



Proposal to Amend the BSE Measures
Applying to Imported Food for Human
Consumption

Consultation Process

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Overview

This discussion paper outlines the New Zealand Food Safety Authority's (NZFSA) proposal to amend the current BSE Country-Categorisation Measure¹, which was put in place to manage the human health risks from bovine spongiform encephalopathy (BSE) in imported bovine meat or products containing bovine meat that are to be sold for human consumption. NZFSA is seeking comments on this proposed BSE Country Categorisation Measure.

The proposed BSE Measure outlined in this discussion document is based upon the recommendations from an Officials Review² of the current BSE Measure, which was commissioned by NZFSA in early 2005. The purpose of the Officials Review (referred throughout as the "Review") was to consider the steps New Zealand is currently taking to manage potential human health risks from BSE in imported foods and, if appropriate, propose changes to the current BSE Measure. The Review's final report was presented to NZFSA on 8 November 2005.

Under the New Zealand (Prescribed Foods) Food Standards 2002, bovine meat and products containing bovine meat are a prescribed food for the purposes of managing BSE. The proposed BSE Measure does not suggest removing or amending this standard. It proposes changes, as recommended by the review, to the country-categorisation system, including the way countries are categorised, and better defines the commodities that are considered to be a risk and therefore require to be monitored.

Copies of the Review are available from NZFSA's website at: www.nzfsa.govt.nz. If you do not have access to the web and would like a hard copy please contact NZFSA.

¹ *Measure to Provide Ongoing Management of the Human Health Risks Associated with Imported Food Products Potentially Containing the Bovine Spongiform Encephalopathy Agent* see www.nzfsa.govt.nz

² *Officials' Review of New Zealand's BSE Country Categorisation Measure* see www.nzfsa.govt.nz

Consultation

Consultation on this proposed BSE Measure involves importers, the science community, other regulators and major trading partners. Submissions are invited from any interested party, whether representing organisations or acting as individuals. When sent on behalf of an organisation, the submission should include the position in the organisation of the person signing the submission and the extent of internal consultation undertaken in preparing the submission. All submission formats will be accepted. Please address the questions under the subject areas detailed in Page 9 *Questions and Submission Form*. However, you are welcome to comment on any additional matter relating to the proposed food standard.

Address for submissions

Please send your submission to:

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Closing date for submissions

The closing date is 19 May 2006.

Official Information Act

The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are in the OIA. Submitters may wish to indicate grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

Process after submissions close

After analysing submissions, NZFSA will make recommendations to the Minister for Food Safety and Cabinet Economic Development Committee. If the Minister and Cabinet Committee agree to the new BSE Measure, a Standard Management Rule will be developed in order to implement the Measure. This will involve the categorisation of countries according to the Measure. The target date for this coming into force is 24 July 2006. The categorisation of countries will be an ongoing process.

| Process | Target Date |
|--|------------------------|
| Consultation | 7 April – 19 May 2006 |
| Analysis of submissions & revision of measure | 19 May – 30 May 2006 |
| Government consideration of revised draft measure | 1 June – 19 June 2006 |
| Development of Standard Management Rule & Implementation | 20 June – 24 July 2006 |

Disclaimer

Every effort has been made to ensure the information in this report is accurate. NZFSA does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred. The proposals in this paper are for consultation purposes and do not necessarily represent agreed Government policy.

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1 Glossary

Bovine spongiform encephalopathy (BSE): A fatal, feed-borne, neurological disease of cattle that may cause variant Creutzfeldt Jakob disease (vCJD), a very rare food-borne illness in humans, resulting from consumption of products contaminated with bovine central nervous tissue.

BSE Measure: New Zealand's regulations to control the risk of the BSE agent entering the human food chain. The current BSE Measure is described in the Ministry of Health document "*Measure to Provide Ongoing Management of the Human Health Risks Associated with Imported Food Products Potentially Containing the Bovine Spongiform Encephalopathy Agent*" and is enabled by Section 11D of the Food Act 1981. The proposed BSE Measure is outlined in this document.

Geographical BSE risk assessment process (GBR): A process used by the European Food Safety Agency to assess the likelihood of BSE being present in a country.

OIE: The World Organisation for Animal Health responsible for setting risk-based standards to protect humans and animals from diseases which could be spread in animals and animal products, while at the same time avoiding unnecessary barriers to trade

OIE Code: As used in this Review, the *Terrestrial Animal Health Code*, produced by the OIE, provides the international standards to protect against the spread of BSE to humans or animals through the trade in animals and animal products.

BSE prion: A proteinaceous agent generally considered to be the cause of BSE.

Sanitary and Phytosanitary Agreement of the World Trade Organization (SPS): An international agreement that sets out the framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimise their negative effects on trade.

Specified risk materials (SRMs): As used in this Review, those cattle tissues that have been demonstrated to contain BSE infectivity and are excluded from the food and feed chains to prevent humans or animals consuming the BSE agent.

Transmissible spongiform encephalopathy(ies) TSE(s): A group of related neurological diseases of humans and animals, of which BSE is one.

Variant Creutzfeldt Jakob disease (vCJD): The fatal human neurological disease that has been transmitted to humans through consumption of products contaminated with central nervous tissue of cattle infected with BSE.

2 Background

2.1 History of measures to manage the potential risk of BSE in imported food

New Zealand is free from the animal disease BSE. In other countries, the presence of the BSE agent in bovine meat products has been linked to a variant of the human disease, Creutzfeldt-Jakob disease (vCJD). New Zealand has had measures in place to manage the potential human health risks associated with the presence of the BSE agent in imported food since 1996. Background to the history of BSE and vCJD, including the science, worldwide incidence, international regulatory environment for managing BSE risks and need for a review is discussed in the final report produced by the Review Team - *Officials' Review of New Zealand's BSE Country Categorisation Measure*.

The following is a summary of New Zealand's regulatory response to the human health risks from BSE in imported food:

- **April 1996 - suspension of United Kingdom imports** when the link between vCJD in humans and BSE in cattle was confirmed. By the end of 2000 the increased occurrence of BSE in cattle internationally and concerns about animal feeding practices suggested action needed to be taken against a wider range of risk countries.
- **5 January 2001 – Emergency Food Standard was established for bovine meat products making these products a prescribed food to be monitored for BSE.** A 'prescribed food' is a food identified as having a high risk; to protect public health such foods are monitored prior to release for sale. Thirty-one countries were identified as having inadequate controls or surveillance programmes for managing BSE and so imports of bovine products from these countries were prohibited. An Emergency Food Standard has effect for six months and so it was necessary to impose permanent import control measures to ensure ongoing protection of the public health from the risk of vCJD.
- **April 2001 – Consultation on including bovine meat products as a 'permanent' Food Standard.** Ministry of Health released a public discussion document *Proposal for a Legislative Change to Provide Ongoing Management of the Human Health Risks Associated with Imported Food Products Contaminated with the Bovine Spongiform Encephalopathy Agent*. The discussion document indicated the referred option was an amendment to the Food Standards ensuring bovine products for human consumption remained a prescribed food. This option was supported by submissions.

- **5 July 2001 – New food standard introduced** for “Any meat or other food product of a bovine animal, and any food product derived from or containing the meat or products of a bovine animal” to be monitored for BSE.
- **14 January 2002 – introduction of the current BSE Measure.** The current BSE Measure applying to imports of bovine meat products for human consumption was introduced to implement the Food Standard. This followed a period of extensive consultation. The current BSE Measure categorises countries from one to five. It also excludes the products listed in the OIE Code as being able to be traded safely regardless of the BSE status of the exporting country as BSE infectivity is not detectable in the tissues or products listed. This list includes the following foods: milk and milk products; gelatine and collagen prepared from hides; protein-free tallow; dicalcium phosphate with no trace of protein or fat; blood and blood by-products. A summary of the key features of this category is available in section 4.6 of the Review report.

2.2 Officials Review of New Zealand's Country Categorisation Measure

The Review was initiated in response to international experience gained since the height of the BSE epidemic, advances in the scientific understanding of BSE and the associated risk of vCJD from BSE in food, and changes to the international standard (the World Organisation for Animal Health's (OIE) *Terrestrial Animal Health Code*) on which the current BSE Measure is based. Many other countries, such as Australia and Canada, are reviewing, or have reviewed, their import requirements for imported bovine products in light of these changes.

The Review Team consisted of specialists from broad range of areas including the biosecurity, public health and public policy fields. New Zealand has particular expertise in BSE and this was represented on the Review Team. The science community was consulted in the development of the recommendations.

The Review recommended that New Zealand should revise its current BSE Measure in the following ways:

- **Recommendation 1:** New Zealand should move to a three-category system for categorizing the BSE risk of exporting countries.
- **Recommendation 2:** New Zealand should adopt international risk assessments of the required standard, rather than conduct its own risk assessments separate from those of other nations.
- **Recommendation 3:** New Zealand should exempt processed foods containing minimal bovine ingredients from the commodities covered by the BSE Measure.

- **Recommendation 4:** New Zealand should allow gelatine to be traded freely, regardless of the exporting countries' BSE-risk status.
- **Recommendation 5:** New Zealand should adopt a consistent framework for determining the acceptability of imported products and the need for any certification.
- **Recommendation 6:** New Zealand should remove age restrictions on the source of commodities are derived, and not specify measures to provide for traceability.

The Review concluded that “these recommended standards are consistent with the available scientific evidence and the emerging standards of other trading nations. To some extent these recommendations anticipate regulations expected to be put in place internationally over the next two or three years”.

3 Future Options

3.1 Options considered by NZFSA

Three options were considered by NZFSA following the presentation of the final report of the Review Team. These were to:

- Take no action and leave the current BSE Measure in place,
- Adopt the Review's recommendation that the Measure be revised and adoption of some of the specific recommendations of the Review. Revise the current BSE Measure so it reflects the changes that have been adopted into the current OIE Code, but not those that have been indicated or are anticipated to be adopted into the Code in future.
- Adopt all of the Review's recommendations.

NZFSA discounted the first of these two options as they were not considered to provide an adequate response to the current science and the direction being taken internationally. A summary of the reasons is outlined below:

- **The current BSE Measure is not consistent with current science or understanding of BSE and vCJD.** The Review found that scientific understanding of BSE has advanced significantly since New Zealand's current BSE Measure was put in place. New findings have changed assessments both of the risks to human health posed by the BSE agent, and of the measures that are necessary to protect human health. The BSE measures adopted internationally and by New Zealand reflect a precautionary approach which was taken during a time of uncertainty. There were concerns that the large number of BSE cases that occurred in cattle in the United Kingdom in the late 1990s indicated a vCJD epidemic of similar proportions could occur in humans in the future. We now know that such an epidemic is not going to occur, and the measures adopted are in excess of what is required to manage the potential risks. As discussed in the Review these findings include:
 - **Infectivity of BSE agent and presence in cattle:** It is now known that BSE infectivity is not detectable in muscle (that is, in 'meat'), but is confined to a limited range of tissues, most of which are not usually regarded as 'meat'. Further, BSE is not easily transmitted to humans even by those cattle tissues which have been shown to contain the BSE infectivity. Even with the massive exposure to BSE agent in the United Kingdom before infective tissues were removed from the food chain, vCJD cases have been much fewer than expected.

- **Preventing infection in cattle:** The infectious agent is transmitted between cattle only through consuming contaminated tissues, and it is relatively easy to remove potentially infected tissues from the animal feed chain. The ruminant-to-ruminant feed ban imposed after 1996 has effectively broken the cycle of infection in cattle, with BSE rates globally dropping significantly over the past three years.
- **Neither the current BSE Measure nor a partial adoption of the Review recommendations will be consistent either with the international standard – the OIE *Terrestrial Animal Health Code* (the “Code”) – or changes expected to take place in the next few years:** The World Trade Organization (WTO) SPS Agreement sets out the framework of rules and disciplines which provide countries to take scientifically justified measures to protect human, animal or plant life or health while minimising their negative effects on trade. The OIE provides risk-based standards, which are agreed by member countries through consensus. The OIE publishes its standards in the Code. Countries are required to base their measures on international standards such as the Code unless there is scientific justification not to do so. As a trading nation New Zealand needs to adopt measures that are consistent with international standards and our trade obligations. The current New Zealand BSE Measure closely follows the now out-of-date recommendations of the 2002 edition of the OIE’s Code. The Code was revised significantly in May 2005 in light of new scientific information, and accordingly it is now appropriate to reconsider New Zealand’s BSE Measure. The OIE’s Terrestrial Animal Health Standards Commission has proposed further changes to the Code’s BSE chapter and appendix, which are expected to be adopted over the next two or three years. These changes move from an incidence-based approach to a commodity-risk approach.
- **BSE infectivity in meat:** Experiments show that BSE infectivity in cattle is largely confined to the central nervous system: brain, spinal cord, eye, and associated ganglia, with a small amount sometimes detectable in tonsils and distal ileum (part of the small intestine). With the exception of these last two tissues, infectivity is not detectable until around 32 months after inoculation. Cattle are usually slaughtered for beef at less than this age and it is relatively simple to remove these potentially infected tissues from the human food chain. In regard to the age-related restrictions in the current BSE Measure, the European Union its updated *TSE Roadmap* (released 15 July 2005), which lists possible amendments to the BSE legislation and includes the proposal that the age from which the backbone in cattle has to be defined as an SRM and removed from the food chain be raised in the short to medium term.
- **Mechanically recovered meat:** Tissues from the central nervous system were not a feature of the British diet and it is now believed that it was the dorsal root ganglia in mechanically recovered meat that exposed British consumers to BSE infectivity in their

diet. Mechanically recovered meat is recovered from bones (such as the backbone) of cattle by high pressure techniques. The resulting product, a meat paste, was commonly used in burgers, sausages, pies, baby food and similar processed products.

- **Gelatine:** Originally there were fears that the BSE prion might be present in gelatine prepared from bovine tissues, and this led to precautionary measures to protect consumers in New Zealand and overseas. The scientific basis of this risk has recently been reviewed by NZFSA, whose analysis was also subjected to peer review. Recent experimental studies have confirmed that the chemical processes used in the manufacture of gelatine (see Appendix 2) are sufficient to inactivate any BSE infectivity that might have been present in the raw material, even under worst-case conditions. In January 2006 the European Food Safety Authority (EFSA) published a risk assessment that quantified the residual BSE risk in gelatine extracted from bovine bones for human health. EFSA supported the assessment and noted in its recommendations that the risks to humans from consuming gelatine produced from bones including the skull and vertebral column sourced from cattle of any age are very low and these findings do not support the continuation of the current gelatine restrictions prohibiting the inclusion of skull and vertebral column.
- **Inconsistent with stance taken by NZFSA and other government agencies in the international forum:** NZFSA is supporting a move to a science-based and risk-based approach for food safety.
- **Will be out-of-step with other countries:** While there is considerable variation in the BSE protection measures taken by our major trading partners, several of them are reviewing their measures for the same reasons as New Zealand, with countries such as Canada and the US supporting the changes to the OIE Code. It is generally agreed that simpler standards can ensure the safety of beef products for human consumption, while also reducing barriers to trade.
- **It will not resolve the problems NZFSA has encountered with categorising countries under the current BSE Measure.** The Review found that “many countries, including New Zealand, are finding categorisation to be complex and time consuming”. Issues include:
 - Very few countries have applied to NZFSA for country categorisation or equivalency. This is partly due to New Zealand being a minor market, and therefore there being little incentive for countries to go through the considerable work of applying. This creates difficulties for importers, since countries that are not categorised or assessed cannot export product to New Zealand.

- The process of assessing countries' applications for categorisation is time-consuming and difficult. Language difficulties arise, and it has become clear that some sort of verification of the information contained in some of the applications is necessary.
- A country's categorisation needs to be continually reviewed due to changes over time. Categorised countries are supposed to advise New Zealand of any relevant changes, but in reality New Zealand must be proactive.
- There is a need to ensure that changes in science and understanding around BSE are reflected in the categorisation system. Countries that have been categorised should have their categories reviewed in light of these changes.
- **Unnecessary trade barriers:** Given the risks do not warrant the measures being taken, and there are problems around the categorisation of countries, trade is being unjustifiably restricted.

3.2 NZFSA's selected option – adoption of all of the Review's Recommendations:

NZFSA proposes to adopt the recommendation of the Review that a revised BSE Measure be adopted. It also proposes to adopt all the specific recommendations of the Review. This is considered to be the best option as is fully supported by current science, follows the approach to food safety being advocated by NZFSA internationally, and is consistent with international regulatory requirements. It would also resolve the problems experienced by the implementation of the current BSE Measure.

This option has the following advantages:

- Consistent with current science and understanding around BSE and vCJD.
- The proposed changes will not significantly (or even measurably) decrease the already very high level of protection of New Zealand consumers against vCJD.
- Consistent with the current international standard and proposed international regulatory changes that are likely to take place in the next few years.
- Consistent with the direction that many of our major trading partners are taking.
- Consistent with the stance NZFSA and other Government agencies are taking internationally where we are advocating for a move to a science-based and risk-based approach for food safety – including for the risk from BSE in food.
- It would resolve the problems with the current country-categorisation system.

- It would remove unnecessary trade barriers, particularly for gelatine and de-boned beef, but also barriers created as a result of NZFSA being unable to categorise some countries because of the current categorisation system.

The proposed changes have been outlined below under each of the Review's specific recommendations. Specific import requirements have also been covered in the following section. Should this proposal be adopted following consultation, countries will need to be categorised and this information incorporated into a Standard Management Rule for Bovine Products.

4 Proposal to Amend New Zealand's BSE Measures

NZFSA proposes to adopt the recommendations of the Review Team that the current BSE Measure be revised. It also proposes to follow the Review's specific recommendations with the following being proposed:

4.1 Country-categorisation system:

NZFSA proposes to move to the Review's recommended three-category system for categorising the BSE risk of exporting countries.

The three categories proposed by the Review Team are based on the revised OIE Code. The criteria for defining the OIE Code's three categories are very different than those used to define the previous five categories. The OIE has moved away from the categories being based on the BSE incidence for the country being categorised, to recognition of risk assessments and measures in place to effectively manage the risk of BSE.

The Review Team considered that the BSE-risk posed by a country would broadly fall into two categories: negligible risk and risk. However, an additional category was recommended for countries that had previous cases of BSE and had implemented controls but for less than seven to eight years (relates to the incubation period of the disease). Bovine products from such countries might still pose a theoretical risk in that that infectivity might exist in cattle born and exposed to the BSE agent before controls were in place. This additional category takes account of this risk factor and allows countries to move from the unmanaged risk category (Category 3) into the managed risk category (Category 2) after specific controls to manage BSE had been put in place, and for countries to move from the managed risk category to the negligible risk category (Category 1) after these specific controls have been in place for a set time and have been proved to be effective by the absence of an BSE incident. Countries that are not categorised would default into the unmanaged risk category.

The categories are outlined in Table 1.

Table 1: Recommended three-category system for New Zealand

| Category | Definition |
|----------|---|
| 1 | <p>Must meet following conditions:</p> <p>Risk assessment conducted (based on OIE Code Article 2.3.13.2 (1) or equivalent) which concludes:</p> <ol style="list-style-type: none"> 1. Demonstrate currently operating Type B surveillance in accordance with OIE Code Article 3.8.4.3, and 2. OIE Code Article 2.3.13.2 criteria (2) – (4) met for at least seven years, and 3. EITHER: <ol style="list-style-type: none"> a) Have never had a BSE case, and likelihood BSE exists in the country is negligible and effective ruminant-to-ruminant feed ban in place for at least eight years, or equivalent safeguard <p>OR:</p> <ol style="list-style-type: none"> b) Have not had BSE cases in cattle for at least seven years, and all the following have been met for at least seven years: <ul style="list-style-type: none"> • Effective surveillance programme in place (met relevant OIE Code criteria that applied at the time) • Measures to eradicate BSE cases are effective (includes destruction of any confirmed BSE cases; veterinary administration has authority over any animal suspected or confirmed as having BSE) • Effective ruminant-to-ruminant feed ban in place for at least eight years. <p>OR</p> <ol style="list-style-type: none"> c) Have had BSE cases in imported cattle only during the past seven years but can provide satisfactory assurances that indigenous cattle have not been infected, and all the following have been met for at least seven years: <ul style="list-style-type: none"> • Effective surveillance programme in place (met relevant OIE Code criteria that applied at the time) • Measures to eradicate BSE cases are effective (includes destruction of any confirmed BSE cases; veterinary administration has authority over any animal suspected or confirmed as having BSE) • Effective ruminant-to-ruminant feed ban in place for at least eight years. |

| | |
|---|--|
| <p style="text-align: center;">2</p> | <p>Countries that have had indigenous cases within the last seven years, and risk assessment conducted (based on OIE Code Article 2.3.13.2 (1) or equivalent) that concludes:</p> <ol style="list-style-type: none"> 1. Demonstrates currently operating Type A surveillance in accordance with OIE Code Article 3.8.4.3, and 2. All of the following are in place and effectively enforced but any one or more of the following has not been in place or effective for at least seven years (eight years for the ruminant-to-ruminant feed ban): <ol style="list-style-type: none"> a) OIE Code Article 2.3.13.2 criteria (2) – (4) b) Ruminant-to-ruminant feed ban c) Effective surveillance programme in place (met relevant OIE Code criteria for surveillance that applied at the time) d) Measures to eradicate BSE cases are effective (includes destruction of any confirmed BSE cases; veterinary administration has authority over any animal suspected or confirmed as having BSE). |
| <p style="text-align: center;">3</p> | <p>Countries that cannot meet requirements of other categories, i.e.:</p> <ol style="list-style-type: none"> 1. No risk assessment (based on OIE Code Article 2.3.13.2 (1) or equivalent) has been conducted <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> 2. Risk assessment (based on OIE Code Article 2.3.13.2 (1) or equivalent) concludes that any one of the following is not in place or if in place is not effective: <ol style="list-style-type: none"> a) OIE Code Article 2.3.13.2 criteria (2) – (4) b) Ruminant-to-ruminant feed ban (includes destruction of any confirmed BSE cases; veterinary administration has authority over any animal suspected or confirmed as having BSE) c) Effective surveillance programme in place (met relevant OIE Code criteria for surveillance that applied at the time) d) Measures to eradicate BSE cases are effective. |

4.2 Determining a country's BSE risk category

NZFSA proposes to adopt the recommendation of the Review regarding how a country's risk category should be determined. Rather than New Zealand continuing to attempt to conduct its own risk assessments, it should use international risk assessments that are of the required standard (OIE Code Article 2.3.13.2 (1) or equivalent) in order to determine what category a country falls into in the revised BSE Measure.

In the short to medium term, it is proposed that the European Union geographical BSE risk assessment process (GBR) be accepted as equivalent risk assessments, although additional information may be required. Other risk assessments that are considered equivalent to the OIE Code criteria will also be accepted. Once assessments based on the new OIE categorisation systems are available, it is proposed that these will be used as the basis for determining the risk category of a country.

Currently, 66 countries have been assessed and have a GBR categorisation. The adoption of the GBR country categorisation system would increase the potential number of countries from which New Zealand can import bovine products while being confident that the methodology to assess a country's GBR is sound and based on the OIE BSE Chapter. A revised GBR would initiate a review of New Zealand's categorisation of that country.

4.3 Excluding processed foods containing negligible bovine meat content from the Measure

NZFSA proposes to adopt the recommendation excluding processed foods containing negligible bovine meat from the revised BSE Measure. These are defined as:

- Processed foods such as bouillon, soups, and stock cubes that contain negligible meat content (i.e. less than 2% of rendered fat and meat extract in the ready-to-serve product after added water).
- Other products such as salad dressing, dairy-base dip, flavouring, seasoning preparations and cheeses containing 3% or less of meat ingredients.

The Review identified as one of the primary problems with the current BSE Measure, difficulties with obtaining certification for processed food products containing negligible bovine meat content. It concluded that the level of risk posed by these products does not justify the monitoring currently required.

While the BSE risk of processed products containing negligible bovine meat content cannot be quantified, the science clearly illustrates there is an extremely low level of risk of BSE from such products. As a result, the high degree of scrutiny required to monitor these products

cannot be justified by the risk posed and it is recommended that products containing negligible bovine meat content be excluded from the BSE Measure. This is consistent with the approach taken by Canada. Further background to this decision is outlined in the Review Team's final report.

4.4 New gelatine measure

NZFSA proposes to adopt the Review recommendation that gelatine be traded freely regardless of exporting countries' BSE-risk status.

Recent peer-reviewed studies show modern processing methods reduce the infectivity of artificially contaminated raw materials to undetectable levels. This evidence indicates that gelatine should be exempt from measures regardless of the country/region BSE status. The Review's final report includes background to this decision in the form of a scientific paper on the risks posed to the consumer from gelatine.

4.5 Determining the BSE-related restrictions and requirements that apply to imported bovine food commodities

NZFSA proposes to adopt the Review recommendation regarding food commodities covered by the revised Measure and the processing measures that apply to these for each of the three categories. These are contained in Table 2. It is proposed that this table be used as the basis for determining the certification to accompany imported food derived from bovine animals.

Table 2: Commodity-specific mitigation measures

| Summary of processing measures required for imported food derived from bovine animals in order to manage BSE | | | |
|--|----------------------------------|--|---------------------------|
| Commodity | Category 1 country | Category 2 country | Category 3 country |
| a) milk and milk products b) gelatine and collagen prepared from bones, hides and skins c) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow d) dicalcium phosphate (with no trace of protein or fat) e) processed foods containing negligible bovine meat content i.e. 3% or less in the ready-to-serve product (NB: see recommendation 3.2 for specific definition) | No BSE restrictions ³ | No BSE restrictions ⁴ | |
| f) Meat and meat products, including deboned skeletal meat, other than commodities listed elsewhere in this table | | Air injection stunning and pithing prohibited; SRM excluded; mechanically recovered meat excluded; no restriction on age at slaughter. | |
| g) Blood and blood by-products ⁵ | | Air injection stunning and pithing prohibited | |

³ Biosecurity New Zealand requirements apply

⁴ As per footnote 4 above

| | | | |
|---|--|--|------------|
| h) Any food commodities prepared from/containing SRMs (as defined by new OIE Code criteria) | | Prohibited | |
| i) Mechanically recovered meat without age restriction | | Prohibited | |
| j) Tallow (non-protein- free) | | Air-injection stunning and pithing prohibited; not prepared from SRMs | Prohibited |
| k) Tallow derivatives made from non-protein-free tallow | | Air-injection stunning and pithing prohibited; SRMs excluded; produced by hydrolysis, saponification, or transesterification using high temperature and pressure | |
| l) Dicalcium phosphate-containing protein or fat | | Air-injection stunning and pithing prohibited; not prepared from SRMs | Prohibited |

4.6 Traceability of cattle 30 months of age and over

NZFSA proposes to adopt the Review recommendation that the current age restrictions on the source of commodities be removed – this proposal has been reflected in Table 2.

Scientific evidence shows that animals less than 30 months of age and skeletal muscle from animals over 30 months of age pose a negligible risk to consumers. The OIE accepts this evidence but did not adopt the position advocated by New Zealand that accepting such evidence removes both the need for specifying age at slaughter in the Code and the requirement for traceability to verify age a slaughter. This was an interim position and the Terrestrial Animal Health Standards Commission recommended at its September 2005 meeting that the age-at-slaughter restrictions be removed.

4.7 Pre-planned review cycle

NZFSA proposes to adopt the Review Team's recommendation that the revised Measure should be reviewed if reputable new scientific information on the infectivity of TSEs emerges that challenges the basis of the proposals in this Review. These might include:

- a change in the tissues considered to be specified risk materials (SRMs)

- a change in the age profile at which the BSE agent can be detected in cattle
- the emergence of BSE in new species of food animals
- new evidence that the threat of vCJD infections in humans is changing
- new tests enabling BSE-contaminated tissues to be removed from the food chain.

5 Import Requirements

5.1 Standard Management Rule for Bovine Products

Once the consultation period has ended and NZFSA has considered all submissions, the proposed Measure may be amended as a result of submissions. The resulting measure will be considered by Government before being finalised. NZFSA will then implement the revised Measure and develop a new Standard Management Rule, which will specify the import requirements for product from each country (using Table 2) and clearance options.

5.2 Categorisation of countries under the Revised BSE Measure

NZFSA proposes to follow the recommendations made in the Review around using GBRs to determine a country's BSE risk category and the suggestions made in relation to implementing the revised BSE Measure. Specific information will be required to determine if a country has established effective mechanisms to manage BSE in order to be placed in Category 2 and again to determine if these mechanisms have been in place for the required time in order for a country to move to Category 1. There may be occasions when this specific information is not available from the GBR and in these situations it will be sought directly from the country concerned or from other international risk assessments that meet the required standard.

As a first step NZFSA will categorise countries that have already been categorised under the current Measure under the revised Measure, and reassess any current equivalency arrangements. This will occur prior to the target implementation date of 24 July 2006.

NZFSA will then categorise those countries that have applied for categorisation but their applications have been on hold until after the outcome of the Review. Countries that have not applied for categorisation may be able to be categorised depending on the information available; importers will be able to request NZFSA conduct such as assessment for individual countries. Countries that have not or are not able to be categorised will default into Category 3.

5.3 Clearance Options

Product from countries that are categorised as Category 1 will not be required to obtain NZFSA clearance and NZFSA will advise Customs to facilitate the free entry of these products⁶.

Products from countries that are categorised as Category 2 or 3 and must meet certain processing measures will be required to provide certification signed by the competent authority to attest that the requirements have been met. Products from countries that are categorised as Category 2 or 3 and are not subject to BSE restrictions will be not be required to obtain NZFSA clearance. Where processed products from these countries are targeted by the tariff codes at the border and it is not clear whether they contain bovine ingredients, certification will be required in order for these products to be cleared.

NZFSA proposes to adopt the Review's recommendation that New Zealand accepts assurances where there are equivalent safeguards. More specifically the Review recommended that it would be necessary to:

- identify those countries/regions with which we have an existing equivalency agreement
- identify those systems that could be considered equivalent
- provide or develop criteria for accepting equivalence
- provide or develop third-country trade requirements.

The Review also recommended that New Zealand consider identifying countries that have imported food programmes to manage the risk of BSE that are equivalent to New Zealand's and accept certification for all products from such countries regardless of the country of origin. NZFSA proposes to investigate this option.

5.4 Sampling and Testing

There is no test available in New Zealand to confirm that foods from risk countries that contain meat are free from bovine or bovine products. As a result sampling is not an available option.

Protein free tallow (including protein free tallow derivatives) can be sampled and tested to confirm the level of insoluble impurities is less than the allowable maximum of 0.15% in weight. The sampling and testing requirements remain the same as under the current BSE Measure and are outlined in the current SMR – see www.nzfsa.govt.nz

⁶ Biosecurity New Zealand requirements will still apply.

5.5 Costs

Costs are recovered per the Food (Fees and Charges) Regulations 1997. The current charges for clearance will apply.

6 Questions and Submission Form

What is your view on this proposal? Answering the following questions will help us with our analysis.

Name:

Organisation (if applicable):

Address:

Please comment under the following headings:

1. The consultation process.
2. Future options: NZFSA's selected options
3. Proposal to Amend NZ's BSE Measure:
 - 3.1 Country Categorisation system
 - 3.2 Determining a country's risk category
 - 3.3 Excluding processed foods containing negligible bovine meat content from the Measure
 - 3.4 New gelatine measure
 - 3.5 Determining the BSE-related restrictions and requirements that apply to imported bovine food commodities
 - 3.6 Traceability of cattle 30 months of age and over
4. Import Requirements
5. Any other comments you may have on this proposal.

Note: This is the consultation draft. If a decision is made to introduce a revised BSE Measure for bovine products monitored for BSE, the final version may change after the consultation process.