

APPENDIX 3.8.5.

**FACTORS TO CONSIDER IN CONDUCTING THE
BOVINE SPONGIFORM ENCEPHALOPATHY RISK
ASSESSMENT RECOMMENDED IN CHAPTER
2.3.13.**

Article 3.8.5.1.

Introduction

The first step in determining the bovine spongiform encephalopathy (BSE) risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 1.3. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

1. Release assessment

Release assessment consists of assessing the likelihood that a **transmissible bovine** spongiform encephalopathy (**TBSE**) agent has been introduced via the importation of the following commodities potentially contaminated with a **TBSE** agent:

- a) *meat-and-bone meal* or *greaves*;
- b) live animals;
- c) animal feed and feed ingredients;
- d) products of animal origin for human consumption.

2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

- a) epidemiological situation concerning **all animal TBSE** agents in the country or *zone*;
- b) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed.

The following guidelines are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries, [or to the evaluation of risk arising from trading partners if OIE categorisation of such countries is considered insufficient before trade rules are agreed.] The guidelines are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 3.8.5.2.

The potential for the release of the BSE agent through importation of meat-and-bone meal or greaves

This point is irrelevant if the exposure assessment outlined below in Article 3.8.5.5. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past 8 years. Nevertheless, documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past 8 years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of release of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher release risk than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown release risk.

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR
- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past 8 years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 3.8.5.3.

The potential for the release of the BSE agent through the importation of live animals potentially infected with a **FBSE***Assumptions:*

- Countries which have imported ruminants from countries infected with **animal TBSEs** are more likely to experience BSE.
- Cattle pose the only known risk although other species are under stud.
- Animals imported for breeding may pose a greater risk than animals imported for slaughter because of the hypothetical risk of maternal transmission and because they are kept to a greater age than animals imported for slaughter.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3.).

Question to be answered: Have live animals been imported within the past 7 years?

Rationale: The release risks are dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported animals, including their age at slaughter.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.4.

The potential for the release of the BSE agent through the importation of products of animal origin potentially infected with a TBSE

Assumptions:

- Semen, embryos, hides and skins or milk are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal origin from countries with animal TBSEs are more likely to experience BSE.
- Risk is influenced by the date at which imports occurred, relative to the animal TBSE status of the country of origin.
- Risk is proportional to volume of imports (Article 1.3.2.3.).

Question to be answered: What products of animal origin have been imported within the past 7 years?

Rationale: The release risks are dependent on:

- the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 2.3.13.13.);
- country of origin and its animal TBSE status, which will change as more data become available; this may result from the detection of clinical disease, or following active surveillance, or assessment of geographical BSE risk;
- feeding and management of the animals in the country of origin;
- use to which the commodity has been put as apart from representing risk of developing clinical disease, the slaughter, rendering and recycling in *meat-and-bone meal* of imported animals represents a potential route of exposure of indigenous livestock even if *meat-and-bone meal* and *greaves*, or feedstuffs containing them, have not been imported;
- species;
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at slaughter.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 3.8.5.5.**The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin***Assumptions:*

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant origin.
- Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past 8 years (Articles 2.3.13.3. and 2.3.13.4. in the *Terrestrial Code*)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past 8 years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 3.8.5.6.**Epidemiological situation concerning all animal TSE in the country or zone***Assumptions:*

- BSE may have originated from scrapie of sheep. Countries with scrapie may be at greater risk than those which have demonstrated scrapie freedom.
- Theoretically, scrapie in small ruminants might mask the presence of BSE and no field methods are available to differentiate between different TSEs.
- Available evidence suggests there is no link between chronic wasting disease of cervids and BSE.
- It has been suggested that transmissible mink encephalopathy may be an indicator of a hitherto undefined and hypothetical TSE of cattle.
- If a hypothetical 'spontaneous' TSE of cattle is assumed to occur, it must also be assumed to

occur in all countries at a similar rate.

Question to be answered: Have other animal TSEs been identified in the country? What surveillance is there for TSEs?

Rationale: Surveillance programmes generate a picture of the epidemiological situation of animal TSE. The greater the surveillance effort, the greater the power of the information. Adequately targeted surveillance for BSE, such as described in Appendix 3.8.4, provides more powerful information than generic animal disease surveillance.

Evidence required: Documentation on awareness and surveillance programmes targeting all TSEs of livestock, their legal basis, scale, duration, and data generated.

Article 3.8.5.76.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- BSE of livestock have long *incubation periods* and insidious onset of signs, so cases may escape detection.
- Pre-clinical BSE cannot be detected by any method and may enter rendering, in particular if specified risk materials are not removed.
- Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.
- BSE of livestock may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Appendix 3.6.3.
- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past 8 years?

Rationale: If potentially infected animals or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilized in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients

used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.

- Documentation describing monitoring and enforcement of the above.

Article 3.8.5. **97**.

The overall risk of BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the *risk assessment* to conclude that the cattle population of a country or *zone* is free from BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified.