



PROCEDURES USED BY THE OIE TO DETERMINE THE BSE RISK STATUS OF MEMBER COUNTRIES

COMMUNICATION FROM THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

The following communication, received on 14 June 2013, is being circulated at the request of the OIE.

Summary

To facilitate safe international trade in animals and animal products, the OIE, at the request of member countries, may make an official decision on the risk status of countries for BSE (and certain other diseases, including foot and mouth disease) according to the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)* and specific Resolutions adopted by the World Assembly of Delegates of the OIE (Assembly). These assessments are based on:

- internationally agreed procedures for undertaking an import risk assessment; and
- objective scientific criteria for determining BSE risk status, including requirements for disease surveillance and risk mitigation.

The process of designation of the official BSE risk status of a country is similar to the procedures for elaboration of OIE standards. The official BSE risk status of the cattle population of a country is determined on the basis of several criteria including the outcome of the risk assessment, and risk management including the surveillance plan and results, according to the relevant chapters and articles of the *Terrestrial Code*. The scientific assessment is undertaken by an *ad hoc* group of experts reporting to the OIE Scientific Commission for Animal Diseases (the Scientific Commission). The Scientific Commission reviews the *ad hoc* group recommendations, and, if required, will also make an in-country assessment to clarify or verify aspects of the assessment. The final decision on categorisation is taken by the World Assembly after consideration of this Commission's recommendations. Member countries with an officially recognised BSE risk status must submit an annual reconfirmation to the OIE on activities relevant to surveillance and feed controls. The official risk status is subject to annual re-confirmation by the Assembly following the procedures described in this paper.

In 2004 the OIE adopted the first list of countries with an officially recognised BSE risk status. The official list that was adopted in 2013 is at Annex 1.

1 THE INTERNATIONALLY AGREED PROCEDURES OF THE OIE

1.1. An explanatory document outlining the standard operating procedures for official disease status evaluations has been compiled, and is regularly updated on the OIE website.

1.2. The first step is for the National Delegate of a member country (appointed by the national government) to request, on a voluntary basis, an assessment of their BSE risk. The Delegate prepares a dossier according to the category of risk (controlled or negligible) for which official recognition is sought, based on the questionnaire in Chapter 1.6. of the *Terrestrial Code* and relevant provisions in Chapter 11.5 (BSE) and submits it to the OIE.

1.3. The Scientific Commission is responsible for making recommendations to the Assembly on the BSE risk status of OIE member countries. In this process, the Commission is supported by the OIE *ad hoc* Group on the Evaluation of BSE Risk Status of Member Countries (the *ad hoc* Group). The final decision is taken by the Assembly at the OIE General Session.

1.4. The documentation submitted by the applicant country is distributed electronically to the members of the *ad hoc* Group before the meeting and a hard copy is made available during the meeting. All experts engaged are asked to study the dossiers attentively.

1.5. The experts may make use of any additional, publicly available data on the applicant country in their analysis of the documentation. In the case where clarification is needed, the applicant may be asked to provide additional information, which should be submitted to the *ad hoc* Group to finalise the evaluation. Based on the country's compliance with the provisions of the *Terrestrial Code* (in particular Chapter 11.5.), the *ad hoc* Group makes a written recommendation to the Scientific Commission for consideration.

1.6. The Scientific Commission may endorse or reject the recommendation of the *ad hoc* Group or may defer the decision on the BSE risk status pending the submission of additional information from the applicant. The submission of additional information may enable a final decision by the Scientific Commission (with or without additional input from the *ad hoc* Group). At any step in the process, the Commission may request interviews with representatives of the applicant country, or an in-country mission to verify details provided by the applicant country.

1.7. After the Scientific Commission's meeting, each applicant member country whose dossier has been evaluated by the Commission receives written notification informing them of the outcome of their evaluation, and a summary record of the evaluation including reasons for a positive or negative outcome. In the case of a negative outcome, the notification may also indicate information gaps and/or specific areas that should be addressed in the future.

1.8. A minimum of 60 days prior to each General Session, the Director General circulates a list of the member countries for which the Scientific Commission has recommended recognition of BSE risk status, to all OIE member countries. Delegates can submit their comments or objections on the outcome of the evaluation in writing to the OIE. Objections, if based on scientific grounds, are referred to the Scientific Commission, which may ask the advice of the *ad hoc* Group. We also encourage direct dialogue between objectors and applicants, and therefore refer relevant objections to the applicant member country for them to provide clarification to the objecting member country, with a copy to OIE Headquarters. If clarification is delayed, the Scientific Commission may decide to withdraw the proposed recommendation or defer a final decision pending the submission of additional evidence.

1.9. Delegates have a second opportunity to comment on the proposed BSE risk status of member countries at the World Assembly, following the report of the Scientific Commission and the presentation of a draft resolution on official BSE risk status recognition.

1.10. Delegates may prepare amendments, abstain or vote against the adoption of the Resolution containing the updated list of officially recognised BSE risk status of member countries.

1.11. Decisions to categorise OIE member countries for BSE risk status and other designated diseases are formally adopted by resolution of the World Assembly. In most cases these Resolutions are adopted unanimously after discussion.

2 ASSESSMENT BASED ON OBJECTIVE SCIENTIFIC CRITERIA

2.1. The *Terrestrial Code* sets out the requirements to be considered in the assessment of a country's BSE risk, including a questionnaire (see Chapter 1.6.) requesting specific information for evaluating applications for official recognition. The three levels of BSE risk recognised by the OIE are: negligible BSE risk, controlled BSE risk, or undetermined BSE risk.

2.2. The experts in the *ad hoc* Group are appointed by the OIE Director General on the basis of scientific excellence and geographical balance. All members of the *ad hoc* Group are internationally renowned BSE experts who have been active in the field for decades and have an in depth knowledge of the science of BSE and the BSE history of countries and regions of the world.

2.3. The members of the Scientific Commission and the *ad hoc* Group must comply with OIE requirements and procedures on confidentiality and conflict of interest.

2.4. For reasons of confidentiality, the BSE dossiers submitted to the OIE are not distributed to other OIE member countries, regardless of the outcome of the assessment. Similarly, rejected applications always remain strictly confidential to the member country applicant. However, OIE member countries may request the dossier and seek additional information directly from the applicant member in the context of bilateral negotiations.

2.5. Article 5.3.5 (point 11) of the *Terrestrial Code* recommends that exporting countries provide access to procedures and systems that are the subject of an equivalence judgment upon request of the importing country. The same principle applies to decisions on official status.

3 THE SIGNIFICANCE OF AN OFFICIAL DECISION ON BSE RISK STATUS

3.1. OIE member countries may make a self-declaration as to the freedom of a country, zone or compartment from OIE listed diseases. However, the OIE does not publish self-declaration for BSE or a short list of other diseases that are the subject of the OIE procedure for official recognition of disease status.

3.2. The OIE considers that all resolutions adopted by the World Assembly, including those dealing with the official recognition of risk status for BSE, fall into the SPS Agreement definition of "standards, guidelines and recommendations". The official recognition of a country's BSE risk status is an affirmation that the country meets the standards set out in the *Terrestrial Code*. When importing cattle or products of bovine origin, WTO Members should apply measures that are appropriate to the official BSE risk status of the exporting country and the provisions in this Code.

4 MAINTENANCE OF THE OFFICIAL BSE RISK STATUS

4.1. In order to maintain a "negligible risk" or "controlled risk" status, member countries must notify the OIE of any changes in the epidemiological situation and other significant events related to BSE. In addition, OIE member countries must submit an annual reconfirmation relevant to the risk assessment, including changes in legislation, importation of animals and commodities, controls at feed mills, and BSE surveillance.

4.2. The Scientific Commission is responsible for reviewing the official BSE status of member countries.

4.3. For highly contagious diseases such as FMD, the OIE suspends an official disease-free status upon receiving notification of a disease outbreak. However for a non-contagious disease such as BSE, a new case does not automatically lead to suspension of risk status. Rather, the maintenance of an official BSE risk status remains dependent on continued compliance with OIE standards (subject to annual re-evaluation) and reporting as described above.

4.4. In the case of countries in the negligible risk category, any evidence of new, epidemiologically significant findings, including the detection of a case in an indigenous animal, is evaluated very carefully by the OIE. Providing that the situation complies with the provisions in the *Terrestrial Code*, the status may be maintained. For example, a "negligible risk" country that reports a case of BSE in an indigenous bovine animal may maintain this status providing that the case occurred in an animal born more than 11 years ago, and that all other relevant *Terrestrial Code* provisions are satisfied. In the case of a "controlled risk" country which has reported cases of BSE, the status would not change if a small number of new cases were reported, provided that there is no significant change in the epidemiology of BSE and the effective application of risk mitigation measures in the country.

4.5. In general, the detection of BSE cases demonstrates that the surveillance system is working as it should.

4.6. After consultation with the Scientific Commission, the OIE informs all member countries of the suspension or re-instatement of an official disease status via publication of a notice on the OIE website.

Sources of information cited in this paper

- *Terrestrial Animal Health Code*

Chapter 1.6 Provisions on official recognition of a member country's risk status for BSE (and other diseases), including the Questionnaire to be used in applications for recognition of BSE risk status: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.1.6.htm

Chapter 11.5 on BSE:

http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.11.5.htm

- OIE procedures for official recognition of disease status: "<http://www.oie.int/en/animal-health-in-the-world/official-disease-status/official-recognition-policy-and-procedures/>"

Resolutions of the OIE World Assembly of Delegates

Recognition of the contagious bovine pleuropneumonia disease status of member countries - Resolution No. 20 of the 81st General Session (2013)

"<http://www.oie.int/en/about-us/key-texts/resolutions-and-recommendations/resolutions-adopted-by-the-oie-international-committee/>"

Financial obligations - Resolution No. 26 of the 80th General Session (2012)

http://www.oie.int/fileadmin/Home/eng/About_us/docs/pdf/A_RESO_2012_Public.pdf

- Procedures for member countries for the official recognition and maintenance of disease status of certain animal diseases or risk status of bovine spongiform encephalopathy and for the endorsement of a national official control programme 30 of the 81st General Session (2013)

"<http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/>"

- BSE Internet portal: <http://www.oie.int/en/animal-health-in-the-world/bse-portal/>

- BSE annual reconfirmation form: Available for download at: "<http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/>"

ANNEX 1
RESOLUTION NO. 20

RECOGNITION OF THE BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS
OF MEMBER COUNTRIES

CONSIDERING THAT

1. During the 67th General Session the OIE World Assembly of Delegates (Assembly) established a procedure for annually updating a list of Member Countries, categorised by their bovine spongiform encephalopathy (BSE) risk according to the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)*,
2. During the 80th General Session, the Assembly adopted Resolution No. 25, which specified and updated the procedure for Member Countries to follow to achieve official recognition and maintenance of status of certain diseases,
3. During the 80th General Session, the Assembly adopted Resolution No. 26, which specified and updated the financial implications for Member Countries applying for evaluation of official recognition or re-instatement of disease status to meet part of the costs defrayed by the OIE in the evaluation process,
4. Information published by the OIE is derived from declarations made by the OIE Delegate of Member Countries. The OIE is not responsible for publication and maintenance of Member Countries disease status based on inaccurate information or non-reporting of changes in epidemiological status or other significant events subsequent to the time of declaration of the BSE risk status.

THE ASSEMBLY

RESOLVES THAT

1. The Director General publish the following list of Member Countries recognised as having a negligible BSE risk in accordance with Chapter 11.5. of the *Terrestrial Code*:

Argentina	Iceland	Paraguay
Australia	India	Peru
Austria	Israel	Singapore
Belgium	Italy	Slovenia
Brazil	Japan	Sweden
Chile	Netherlands	United States of America
Colombia	New Zealand	Uruguay
Denmark	Norway	
Finland	Panama	

2. The Director General publish the following list of Member Countries recognised as having a controlled BSE risk in accordance with Chapter 11.5. of the *Terrestrial Code*:

Bulgaria	Germany	Malta
Canada	Greece	Mexico
Chinese Taipei	Hungary	Nicaragua
Costa Rica	Ireland	Poland
Croatia	Korea (Rep. of)	Portugal
Cyprus	Latvia	Slovakia
Czech Republic	Lichtenstein	Spain
Estonia	Lithuania	Switzerland
France	Luxembourg	United Kingdom

AND

3. The Delegates of these Member Countries shall immediately notify the Headquarters if BSE occurs in their countries or their territories.
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(Adopted by the World Assembly of Delegates of the OIE on 28 May 2013)
