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RURAL AND REGIONAL AFFAIRS AND TRANSPORT REFERENCES COMMITTEE INQUIRY INTO BEEF IMPORTS INTO AUSTRALIA

SUBMISSION FROM FOOD STANDARDS AUSTRALIA NEW ZEALAND

April 2013

Introduction

Food Standards Australia New Zealand (FSANZ) welcomes the opportunity to provide a submission to the Senate Rural and Regional Affairs and Transport References Committee 'Inquiry into Beef Imports into Australia'. Within Australia's food regulatory system, FSANZ has a number of functions that contribute to the safety of Australia's food supply. The functions relevant to this submission are: the development of food regulatory measures; the development of assessment policies in relation to food imported into Australia; and to coordinate actions by State and Territories to recall food under State and Territory law.

Specifically, of the issues identified under the Terms of Reference of the Senate Inquiry, those falling under the purview of FSANZ and the extent to which they are addressed in this submission are:

(a) The possible imminent importation of beef products from countries whose cattle herds have bovine spongiform encephalopathy (BSE) and/or foot-and-mouth disease (FMD); and

(b) The processes undertaken by Australian government agencies in determining risk to consumers and industry and the adequacy of such processes.

- The FSANZ role in, and progress on, conducting bovine spongiform encephalopathy (BSE) country risk assessments, implemented in response to the Australian Government's revised BSE policy, to assess the risk to consumers from exported beef products, in accordance with the BSE Standard.

(c) The lessons to be learnt from the recent contamination of the beef supply chain with horse meat throughout Europe and its implications for Australian consumers and industry

- FSANZ plays a key role in coordinating food recall activities on behalf of State and Territory jurisdictions. It also facilitates common approaches in responding to food incidents that span state borders; and in the sharing of information and liaison with international counterpart agencies on emerging issues in the food supply.

(e) The adequacy of Australian food labelling laws to ensure Australian consumers can make a fully informed choice on Australian meat products.

- The FSANZ role in developing and maintaining labelling standards for food products to ensure Australian consumers can make a fully informed choice on Australian meat products.

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Key Points

The BSE Food Regulatory Framework

a) Standard 2.2.1 – Meat and Meat Products of the *Australia New Zealand Food Standards Code* states that bovine meat and meat products must be derived from animals free from BSE. The Standard came into effect in 2001.

b) The revised BSE policy that came into effect 2010 allows the import of certain beef and beef products from countries that apply and are assessed by Australian authorities as being able to demonstrate they have in place, and appropriately monitor, controls necessary to ensure that beef and beef products exported to Australia meet Australia's requirement that beef and beef products be derived from animals free of BSE. Beef and beef products from countries that have not applied to Australia for assessment, or that are assessed as not demonstrating adequate control of BSE, will not be permitted in Australia's food supply.

c) Food Standards Australia New Zealand (FSANZ) uses a methodology adapted from that of the World Organisation for Animal Health (OIE) to determine the BSE risk status of beef and beef products from a country. This is an appropriate mechanism for assessing whether the beef and beef products from a country represent a risk to the health of Australian consumers. FSANZ undertakes a comprehensive risk assessment, including an in-country inspection of applicant countries to determine the systems to manage BSE are adequate to ensure that beef and beef products do not represent a risk to the health of Australian consumers.

d) Of the countries for which FSANZ has finalised assessments – New Zealand, the Netherlands, Croatia and Vanuatu, only the Netherlands has ever had cases of classical BSE. No classical BSE cases have been identified in the Netherlands since 2010 and no BSE-affected cattle have been born subsequent to BSE controls being implemented. None of the countries that have been recommended by FSANZ for approval to export beef or beef products to Australia have current evidence of classical BSE in their national herd.

e) Imports of beef products are permitted from countries which are assessed as being either *Category 1* or *Category 2*. Countries assessed as being *Category 1* are those in which there is a minimal likelihood that the BSE agent has or will become established in the national herd from that country and enter the human food chain. Beef and beef products derived from animals from these countries are therefore regarded as posing a minimal risk to human health. C*ategory 2* countries are those that may have had exposure to BSE-related risk factors in the past but now pose a minimal level of risk through effective implementation of, and compliance with, appropriate BSE control measures. Certification requirements for beef and beef products from *Category 2* countries are more stringent than the requirements for those products from *Category 1* countries.

f) Of the countries assessed to date, New Zealand, the Netherlands and Vanuatu have been assessed as *Category 1*. Croatia has been assessed as *Category 2.* BSE has never been found in Croatia, but Croatia's active surveillance procedures, while currently of high standard, have not been at the appropriate level relative to the size of their national herds for the eight years required by Australian policy.

FSANZ role in maintaining labelling standards for beef products

g) The Australia New Zealand Food Standards Code requires most packaged beef products to be labelled with certain information, including country of origin information, the name or description of the food sufficient to indicate its true nature, and an ingredient list.

h) In December 2012, the Council of Australian Governments (COAG) Legislative and Governance Forum on Food Regulation agreed to extend country of origin labelling requirements to unpackaged beef, sheep and chicken meat sold in Australia. This new requirement will take effect on 18 July 2013.

FSANZ coordination role in food recalls and incidents

i) FSANZ coordinates and monitors food recalls in Australia and also has a responsibility in the coordination of national food incidents, including the dissemination of information and monitoring of emerging issues internationally.

The Role of Food Standards Australia New Zealand

Food Standards Australia New Zealand (FSANZ) is an independent statutory authority established under the Food Standards Australia New Zealand Act 1991 (the FSANZ Act). The food regulation system is described in the Food Regulation Agreement, made between the States, Territories and Commonwealth of Australia on 3 July 2008. The primary purpose of the system, as articulated in the Food Regulation Agreement, is to provide 'safe food controls for the purpose of protecting public health and safety'.

In developing food standards, FSANZ's primary objectives are the protection of public health and safety, the provision of adequate information relating to food to enable consumers to make informed choices and the prevention of misleading or deceptive conduct. Enforcement of the Code is the responsibility of State and Territory and New Zealand enforcement agencies and, for imported food at the Australian border, the Department of Agriculture Fisheries and Forestry (DAFF). The COAG Legislative and Governance Forum on Food Regulation (the Forum), formerly the Australia and New Zealand Food Regulation Ministerial Council, develops policy guidelines that FSANZ has to have regard to when setting food standards.

The objects statement in the FSANZ Act makes it clear that FSANZ is established to give consumers confidence in the quality and safety of the food supply chain, provide a regulatory framework that establishes an economically efficient environment for industry, give consumers information relating to food that enables them to make informed choices, and provide consistency in domestic and international food regulation in Australia and New Zealand, without reducing the safeguards applying to public health and consumer protection. The primary method by which FSANZ achieves the objects of the FSANZ Act is to regulate the supply of food in Australia and New Zealand by making food standards.

The FSANZ Act also requires standards to be based on risk analysis using the best available scientific evidence, promote consistency with international standards, promote an efficient and internationally competitive food industry and promote fair trading in food products. Standards should also be developed with regard to policy guidelines developed by the Ministerial Forum, good regulatory practice and relevant New Zealand standards.

In addition to standards development work, FSANZ has legislative functions that require it to: (1) coordinate and report on food recall activities on behalf of State and Territory jurisdictions; and (2) provide risk assessment advice to DAFF where food imports present a medium or high food safety risk. FSANZ also plays a major role in coordinating jurisdictional activities and facilitating common approaches in responding to food incidents that span state borders.

FSANZ has no role to play in respect of animal health risk assessment or standards. It should also be noted that FSANZ has no powers in respect of enforcement of standards in the Food Standards Code

The BSE Food Regulatory Framework

Requirements of the BSE standard

Standard 2.2.1 – Meat and Meat Products of the *Australia New Zealand Food Standards Code* states that bovine meat and meat products must be derived from animals free from BSE. The following bovine products for human consumption are exempt from the standard and the requirement for a country BSE food safety assessment:

- Collagen from bovine skins and hides (including sausage casings produced from this type of collagen)
- A minor ingredient of a processed product, where that ingredient comprises bovine fat and/or bovine tallow at no more than 300 g/kg of the food
- Gelatine sourced from bovine skins and hides
- Dairy products sourced from bovines.

These exempt products can be sourced from any country and exported to Australia subject to import permit requirements. All other beef products must comply with the BSE Standard.

The BSE country risk assessment process implemented by FSANZ ensures that beef and beef products exported to Australia continue to comply with the BSE standard.

The FSANZ BSE country risk assessment process

The Australian Government's revised policy for the importation of beef and beef products, implemented in March 2010 (Attachment 1), requires that prior to exporting beef to Australia a country must apply for assessment to the Australian BSE Food Safety Assessment Committee. The policy change that allows a BSE risk assessment to evaluate the human health risk from beef and beef products from any country is consistent with the international standard for BSE developed by the World Organisation for Animal Health (OIE) and is based on a science-based risk assessment methodology. No changes to the BSE standard were made in revising the BSE policy.

The request for a risk assessment by an applicant country must be accompanied by comprehensive information in accordance with the Australian Questionnaire to Assess BSE Risk (Attachment 2). The risk assessment is undertaken by FSANZ and is an analysis of the effectiveness of the applicant country's BSE–related control systems throughout the beef production chain. The systems-based risk assessment establishes whether the beef and beef products from a country are derived from animals free from BSE and do not present a risk to the Australian consumer, as required by Australia's BSE standard. There is no current test for BSE in the live animal or in beef products and the systems approach affords the highest level of confidence in assessing the BSE risk status of a country's beef and beef products.

The comprehensive risk assessment undertaken by FSANZ is complemented by an in-country verification of BSE-related systems and surveillance measures in the applicant country.

FSANZ determines a risk category for each applicant country and provides this advice to the Department of Agriculture, Fisheries and Forestry (DAFF). DAFF is responsible for implementing relevant requirements at the border through application of the necessary import certification for imported beef and beef products, in accordance with Australia's BSE policy.

Desk assessment process

Countries wanting to export beef or beef products to Australia must apply to the Australian BSE Food Safety Assessment Committee (the Committee) for a determination of its country BSE risk status. The application must include a completed Australian Questionnaire to Assess BSE risk (Attachment 2), which must be completed by the national competent government authority. 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 across five key areas:

1. Risk assessment requirements regarding BSE risk release and exposure
2. Other system requirements
    a. BSE awareness program
    b. Compulsory notification and investigation of BSE cases
    c. Diagnostic capability
    d. Animal traceability and identification systems
    e. Animal slaughter and processing systems
3. BSE surveillance and monitoring system
4. BSE history of the country
5. Ongoing review of country BSE status and additional data

In general, the data requirements are consistent with those of the OIE's Terrestrial Animal Health Code, 2009 but have been supplemented to address food safety in the areas of slaughter practices and product traceability. Based on the submitted information 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 is then undertaken by FSANZ.

The range of factors examined in the risk assessment includes the following:

- History of, and regulations related to the importation of meat and bone meal (MBM) and greaves
- History of, and regulations related to the importation of potentially infected live cattle
- History of, and regulations related to the importation of potentially infected bovine products, including by-products that may enter the bovine food supply
- Mechanisms for preventing feeding of proteins of mammalian origin, other than dairy-derived proteins, to cattle. This includes the current and historical regulations and extent of government auditing, border controls, testing of raw material samples, and testing of animal feedstuffs
- Measures to prevent cross-contamination of ruminant feedstuffs from feedstuffs for other domestic species during manufacture, transport, distribution and use
- The destruction of potentially infective bovine-derived materials including cattle that die or require destruction on farms (fallen stock); cattle condemned at slaughterhouses, and potentially infected tissues removed at slaughterhouses. Potentially infective tissues (Specified Risk Materials; SRM) include specified parts of the central nervous system, gastrointestinal tract and lymphatic system
- Ante-mortem and post-mortem procedures to ensure that cattle with central nervous system signs do not enter the human food supply and that specific risk materials are removed from cattle in at-risk age groups, by methods that prevent contamination of the edible carcass
- Ability to identify individual bovine animals and trace their location throughout their lifetime, to ensure that the origin and complete movement history of any bovine animal entering the human food supply can be traced. In the event of a food safety concern,

such a system would allow rapid identification of the origin of a suspect animal, its parentage, offspring and herd cohort animals
- Traceability of beef and beef products to enable rapid food recall if required
- Education and awareness among farmers, veterinarians, slaughterhouse staff, animal feed manufacturers and vendors, rendering plant personnel and personnel involved in the transport of life cattle or ruminant feed
- Compulsory notification of clinical suspects and presence of an appropriate investigation procedure
- National border controls of import or trade in livestock, animal feed, raw materials for animal feed, products and by-products of bovine origin
- Surveillance through collection and testing for BSE infectivity of brainstem samples from routine slaughter, cattle presented for slaughter that do not pass ante-mortem inspection, cattle found dead or subject to emergency termination on farms, and cattle found to have evidence of neurological disease
- Adequacy of surveillance in terms of numbers of cattle tested relative to the size and age distribution of the national herd
- Diagnostic capability of the laboratory system testing brainstem samples for BSE.

In-country verification visits

Verification of control measures implemented by each country is undertaken through an in-country inspection by Australian Government food safety (FSANZ) officials with food safety and agricultural/veterinary expertise. This in-country inspection includes visits to and assessment of the following establishments and systems, as appropriate:

- Offices of the competent authority responsible for BSE prevention and control
- Slaughterhouses
- Rendering facility or facilities
- Animal feed mills
- Farms including dairy and beef farms
- Border Inspection Posts.

Other premises may be inspected, such as cattle sale-yards and retail outlets selling animal feedstuffs. The diagnostic laboratory responsible for BSE surveillance is evaluated and may also be visited. The national bovine identification and traceability system is the subject of a presentation or presentations by expert personnel as part of the visit to the competent authority, and scrutinised as part of the visits to farms and slaughterhouses. The inspection and audit procedures of the competent authority and other responsible government departments are reviewed at both national and regional levels throughout all visits.

Documentation is provided by the appropriate government agencies and includes relevant legislation, official government data records, manuals and standard operating procedures. FSANZ assessors also request and view documents or labels at premises they visit. Inspection may include items such as records of testing of raw materials for feed; ear-tags on cattle; movement documents accompanying shipments of cattle; labels attached to bags of animal feed; records of audits and inspections by government authorities; records of receipt or testing of raw materials; labels on brainstem samples for BSE testing; and other relevant documents or labels depending on the site being inspected. Wherever possible, FSANZ assessors observe operations such as ante-mortem and post-mortem inspection, removal of risk tissues from slaughtered animals, storage of bovine carcasses until negative BSE results are obtained, feed manufacture, animal identification on farms, and inspection of shipments at Border Inspection Posts. Personnel at all premises are asked detailed questions to ascertain their knowledge of BSE and regulations related to its control.

Status of country risk assessments

Since March 2010, FSANZ has received fourteen applications for BSE food safety assessments from: Argentina, Brazil, Chile, Croatia, Latvia, Lebanon, Lithuania, Mexico, the Netherlands, New Zealand, Taiwan (since withdrawn), Turkey, the USA and Vanuatu.

FSANZ has finalised the BSE risk assessments of New Zealand, the Netherlands, Croatia and Vanuatu, and recommended that *Category 1* status be assigned to New Zealand, the Netherlands and Vanuatu. This status means that there is a minimal likelihood that the BSE agent has or will become established in the national herd from that country and enter the human food chain. Beef and beef products derived from animals from these countries are therefore regarded as posing a minimal risk to human health.

FSANZ has recommended that Croatia be assigned *Category 2* status. There have been no reported cases of BSE, but mandatory testing of raw materials used in ruminant feed, and the level of active surveillance, have not been in place for the required minimum of eight years. It was concluded that the risk of BSE entering and recycling within the bovine feed system or entering the human food supply in Croatia is currently well controlled. Beef and beef products from Category 2 countries also pose a minimal risk to human health as a result of the additional certification requirements implemented at the border.

BSE risk assessments for Latvia and Lithuania are close to finalisation. The status of all BSE applications received by FSANZ to date is summarized in **Table 1**.

Table 1 – BSE Country Assessment Status

Country	Proposed date for country inspection	Anticipated date of final report	Assessment status*
New Zealand	Completed May 2011		Assessment finalised NZ assigned **Category 1** status
The Netherlands	Completed March 2012		Assessment finalised The Netherlands assigned **Category 1** status
Croatia	Completed March 2012		Assessment finalised Croatia assigned **Category 2** status
Vanuatu	Completed June 2012		Assessment finalised Vanuatu assigned **Category 1** status
Latvia	Completed September 2012	May 2013	Assessment report being finalised
Lithuania	Completed September 2012	May 2013	Assessment report being finalised
Chile	Completed March 2013	December 2013	Desk assessment and in-country assessment completed, final report in preparation
Brazil	Scheduled for 2013	March 2014	Desk assessment completed, in-country assessment to be confirmed
Argentina	Scheduled August 2013	May 2014	Desk assessment commenced
Mexico	Scheduled August 2013	May 2014	Desk assessment commenced
United States	To be confirmed		Desk assessment drafted. In-country verification visit being scheduled
Turkey	To be arranged		Pending commencement
Lebanon	To be arranged		Pending commencement
Taiwan	N/A		Withdrawn (Feb 2012)

* Reports and status of countries can be found at: http://www.foodstandards.gov.au/consumerinformation/bovinespongiformencephalopathybse/statusofcountrybsefo5388.cfm

Governance of the BSE country risk assessment process

Assessment of Countries

The Australian BSE Food Safety Assessment Committee (the Committee) has been established to oversight the BSE country assessment process. The Committee is chaired by FSANZ and includes an animal health expert from DAFF, risk assessment, food safety and agricultural systems experts. The Committee reviews and provides advice on: the BSE country assessment process and work plan, associated technical materials, country assessments and country visits. It endorses the final country risk assessments and proposed country categories.

A risk assessment, based on the OIE methodology, is undertaken by FSANZ and reviewed by the Committee which prepares a draft report. Verification of in-country control measures may be deemed to be required by the Committee and will require Australian officials to undertake an in-country inspection. The findings of any in-country inspection will be considered by the Committee prior to issuing the draft report to the applicant country for a 60-day comment period. The country review process is predominantly an opportunity for countries to correct any factual errors around the description of the BSE-related control systems in the report.

The draft report is also subject to several rounds of peer-review both within FSANZ and through experts from DAFF. In addition, the final report is provided to the FSANZ Board for any comment prior to public release.

The BSE Food Safety Assessment Committee

Terms of Reference

The BSE Food Safety Assessment Committee will:

- Develop prioritisation criteria and assign priorities to applications received from Applicant Countries;
- Review each Applicant Country's draft assessment report and provide a summary of the Committee's deliberations (based on each of the assessment criteria);
- Determine whether:
    - additional information is required from Applicant Countries in order to determine an appropriate risk category
    - verification of in-country control measures, through an in-country inspection, is required and, if so, consider evidence obtained during the in-country inspection prior to completing its assessment;
- Review each Applicant Country final assessment report, including any supplementary information or comment supplied by Applicant Countries;
- Recommend a final BSE risk assessment category to the Chief Executive Officer, Food Standards Australia New Zealand;
- Review data submitted for the annual update report of a country's the BSE assessment;
- Review and revise the review questionnaire, as appropriate; and
- Provide advice on requests regarding procedures, risk assessment protocols and other related issues.

Members

Dr Marion Healy (Chair)	Executive Manager, Risk Assessment, FSANZ
Dr Paul Brent	Chief Scientist, FSANZ
Dr Helen Scott-Orr PSM	Associate Professor, Faculty of Veterinary Science, University of Sydney
Dr Reg Butler	Principal Veterinary Officer (Animal Biosecurity), DAFF
Dr Scott Crerar	Manager, Production Process Risk Assessment Section, FSANZ
Ms Amanda Hill	Principal Advisor, Food Safety, FSANZ

The Secretariat is provided by FSANZ.

Decision-making process

The Committee is responsible for preparing a final risk assessment report and recommending a BSE risk category for the applicant country to the FSANZ Chief Executive Officer. Subject to consideration by the FSANZ Board and the approval by the FSANZ Chief Executive Officer, the final report, including the recommended BSE risk category, is provided to the Secretary of DAFF, under FSANZ's function as defined in Section 13 *Food Standards Australia New Zealand Act 1991*. The final BSE risk categories of all completed country assessments, other than those being classified as Category 3 are placed on the FSANZ website. DAFF is responsible for approving the importation of beef products and in implementing the certification requirements of the BSE policy at the border.

Annual Review process

Countries assessed as Category1 or Category 2 BSE risk status are required to provide an annual update report advising of surveillance results and information on feed controls and changes to the epidemiological situation for the preceding calendar year by 31 January each year for review by the Australian BSE Food Safety Assessment Committee. If countries do not provide this information, they may lose their categorisation as a Category 1 or Category 2 country until the required information is submitted to the Committee, resulting in suspension of importation of beef and beef products. The annual update report will also need to advise of any changes to BSE legislation, audit findings in rendering plants and feed mills processing ruminant material, audit findings in rendering plants and feed mills processing non-ruminant material and origin of birth of any reported BSE case, consistent with the similar OIE requirement.

A country can also request a review of their risk assessment. The review of the assessment could comprise a number of actions including assessment of additional data, consideration of a change in a country's risk categorisation by the OIE or an 'in-country inspection' by Australian officials. Australia can also initiate a review of the assessed category of a country status if there is an indication that the BSE risks may have altered.

Labelling of Meat Products

The Australia New Zealand Food Standards Code includes certain labelling requirements for packaged and unpackaged foods. For most packaged beef products for retail sale, the labelling requirements include the product name or description sufficient to indicate the true nature of the food (Standard 1.2.2), and an ingredient list (Standard 1.2.4), unless the name of the food would be the ingredients listed in the ingredient list. Food laws also require food to be truthfully labelled. For example, if a product is labelled as 'Beef Lasagne' then it must contain beef.

In accordance with Standard 1.2.11, most packaged beef products must also be labelled with country of origin labelling including:

- A statement that identifies where the food was made or produced; or
- That identifies the country where the food was manufactured or packaged for retail sale; and to the effect that the food is constituted from ingredients imported into that country or from local or imported ingredients, as applicable.

For unpackaged beef products, the labelling requirements also include the product name or description.

In December 2012, the Legislative and Governance Forum on Food Regulation accepted a standard to extend county of origin labelling requirements to include unpackaged beef, veal, sheep and chicken meat. A statement that identifies the country or countries of origin of the meat, or that indicates that the meat is a mix of local and/or imported foods must be provided on or in connection with the display of the food.

In agreeing to this new Standard, Ministers recommended that implementation documentation clarifies that a business can comply with the requirement by displaying a single sign for Australian meat, with imported meat being specifically labelled. The new requirement will take effect on 18 July 2013.

Requirements for defences (safe harbours) to specific country of origin claims such as 'product of' and 'made in' are set out in Australian Consumer Law, which is administered by the Australian Competition and Consumer Commission.

FSANZ Role in Food Recalls and Incidents

Under the FSANZ Act, FSANZ is responsible for coordinating and monitoring food recalls across Australia. Recalls occur as a result of consultation between state and territory government and a sponsor (usually the food product's manufacturer or importer). FSANZ's food recall actions are agreed to and facilitated by a group of senior food enforcement officers in all jurisdictions in accordance with an agreed FSANZ protocol.

FSANZ has an important function in the monitoring of emerging issues, including overseas information sources. Through this monitoring, FSANZ may seek further information from overseas counterpart agencies to help determine the impact, if any, that an overseas food incident or food recall may have on the Australian food supply. FSANZ may then convey this information to States and Territories for appropriate follow up actions that can include sampling and testing and/or the recall of foods on sale in Australia. If it is established that there is an ongoing problem with a particular imported food for which there is a potential

public health risk, FSANZ can provide advice to DAFF around the targeted inspection and testing of this food at the border.

If there were substitution of meat for sale in Australia, this may result in food being recalled. In addition, a National Food Incident Response Protocol has been established by States and Territories for the coordination of incidents of national significance that can be invoked by the relevant state and territory government. FSANZ plays a key role in the coordination of information under these circumstances.

Attachment 1 – BOVINE SPONGIFORM ENCEPHALOPATHY (BSE): REQUIREMENTS FOR THE IMPORTATION OF BEEF AND BEEF PRODUCTS FOR HUMAN CONSUMPTION – EFFECTIVE 1 MARCH 2010

Purpose

To describe the requirements to safeguard the Australian population against exposure to the bovine spongiform encephalopathy (BSE) agent via imported *beef or beef products*. These requirements apply to beef and beef products for human consumption and are in addition to existing sanitary measures.

Summary

The requirements in relation to BSE developed to ensure that imported *beef or beef products* available on the Australian domestic market are safe for human consumption have been updated in response to the changing BSE situation worldwide. Current scientific evidence indicates that the BSE epidemic in cattle peaked in 1992 and that measures to reduce the risk of human exposure to the BSE agent through the food chain have been effective.[1]

The new requirements for consignments from other countries have been developed considering current scientific knowledge and are proportionate to the assessed BSE risk of each country[2]. The assessment of the BSE risk of a particular country involves an analysis of information supplied to Australia on potential factors for BSE occurrence, BSE surveillance and monitoring systems and the BSE history including the implementation of control measures.[3]

Current scientific evidence indicates that there would be a negligible risk of variant Creutzfeldt-Jakob disease in the Australian population as a result of the future consumption of beef and beef products imported from countries which have reported cases of BSE in cattle, provided they demonstrate effective implementation of, and compliance with, control measures designed to ensure beef and beef food products are free of the BSE agent.

In simple terms this means that the importation of beef and beef products from countries with reported cases of BSE will only be permitted if they meet the requirements outlined in the following section.

The following products for human consumption are exempt from these requirements[4]:

- collagen from bovine skins and hides (including sausage casings produced from this type of collagen)
- a minor ingredient[5] of a processed product, where that ingredient comprises –
    - bovine fat, and/or
    - bovine tallow
- gelatine sourced from bovine skins and hides, and

[1] These measures control the spread of BSE in cattle and prevent entry of the BSE agent into the human food chain.
[2] **Country** includes zone or compartment of a country where these are able to be recognised for this disease.
[3] **The detail** of the Australian BSE Food Safety Assessment Process describes the assessment procedures including communicating requirements to applicant countries.
[4] **The products** exempt from the certification requirements are listed in Standard 2.2.1 of the *Australia New Zealand Food Standards Code* obtained from Food Standards Australia New Zealand website: http://www.foodstandards.gov.au.
[5] **minor ingredient** means an ingredient that comprises no more than 300 g/kg of the food.

- dairy products sourced from bovines.

Assessment of Countries

The World Organisation for Animal Health (OIE) has developed a risk assessment methodology to determine the BSE risk status of a cattle population of a country, and this is an appropriate mechanism for assessing whether the beef and beef products from a country represent a risk to the health of Australian consumers. The Australian BSE Food Safety Assessment Committee, chaired by Food Standards Australia New Zealand [6](FSANZ), will use the OIE methodology to undertake a risk assessment analysing information provided by the applicant country and any other relevant information, including any prior categorisation by the OIE. Applications for assessment must be accompanied by information equivalent to that required by the OIE for risk assessment, including details identifying all potential factors for BSE occurrence and their historic perspective. The risk assessment of a country by the committee may also include an 'in-country inspection', led by Australian officials, which will be based on defined criteria and include the specific elements to be considered in the inspection. For example, the inspection may include examining:

- the existing systems in the applicant country to prevent the spread of BSE in the cattle population and from entering the human food chain;
- the existing systems to prevent food for human consumption from becoming contaminated during animal slaughter and processing; and
- any other relevant matter.

Evidence obtained during the in-country inspection will be provided to the Australian BSE Food Safety Assessment Committee to assist in completing its risk assessment.

The outcome of the risk assessment will inform whether the beef and beef products from a country represent a risk to the health of Australian consumers and what import conditions would need to be imposed by Australia before beef and beef products could be imported. In a practical sense, imports will only be permitted from countries which are assessed as being:

> *Category 1* - There is a minimal likelihood that the BSE agent has or will become established in the national herd from that country and enter the human food chain. Beef and beef products derived from animals from these countries are therefore regarded as posing a minimal risk to human health; or
>
> *Category 2*- These countries have either not reported cases of BSE, but there are identified risk factors, or they have reported BSE but pose a minimal level of risk through effective implementation of, and compliance with, appropriate BSE control measures. The risk of beef and beef products potentially containing the BSE agent is mitigated through more stringent certification requirements to reflect this level of risk.

Beef and beef products from countries that have not applied to Australia for assessment or cannot demonstrate through the risk assessment effective implementation of, and compliance with, appropriate measures to control the BSE risk are considered to pose the highest level of risk and Australia will not import products from these countries.

The FSANZ CEO provides the final BSE risk assessment[7] advice to the Deputy Secretary of Biosecurity Services Group (BSG) of DAFF who implements the relevant requirements.

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[6] The Australian BSE Food Safety Committee, is chaired by FSANZ and includes an animal health expert from Department of Agriculture Fisheries and Forestry and food safety and risk assessment experts from FSANZ.
[7] The CEO of FSANZ approves the final assessment report including the BSE risk level.

Requests for assessments will be prioritised by the Australian BSE Food Safety Assessment Committee.

Countries can request a review of their assessment. The review of the assessment could comprise a number of actions including assessment of additional data or an 'in-country inspection' by Australian officials of that country's systems. Australia can also initiate a review of the assessed category of a country status if there is an indication that the BSE risks may have significantly changed. Countries will be required to submit surveillance results and information on feed controls and changes to the epidemiological situation for the preceding calendar year by 31 January each year for review by the Australian BSE Food Safety Assessment Committee.

Transitional Arrangements

Interim arrangements will be applied until 30 June 2011 for countries that can currently export beef and beef products to Australia.

Countries currently eligible to export beef and beef products to Australia:

Until 30 June 2011, countries that can currently export beef and beef products under the 2001 policy on BSE and imported food safety may continue trading beef and beef products under the existing arrangements until the Australian BSE Food Safety Assessment Committee undertakes re-assessment. *Beef or beef products* may continue to be imported into Australia from these countries after 30 June 2011 if an application for assessment as *Category 1* or *Category 2* has been submitted to the Australian BSE Food Safety Assessment Committee and provided no new BSE-risk factors are reported by the country during this period.

Countries that cannot currently export beef and beef products to Australia:

Countries that currently cannot export beef to Australia will only be able to trade *beef or beef products* after the Australian BSE Food Safety Assessment Committee has completed a risk assessment and concluded the risk is *Category 1* or *Category 2*.

Definitions

Country, category

The three country categories are described below. Countries in the *Category 1* are assessed at posing the least risk, whereas countries in the *Category 3* are assessed as posing the greatest risk.

Category 1
Countries assessed by Australia as meeting the 'Negligible BSE Risk' requirements of the *Terrestrial Animal Health Code* of the World Organisation for Animal Health (OIE). Beef and beef products can be imported subject to specific requirements.

Category 2
Countries assessed by Australia as meeting the 'Controlled BSE Risk' requirements of the *Terrestrial Animal Health Code* of the World Organisation for Animal Health (OIE). Beef and beef products can be imported subject to specific requirements.

Category 3 Countries assessed by Australia that do not meet the requirements of either Category 1 or Category 2, or countries that have not applied to be assessed by Australia. Beef and beef products cannot be imported.

Beef and beef products included in these categories are those products not specifically exempt from the requirements of the Australian policy.

Beef or beef food products (Beef and Beef Products)

Products intended for human consumption which contain bovine tissue (including cattle, buffalo and bison). This includes meat, bone and offal but excludes milk, dairy products, gelatine and collagen derived from bovine skins and hides, edible bovine fats and bovine tallows included as a minor ingredient of a processed product.

BSE risk materials

BSE 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.

Mechanically separated meat

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.

Competent National Government Authority

That Authority recognized by Australia that can certify compliance with animal health and sanitary measures contained in these certification requirements. This would usually (but not always) be the national government veterinary administration.

Certification

Official certificates will only be considered by Australian authorities if supplied by the agreed *Competent National Government Authority* in each country.

Certificates must be in the form and manner of the wording agreed between Australia and the exporting country and may be issued retrospectively.

Certificates should have the following attestations.

1*. Category 1 countries*

The *beef or beef food product* is derived from bovine animals[8] that have been born, raised and slaughtered in *Category 1* countries and that passed ante-mortem and post-mortem veterinary inspection under official veterinary supervision.

The *beef or beef food product* is considered to be fit for human consumption.

OR

2. *Category 2 countries*

The *beef or beef food product* is derived from bovine animals that:

. have been born, raised and slaughtered in *Category 1* or *Category 2* countries and that passed ante-mortem and post-mortem veterinary inspection under official veterinary supervision
. were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process

The beef and/or beef product were produced and handled in a manner, under official veterinary supervision, which ensures that they do not contain, and are not contaminated with:

. *BSE risk materials* or
. mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

The *beef or beef food product* is considered to be fit for human consumption.

Implementation of requirements

Upon advice from the FSANZ CEO of a country's BSE risk assessment to the deputy Secretary of BSG of DAFF, the relevant certification requirements for that country's BSE risk assessment are implemented through the *Imported Food Control Act 1992* and its subordinate legislation the *Imported Food Control Regulations 1993*.

[8] **Note**, where the product includes *beef and/or beef products* derived from bovine animals from countries with differing BSE status, the product will be required to be certified in accordance with the requirements for the country or zone with the highest risk.

Attachment 2 – 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 11.6 – Bovine Spongiform Encephalopathy* of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code*, 2009.

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.*[9]

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 claimed)	**Type of plant (renderer or feed mill)**	**Number of plants processing non-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**

[9] 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.

		(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 2.4.6. of the OIE Manual?
- 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[10]) and mechanically separated meat[11] 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.

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

[10] 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.

[11] 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.

Evidence required:

2.5.5. Documentation of controls for the removal of BSE specified risk materials[12] 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 11.6 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 11.6 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 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

[12] 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.

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 11.6 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.