan José Badiola Díez and Mark Stevenson as new members in the Group.

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

Dr Ximena Melón was appointed Chair and Dr Lesley van Helden 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.

[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 2020 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. Evaluation of applications from Members for the official recognition of their negligible BSE risk status

3.1. Bolivia

In accordance with the established procedures, the OIE Headquarter staff from Bolivia supporting the secretariat withdrew from the decision process on Bolivia's dossier.

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

- Risk assessment for entry of the BSE agent

  The Group took note that BSE was considered an exotic disease by the regional (Andean Community of Nations - CAN) and national legislation. CAN regulation 1587/2013 laid down the prohibitions and sanitary requirements regarding BSE to be applied when CAN members (such as Bolivia) import bovine commodities. The Group acknowledged that prohibition of importation of bovines and ruminant-derived meat-and-bone meal (MBM) or greaves from countries affected by transmissible spongiform encephalopathies (TSEs) was in place since 2001.

  With respect to importation of live cattle, the Group noted that imports into Bolivia during the last seven years were from four neighbouring countries with negligible BSE risk status.

  With regard to importation of MBM or greaves of ruminant origin, Bolivia in the last 8 years has imported MBM and greaves from countries with negligible BSE risk status to supply raw material to the pet food industry, as well as to other non-ruminant species.

  Pertaining to feedstuff containing MBM or greaves of ruminant origin, the Group was informed on the imports of pet food. The country of origin (negligible risk) and the intended use (pet food packaged for direct sale) were considered to have an insignificant risk.

  Concerning imports of products of bovine origin, the Group noted that a variety of products of bovine origin for human consumption have been imported either from countries that were initially controlled BSE-risk that were subsequently granted negligible BSE-risk status or negligible BSE-risk countries for the entire period.

  After discussion of the entry assessment, the Group concluded that the risk that the BSE agent could have entered Bolivia during the interval covered by the assessment was negligible.

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

  The Group noted that since 2005 a list of tissues and organs considered specified risk material (SRM) has been approved by Administrative Resolution of SENASAG. The Group noted that the aforementioned list followed the WHO classification of infectivity, and was not in full agreement with the materials listed in Article 11.4.14 of the *Terrestrial Code.* Nonetheless, SRM and other materials listed in Article 11.4.14. as well as leftover material not destined for human consumption were subjected to rendering consistent with the parameters stated in Article 11.4.19. of the *Terrestrial Code* for the reduction of BSE infectivity.

  The Group acknowledged that there were six animal rendering plants in Bolivia. Of these, only one produced MBM derived from cattle, whereas the rest produced materials that do not constitute a BSE risk. The Group acknowledged that since 2005 rendered materials have been processed at 133°C for at least 20 minutes with a minimum absolute pressure of 3 bar, according to Resolution No. 027/2005. All six plants were registered and monitored by SENASAG. The Group took note that bone ash was produced in only one plant by heating the bones to not less than 600°C for one hour, with a proven absence of bone fragments, blood and muscle tissues, in accordance with Resolution No. 027/2005. According to the regulation in place, only bovine bone ash was permitted to be fed to ruminants.

The Group noted that there was no collection system for animals found dead on farms. The Group took note that fallen stock in the field were either buried or scavenged by wild animals, whereas fallen stock during transport and in abattoir pens were considered unfit for human consumption and were either buried or incinerated. Materials condemned as not suitable for human consumption were removed from the slaughter line for denaturation and destruction. Regulations regarding these measures have been in place since 2001.

The Group acknowledged that legislation prohibiting the feeding of ruminants with feed of ruminant origin has been in force since 2001.

With regard to feed mills, the Group took note that visual and record inspections have been carried out in the last 8 years and that sampling to check for the absence of prohibited proteins for ruminants were conducted in 2018 and 2019. Direct microscopy was used to monitor for cross-contamination of ruminant feed with bone fragments, blood and muscle. Analytical capabilities have been available in the LIDIVECO laboratory of the city of Cochabamba since 2018.

The Group noted that whereas imported or nationally produced MBM could be used for pet food or other non-ruminant species, such as pigs, poultry and fish, ruminant MBM were prohibited to be incorporated into ruminant feed. The Group took note that feed mills that produced feed for both ruminants and non-ruminants used separate lines to avoid cross-contamination.

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

b) Surveillance according to Articles 11.4.20. - 11.4.22.

The Group noted that the surveillance undertaken over the seven-year period from 2012 to 2019 met the requirements of type B surveillance according to Article 11.4.22. on surveillance for BSE in the *Terrestrial Code*. Based on the additional information, 192,640.50 surveillance points were collected, compared to a minimum requirement of 150,000 for an adult cattle population of 5,467,089 over two years of age.

The Group took note that Bolivia's surveillance programme for BSE targeted at least three of the four surveillance subpopulations every year, except in 2015 and 2016 when only routine slaughter and clinical suspects were sampled. The Group commented on the heavy reliance on the testing of clinical suspects to accumulate surveillance points. The Group emphasised that according to point 1 of Article 11.4.21. of the *Terrestrial Code*, BSE clinical suspects consist of those cattle affected by illnesses refractory to treatment and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness. While the Group acknowledged that BSE had been excluded in the final diagnosis of all clinical suspects that were identified, it was noted that BSE clinical suspects consisted of cattle displaying neurological signs that partially matched the definition in Article 11.4.21. The Group considered that Bolivia's criteria to assign animals to the rest of the subpopulations (fallen stock and emergency slaughter) was consistent with Chapter 11.4.

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

- Awareness programme

The Group noted that an awareness programme on BSE was initiated in 2005, and that it was reinforced through the implementation of nervous syndromic surveillance by SENASAG. The Group noted that the programme was continuously applied and covered the entire country, although it is acknowledged that the degree of implementation of the programme has been variable in the nine departments of the country, all relevant stakeholders have participated.

From the additional information, the Group acknowledged that a contingency plan approved outlined the preparedness plan should a case of BSE arise. The plan falls under the framework of the SINAEZ (Sistema Nacional de Emergencia Zoosanitaria) since 2006.

- Compulsory notification and investigation

The Group noted that transmissible spongiform encephalopathies were declared to be notifiable throughout the country under relevant legislation in 2001 (Ministerial Resolution No. 017/01). The Group acknowledged that promotion of compulsory notification fell under the responsibility of the awareness programme. The Group noted that penalties related to lack of reporting were not specified. The Group further 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 at the Veterinary investigation and diagnostics Laboratory of Santa Cruz (LIDIVET), which is the official reference laboratory for BSE in Bolivia. The Group was informed that since the implementation of the surveillance plan in Bolivia in 2005, histopathology alone was used for BSE diagnosis until 2015, when immunohistochemistry was introduced as the primary test. Samples with a positive or inconclusive result would be referred to an OIE Reference Laboratory for confirmation. The Group took note that since 2015 all animals that were rabies negative, have been also examined with both histopathology and immunohistochemistry.

The Group concluded that the laboratory examination for BSE carried out in Bolivia was compliant with the *Terrestrial Manual*.

d) BSE history in the country

The Group acknowledged that to date, BSE has never been reported in Bolivia.

e) Compliance with the questionnaire in Chapter 1.8.

The Group agreed that the dossier submitted was compliant with the format of the questionnaire of Chapter 1.8. of the *Terrestrial Code*. Nevertheless, the Group pointed out that a lack of conciseness and data inconsistency for a number of elements resulted in several additional questions being raised. As a consequence, the Group encountered significant challenges in undertaking the evaluation of this application.

f) Conclusion

- Recommended status

Considering the information submitted in the dossier and Bolivia'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 BSE questionnaire in Chapter 1.8. of the *Terrestrial Code*. The Group therefore recommended that Bolivia be recognised as a 'negligible BSE risk' country.

However, the Group advised that Bolivia should:

- Focus the reporting of inspections and infractions at rendering plants and feed mills on activities relevant to BSE-risk and;

- Refine the definition of BSE clinical suspects and the criteria to include them in the nervous syndromic surveillance part of the epidemiological surveillance system (SINAVE) to ensure compliance with Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*.

3.2. United Kingdom (zonal BSE negligible risk status for Jersey)

In August 2019, the United Kingdom submitted a dossier seeking recognition for Jersey as a zone posing a negligible BSE risk.

The Group requested additional information and received clarification from Jersey. 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

  With respect to importations of MBM, greaves and feed containing either, the Group acknowledged that, based on the additional information provided, Jersey had not imported feed for livestock, including poultry and horses, containing MBM since 1996. The vast majority of feed for animals other than cattle had historically been imported from a United Kingdom zone with a controlled BSE risk status, where they were either produced to European Union (EU) standards which are equivalent to the measures described in the *Terrestrial Code* or underwent EU inspection at a Veterinary Border Inspection Post. Nevertheless, the Group pointed out that Jersey therefore relied entirely on clearance of products in other EU Members and that success of this approach relied on effectiveness of border inspections outside of Jersey.

  Regarding importations of live cattle, the Group acknowledged that these had been prohibited since 1878 to maintain genetic integrity of the population and to prevent disease incursions.

  The Group noted that the vast majority of products of bovine origin were imported into Jersey for human consumption at least since 2015 from other zones of the United Kingdom, and that limited amounts were imported from other countries having controlled or negligible BSE risk status. The Group also noted that products of ruminant origin imported into Jersey would have been produced according to EU standards, which would provide an equivalent level of assurance as the *Terrestrial Code*, and that neither tallow, MBM and offal were imported.

  Even though the information on volumes of importation was not provided for the relevant period of time, based on the ongoing implementation of measures in accordance with EU Legislation for at least the preceding 8 years, the Group concluded that the risk that the BSE agent could have entered Jersey during the interval covered by the assessment was negligible.

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

  The Group noted that definition, collection and disposal of specified risk material (SRM) (i.e., brain, spinal cord, vertebral column, eyes, tonsils) followed European Union regulations (EC) No 999/2001 and No 1069/2009. From the additional information provided, the Group acknowledged that legislation regulating waste management had been in force since 2005, and that all on farm casualty slaughtered animals and fallen stock were collected by state-sponsored knackermen. These carcasses, as well as all animal by-products (ABP) from the slaughterhouse, including SRM, were sent to the incinerator to be destroyed as Category 1 and 2 ABP. The ashes were then buried in appropriately lined pits at the government-owned waste plant, which has been regulated under the Waste Management (Jersey) law since 2005.

  The Group acknowledged that there has not been a single rendering facility in Jersey for the last ten years.

  The Group agreed that a ban on feeding MBM or tallow derived from Category 1 and 2 materials, as well as processed animal protein (PAP) derived from Category 3 material, as defined by EU Legislation, from both ruminants and non-ruminants to all farmed animals ('total feed ban') has been in place in the EU, including Jersey, since 2001. The Group noted that an on-farm feed sampling programme where feed was tested for the presence of animal protein using microscopy started in the cycle 2018-19. Results covering 76% of dairy farms and 83% of Jersey's cattle population were provided; all samples were negative.

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

b) Surveillance according to Articles 11.4.20.-11.4.22.

The Group noted that the surveillance undertaken over a six-and-a-half-year period from 2012 to 2018 exceeded the minimum requirements of type B surveillance according to Article 11.4.22. on surveillance for BSE in the *Terrestrial Code*. Based on the information provided in the dossier, 1,431.4 surveillance points were collected, compared to a minimum requirement of 200 for an adult cattle population over two years of age of 2,736 adult cattle.

The Group acknowledged that the age of cattle was determined from records through a passport and an identification database with each individual having a unique identification displayed on two ear tags. Dentition was used for verification of age if necessary.

Even though Jersey's definition of clinical suspects did not include an age limit, and that from 2013 the age limit for fallen stock and casualty slaughter was fixed at 48 months, the Group considered that Jersey's definition of surveillance subpopulations was in accordance with Article 11.4.21. point 1 of the *Terrestrial Code*.

The Group took note that Jersey's surveillance programme for BSE targeted all four surveillance subpopulations every year until 2013, when sampling of routine slaughter ceased. Only one clinical suspect was reported in Jersey since 2012.

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

- Awareness programme

  The Group acknowledged that awareness activities for BSE had been in place involving farm animal veterinary practitioners, private and government veterinarians, abattoir workers and those performing on-farm slaughter and fallen stock collection. The Group noted that 79% of dairy farms and more than 40% of cattle farms were visited for BSE awareness related discussions in 2019. The Group took note that private veterinarians received information on BSE through the veterinary literature (e.g. the Veterinary Record), and that government veterinarians have access to government training materials. However, relevant information such as the start year, the continuous application and examples of training materials, such as leaflets or manuals were not provided, although a question on this subject was raised. The Group also noted that a description of the awareness programme's geographical coverage was implied, but not clearly provided. Nonetheless, the Group considered that considerable awareness amongst stakeholders most likely existed as the result of the more than 150 cases of BSE reported between 1988 and 2001.

  The Group concluded that, based on the information provided, this awareness programme met the requirements of the *Terrestrial Code*; however, the Group recommended that Jersey keep records detailing when and where the training occurred and the materials used, to demonstrate that courses occur with sufficient frequency.

  The Group acknowledged that practices for dealing with a BSE case were outlined in the EU Legislation (Transmissible spongiform encephalopathy) (Jersey) Regulation 2015.

- Compulsory notification and investigation

  The Group noted that BSE was declared a notifiable disease under relevant legislation since 1988, and that it was currently notifiable under EU Legislation adopted by Jersey in 2015. The Group acknowledged that compensation was provided to farmers for animals killed as part of a BSE investigation, and that penalties were in place for failure to report BSE cases. The Group therefore concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- Laboratory examination

  The Group took note that there were no laboratories in Jersey and that primary testing for BSE diagnosis was conducted at an APHA-designated laboratory (LGC Risley, now named Eurofins) using BioRad TeSeE rapid testing. Secondary testing of inconclusive or positive samples was done at APHA Weybridge (the UK National Reference Laboratory, which is an EU and OIE Reference Laboratory) with confirmatory western blotting and histology/immunohistochemistry. The Group acknowledged that the protocol described was put in place in 1998 and that no changes had been reported since then.

  The Group concluded that the laboratory examination for BSE carried out in Jersey was compliant with the *Terrestrial Manual*.

d) BSE history in the country

The Group noted that BSE was first reported in 1988 with the last case in 2002. Overall there were 151 cases with the most recently affected birth cohort in 1993. The outbreak in Jersey mirrored the outbreak in the mainland United Kingdom with the same control measures adopted that were progressively enhanced over time. A ruminant to ruminant feed ban was introduced in 1989, extended to a mammalian to ruminant ban in 1994, followed by a mammalian to all farmed animal ban in 1996 and finally a ban on processed animal protein from both ruminants and non-ruminants to all farmed animals ('total feed ban') from 2001. Legislation for BSE and associated control measures, surveillance, etc. mirror those implemented within the EU.

e) Compliance with the questionnaire in Chapter 1.8.

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

f) Conclusion

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

However, the Group advised that Jersey should:

- Keep records of importation for the last seven years.

- Maintain documentary evidence on the implementation of the awareness programme.

4. Finalisation and adoption of the draft report

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

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…/Appendices

Appendix I

ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION OF MEMBERS
Paris, 25-26 September 2019

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Terms of reference

The OIE *ad hoc* group on bovine spongiform encephalopathy (BSE) risk status of Members (the Group) is expected to evaluate a dossier for the official recognition of a Member's BSE risk status.

1. Prerequisites

All experts should:

a) Sign off the OIE Undertaking on Confidentiality of information.
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 (i.e., 11 September 2019).

2. Prior to the teleconference

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the 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 Member. 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 (the Group), including the dossiers received from applicants at least 1 month before the Group meeting (i.e., 25 August 2019). 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 Members.
e) Send the completed form for each dossier and the possible questions to the SD, 10 days before the teleconference (i.e., 15 September 2019).
f) The SD compiles the forms and the questions to be forwarded to the applicant Members 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.

3. During the teleconference

The Chair should 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.

If the Group decides during the teleconference that additional information should be requested to the applicant Members before an informed conclusion can be drawn, the SD forwards the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all Group members are taken into consideration.

The Group should provide a detailed report to recommend to the Scientific Commission for Animal Diseases the Member should be (or not) recognised with an official BSE risk status, and to indicate any information gaps or specific areas that should be addressed in the future by the Member.

4. After the teleconference

The SD circulates to the Group the draft report no more than seven days after the teleconference (no later than 3 October 2019). The Group finalises the report within the following week (indicative deadline: 10 October 2019).

After endorsed by the Scientific Commission, the SD circulates to the Group the final version of the report.

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Appendix II

ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION OF MEMBERS
Paris, 25-26 September 2019

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Agenda

1. Adoption of the agenda and appointment of chairperson and rapporteur.
2. Evaluation of applications from Members for official recognition of BSE negligible risk status
   2.1. Bolivia
   2.2. United Kingdom – zone of Jersey
3. Finalisation and adoption of report.

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Appendix III

ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION OF MEMBERS
Paris, 25-26 September 2019

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