5.6 Recommendation 1: Country Categorisation system

It is recommended that New Zealand move to a three-category system for categorising the BSE risk of exporting countries. The categories are outlined in Table 6.

Table 6: Recommended three-category system for New Zealand

Category	Definition
1	Must meet following conditions: Risk assessment conducted (based on OIE Code Article 2.3.13.2 (1) or equivalent) which concludes: 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: 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 OR 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: • 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. OR 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: • 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.
2	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: 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): 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).
3	Countries that cannot meet requirements of other categories, i.e.: 1. No risk assessment (based on OIE Code Article 2.3.13.2 (1) or equivalent) has been conducted OR 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: 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.

21 CoA is a certificate of analysis, a commercially managed quality assurance document, which specifies information about raw materials and components such as chemical analysis, sources, processing parameters,

5.7 Recommendation 2: Determining a country's BSE risk category

Because of the difficulties and inefficiencies of New Zealand conducting its own risk assessments, it is recommended that these should be based on OIE Code Article 2.3.13.2 (1) or equivalent.

In the short to medium term, European Union geographical BSE risk assessment process (GBR) should 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, these will be used as the basis for determining the risk category of a country. The background to this recommendation is set out in Appendix 1.

5.8 Recommendation 3: Excluding processed foods containing negligible bovine meat content from the Measure

There is a need to resolve one of the primary problems identified with the current BSE Measure, namely that there are difficulties with obtaining certification for processed food products containing negligible bovine meat content. The level of risk posed by these products does not justify the monitoring currently required.

As noted in section 5.1 on ALOP, no country has expressed an explicit ALOP for vCJD, but the levels of control taken by various countries suggest implicit ALOPs. It is impossible to determine meaningful numerical estimates of changes in risk. Where a product clearly contains a bovine ingredient in small quantities there is justification for excluding it from the BSE Measure as evidenced by the following points:

- The original measure was set at a precautionary level when there was uncertainty regarding the risks to human health. Subsequent research has shown the risk to be very low with the CDC[22] now estimating that the risk to humans in the UK (the region with the highest number of BSE cases) is about one case of vCJD per 10 billion servings of products containing beef. The estimation includes beef products that contain high percentages of mechanically recovered meat such as burgers. This proposal is to only exclude products containing three percent or less of products derived from bovine animals, significantly reducing the risk estimated by the CDC.
- Calculating a numerical estimate of changes in risk is not possible to any meaningful extent. Allowing such products to be excluded from the requirements will make a very small difference in risk and is consistent with the SPS Agreement (see Appendix 3).
- All countries that have detected BSE have in place policies to protect their own citizens by maintaining a ruminant to ruminant feed ban and excluding SRMs from all food and feed chains.

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 – the definition of such products is given in Table 7. This exclusion is consistent with the approach taken by Canada.

Refer to Appendix 3 for background on this recommendation.

5.9 Recommendation 4: New gelatine measure

It is proposed that gelatine be traded freely regardless of exporting countries' BSE-risk status. Recent peer-reviewed studies show modern processing methods and dilution rates applied in normal manufacturing 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 independent and reputable peer-reviewers of the NZFSA commissioned review, which is provided in Appendix 2, have endorsed this approach.

22 Centres for Disease Control & Prevention, Department of Health & Human Sciences, US Government: see http://www.cdc.gov/ncidod/dvrd/vcjd/risk_travelers.

5.10 Recommendation 5: Determining the BSE-related restrictions and requirements that apply to imported bovine food commodities

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	No BSE restrictions	No BSE restrictions	
b) gelatin 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			
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[23]		Air injection stunning and pithing prohibited	
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

NOTE: The following products are not included in this import measure and can be imported from any country:[24]

- Processed foods such as bouillon, soups, and stock cubes that contain a 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.

24 Cooper, JD, Bird, SM. (2002) UK dietary exposure to BSE in beef mechanically recovered meat: by birth cohort and gender. Journal of Cancer Epidemiology and Prevention. 7 (2). 59-

5.11 Recommendation 6: Traceability of cattle 30 months of age and over

The current OIE Code accepts the scientific evidence that animals less than 30 months of age and skeletal muscle from animals over 30 months of age pose a negligible risk to consumers. However, the OIE did not adopt the position advocated by New Zealand that accepting this 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.

The review team agrees that the scientific evidence should be the basis for the measures that New Zealand adopts to protect consumers, and therefore recommends removing age restrictions on the source of commodities (as set out in Table 7). The other measures, by banning SRMs from Category 2 and 3 countries, take account of age-related contamination.

Similarly, the Review recommends no specific measures to provide for traceability.

However, despite being based on scientific consensus, the fact that this recommendation differs from the current OIE Code and the requirements of many other countries may create a problem of risk perception among some consumers.

5.12 Summary of key differences in proposed New Zealand system

The following are the key points in the proposed New Zealand BSE Measure that differ from the OIE Code:

- Countries that can show via risk assessment that exposure to BSE has not occurred will no longer be required to have a ruminant-to-ruminant feed ban in place for eight years.
- Category 2 recognises countries that have conducted a risk assessment and have measures to manage BSE in place.
- Deboned skeletal meat and any other meat products (except mechanically recovered meat) from all country categories can be traded without the existing 30-month age restriction.
- Gelatine derived from bones by modern processes is deemed to be of no BSE risk and can be traded unrestricted regardless of country category.
- Food products containing minimal bovine ingredients are excluded from the BSE Measure.

5.13 Implementation issues

The implementation of the proposed revised Measure is outside the terms of reference for this Review. The implementation issues listed below are only as far as they affect the design of the Review's recommendations.

1. *Certification:* The Review has recommended New Zealand accepts assurances where there are equivalent safeguards. It will 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.

It is 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.

2. *Categorisation:* Few countries have applied for New Zealand's current country categorisation, and this has caused difficulties for importers. It will be necessary to:

- provide or develop assessment scales related to other categorisation systems such as GBRs, the OIE Code, etc.
- provide for importer-driven assessments where exporting countries have not applied
- provide criteria for equivalent categorisation based on the risk assessment of release and exposure, the effectiveness of the awareness programmes, compulsory notification, and surveillance systems.

3. *Risk communication:* The level of public concern about BSE and vCJD, although possibly declining, remains high. Adoption of recommendations from this Review, particularly those that pre-empt future decisions by the OIE, will need to be communicated within their scientific and regulatory context.

5.14 Potential for alignment with the Australian standard

Although NZFSA has been involved in technical discussions on a revised Australian BSE standard, there appear to be significant delays in resolving differences amongst the various Australian stakeholders. At this stage it appears unlikely that a revised Australian standard will emerge in time to be considered by this Review.

5.15 Consistency between NZFSA and Medsafe on gelatine content of foods and pharmaceuticals

Although NZFSA and Medsafe discuss policies to minimise the risk of TSE transmission, their policies for food and medicines, respectively, may differ in some cases, for reasons including:

- Medsafe considers products that are manufactured and administered by many routes, whilst NZFSA considers risks from BSE transmissible orally in food.
- Medsafe is currently working to compare and align its policies with Australia in view of the proposed trans-Tasman therapeutics agency.

Veterinary medicines in New Zealand are managed by NZFSA and are outside the proposed trans-Tasman therapeutics agency.

Although there is considerable consistency between the proposed NZFSA measures and Medsafe measures to control risks posed by gelatine, for the reasons outlined above there is no intention to formally align the standards. Medsafe currently does not assess risks posed by biological medical devices, although the proposed trans-Tasman therapeutics agency will subject these to full evaluation.

Also, Medsafe does not control dietary supplements or complementary medicines (although the proposed trans-Tasman therapeutics agency is likely to control therapeutic-type dietary supplements), and thus does not consider risks posed by their ingredients. Currently dietary supplements are regulated under the Food Act 1981 and fall under the definition of "food" in this Act. They are required to meet the requirements of the Act and its regulations. Under Clause 6 of the Prescribed Food Regulations, any food product derived from a bovine animal is a "prescribed" food and can be monitored for the presence of BSE. As a result, dietary supplements are covered by the current BSE Measure and will be covered by any new BSE Measure.

With regard to actions in the event of an emergency or new event, Medsafe would need to consider products manufactured and administered by many routes, and associated risk-benefit balances affected by the event. Medsafe would exchange information and expertise with NZFSA in such a situation, but they would not necessarily formally align their policies.

5.16 Pre-planned review cycle

The review team recommends 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.