3. Worldwide incidence of BSE/vCJD

BSE was first detected in the United Kingdom in 1986 and has now occurred in more than 20 countries (see Table3) either directly or indirectly from the importation of infected cattle or infected meat and bone meal from countries where BSE has occurred, particularly the UK.

Table3 : Confirmed cases of BSE worldwide as at January 2005[13]

	2004	2003	Total since 1987
UK (GB & Northern Ireland)	338	611	182,792
Austria	0	0	1
Belgium	7	15	124
Czech Republic	4	4	12
Denmark	1	2	14
Finland	0	0	1
France	31	137	923
Germany	32	54	330
Greece	0	0	1
Ireland	68	182	1425
Italy	3	31	122
Luxembourg	0	0	2
Netherlands	5	19	76
Poland	7	5	16
Portugal	36	133	898
Slovak Republic	2	2	15
Slovenia	1	1	4
Spain	53	167	448
Canada	0	1	2
Falkland Isles	0	0	1
Israel	0	0	1
Japan	4	2	11
Liechtenstein	0	0	2
Oman	0	0	2
Switzerland	0	21	453
United States	0	1	1
Total			4 885

13 http://www.food.gov.uk/bse/facts/worldwidefig/

3.3 Associated vCJD situation

The relative numbers of BSE cases strongly suggest that the exposure of humans to BSE in any country outside the UK must be at least a hundred times less than what was experienced in that country before anti-BSE measures began to take effect. The other countries that have reported cases of BSE applied control measures at a much earlier stage in their BSE epidemic than did the UK.

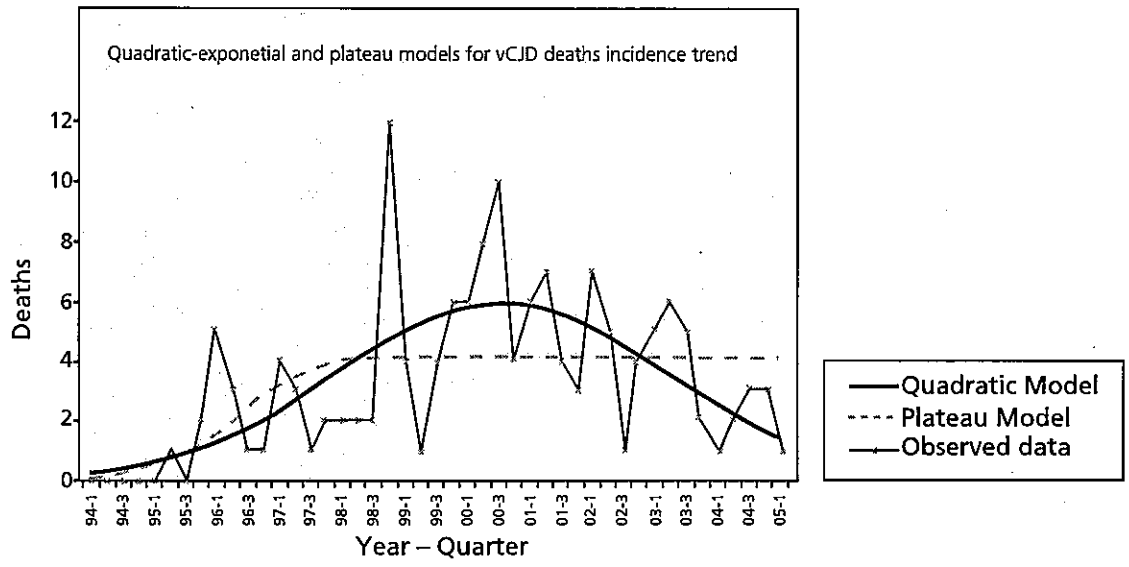
Thus the BSE risk to humans should be at least a hundred times, probably a thousand times, less in any country other than the UK. In a travel advisory, the US Centers for Disease Control estimate that even in the UK the current risk of acquiring vCJD from eating beef and beef products appears to be extremely small, perhaps about one case per 10 billion servings.[14]

Any comparison of actual number of cases will be influenced by the way in which the vCJD epidemic is evolving. Putting aside the issue of person-to-person spread of vCJD (through blood transfusions, for example), it is now apparent that the vCJD epidemic has peaked, or at least reached a plateau (see Figure 3 below). The data suggests that the incidence of vCJD is declining, not merely plateauing.[15,16]

Human susceptibility to CJD is to a large extent governed by a single amino acid on the gene responsible for making the PrP, the so-called 'prion protein'. The particular amino acid can be either methionine or valine, and its position on the gene is known as codon 129. So far all but one of vCJD cases have been in people homozygous for methionine at codon 129. That is, their prion protein gene had methionine on each strand of its DNA. Recently though, infection was detected in a person heterozygous (methionine and valine) at codon 129. This suggests the possibility of a so-called 'second wave' of vCJD.

The proportion of the European population which is heterozygous at codon 129 is roughly similar to the proportion homozygous for methionine. Animal models strongly suggest that heterozygous individuals are likely to have partial resistance to infection, and so any second wave of foodborne vCJD is likely to be smaller than what has been observed already.

Figure 3: vCJD deaths: incidence trends



14 http://www.cdc.gov/ncidod/diseases/cjd/bse_cjd.htm
15 http://www.cjd.ed.ac.uk/twelfth/rep2003.htm
16 Nick Andrews, http://www.cjd.ed.ac.uk/vcjdqmar05.htm

4 International Regulatory Environment for managing BSE risks

4.3 Key regulatory bodies: the WTO and the OIE

The World Trade Organization (WTO) SPS Agreement sets out the framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures, such as BSE measures. It provides for countries to take scientifically justified measures to protect human, animal or plant life or health while minimising their negative effects on trade.

Under the SPS Agreement, the World Organisation for Animal Health (OIE) provides risk-based standards, which are agreed by member countries through consensus.

The OIE publishes its standards in its Terrestrial Animal Health Code ("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.

4.4 Safeguards

Tables 4 and 5 summarise the OIE Code's standards across various categories. Both Tables are from the current (2005) edition of the Code.

Table 4 shows the commodities (and products made from these commodities and containing no other tissues from cattle) that may be traded without BSE-related conditions, regardless of the BSE risk status of the cattle population of the exporting country.

Table 4: Tissues that can be traded safely regardless of the BSE status of the exporting country[17]

a) milk and milk products

b) semen and in vivo derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society

c) hides and skins

d) gelatine and collagen prepared exclusively from hides and skins

e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow

f) dicalcium phosphate (with no trace of protein or fat)

g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which 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, and which were subject to ante-mortem and post-mortem inspections and were not suspect or confirmed BSE cases; and which has been prepared in a manner to avoid contamination with tissues [listed in Table 5 below]

h) blood and blood by-products, from cattle which 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.

These guidelines recognise that BSE infectivity is not detectable in the tissues or products listed.

Because of what is now known about the distribution of BSE infectivity within the animal, and the age at which tissues become infective, it is possible to promulgate measures that will permit safe trade of a range of other tissues, even from countries where BSE is present.

For such cases, the OIE's Code recommends the exclusion from traded commodities of a range of specified risk materials. These are shown in Table 5. (Vertebral column, or "backbone", is included because of the difficulty of completely removing the spinal cord and dorsal root ganglia from the surrounding bone). See Appendix 1 for an outline of the OIE Code's recommended safeguards.

17 http://www.oie.int/eng/en_index.

Table 5: Tissues (specified risk materials, in bold) that should be excluded from export from countries with a BSE risk.[18]

1) From cattle of any age ... the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: ***tonsils and distal ileum***, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle that were at the time of slaughter over 30 months of age ... the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: ***brains, eyes, spinal cord, skull, vertebral column*** and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

4.5 Trading partners' measures

There is considerable variation among the BSE-protection measures taken by New Zealand's trading partners:

- *European Union:* All 25 Members of the European Union are bound by Community Law. The European Food Safety Agency applies a five-category risk assessment.
- *United States:* Following the discovery of BSE in the US, the policy position has changed from recognition of BSE-free areas to focusing on commodity-specific measures (this means the removal of SRMs from New Zealand's US beef exports). The US supports the current OIE Code, whereby the emphasis shifts from the incidence of BSE to the systems in place to control and monitor.
- *Australia* is also reviewing its BSE measures. While there was support for following the OIE Code, there will be some resistance to shifting from an incidence-based approach to a commodity-risk approach. Currently Australia prohibits all beef imports from its Category D countries.
- *Japan* takes an extremely risk-averse approach and has banned US and Canadian beef imports. This approach has seen the issue raised at the SPS Committee, and although the US and Japan have been working on this impasse over the last two years to reach agreement, trade has still not resumed (as at 15 August 2005).
- *Canada* has just developed a new draft BSE measure. This is based on the OIE Code, but would include New Zealand in Category 1. Briefly, the new measure proposes no restrictions for Category 1 countries (other than for cell lines and veterinary biologics prepared from SRMs from Category 2 and 3 countries), some restrictions for Category 2 and a mix of restrictions and prohibitions for Category 3 countries. No restrictions are proposed for any Category 3 country for products originally listed as the OIE exemptions. Although the new draft Canadian measure is based on the current OIE Code, it does not exempt deboned muscle meat, but instead refers to meat and meat products for which there is a prohibition for stunning, pithing and the inclusion of SRMs for Category 2 and 3 countries. The Canadian Government will recognise equivalence in its assessments

4.6 New Zealand's measures

New Zealand released its current BSE measures in December 2001[19]. In summary the categories are:

- *Category 1:* Country or region free of indigenous BSE required to attest that bovine products are sourced from the Category 1 country
- *Category 2:* Country or region provisionally free of indigenous BSE with no cases reported: can trade with restrictions
- *Category 3:* Country or region provisionally free of indigenous BSE with at least one case reported: can trade with restrictions
- *Category 4:* Country or region with low incidence: can trade with restrictions
- *Category 5:* Country or region with high incidence: can trade with restrictions.

All categories of country can trade at least some products if sanitary measures are in place to manage the risk, but the restrictions are progressively tighter from Categories 2 through 5. Category 2 countries must remove SRMs, have ante-mortem inspections and ruminant-to-ruminant feed bans, and not use pithing or air stunning. The allowable age of the relevant animal decreases as the risk category increases, and traceability is required for products from Category 5 countries.

In addition, New Zealand has an equivalence agreement with the European Union, SPS arrangements with some other trade partners, and is working towards an equivalence agreement with the United States. Bilateral negotiations for minimal BSE-related access restrictions on New Zealand beef products which are under way with other countries are based around conformity with OIE standards.

18 http://www.oie.int/eng/en_index.htm.

19 See 'Measure to provide ongoing management of the human health risks associated with imported food products potentially containing the Bovine Spongiform Encepthalopathy Agent', December 2001. Found at http://www.nzfsa.govt.nz/imported-food/bse-categorisation/bse-final-measure.pdf

5. Recommendations: a revised BSE measure for New Zealand

Scientific understanding of BSE has improved 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.

There also as been a growing awareness of inconsistencies and problems in the application of the current measure.

Any changes need to be based on peer-reviewed science and be consistent with society's expectations for protection from vCJD.

5.3 What is New Zealand's "appropriate level of protection"?

Appropriate level of protection (ALOP) is the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health with its territory. This concept is also known as 'acceptable level of risk'.

No country has expressed an explicit appropriate level of protection (ALOP) for the prevention of disease in humans, including vCJD. The levels of control taken by various countries suggest implicit ALOPs.

For example, Japan has taken an extremely risk-averse position, implicitly valuing a life saved from vCJD at around about NZ$5 billion.[20] Australia has adopted more conservative prevention measures than New Zealand, implying a higher ALOP than ours.

Generally speaking, risk aversion to vCJD around the world is so high that ALOP has ceased to have any rational meaning.

In the environment of concern and uncertainty that reigned in 1996 – there was worldwide concern that a major outbreak of vCJD was beginning, the epidemiology was not understood, and estimates of possible deaths ranged as high as hundreds of thousands over decades – very tough control measures were adopted.

In the event, the epidemic peak has passed with fewer than 200 deaths worldwide and, although a second peak in the heterozygous population is possible (refer section 3.1), total deaths are unlikely to exceed 500 worldwide.

The measures have therefore delivered a higher level of protection than was anticipated. The estimated risk to New Zealand consumers is now in the order of one case in several decades – effectively below the level where an ALOP has any useful value as a risk management tool.

This high level of protection has been maintained even though not all theoretical risk pathways have been closed:

- In common with most other countries, New Zealand has continued to trade without restriction with countries assessed as having a similar risk of BSE to New Zealand. These assessments do not imply zero risk. However, the lower-risk (and still not 'zero-risk') alternative, namely excluding specified risk materials sourced from any country, would have significant cost and trade consequences for an immeasurably small reduction in risk.
- Gelatine derived from cattle bones has been regarded as possibly posing some small risk, based on the source country of the bones and has been controlled to some extent. But gelatine is ubiquitous in food and pharmaceutical products, its presence is often not apparent on specifications or in customs declarations, and its origin is usually very difficult to determine.
- There have been problems with processed foods containing minimal bovine ingredients not always being declared and imported with the appropriate competent authority certification.
- There are acknowledged problems with ensuring that there is no brain or spinal cord tissue cross-contamination of carcasses from stunning, decapitation and carcass splitting.
- There are no controls on specified risk materials produced in New Zealand despite a non-zero (but extremely low) risk that BSE in present in New Zealand but remains undetected.

This Review does not recommend that these gaps need to be addressed. Any changes will not significantly (or even measurably) increase the already very high level of protection of New Zealand consumers against vCJD.

It should be noted that section Recommendation 2 in section 5.5 includes the proposal that processed foods containing minimal bovine ingredients be excluded from the list of commodities covered by the BSE Measure.

20 An estimate based on the human incidence attributed to the UK and the cost of measures to exclude possible cases of BSE from the food chain in

5.4 Country categorisations

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.

This Review proposes that New Zealand move from the current categorisation system to the European Union's geographical BSE risk assessment process (GBR) as the basis for determining the BSE risk category of a country (or an equivalent assessment), and migrate to OIE categorisation systems as these come on track. The process for establishing and maintaining GBRs is set out in Appendix 1.

5.5 Overview of recommendations

This Review recommends a number of changes, based on the current peer-reviewed scientific data, to rationalise and simplify New Zealand's current BSE Measure without generating any measurable or calculable increase in risk to New Zealand consumers.

These recommendations are, in summary:

- adopting the country categorisations adopted by the European Union as an interim measure, but then adopting those produced by the OIE as they come on stream
- assessing countries' BSE risk within three rather than five categories, with escalating control as risk increases
- excluding specified risk materials (SRMs) from any country with residual risk of BSE
- adopting the OIE's broader category of minimal-risk commodities, and allowing them to be imported (see Table 7) if there are verifiable controls in the exporting country
- accepting that the 30-month age cut-off is not relevant for the importation of the OIE-listed commodities
- accepting that there is no significant risk with gelatine from any source, assuming verification (possibly by certificate of analysis[21]) of the production process
- excluding processed food products containing minimal bovine ingredients from the commodities covered by the BSE Measure (see Table 7).