AUSTRALIAN QUESTIONNAIRE TO ASSESS BSE RISK

Introduction

Acceptance of a submission from an applicant country for an assessment of BSE risk is based on the provision of comprehensive data and supporting evidence from the Competent Authority over the five areas listed below. In general, the data requirements are consistent with those of *Chapter 11.4 – Bovine Spongiform Encephalopathy* of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code*, 2019.

A risk assessment to determine the BSE risk status of the cattle population and whether the beef and beef products from a country represent a risk to the health of Australian consumers will be undertaken by Food Standards Australia New Zealand (FSANZ). This document sets out the criteria under the five areas that will be examined to determine BSE risk. Applicant countries should also refer to the documents explaining the assessment process (link) and the requirements for the importation of beef and beef products for human consumption (link).

Countries should note that as part of the assessment, verification of in-country control measures may be undertaken by in-country inspection and the results of any such inspections will be considered prior to completing the country assessment. Countries will be required to provide an annual update report by 31 January to the Australian BSE Food Safety Assessment Committee (the Committee) as described in Section 5. Countries are also required to report to the Committee, within 24 hours, any exceptional developments in regard to the countries BSE status e.g. identification of the first indigenous case of BSE.

The document comprises the following:

Section 1 – Risk assessment requirements regarding risk release and exposure

Section 2 – Other system requirements

- Ongoing BSE awareness program
- Compulsory notification and investigation of BSE cases
- Diagnostic capability
- Animal traceability and identification systems
- Animal slaughter and processing systems

Section 3 – BSE surveillance and monitoring system

Section 4 – BSE history of the country

Section 5 – Ongoing review of country BSE status and additional data

SECTION 1 – RISK ASSESSMENT REQUIREMENTS – RISK RELEASE AND EXPOSURE

This section provides guidance on the data gathering and presentation of information required to support the risk release and exposure assessment aspects in respect of a country's BSE status within its cattle population.

In each of the five areas of release and exposure assessment that follow, guidance is provided in terms of the question and the evidence required for the Committee to make an assessment of a country's risk in these areas.

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

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?

Evidence required:

1.1.1. 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

1.1.2. Documentation on annual volume, by country of origin, of *meat-and-bone meal*, *greaves* or feedstuffs containing them imported during the past 8 years.

1.1.3. Documentation describing the species composition of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.

1.1.4. Documentation, from the *Veterinary Service* of 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.

1.2 The potential for the release of the BSE agent through the importation of potentially infected live cattle

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

Evidence required:

1.2.1. Documentation including tables on the country of origin of imports. This should identify the country of origin of the cattle, the length of time they lived in that country and of any other country in which they have resided during their lifetime.

1.2.2. Documentation including tables describing origin and volume of imports.

1.2.3. Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

1.2.4. Documentation showing BSE status of the country(s) from which cattle have been imported in the last seven years.

1.3 The potential for the release of the BSE agent through the importation of potentially infected products of bovine origin

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

Evidence required:

1.3.1. Documentation on the country of origin of imports. This should identify the country of origin of cattle from which the products were derived, the length of time they lived in that country, *zone* or *compartment* and of any other country in which they have resided during their lifetime.

1.3.2. Documentation describing origin and volume of imports

1.3.3. Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country, *zone* or *compartment* of origin.

1.4 The origin of bovine carcasses, by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of cattle feed production

The overall risk of BSE in the cattle population of a country 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. As part of the *risk assessment*, a country must demonstrate the measures taken to manage any risks identified. If potentially infected cattle 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 cattle feed, the risk of cross-contamination exists.

Question to be answered: How have bovine carcasses, by-products and slaughterhouse waste been processed over the past 8 years?

Evidence required:

1.4.1. Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.

1.4.2. Documentation including tables describing the fate of imported cattle, including their age at slaughter or death.

1.4.3. Documentation describing the definition and disposal of specified risk material, if any.

1.4.4. Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.

1.4.5. 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.

1.4.6. Documentation describing the end use of imported cattle products and the disposal of waste.

1.4.7. Documentation describing monitoring and enforcement of the above.

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

Regardless of whether *meat-and-bone meal* or *greaves* has been fed, either deliberately or accidentally, in the past 8 years, documentation should be provided on the control systems (including relevant legislation, standards and guidelines) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to cattle. In general to obtain Category 1 risk status, countries would need to be able to demonstrate that the ruminant feed ban has been effective for at least 8 years following the birth of the youngest case.

Question to be answered: Has *meat-and-bone meal* or *greaves* of bovine origin been fed to cattle within the past 8 years?

Evidence required:

1.5.1. Documentation describing the use of imported *meat-and-bone meal* and *greaves*, including the feeding of any animal species.

1.5.2. Documentation describing the use made of *meat-and-bone meal* and *greaves* produced from domestic cattle, including the feeding of any animal species.

1.5.3. Documentation on the measures taken to control cross-contamination of cattle feedstuffs with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding.

1.5.4a) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing ruminant material or mixed species containing ruminant material, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves.*[1]

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Number of plants processing ruminant material	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with sampling	Total number of plants in (C) with positive test results
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2 etc.	Renderer						
	Feed mill						

1.5.4b) Documentation, in the form of the following table, on the audit findings in rendering plants and feed mills processing non-ruminant material, related to the prohibition of the feeding of *meat-and-bone meal* and *greaves* to ruminants.

Year (information should be provided for each of the 8 years for effectiveness is	Type of plant (renderer or feed mill)	Number of plants processing non-ruminant	Number of plants in (A) inspected	Total number of visual inspections in (B)	Total number of plants in (B) with infractions	Total number of inspected plants in (B) with	Total number of plants in (C) with positive test results

[1] By prior agreement, applicant countries may seek to modify the nature and format of the information on audit findings as they specifically relate to a country's controls with respect to animal rendering and feeds.

claimed)		material				sampling	
		(A)	(B)			(C)	
Year 1	Renderer						
	Feed mill						
Year 2 etc.	Renderer						
	Feed mill						

1.5.5a) Documentation, in the form of the following table, on each plant above processing ruminant material or mixed species containing ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow up results
Year 1	Renderer	ID 1			
		ID 2			
		ID 3 etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3 etc.			
Year 2 etc.	Renderer				
	Feed mill				

1.5.5b) Documentation, in the form of the following table, on each plant above processing non-ruminant material with infractions, specifying the type of infraction and the method of resolution.

Year (information should be provided for each of the 8 years for effectiveness is claimed)	Type of plant (renderer or feed mill)	Plant ID	Nature of infraction	Method of resolution	Follow up results
Year 1	Renderer	ID 1			
		ID 2			
		ID 3 etc.			
	Feed mill	ID 1			
		ID 2			
		ID 3 etc.			
Year 2 etc.	Renderer				
	Feed mill				

1.5.6. Documentation explaining why, in light of the findings displayed in the preceding four tables, it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or *greaves* of bovine origin.

1.5.7. Documentation of husbandry practices (multiple species farms) which could lend themselves to cross-contamination of cattle feed with *meat-and-bone meal* and *greaves* destined to other species.

SECTION 2 – OTHER REQUIREMENTS

2.1 Ongoing BSE awareness program

An awareness program is essential to ensure detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses.

Questions to be answered:

- Is there a BSE awareness programme?
- What is the target audience?
- What is the curriculum and how long has it been in place?
- Is there a contingency and/or preparedness plan that deals with BSE?

Evidence required

2.1.1. Documentation indicating when the awareness program was instituted and its continuous application and geographical coverage.

2.1.2. Documentation on the number and occupation of persons who have participated in the awareness program (veterinarians, producers, workers at auctions, slaughterhouses, etc.)

2.1.3. Documentation of materials used in the awareness program (the manual, supportive documents, or other teaching materials).

2.1.4. Documentation on the contingency and/or preparedness plan

2.2 Compulsory notification and investigation of BSE cases

BSE is a notifiable disease under OIE. The socio-economic implications associated with BSE require that there be incentives and/or obligations to notify and investigate suspect cases.

Questions to be answered:

- What guidance is given to veterinarians, producers, workers at auctions, slaughterhouses, etc. in terms of the criteria that would initiate the investigation of an animal as a BSE suspect? Have these criteria evolved and have they been evaluated and revised as necessary?

- What were the date and content of the legal act making notification of BSE suspects compulsory?

- What are the measures in place to stimulate notification, such as compensation payments, or penalties for not notifying a suspect?

Evidence required

2.2.1. Documentation on the date of official publication and implementation of compulsory notification including a brief description of incentives and penalties.

2.2.2. Documentation on the manual of procedures for investigation of suspect animals and follow-up of positive findings.

2.2.3. Documentation on the procedures for, and experience with, maintaining notification rules, penalties and incentives.

2.3 Diagnostic capability - examination in an approved laboratory of brain or other tissues collected within the framework of a surveillance system

Questions to be answered:

- Are the diagnostic procedures and methods those described in Chapter 3.4.5 of the OIE Manual of diagnostic tests and vaccines for terrestrial animals 2019?

- Have these diagnostic procedures and methods been applied through the entire surveillance period?

Evidence required

2.3.1. Documentation as to the approved laboratories where samples of cattle tissues from the country are examined for BSE. (If this is located outside the country, information should be provided on the cooperation agreement).

2.3.2. Documentation of the diagnostic procedures and methods used.

2.3.3. Documentation that the diagnostic procedures and methods have been applied through the entire surveillance period.

2.4 Animal traceability and identification systems

Questions to be answered:

- What systems are in place to ensure the effective and timely identification and tracing of potentially BSE infected cattle, their birth and feed cohorts?

Evidence required

2.4.1. Documentation of the herd identification systems in the country, including any relevant legislation and/or industry standards.

2.4.2. Documentation of the process and timeframe whereby cattle at slaughter that are suspected to be BSE positive can be identified and traced back to the farm of origin and farms of residence.

2.4.3. Documentation of the process and timeframe whereby cattle from the same birth or

feed cohort to the BSE positive cases can be identified and traced forward to the point of slaughter, death or residence.

2.4.4. Documentation of the risk management of cattle suspected to have been exposed to feed that has been cross-contaminated with *meat-and-bone meal* or *greaves* of bovine origin identification and trace forward to the point of slaughter death or residence.

2.5 Animal slaughter and meat processing systems

Questions to be answered:

- Are there effective controls around the slaughter and processing of cattle to prevent food for human consumption from becoming contaminated with potentially BSE infected materials (BSE risk materials[2]) and mechanically separated meat[3] from the skull and vertebral column from cattle over 30 months of age?

- Are there effective and timely systems for accurate identification, traceability and recall of meat and meat products?

Evidence required:

2.5.1. Documentation on ante and post-mortem inspection and stunning and slaughtering methods used for cattle at abattoirs.

2.5.2. Documentation of the measures and controls in place during processing to prevent cross-contamination of meat and meat products for human consumption with potentially BSE-infected materials.

2.5.3. Documentation of the system used to identify, trace (trace-forward and trace-back) and recall the food products derived from specific bovine animals or from animals slaughtered in a specific facility.

2.5.4. Documentation of a contingency plan for product recall should the BSE agent potentially be present in human food products.

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[2] BSE specified risk materials are tonsils and distal ileum from bovine animals of any age; brains, eyes, spinal cord, skull and vertebral column of bovine animals over 30 months of age.

[3] Mechanically separated meat is meat produced from meat recovery systems using meat/bone separation machines. The process involves the comminuting, grinding or pulverising of bones to retrieve attached muscle portions. It is very fine texture and is the residue of meat removed from these bones after the boning operation.

- Are there effective controls for managing the risk of cross-contamination of meat products with BSE-infected material?

Evidence required:

2.5.5. Documentation of controls for the removal of BSE specified risk materials[4] at slaughter from animals used as food for human consumption, including ageing of cattle to comply with Australia's certification requirements.

2.5.6. Documentation of the regulations or policies pertaining to cross-contamination, with respect to BSE, during slaughtering of bovine animals and processing of the bovine carcass.

2.5.7. Details on the date of implementation of any regulations/policies and documentation of the effectiveness and compliance with any regulations.

2.5.8. Documentation of the regulations pertaining to sanitation of equipment and facilities, with respect to BSE, during slaughtering of bovine animals and processing of the bovine carcass.

2.5.9. Details on the date of implementation of any regulations/policies and documentation of the effectiveness and compliance with any regulations.

SECTION 3 – BSE SURVEILLANCE AND MONITORING SYSTEM

Chapter 11.4 of the OIE Animal Health Terrestrial Code prescribes the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above minimal threshold prevalence.

Questions to be answered:

- Does the BSE surveillance programme within the country comply with the guidelines in Chapter 11.4 of the OIE *Terrestrial Animal Health Code*?
- What were the results of the investigations?

Evidence required

3.1. Documentation that the samples collected are representative of the distribution of cattle population in the country.

3.2. Documentation of the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified)

3.3. Documentation of the means and procedures whereby samples were assigned to the cattle

[4] BSE specified risk materials are tonsils and distal ileum from bovine animals of any age; brains, eyes, spinal cord, skull and vertebral column of bovine animals over 30 months of age.

subpopulations including the specific provisions applied to ensure that animals described as clinically suspect met the conditions of the OIE Code.

3.4. Documentation and justification of the number of animals meeting the definition of clinically suspect as compared to the numbers of clinically suspect samples submitted in previous years in accordance to the former provisions in the OIE *Code*, and explanation of possible differences.

3.5. Documentation, based on the following table, of all clinically suspect cases notified complying with the definition in the OIE Code.

Laboratory identification number	Age	Clinical signs	Point of detection (farm, market channels, slaughterhouse)

3.6. Documentation according to the following table that the number of target points applicable to the country, and its BSE surveillance requirements (Type A or type B surveillance as a result of the risk assessment of section 1) are met as described in Chapter 11.4 of the OIE Terrestrial Animal Health Code.

SUMMARY TABLE FOR BSE SURVEILLANCE								
Year: (complete a separate table for each year of surveillance)								
	Surveillance subpopulations							
	Routine slaughter		Fallen stock		Casualty slaughter		Clinical suspect	
	Samples	Points	Samples	Points	Samples	Points	Samples	Points
>1 and <2 years								
≥2 and <4 years								
≥4 and <7 years								
≥7 and <9 years								
≥9 years								
Subtotals								
Total points								

3.7. Indicate the population and structure of the cattle population, including the number of adult cattle (over 24 month of age) in the country.

SECTION 4 – BSE HISTORY OF THE COUNTRY

The categorization of a country to either Category 1 or Category 2 risk is dependent upon: the outcome of the risk assessment elements described in section 1, compliance with the provisions described in section 2, the results of surveillance described in section 3, and the history of BSE in the country making application. This section provides the opportunity to describe the BSE history in the country.

Questions to be answered

Has BSE occurred in the country? If so, when?

How has it been dealt with?

Evidence required

4.1. Documentation of whether a case of BSE has ever been diagnosed in the country.

In the case of positive BSE findings:

4.2. Documentation on the origin of each BSE case in respect to the country. Indicate the birth date and place of birth.

4.3. Indicate the most recent year of birth in relation to all BSE cases

4.4. Documentation that:

the case(s) and

all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

SECTION 5 – ONGOING REVIEW OF COUNTRY BSE STATUS AND ADDITIONAL DATA

5.1 Annual review

Countries categorised as Category 1 or Category 2 will be required to submit an annual update report to the Australian BSE Country Categorisation Committee by 31 January each year to enable a review of their country BSE risk status. Additionally, countries are also required to report to the Committee within 24 hours, any exceptional developments in regard to the countries BSE status e.g. identification of the first indigenous case of BSE. The annual report will be required to include details and data on:

- The preceding calendar year's surveillance results
- Any changes to the epidemiological situation for the preceding calendar year, including any new BSE cases and associated investigations
- Any changes to BSE-related legislative controls
- Information on feed controls, including audit findings in rendering plants and feed mills processing both ruminant and non-ruminant material.

If countries fail to provide the above information to the Committee by the due date, they will be advised by the Committee and given three months to provide the information. If countries

then fail to provide the information and/or there are deficiencies in the data supplied, this will result in their BSE risk status being revoked.

5.2 The need for additional data and/or audit inspections

Upon applying for a BSE risk status assessment, applicant countries may be requested to supply additional data if the FSANZ risk assessor determines that the data package is insufficient. In addition, the risk assessor may decide that an in-country inspection and/or audit are necessary and/or desirable. Criteria for triggering an in-country inspection may include one or a number of the following factors or any other factor that the Committee considers relevant:

- Incomplete information and data provided in the country submission
- BSE cases reported from cattle born in the previous five years in the applicant country
- The general history of trade and knowledge of infrastructure and food safety and veterinary services in the applicant country
- Request by the applicant country for an in-country inspection to verify the effectiveness of controls
- Timely capacity to identify, trace and report on any animals, derived risk materials and cohorts with respect to positive BSE cases.

Countries will be notified of this intention and given details of, and appropriate notice for, such an inspection. Results of the in-country inspection will be taken into account prior to making a final decision on a country's BSE risk status.

5.3 Additional data required if a country reports a BSE case

Upon notifying a new case of BSE, a country that has been given either a Category 1 or Category 2 BSE risk status is required to provide a report on the epidemiological investigation into the BSE case(s) and provide any other information to justify the continuation of its current Australian BSE status. Such data should be provided as soon as possible after the epidemiological investigation is completed, with FSANZ reserving the right to suspend a country's status at any time, including before the information is provided, until it is satisfied with the submitted information.

For Category 2 countries, the new data will generally be assessed through the annual review process at the beginning of each year. For Category 1 countries however, there will be a need to rapidly review the epidemiological data to determine whether the country maintains its Category 1 status.