

# **Officials' Review of New Zealand's BSE Country-Categorisation Measure**

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## Glossary

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| advanced meat recovery (AMR)                   | <p>A mechanical process that removes attached skeletal muscle tissue from livestock bones without incorporating significant amounts of bone and bone products into the final meat product; is less likely to contain central nervous tissue than mechanically recovered meat.</p> <p>See also “mechanically recovered meat” in this glossary and <a href="http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-038IF.htm">www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-038IF.htm</a>.</p> |
| bovine spongiform encephalopathy (BSE)         | <p>A fatal, feed-borne, neurological disease of cattle that may cause variant Creutzfeldt Jacob disease (vCJD), a very rare food-borne illness in humans, resulting from consumption of products contaminated with bovine central nervous tissue.</p>  |
| BSE Measure                                    | <p>New Zealand’s regulations to control the risk of the BSE agent entering the human food chain; formerly, the “Measure to Provide Ongoing Management of the Human Health Risks Associated with Imported Food Products Potentially Containing the Bovine Spongiform Encephalopathy Agent” administered by the Ministry of Health and enabled by Section 11D of the Food Act 1981</p>   |
| certificate of analysis (CoA)                  | <p>A commercially managed quality-assurance document that provides information on the purity and provenance of a raw material or intermediate or fully finished product.</p>   |
| Codex Alimentarius Commission (Codex)          | <p>The organization that sets international food standards to protect the health of consumers and promote fair practices in food trade</p>   |
| geographical BSE risk assessment process (GBR) | <p>A process used by the European Food Safety Agency to assess the likelihood of BSE being present in a country.</p>   |
| greaves  | <p>The unmelted residue left when animal fat has been rendered.</p>  |
| indigenous                                     | <p>Born or produced in a country; not introduced.</p>  |
| meat and bone meal (MBM)                       | <p>As used in this Review, this includes solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids.</p>   |
| mechanically recovered meat (MRM)              | <p>Beef product that results from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses; implicated in the spread of vCJD to humans because MRM recovered from the vertebral column (‘backbone’) of cattle may be contaminated</p>  |

|  |   |
|--|---|
|  | with central nervous tissue, which contains infectivity in cattle with BSE.   |
|  | See also “advanced meat recovery” in this glossary and <a href="http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-038IF.htm">www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-038IF.htm</a>   |
| Medsafe  | New Zealand Medicines and Medical Devices Safety Authority; the division of the Ministry of Health that manages and enforces safety standards for medicines and medical devices.  |
| 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.                     |
| pithing  | A slaughtering technique where a rod is inserted into the central nervous system of a stunned animal to immobilise it; may lead to contamination of the carcass with central nervous tissue   |
| prion  | A proteinaceous agent generally considered to be the cause of TSEs.   |
| PrP <sup>SC</sup>  | The abnormally folded form of a protein known as PrP, which is found in all nervous tissue. PrP <sup>SC</sup> is considered by many to be synonymous with ‘prion’.  |
| 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 Jacob disease (vCJD)                                   | The fatal human neurological disease that is transmitted to humans through consumption of products contaminated with central nervous tissue of cattle infected with BSE.  |

## Executive Summary

Bovine spongiform encephalopathy (BSE) is a serious neurological disease of cattle that is believed not to be present in New Zealand.

BSE-protection measures have applied to beef and beef products imported into New Zealand for human consumption since the discovery that BSE-infected meat was the likely cause of a number of cases of variant Creutzfeldt Jacob disease (vCJD), a serious and fatal neurological condition of humans. Most of these cases of vCJD were in the United Kingdom; there have been none in New Zealand.

The latest scientific evidence suggests that New Zealand can modify the BSE measures it applies to imported products containing beef, while still ensuring that these products are safe for human consumption.

Led by international regulators, many countries are now reviewing their standards in the light of science and practical experience that shows that:

- The risk of a large-scale epidemic of vCJD among humans is much smaller than at first feared.
- BSE infectivity is not found 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.
- Simpler standards can ensure the safety of beef products for human consumption, while also reducing barriers to trade.

This paper recommends that New Zealand should revise its current anti-BSE measures in the following ways:

- Recommendation 1: New Zealand should move to a three-category system for categorising 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, and not specify measures to provide for traceability.

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.

This Review has been prepared for the New Zealand Food Safety Authority, who will make any resulting recommendations to the Government. The analysis and recommendations in this Review have not been subject to external consultation.

## 1. Introduction

The purpose of this Review is to consider the steps New Zealand is currently taking to manage the human-health risks of bovine spongiform encephalopathy (BSE) in imported foods and, if appropriate, to propose changes to the current BSE Measure.<sup>1</sup>

The Terms of Reference for this Review are set out in Appendix 6.

BSE is a neurological disease of cattle that can lead to the fatal variant Creutzfeldt Jacob disease (vCJD) in humans.

Since 1996, New Zealand has taken steps to manage the potential human-health risks of the BSE agent in imported food. In January 2002 new import procedures<sup>2</sup> were introduced requiring that bovine meat products can only be imported into New Zealand when certified to a level commensurate with the exporting country's BSE status.

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 Terrestrial Animal Health Code of the OIE, the World Organisation for Animal Health.

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. For this reason, the review team has based its proposals on the science-based negotiating position of the New Zealand Government for further revisions to the Code. Where the review team's proposals go beyond the current (2005) Code, these are noted in the text of this Review.

An independently chaired committee of officials (see Appendix 4 for membership) has conducted this Review with independent advice from an interdepartmental advisory group (IDAG), whose terms of reference are in Appendix 7 of this report.

No attempt has been made to consult with wider stakeholder groups. Such consultation will be the responsibility of the New Zealand Food Safety Authority (NZFSA) once it has considered its response to the recommendations in this report.

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<sup>1</sup> New Zealand's BSE control measures are codified in "Measure to Provide Ongoing Management of the Human Health Risks Associated with Imported Food Products Potentially Containing the Bovine Spongiform Encephalopathy Agent" (New Zealand Ministry of Health, December 2001), and are enabled by Section 11D of the Food Act 1981.

<sup>2</sup> This review considers only imports of bovine food products. BSE export requirements for such products are set by the importing country and are administered in New Zealand by the Ministry of Agriculture and Forestry.

## **2. Scientific background**

BSE is a member of a family of diseases known as transmissible spongiform encephalopathies (TSEs). It is a fatal, feed-borne, neurological disease of cattle, which originated through, and has been amplified by, the feeding to cattle of meat-and-bone meal contaminated with an agent related to, and perhaps originating from, the agent that causes scrapie in sheep.

In 1996 human cases of a new TSE known as variant Creutzfeldt Jacob disease (vCJD) were reported. The disease is always fatal in humans. These vCJD cases were soon shown to be caused by human infection with the BSE agent.

Because of this risk to human health, many precautionary measures were implemented around the world to reduce the potential for BSE to be transmitted to humans via food products derived from cattle.

However, in the intervening years much has been learned about BSE and the risk to human health, and in many countries some of the precautionary measures put in place after 1996 are being reviewed.

### **2.3 Infectivity of agent**

TSEs are generally considered to be caused by infection with a proteinaceous agent known as a “prion”.

The dose of this agent needed to infect cattle is very small. This was a source of major concern in 1996 when the first cases of vCJD occurred but it is now known that this infectious agent does not easily cross the species barrier into humans. Thus the development of vCJD from exposure to the BSE agent is much more rare than was thought likely in 1996. 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 and the vCJD epidemic is now declining (see Figure 3).

### **2.4 Presence of infective agent**

Since 1996 the specific tissues that are likely to contain the BSE agent, and the time that they become infectious, have become better defined. It is now known that detectable infectivity is restricted to only a few bovine tissues; over 40 bovine tissues have been tested, have not been shown to contain the BSE agent, and are thus regarded as safe. Moreover, it is relatively simple to remove potentially infected tissues from the human food chain. All countries with BSE require these tissues to be removed from all animals slaughtered for food, and that these tissues then be destroyed.

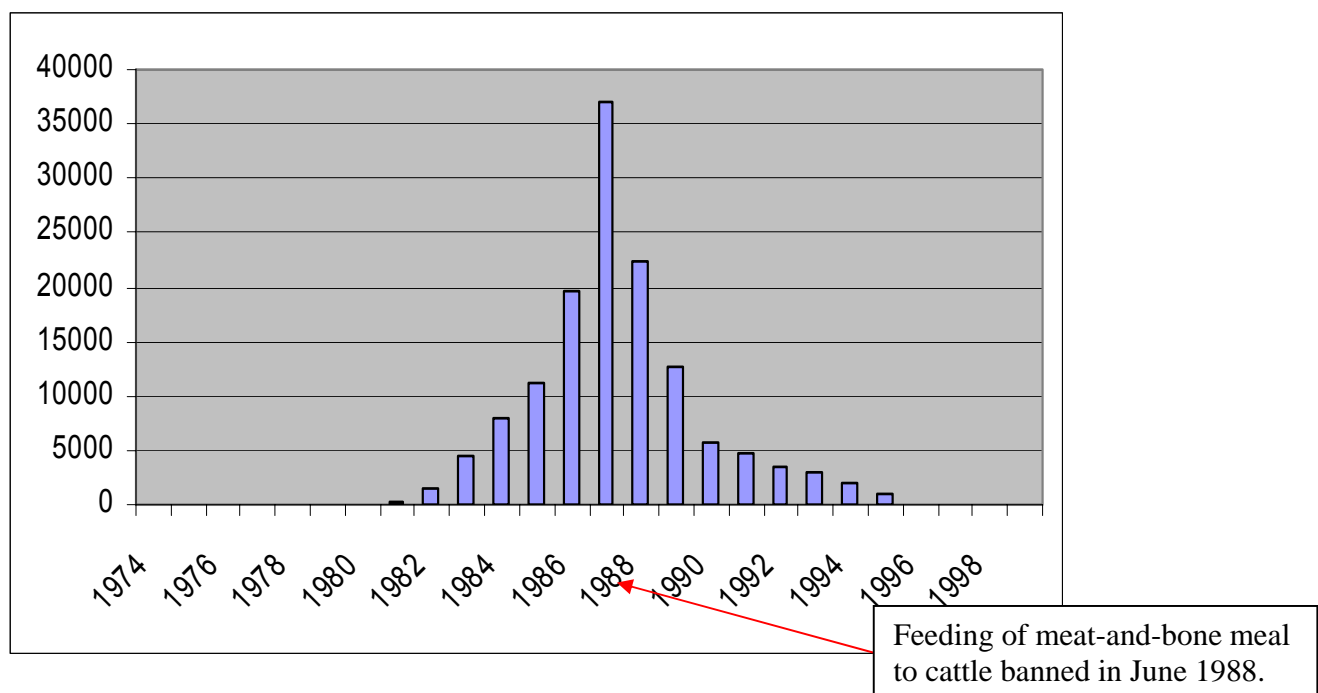
## 2.5 Preventing infection of cattle

The infectious agent is transmitted between cattle only through ingestion of 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 been rigorously observed and has effectively broken the cycle of infection in cattle, with BSE rates globally dropping significantly over the past three years.

Nevertheless, while the incidence of BSE in cattle has fallen significantly in the UK and the European Union, sporadic cases are still seen occasionally in countries in which contaminated stockfeed was fed in the past.

The effect of the initial feed ban in the United Kingdom is shown in Figure 1. From 1993 on, BSE incidence in the UK declined steadily, with only 338 cases occurring in 2004.<sup>3</sup>

**Figure 1: BSE cases in the United Kingdom, by year of animal's birth**



## 2.6 BSE and vCJD

In early 1996 the first cases of variant Creutzfeldt Jakob disease (vCJD) were reported in the United Kingdom. Biochemical studies and inoculation of laboratory animals provided very strong evidence that vCJD was caused by the same infectious agent that caused bovine spongiform encephalopathy (BSE), a progressive neurological disease which, by 1996, had

<sup>3</sup> [http://www.oie.int/eng/info/en\\_esbru.htm](http://www.oie.int/eng/info/en_esbru.htm)

killed over 158,560 British cattle.<sup>4</sup> Since 1996 around 157 people in the UK have died from vCJD, and a small number of cases have been reported from other countries (nine in France, and one each in Canada, Ireland, Italy, the United States, Hong Kong and Japan<sup>5</sup>). The vCJD cases outside the European Union are all believed to have been acquired while the people were staying in the UK.

In 1996, when the British government announced that vCJD was most probably caused through humans becoming infected with the same agent that caused BSE in cattle, it was assumed that infection had been acquired through eating BSE-contaminated beef (that is, cuts of meat from cattle infected with BSE).

In 1996, not a lot was known about BSE and even less about vCJD. Thousands of BSE cases were still occurring each year and it was feared, with some reason, that a vCJD epidemic in humans of similar proportions to the cattle epidemic of BSE could be about to unfold. Fortunately, a lot has been learned since, and it is now clear that these fears are not going to be realised.

## **2.7 BSE infectivity in meat**

A large number of studies, known as 'bioassays', have been carried out to determine which tissues in BSE-infected cattle carry the BSE agent.

Table 1 shows the very broad range of tissues that have been collected from cattle showing clinical BSE and injected into mice without producing signs of TSE. Similar bioassays conducted by inoculation of tissues into cattle have since failed to detect BSE infectivity in a similar range of tissues (muscle, sciatic/radial nerves, salivary gland, liver, spleen, thymus, lymph nodes, white blood cells, bone marrow, skin and urine)<sup>6</sup>.

It is significant that BSE infectivity has not been detected in any of the tissues that are commonly eaten (the muscles, or 'meat', and milk) or traded internationally (semen and embryos).

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<sup>4</sup> <http://www.defra.gov.uk/animalh/bse/statistics/bse/monthlystats.pdf>

<sup>5</sup> <http://www.promedmail.org/pls/promed/f?p=2400:1000>

<sup>6</sup> Dr Danny Matthews. Veterinary Laboratories Agency. United Kingdom. Personal communication with Stuart C MacDiarmid, October 2004.

**Table 1: Tissues from confirmed, naturally-occurring cases of BSE in cattle in which no infectivity was detected by bioassay in mice injected both intracerebrally and intraperitoneally <sup>7</sup>**

|  |   |
|--|---|
| <p><b><i>Nervous tissues</i></b><br/>           Cerebrospinal fluid<br/>           Cauda equina<br/>           Peripheral nerves:<br/>           - sciaticus<br/>           - tibialis<br/>           - splanchnic</p>   | <p><b><i>Lymphoreticular tissues</i></b><br/>           Spleen<br/>           Tonsil*<br/>           Lymph nodes<br/>           - prefemoral<br/>           - mesenteric<br/>           - retropharyngeal</p>   |
| <p><b><i>Alimentary tract</i></b><br/>           Oesophagus<br/>           Reticulum<br/>           Rumen (pillar)<br/>           Rumen (oesophageal groove)<br/>           Omasum<br/>           Abomasum<br/>           Proximal small intestine**<br/>           Distal small intestine<br/>           Proximal colon<br/>           Distal colon<br/>           Rectum</p> | <p><b><i>Reproductive tissues</i></b><br/>           Testis<br/>           Prostate<br/>           Epididymis<br/>           Seminal vesicle<br/>           Semen<br/>           Ovary<br/>           Uterine caruncle<br/>           Placental cotyledon<br/>           Placental fluids :<br/>           - amniotic fluid<br/>           - allantoic fluid<br/>           Udder<br/>           Milk</p> |
| <p><b><i>Other tissues</i></b><br/>           Blood :<br/>           - buffy coat<br/>           - clotted<br/>           - foetal calf<br/>           - serum<br/>           Bone marrow<br/>           Fat (midrum)<br/>           Heart<br/>           Kidney</p>   | <p>Liver<br/>           Lung<br/>           Muscle<br/>           - semitendinous<br/>           - diaphragma<br/>           - longissimus<br/>           - masseter<br/>           Pancreas<br/>           Skin<br/>           Trachea</p>   |

\* Tonsil was found positive in the cattle bioassay.

\*\* Infectivity has been detected in the distal ileum of cattle **experimentally** infected with a large oral dose of infected brain.

It can be seen, then, that BSE infectivity is not found in the tissues that people commonly regard as 'beef' and eat. How, then, did people become infected with the BSE agent? Pathogenicity experiments in mice and cattle have shown that infectivity in cattle is largely

<sup>7</sup> [http://europa.eu.int./comm/food/fs/sc/ssc/out296\\_en.pdf](http://europa.eu.int./comm/food/fs/sc/ssc/out296_en.pdf)

confined to the central nervous system: brain, spinal cord, eye, and associated ganglia, with a small amount sometimes detectable in tonsils and terminal ileum (see Table 2). **Mice bioassays have been shown to be a very sensitive method for detecting the BSE agent.**

**Table 2: Distribution of BSE infectivity in the tissues of a clinically affected cow<sup>8</sup>**

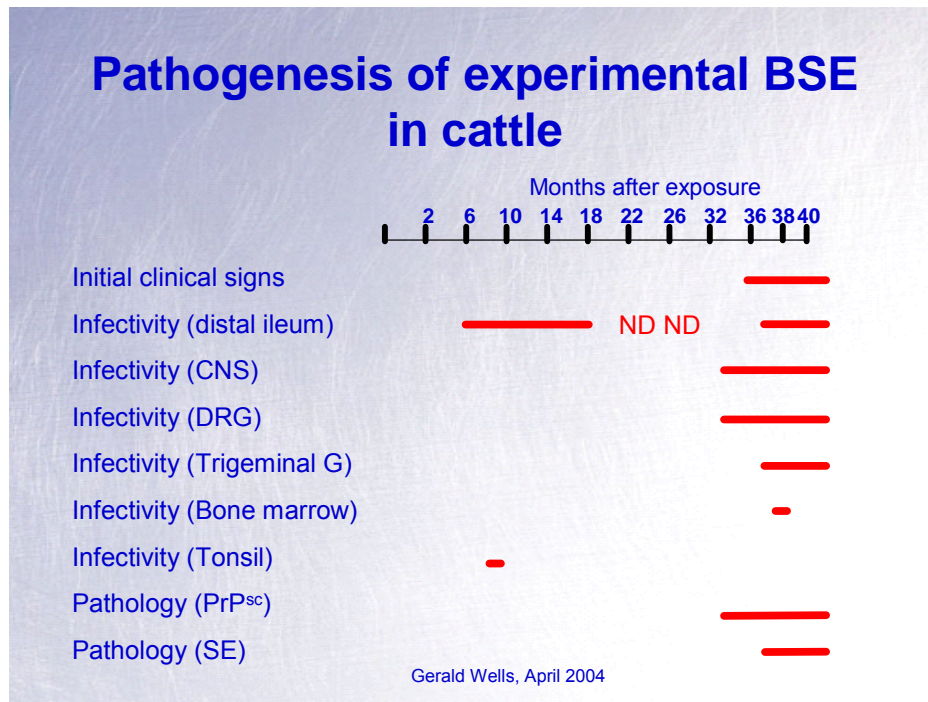
| Tissue              | ID50 per case | % Total infectivity |
|---------------------|---------------|---------------------|
| Brain               | 25,000        | 60.2%               |
| Spinal cord         | 10,000        | 24.1%               |
| Dorsal root ganglia | 1,500         | 3.6%                |
| Trigeminal ganglia  | 1,000         | 2.4%                |
| Distal ileum        | 4,000         | 9.6%                |
| Tonsil              | 0.25          | < 0.1%              |

BSE infectivity is not detectable in any of these tissues until relatively late in the course of the disease in cattle – nor is the accumulation of the abnormal form of the prion protein PrP<sup>SC</sup>, which is associated with this family of diseases, nor lesions in the brain (See Figure 2).

It can be seen that, with the exception of distal ileum (part of the small intestine) and tonsil (a single experimental result only), infectivity is not detectable until around 32 months after inoculation. Cattle are usually slaughtered for beef at less than this age.

<sup>8</sup> Adapted from the European Commission's Scientific Steering Committee

**Figure 2: The pathogenesis of experimental BSE in cattle showing the times after inoculation when infectivity, abnormal prion protein and lesions become detectable<sup>9</sup>**



Since tissues from the central nervous system were not a feature of the British diet, it remained unclear how humans had become exposed until ‘mechanically recovered meat’ came under the spotlight. Mechanically recovered meat is recovered from bones (such as the vertebral column) 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.

Spinal cord was removed before vertebral columns were processed to harvest this meat, but each segment of the backbone includes two dorsal root ganglia. These were being collected along with the meat paste, and therefore as much as 2% of the resulting product could be central nervous system tissue. That is, a 100 gram sausage might contain two grams of infectious material, and the infectious oral dose of BSE for a sheep had been shown to be only 0.5 grams. It is now considered probable that it was the dorsal root ganglia in mechanically recovered meat that exposed British consumers to BSE infectivity in their diet<sup>10, 11</sup>.

<sup>9</sup> Based on data in [http://europa.eu.int/comm/food/fs/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html) . Dr Gerald Wells. Veterinary Laboratories Agency. United Kingdom. Personal communication with Stuart C MacDiarmid, April 2004. Since published; Wells GAH, Spiropoulos J, Hawkins SAC, Ryder SJ (2005) Pathogenesis of experimental bovine encephalopathy: preclinical infectivity in tonsil and observations on the distribution of lingual tonsil in slaughtered cattle. *Veterinary Record* **156**; 401-407.

<sup>10</sup> Chadeau-Hyam M, Tard A, Bird S, Le Guennec S, Bemrah N, Volatier J-L,

## 2.8 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. The full analysis is attached in Appendix 2.

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. The experimental studies were designed to insure that they accurately represented the “lowest common denominator” of current industrial processes. That is, the times, temperatures and alkaline pH were the lowest found in industrial gelatine production.<sup>12</sup>

Gelatine produced by modern industrial processes can thus be considered to pose no BSE risk to consumers, regardless of the source country from which it is derived.

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Alperovitch A. Estimation of the exposure of the French population to the BSE agent: comparison of the 1980-95 consumption of beef products containing mechanically recovered meat in France and the UK, by birth cohort and gender. *Statistical Methods in Medical Research*. 2003. 12:247-260.

<sup>11</sup> Cooper JD, Bird SM. UK dietary exposure to BSE in beef mechanically recovered meat: by birth cohort and gender. *Journal of Cancer Epidemiology and Prevention*. 2002. 7: 59-70.

<sup>12</sup> Dr. Uwe Seybold, DGF STOESS AG, Eberbach, Germany. Personal communication with Stuart C MacDiarmid, 30 May 2005.

### 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<sup>13</sup>**

|                            | 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                |
| <b>Total</b>               |      |      | <b>4,885</b>     |

<sup>13</sup> <http://www.food.gov.uk/bse/facts/worldwidefig/bseincidence2004>

### **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.<sup>14</sup>

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<sup>15 16</sup>.

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.

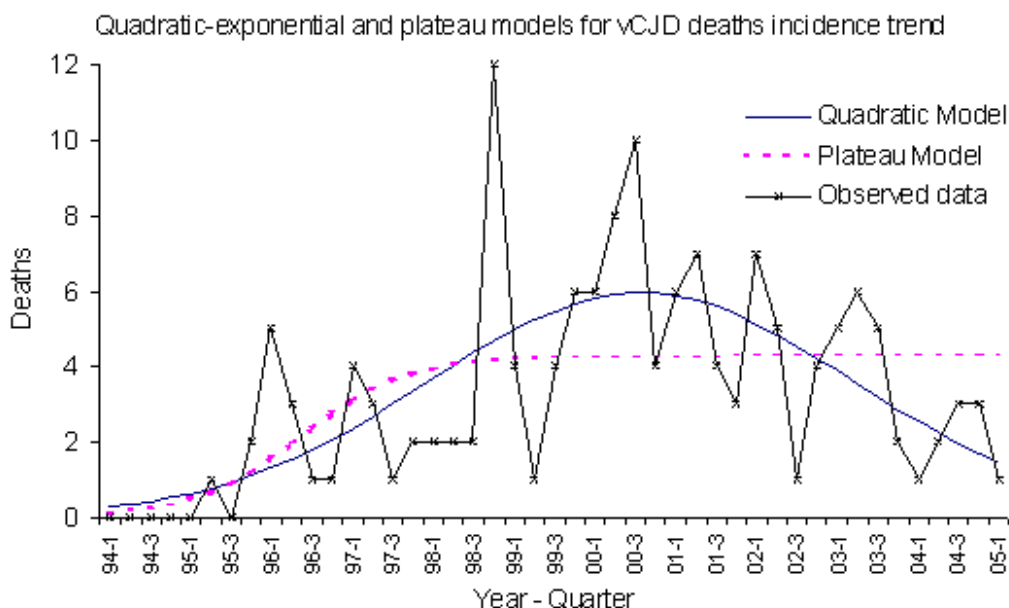
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<sup>14</sup> [http://www.cdc.gov/ncidod/diseases/cjd/bse\\_cjd.htm](http://www.cdc.gov/ncidod/diseases/cjd/bse_cjd.htm)

<sup>15</sup> <http://www.cjd.ed.ac.uk/twelfth/rep2003.htm>

<sup>16</sup> Nick Andrews, <http://www.cjd.ed.ac.uk/vcjdqmar05.htm>

**Figure 3: vCJD deaths: incidence trends**



#### 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<sup>17</sup>**

|    |   |
|----|---|
| a) | milk and milk products  |
| b) | semen and <i>in vivo</i> 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.

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<sup>17</sup> [http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm).

**Table 5: Tissues (specified risk materials, in bold) that should be excluded from export from countries with a BSE risk.<sup>18</sup>**

|  |
|--|
| <p>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: <b>tonsils and distal ileum</b>, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.</p> <p>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: <b>brains, eyes, spinal cord, skull, vertebral column</b> and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.</p> |
|--|

#### 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

<sup>18</sup> [http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm).

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<sup>19</sup>. 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.

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<sup>19</sup> See 'Measure to provide ongoing management of the human health risks associated with imported food products potentially containing the Bovine Spongiform Encephalopathy 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 has 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.<sup>20</sup> 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.

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<sup>20</sup> 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 Japan

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 is 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.

#### **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<sup>21</sup>) of the production process
- excluding processed food products containing minimal bovine ingredients from the commodities covered by the BSE Measure (see Table 7).

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<sup>21</sup> 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, etc

## 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        | <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"> <li>1. Demonstrate currently operating Type B surveillance in accordance with OIE Code Article 3.8.4.3, <b>and</b></li> <li>2. OIE Code Article 2.3.13.2 criteria (2) – (4) met for at least seven years, <b>and</b></li> <li>3. EITHER:               <ol style="list-style-type: none"> <li>a) Have never had a BSE case, <b>and</b> likelihood BSE exists in the country is negligible <b>and</b> effective ruminant-to-ruminant feed ban in place for at least eight years, or equivalent safeguard</li> </ol> <p>OR:</p> <ol style="list-style-type: none"> <li>b) Have not had BSE cases in cattle for at least seven years, <b>and</b> <b>all</b> the following have been met for at least seven years:                   <ul style="list-style-type: none"> <li>• Effective surveillance programme in place (met relevant OIE Code criteria that applied at the time)</li> <li>• 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)</li> <li>• Effective ruminant-to-ruminant feed ban in place for at least eight years.</li> </ul> </li> </ol> <p>OR</p> <ol style="list-style-type: none"> <li>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, <b>and</b> <b>all</b> the following have been met for at least seven years:                   <ul style="list-style-type: none"> <li>• Effective surveillance programme in place (met relevant OIE Code criteria that applied at the time)</li> </ul> </li> </ol> </li> </ol> |

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

## **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<sup>22</sup> 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.

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<sup>22</sup> Centres for Disease Control & Prevention, Department of Health & Human Sciences, US Government: see [http://www.cdc.gov/ncidod/dvrd/vcjd/risk\\_travelers.htm](http://www.cdc.gov/ncidod/dvrd/vcjd/risk_travelers.htm)

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.

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

Table 7 summarises the list of food commodities recommended for coverage by this import policy and mitigation measures that should apply to these commodities for each of the three categories. Depending on the nature of the commodity, certain BSE-related restrictions may be applicable. This Table should be used as the basis for determining the certification to accompany imported food derived from bovine animals.

**Table 7: Commodity-specific mitigation measures**

| <b>Summary of processing measures required for imported food derived from bovine animals in order to manage BSE</b>  |                           |  |                           |
|--|---------------------------|--|---------------------------|
| <b>Commodity</b>   | <b>Category 1 country</b> | <b>Category 2 country</b>  | <b>Category 3 country</b> |
| a) milk and milk products<br>b) gelatin and collagen prepared from bones, hides and skins<br>c) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow<br>d) dicalcium phosphate (with no trace of protein or fat)<br>e) processed foods containing negligible bovine meat content i.e. 3% or less in the ready-to-serve product | No BSE restrictions       | No BSE restrictions  |                           |
| 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 <sup>23</sup>   |                           | 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<sup>24</sup>:

- 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.

### **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 at 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.

<sup>24</sup> Subject to Biosecurity NZ requirements

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.

## Appendix 1: OIE Code Safeguards

When considering whether to permit the importation of foods from countries where BSE has been shown to be present, or where the BSE status has not been determined, the OIE's 2005 edition of the Terrestrial Animal Health Code recommends the following measures to protect the consumer:

- 1) That the cattle from which the *fresh meat* and *meat products* originate:
  - a) are not suspect or confirmed BSE *cases*;
  - b) have not been fed meat-and-bone meal or greaves;
  - c) were subjected to ante-mortem and post-mortem inspections; and
  - d) 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.
- 2) That ante-mortem and post-mortem inspections were carried out on all cattle from which the fresh meat and meat products originate.
- 3) That cattle from which the fresh meat and meat products destined for export originate 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.
- 4) That the fresh meat and meat products do not contain:
  - a) the tissues listed in Table 5 (in body of report)
  - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age, or
  - c) nervous and lymphatic tissues exposed during the de-boning process

and that all of these have been completely removed in a manner to avoid contamination with these tissues.

BSE infectivity has not been detected in skin (see Table 1 in body of report), and for this reason no BSE-specific safeguards are required for gelatine prepared solely from hides and skins. However, gelatine is also manufactured from bones and so, if such gelatine were to be imported from a country where BSE is present, or where the BSE status has not been determined, the OIE's 2005 edition of the Terrestrial Animal Health Code recommends the following measures to protect the consumer:

- a) skulls and vertebrae (except tail vertebrae) have been excluded
- b) the bones have been subjected to a process which includes all the following steps:
  - i) pressure washing (degreasing)
  - ii) acid demineralisation
  - iii) prolonged alkaline treatment

- iv) filtration,
  - v) sterilisation at  $\geq 138^{\circ}\text{C}$  for a minimum of 4 seconds,
- or to an equivalent process in terms of infectivity reduction.

## **Appendix 2: European Union's Geographical BSE Risk-Assessment System**

### **Introduction**

The main task of the agency completing the geographical BSE risk assessment (GBR) assessment (namely, the Scientific Steering Committee (SSC) of the European Union and, since 2003, the European Food Safety Authority as defined and amended by the SSC) is to assess whether the presence of one or more infected cattle in a given country is:

- highly unlikely (GBR I)
- unlikely, but not excluded (GBR II)
- likely, but not confirmed or confirmed at a lower level (GBR III)
- confirmed at higher level (GBR IV)

The following should be noted when considering the GBR assessment process within its five-category system:

- In making the GBR assessment, a reasonable worst-case (i.e. conservative) position has been taken every time data were insufficient.
- The SSC has stated that it is aware that the borderline between GBR levels III and IV has to remain arbitrary, as no clear scientific justification can be provided for this differentiation. GBRs adopt the OIE threshold, i.e. an incidence of more than 100 confirmed BSE cases per million within the cattle population over 24 months of age in the country or zone, calculated over the past 12 months.
- The SSC also agrees with the OIE that, under certain circumstances, countries with an observed domestic incidence between 1 and 100 BSE-cases per million adult cattle calculated over the past 12 months should be put into the highest risk level – if, for example, there are clear indications that the true clinical incidence is in fact higher than 100 per million adult cattle calculated over the past 12 months.
- The SSC believes that decisions aimed at managing the BSE risk are the responsibility of the authorities in charge, and might need to take into account other aspects than those covered by this risk assessment.
- The GBR of a country has no direct bearing on human exposure to BSE. The SSC has stated that, at a given GBR, the risk that food is contaminated with the BSE agent depends on three main factors:
  - a. the likelihood that infected bovines are processed (i.e. whether systems exist to detecting and exclude at-risk animals from processing)
  - b. the amount and distribution of infectivity in BSE-infected cattle at slaughter (killing methods, age of animals)

- c. the ways in which the various tissues that contain infectivity are processed (SRMs, mechanically recovered meat, advanced meat recovery).

The GBR levels, New Zealand's BSE categories, and the current and recently accepted OIE code categories roughly align in the following way:

| GBR levels  | NZ Current BSE Measure categories   | Current OIE Code recommendations   | Future OIE Code recommendations & proposed NZ BSE Measure (key differences discussed next section) |   |
|---|---|--|--|---|
| I Highly unlikely   | Category 1: Country or region free of indigenous BSE  | BSE-free country or zone   | Negligible BSE risk<br>(Some fall into next category, "controlled BSE risk".)                      |   |
| II Unlikely but not excluded  | Category 2: Provisionally free country or region where no indigenous case has been reported                                       | Provisionally BSE-free country or zone                                   | Controlled BSE risk<br><br>(Can include countries previously categorised in the NZ system as 1-5)  | Undetermined BSE risk<br><br>(Can include countries previously categorised in the NZ system as 2-5) |
| III Likely but not confirmed or confirmed at a lower level (incidence <100) | Category 3: Provisionally free country or region where at least one indigenous case has been reported<br>Incidence: <1/m(E4x12) † | Country or zone with a minimal BSE risk<br>Incidence: <2/m(E4x12) *      |  |   |
|   | Category 4: Country or region with low incidence of BSE<br>Incidence: 1/m ≤ 100/m(12) §   | Country or zone with a moderate BSE risk<br>Incidence: 2/m (<4x(E4x12) † |  |   |
| IV Confirmed at a higher level (incidence ≥ 100)                            | Category 5: Country or region with high incidence of BSE<br>Incidence: I > 100/m(12) ¥  | Country or zone with a high BSE risk ‡                                   |  |   |

Key to incidence rates:

\* Less than two indigenous BSE cases per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age.

† Less than two indigenous BSE cases per million for less than four consecutive 12-month periods

‡ Unable to demonstrate whether it meets requirements of other OIE categories

† Less than one indigenous case per million during each of the last four consecutive 12-month periods within the bovine population over 24 months of age

§ Less than one indigenous case per million within bovine population over 24 months of age

¥ Greater than 100 cases per million within the bovine population over 24 months of age

GBR assessments are based on the current OIE Code recommendations for risk analysis. The categories align with those recommended by the OIE, even though there are four GBR categories and five OIE Code categories.

The new three-category system to be adopted by the OIE is a significant change and sets the 'bar' at a very high level for entry to the 'Negligible BSE risk' category. New Zealand has had to enhance its surveillance programme to meet the new requirements. If the GBRs align with the OIE 3 category system in future, then we will need to consider the effects of this on our imported food Measure.

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. New Zealand's proposed BSE Measure reflects this shift. Key differences between New Zealand's proposed Measure and the OIE Code recommendations are outlined in the section below.

The OIE is recognised by the SPS Agreement as the relevant international organization that develops the sanitary measures required to manage human and animal health risks associated with BSE. As a signatory, New Zealand is obliged to base its measures on the relevant international standards where they exist, and otherwise to be judged scientifically.

Since 1989, the European Commission, in close co-operation with the Member States, has taken a series of measures to manage the risk of BSE in the European Union. Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 brings all existing BSE measures as adopted over the years through more than 60 Commission Decisions into a single, comprehensive framework, consolidating and updating them in view of scientific advice and international standards. In addition, it introduced a number of new instruments to manage the risk of BSE and other similar diseases such as scrapie in all animal species and relevant products.

Currently, 66 countries have been assessed and have a GBR categorisation. The adoption of the GBR country categorisation system would increase New Zealand's international trade and alleviate resource difficulties, whilst being confident that the methodology to assess a country's GBR is sound and based on the OIE BSE Chapter (as detailed below).

It should be noted that the GBR is based on animal health, and has no direct bearing on human exposure to BSE. GBR would, however, provide New Zealand with a base categorisation system (indicating a country's BSE-risk status) enabling human-health standards to be applied by New Zealand in a manner appropriate to that country's BSE-risk status.

## **Methodology for GBR Determination**

The final opinion of the SSC on the GBR (adopted 6 July 2000) describes the transparent and qualitative nature of this methodology. In addition, it also states that its limitations should be

understood in the context of present scientific knowledge on BSE, and of the availability and quality of data. Therefore, as both knowledge and data evolve, and with the advancement of new diagnostic methods, the SSC states that the methodology may need to be revised and/or its application to particular countries be repeated (i.e. a reassessment).

This statement ensures that a country's GBR is kept up to date with any changes (either science-based or specific to a country) – a requirement that creates difficulties for New Zealand, due to the resources required.

The last update was released on 11 January 2002, and the methodology detailed below is based on the latest "Update of the Opinion of the SSC on the GBR".

Basically, the GBR methodology tries to answer two questions:

1. Is there a risk that the BSE agent was imported into the country under consideration?
2. If the BSE agent was introduced into a country, would it have been recycled and amplified, or was the BSE/cattle system of that country able to eliminate the agent?

## **Basic Assumptions**

### Origin and transmission

The assessment of the GBR is based on the assumption that BSE originated from the United Kingdom (UK) and that the agent was transmitted through the recycling of bovine tissues into animal feed.

Thus for countries other than UK, the importation of contaminated feed or infected animals is the only possible initial source of BSE that is considered. No other sources or transmission routes are considered, as they have not been scientifically confirmed

### Geographical Limitation

Present GBR risk assessments only address entire countries and national herds due to limited regional data. Therefore it should be noted that free trade zones are not considered.

### Information Factors

Eight factors are used for assessing the GBR:

1. Structure and dynamics of the cattle, sheep and goat populations
2. Surveillance of BSE
3. BSE-related culling
4. Import of cattle and meat and bone meal (MBM)
5. Feeding
6. Bans on meat-and-bone meal (MBM)

7. Bans on risk materials (SRMs)
8. Rendering.

A qualitative model of the BSE/cattle system details the interaction between these factors. Factors can activate or prevent the activation of the loop, or slow down or reverse the building up of BSE infectivity within the system.

### External Challenge

The initial sources of BSE must come from outside the relevant country. Two possible outside sources are considered in the model: import of infected cattle, or import of contaminated MBM (factor 4). These are referred to as an external challenge.

The term “external challenge” refers to both the likelihood and the amount of the BSE agent entering a defined geographical area in a given time period, through infected cattle or MBM. The following basic guidelines for assessing the external challenge are:

1. The external challenge is regarded independent from the size of the challenged BSE/cattle system, and in particular the size and structure of the cattle population.
2. The assumed challenge resulting from imports from the UK during the peak of the BSE-epidemic in the UK is the point of reference.
3. The challenge resulting from imports during other periods and from other BSE-affected countries is established in relation to this baseline.

It should be noted that imports from all countries with a BSE risk are considered when assessing the external challenge of an individual country. This is in light of scientific knowledge that active surveillance (testing of cattle that are not notified as BSE suspects, but belong to risk sub-populations) detects BSE cases that would have remained undetected by passive surveillance, which targets cattle with neurological symptoms.

### Stability

The ability of a BSE/cattle system to prevent the introduction of the BSE agent and to reduce the spread of the BSE agent within its borders is referred to as the stability of the system. Therefore, feeding of MBM to cattle (factor 5), rendering (factor 8) and SRM bans (factor 7) are the main stability factors which could either eliminate BSE over time (“stable” system) or amplify it (“unstable system”).

Surveillance (factor 2) activities (both active and passive) that ensure the detection, isolation and destruction of BSE cases and cattle at risk of being infected would also enhance the stability of a system. In combination with appropriate culling (factor 3); both these factors would improve the stability by supporting the exclusion of BSE-infectivity from the system.

### Internal Challenge

The likelihood of, and the amount of the BSE-agent being present and moving in a specific geographical area in a given period of time, are known as the “internal challenge”. Therefore,

the overall challenge is the combination of external and internal challenges being present in a BSE/cattle system at a given point of time.

### Interaction of Overall Challenge and Stability over Time

Four basic combinations of stability and challenge are:

1. A “stable” system is not or only slightly “challenged”  
This is the best situation.
2. A “stable” system is significantly “challenged”  
This is still rather good, because the system will be able to cope with the challenge, even if this might need some time.
3. An “unstable” system is not or only slightly “challenged”  
As long as BSE is not entering the system, the situation is good. However, even a small challenge could spark the amplification of the BSE problem.
4. An “unstable” system is “challenged”  
This is an unfortunate situation. The BSE infectivity will be amplified and an epidemic can develop.

### **Procedure for Assessing the GBR**

1. Appraisal of the quality of the available data
2. Assessment of the Stability of the BSE/cattle system (over time)
  - 2.1 Ability to identify BSE-cases and to eliminate animals at risk of being infected before they are processed (Factors 1, 2 and 3). The quality of the surveillance (factor 2) is of critical importance for this aspect of stability.
  - 2.2 Ability to avoid recycling BSE-infectivity, should it enter processing (Factors 5, 6, 7, and 8)
  - 2.3 Overall assessment of the stability (over time)
3. Assessment of the challenges to the system (over time)
  - 3.1 External challenge resulting from importing BSE (factor 4)
  - 3.2 Internal challenge resulting from domestic infected animals
  - 3.3 Overall assessment of the challenges (over time)
4. Conclusion on the resulting risks (over time)
  - 4.1 Interaction of stability and challenge (over time)
  - 4.2 Risk that BSE-infectivity enters processing (over time)
  - 4.3 Risk that BSE-infectivity is recycled and the disease propagated (over time)

## 5. Conclusion on the Geographical BSE-Risk

- 5.1 The current GBR as function of the past stability and challenge
- 5.2 The expected development of the GBR as a function of the past and present stability and challenge
- 5.3 Recommendations to influence the expected development of the GBR

### **GBR Updates – Process for Review**

New scientific knowledge and data which may arise trigger an update to the GBR methodology, including re-apply it to countries that were assessed previously. Therefore, the GBR report/opinion is subject to change as more scientific evidence becomes available.

New evidence or knowledge may relate to the source of BSE, to the diagnosis and transmissibility of BSE, or to the infective dose for humans. In addition, developments in surveillance and management techniques or new tests to assess the prevalence of sub-clinical BSE conducted in a country may also lead to the need for a selective re-assessment of a particular GBR.

However, the SSC's experience in assessing changes in the challenges and stability of countries suggests that trends in incidence figures may allow new conclusions to be drawn only after three to five years. In any case, the current assessments have to be updated from time to time.

With the proposed adoption of the GBR country categorisation system, New Zealand would have to decide whether this level of process review is adequate or whether to develop its own criteria for review.

### **GBR's relationship with the OIE Code on BSE**

As mentioned previously, the method for assessment of the GBR is comparable to the OIE guidance on risk analysis, and in particular to the chapter on risk assessment. Each proposes very similar factors that are to be taken into account.

The SSC method also involves an external review of the GBR on the basis of information provided by countries. Considering the long incubation period of the disease and its initially slow progress, it tries to cover the last 20 years.

The latest updates to the OIE BSE chapter must also be considered when adopting the GBR system. New Zealand must ensure that the GBR methodology is still in line with OIE requirements. The latest measure in relation to country categorisation adopted by the OIE is the change from a five-category system to a three-category system, namely: negligible BSE Risk, controlled BSE risk and undetermined BSE risk.

This change in the number of categories does not change the method of categorisation, but rather the outcome of the assessment.

The GBR methodology for country categorisation remains in line with OIE requirements and New Zealand's adoption of the GBR system would align it with the European Union (EU) BSE country categorisation and the OIE BSE chapter.

## **Appendix 3: Exempting processed foods containing minimal bovine ingredients from the BSE Measure**

An exemption is the preferred option for the reasons outlined below. Other options were considered and the arguments for and against each are noted.

**Problem:** Bovine-derived ingredients are often a minor component of imported ingredients used to make products. For some products, this trail can involve more than three countries' competent authorities. Importers are currently required to obtain a trail of competent authority certification back to the country in which the bovine animal used in the ingredient was born, reared and slaughtered. Obtaining this certification for some products has proved to be very difficult or impossible for New Zealand importers.

### **Option One: Exemption of processed food**

Remove the requirement for certification for processed products containing a small percentage of bovine material when consumed.

Exempting processed products containing negligible bovine meat content is consistent with the Canadian Meat Inspection Regulations, which states:

- “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) are exempt from the Meat Inspection Regulations.
- Other products such as salad dressing, dairy-base dip, flavouring, seasoning preparations and cheeses containing 3% or less of meat ingredients are not considered meat products for the purpose of the Meat Inspection Regulations.
- These products are not subject to CFIA meat import controls and can be imported from any country.”

It is recommended that the threshold be set at three percent to reflect the reality of the beef content in many processed products. These products pose negligible risk but are captured by current measures. Setting one threshold also prevents confusion, for example around deciding whether a product is flavouring (at the Canadian three percent or less) or whether it is a stock cube (at less than two percent).

While an informal survey has been carried out to ascertain the beef content in many processed foods, it is recommended that a more detailed survey be completed to determine if three percent is a realistic cut-off point and what proportion of processed foods would fall into the category of three percent or less. If the survey shows that a significant amount of processed foods contain less than two percent beef, or four percent or less, the limit should be adjusted.

It is suggested that the Manufactured Food Database may be a useful resource for such a survey. The database collects information from food manufacturers, 20% of which are based

in Australia with the remainder in New Zealand; all foods are sold in New Zealand. The labelling survey that was completed in 2004 could be used to collect information on foods from other countries and to ascertain if there are significant differences in manufacturing practices.

This information may then be used to categorise foods so they can easily be identified at the border as falling into the exempted categories e.g. all noodle packs with meat flavour sachets may be exempted as all those surveyed contained less than two percent beef. A review of the tariff codes will be necessary when establishing a new standard and the exempted foods should be kept in mind during this process as eliminating tariff codes that target exempted processed foods would be the ideal option.

A database of exempted and non-exempted products should be developed and built upon over time for use by Health Protection Officers. Health Protection Officers should be given training to ensure they understand criteria for exempted products and can investigate new products and refer them to be approved for adding to the database.

### **Background**

When BSE was first discovered most countries responded with conservative measures to reflect the unknown level of risk of BSE and the severe consequences to public health. Since the last New Zealand measure was implemented in 2001, significantly more is known about the disease. Production and processing controls have dramatically reduced the incidence of BSE and products have been exempted from measures as the evidence has shown these products to pose negligible or non-existent risk.

The major source of human exposure to the BSE agent was meat recovered mechanically (MRM) from bovine vertebral columns.<sup>25</sup>

Mechanical recovery of meat from vertebral columns is now prohibited in the European Union.

The source of BSE infectivity in MRM was from fragments of spinal cord remaining after incomplete removal, and from dorsal root ganglia (DRG).

It was concern over the presence of DRG in T-bone steaks which led to a British ban on bone-in beef. However, it has been estimated that an individual consuming one DRG from a BSE-infected carcass would ingest only between 0.015 and 0.5 of a human oral ID<sub>50</sub> (infectious dose 50%).<sup>26</sup>

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<sup>25</sup> 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). 59-70.

<sup>26</sup> Gale, P. (1998) Quantitative BSE risk assessment: relating exposure to risk. *Letters in Applied Microbiology*. 17. 239-242.

In 1995, the last year in which MRM was harvested in the UK, it has been estimated that the BSE infectivity present in beef MRM was 12.8 (CL<sub>95%</sub> 10.6 – 14.9) bovine ID<sub>50</sub> **per tonne**.<sup>27</sup>

One human ID<sub>50</sub> is approximately 10 bovine ID<sub>50</sub>.<sup>28</sup> This means that BSE contamination of beef MRM in 1995 would have been about 1.28 human ID<sub>50</sub> per tonne. That is, a person would need to consume a tonne of MRM to have a 50% chance of becoming infected.

A product containing 3% of beef, if made from British MRM in 1995, would contain no more than about 0.04 human ID<sub>50</sub> per tonne. That is, for a consumer to have a 50% chance of becoming infected with BSE, they would need to consume 25 tonnes of the product. This is, however, a worst-case scenario, as harvesting of MRM from vertebral columns was banned in the UK in 1995, and the incidence of BSE in the UK has dropped from 14,562 cases in that year to 151 cases in 2005.<sup>29</sup> That is, the incidence of BSE in the UK, the worst affected country, has declined nearly a hundredfold since 1995.

While the BSE risk cannot be precisely 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 such products cannot be justified by the risk posed.

### **Consistency with International Standards**

Under the WTO Sanitary and Phytosanitary Agreement, member countries should only apply measures that are necessary to protect human, animal or plant health. The Agreement provides for more conservative measures where there is uncertainty as was the situation when BSE first emerged. There is now a better understanding of the disease and the source of the risk so that, although the risk may not be quantitatively measured in any meaningful way, it can be qualitatively assessed against the probability of ‘entry, establishment or spread’<sup>30</sup> of the disease.

International standards have taken a broad approach to defining meat with the OIE and the EU defining meat as ‘all edible parts of an animal’ and Codex defining it as ‘all parts of the animal that are intended for, or have been judged as safe and suitable for, human consumption’. The preferred method of avoiding inadvertent capture of products posing negligible or non-existent BSE risk is to exempt by commodity.

Exempting processed products containing three percent or less of bovine meat will be consistent with international practice in terms of risk assessment and through the use of exemptions.

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<sup>27</sup> 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). 59-70.

<sup>28</sup> Grist, EPM. (2005) Transmissible spongiform encephalopathy risk assessment: the UK experience. *Risk Analysis*. 25 (3). 519-532.

<sup>29</sup> [Http://www.oie.int/eng/info/en\\_esbru.htm](http://www.oie.int/eng/info/en_esbru.htm)

<sup>30</sup> Definition of risk assessment, SPS Agreement, Annex A, par 4 found at [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)

**Option Two: Status Quo**

Require all processed products containing bovine derived ingredients to be accompanied by competent authority certification.

**Argument for:**

It may be perceived that the status quo is a belts and braces approach to food safety and if it results in the saving of one life (although it would not be possible to attribute any saving to such a measure) it will have been worth the cost and administrative difficulties.

**Argument against:**

The Code of Good Regulatory Practice notes that regulatory benefits should outweigh the costs and regulation should be to the minimum extent necessary.

Beef content in processed foods is often sourced from different countries depending on availability and market price. Continuing with the status quo will require substantially more resource from regulators (to monitor) and from importers. There is no evidence to suggest that the costs of this regulation will measurably increase New Zealand's level of protection from vCJD.

**Option Three: Case-by-case assessment**

Decide exemptions product by product following individual risk assessments.

**Argument for:**

Science-based, consistent with SPS Agreement

**Argument against:**

Expensive exercise and not likely to be taken up by importers as the need for a new risk assessment may arise each time the supply is changed.

The costs would not outweigh the benefits.

## **Appendix 4: Does gelatine pose a BSE risk to consumers?**

*Stuart C MacDiarmid, Principal Adviser, Zoonoses and Animal Health, New Zealand Food Safety Authority*

BSE is a member of a family of diseases known as transmissible spongiform encephalopathies (TSEs). These are generally considered to be caused by infection with proteinaceous agents known as a “prions”.

In 1996, human cases of a new TSE known as variant Creutzfeldt-Jakob disease (vCJD) were reported in the United Kingdom and were soon shown to be caused by human infection with the BSE agent. Because of this BSE risk to human health, many precautionary measures were implemented around the world at that time. Because of fears that the BSE prion might be present in foods prepared from bovine tissues, including gelatine, precautionary measures to protect consumers were implemented in New Zealand and overseas.

However, in the intervening years much has been learned about BSE and the risk to human health, and in a number of countries some of the precautionary measures put in place after 1996 are being reviewed.

Total world production of gelatine in 2003 was 278,300 tonnes.<sup>31</sup> Probably around 65% of this was produced from bovine materials.<sup>32</sup> Gelatine is made either from hides or bones and although there are differences in the processes, both involve a series of chemical steps which have some capacity to inactivate the BSE agent.<sup>33, 34</sup>

### **Raw materials**

Gelatine is produced either from skin or bones of cattle and pigs. BSE is not a disease of pigs, so gelatine produced from porcine raw materials has never been of concern.

Hides are considered a safe source of raw material because BSE infectivity has not been found in skin, even in advanced clinical cases.<sup>35</sup> More gelatine is produced globally from skins than from bone.<sup>36</sup> BSE infectivity has been found in the bone marrow in advanced

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<sup>31</sup> [http://www.geafiltration.com/html/library/gelatin/gelatin\\_world\\_production.htm](http://www.geafiltration.com/html/library/gelatin/gelatin_world_production.htm)

<sup>32</sup> Based on figures cited in Schrieber R, Seybold U (1993) Gelatine production, the six steps to maximum safety. In *Transmissible Spongiform Encephalopathies – Impact on Animal and Human Health*. Edited by F Brown. Developments in Biological Standardization. Volume 80. Karger, Basel: 195- 198.

<sup>33</sup> Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39. 329-338.

<sup>34</sup> Schrieber R, Seybold U (1993) Gelatine production, the six steps to maximum safety. In *Transmissible Spongiform Encephalopathies – Impact on Animal and Human Health*. Edited by F Brown. Developments in Biological Standardization. Volume 80. Karger, Basel: 195- 198.

<sup>35</sup> [http://europa.eu.int./comm/food/fs/sc/ssc/out296\\_en.pdf](http://europa.eu.int./comm/food/fs/sc/ssc/out296_en.pdf)

<sup>36</sup> [http://www.geafiltration.com/html/library/gelatin/gelatin\\_world\\_production.htm](http://www.geafiltration.com/html/library/gelatin/gelatin_world_production.htm)

disease in a single experimentally-infected animal<sup>37</sup>, but has not been detected in bone marrow of infected cattle before they show clinical signs.

The global BSE epidemic is in decline, although occasional cases are still detected in countries with a history of feeding cattle on meat and bone meal containing the BSE agent, and occasional cases may also be expected, in future, in countries hitherto considered BSE free.

The first step in processing the bones for gelatine manufacture is to grind them into pieces. Hides and skins are also chopped into small pieces. Hides may arrive at the gelatine plant in the form of 'hide splits', a by-product of the tanning industry. Hide splits are the lower part of the cutis or corium.<sup>38</sup> The upper part of the cutis is used for leather production.

Gelatine is produced either from bone or from skin. The two raw materials are not mixed.

## Dilution

As with all infections, with BSE there is a minimum level of infectivity necessary to transmit the infection. In the case of transmission to humans, there is also a species barrier to be surmounted.

Should an animal infected with BSE pass ante-mortem inspection and contribute raw materials to gelatine manufacture, its tissues would be diluted by those from a large number of normal, uninfected animals. The average weight of raw material used from one animal, depending on age, will be approximately 10-15 kg.<sup>39</sup> (In New Zealand, where gelatine is manufactured from head skins, the average weight is 3 kg.<sup>40</sup>) The normal batch size used in the industrial production of gelatine varies from around 20,000 to 100,000 kg. (In New Zealand, the normal batch size is 28,000 kg.)

This means that the dilution factor of raw material from one animal into an industrial batch is between  $10^{3.5}$  and  $10^5$ . So, regardless of any further treatment, in theory only in advanced clinical disease would there be detectable infectivity in the final product.<sup>41</sup>

In the country with the highest incidence of BSE, the UK, there were 338 cases of the disease in 2004. That is, the annual BSE incidence rate is 68 per million cattle over 24 months of age.<sup>42</sup> This is the highest rate in the world.

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<sup>37</sup> Based on data in [http://europa.eu.int/comm/food/fs/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html) . Dr Gerald Wells. Veterinary Laboratories Agency. United Kingdom. Personal communication with Stuart C MacDiarmid, April 2004.

<sup>38</sup> Dr. Uwe Seybold, DGF STOEES AG, Eberbach, Germany. Personal communication with Stuart C MacDiarmid, 8 June 2005.

<sup>39</sup> Schrieber R, Seybold U (1993) Gelatine production, the six steps to maximum safety. In Transmissible Spongiform Encephalopathies – Impact on Animal and Human Health. Edited by F Brown. Developments in Biological Standardization. Volume 80. Karger, Basel: 195- 198.

<sup>40</sup> Mr. Steve Ford, Purchasing Manager, Gelita New Zealand Ltd. Personal communication with Stuart MacDiarmid, 5 April 2005.

<sup>41</sup> Schrieber R, Seybold U (1993) Gelatine production, the six steps to maximum safety. In Transmissible Spongiform Encephalopathies – Impact on Animal and Human Health. Edited by F Brown. Developments in Biological Standardization. Volume 80. Karger, Basel: 195- 198.

<sup>42</sup> [http://www.oie.int/eng/info/en\\_esb.htm](http://www.oie.int/eng/info/en_esb.htm)

Using the data given above for average weight of raw material per animal and average industrial batch size, it can be calculated that the average number of animals contributing to a single batch is 4,800 (SD 1,880).<sup>43</sup> From these data and the annual incidence of BSE in the United Kingdom in 2004, it can be calculated using the software programme @Risk<sup>44</sup> that the mean number of BSE cases which could contribute to a batch of gelatine, assuming that they were to escape detection, would be 0.33 animals per batch (upper 95 percentile, 0.66 animals).

I developed an @Risk simulation model to estimate the likely BSE contamination of gelatine produced in the UK from bones including the vertebral column (vertebral column is actually banned from all food uses in the UK and so is not, in reality, used in gelatine production). If vertebral column of cattle were used in the production of gelatine, BSE infectivity could be present in remnants of spinal cord and associated dorsal root ganglia (DRG). It has been estimated that the weight of DRG in a typical carcass is 30 g and the weight of spinal cord is 200 g.<sup>45</sup> The simulation model assumed that something between 0 and 100% of the spinal cord might remain in vertebral column used in gelatine production, but that the most likely quantity was 10%. The model further assumed that all the DRG material would be included.

In an assessment of the risk to human health from inclusion of DRG in foods such as 'T bone' steaks, Comer assumed that the best estimate of the oral infectivity for humans of spinal cord and DRG derived from cases of BSE is 1 human oral ID<sub>50</sub> /g,<sup>46</sup> with a confidence range of 0.0001 to 10.<sup>47</sup>

Using the data outlined above, the @Risk model estimated that the mean BSE contamination of raw material containing vertebral column of UK origin (an extremely unrealistic scenario) would be  $9.8 \times 10^{-7}$  human oral ID<sub>50</sub> /Kg (upper 95%  $3.03 \times 10^{-6}$ ).

It can be expected, on the basis of experimental studies described below, that this quantity of BSE infectivity is likely to be eliminated entirely by the processes used to manufacture gelatine.

## Removal of hair

After skin has been chopped into small pieces, hair is removed by tumbling in drums containing a mixture of sodium sulphide and lime.<sup>48</sup> This process not only removes the hair, but would also be expected to remove any surface contamination with tissues (such as brain)

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<sup>43</sup> Terry Ryan, Senior Adviser (Epidemiology & Public Health), New Zealand Food safety Authority. Personal communication with Stuart MacDiarmid 22 April 2005.

<sup>44</sup> @Risk, Palisade Corporation, Newfield, NY USA.

<sup>45</sup> Source: [http://europa.eu.int/comm/food/fs/sc/ssc/out13\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/out13_en.html)

<sup>46</sup> ID<sub>50</sub>: this means "the dose which will infect 50% of recipients".

<sup>47</sup> Comer, PJ (1997) Assessment of risk from possible BSE infectivity in dorsal root ganglia. Risk assessment for the Ministry of Agriculture, Fisheries and Food and the Spongiform Encephalopathy Advisory Committee. Det Norske Veritas, Technical Consultancy Services, London. 16 pages.

<sup>48</sup> Mr Steve Ford, Purchasing Manager, Gelita New Zealand Ltd. Personal communication with Stuart MacDiarmid, 5 April 2005.

which might contain BSE agent. Hide splits, which are a by-product of the tanning industry, do not have hair.

### **Bone degreasing**

Bone itself is free from BSE infectivity, but infectivity has been detected in bone marrow in a single advanced clinical case in an experimentally-infected animal. Infectivity is, of course, present in high concentration in spinal cord and dorsal root ganglia, both of which can be expected to contaminate vertebral column used to produce the degreased chipped bone (DCB) used in the manufacture of gelatine.

Before bone can be used to manufacture gelatine, fat must be removed. This is done by crushing the bones to a particle size of less than 12 mm and then washing and degreasing the resulting chips with hot water to remove residues of fat, marrow and other soft tissues such as spinal cord and dorsal root ganglia. (In Europe, where BSE is present, vertebral columns are classified as 'specified risk material' (SRM) and are not used in gelatine production.)

Studies conducted on the ability of the degreasing process to remove nervous tissue proteins from bones demonstrated that degreasing eliminated 98% to 99% of such proteins.<sup>49</sup> It has been estimated that the degreasing process alone would reduce any BSE contamination of bone by a factor of approximately  $10^2$ .<sup>50</sup>

### **Acid treatment**

Before bone chips can be used to produce gelatine, the minerals calcium and phosphorus must be removed. This is achieved by immersion of the DCB in hydrochloric acid (approximately 4%, <pH 1.5) for a period of at least 2 days. This intensive acid treatment changes the internal structure of the collagen protein, from which gelatine is extracted, as well as the structure of the BSE prion protein. On the basis of previous studies<sup>51</sup>, this acid treatment would be expected to reduce the titre of any BSE infectivity which might be present. The demineralized bone is known as ossein.

### **Alkaline treatment**

The next step in the production of gelatine is to soak the materials (pieces of skin or ossein) in a saturated lime solution, >ph 12.5, for a period of between 20 and 50 days<sup>52,53</sup> (40 in New Zealand.<sup>54</sup>)

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<sup>49</sup> Manzke U, Schlaf G, Poethke R, Felgenhauer K, Mäder M (1996) On the removal of nervous proteins from materials used for gelatine manufacturing during processing. *Pharmazeutische Industrie*, 58 (9). 837-841.

<sup>50</sup> Pharmaceutical Research & Manufacturers of America BSE Committee (1998) Assessment of the risk of bovine spongiform encephalopathy in pharmaceutical products. *BioPharm*, 11 (3). 18-30.

<sup>51</sup> Brown P, Rohwer RG, Gajdusek DC (1986) Newer data on the inactivation of scrapie virus or Creutzfeldt-Jakob disease virus in brain tissue. *Journal of Infectious Diseases*, 153. 1145-1148.

<sup>52</sup> Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39. 329-338.

A treatment sometimes used with a raw material known as hidesplits (split form of skin) is to soak the material in 0.3n sodium hydroxide (caustic soda) for around 14 days.

As with the acid treatment referred to above, this alkaline treatment changes the internal structure of the collagen protein, as well as the structure of the BSE prion protein. On the basis of studies conducted into the destruction of TSE agents<sup>55</sup>, it has long been expected that the time, temperature and concentration of these alkaline treatments would significantly reduce the titres of any BSE infectivity present in the raw materials.<sup>56</sup>

### **Further acid treatment**

Some gelatine is also produced from ossein (demineralized bone) by an acid process, rather than by an alkaline one. In this acid process, the ossein is immersed for 12-24 hours in dilute acid at pH2-3.5.

### **Extraction of gelatine**

After the skin or ossein has been subjected to alkaline or acid treatment, gelatine is extracted by a series of hot water steps. The gelatine extract is purified by filtration through diatomaceous earth and cellulose filter plates, and this process removes suspended particles.<sup>57,58</sup>

The purified gelatine solution is concentrated by evaporation in partial vacuum and the concentrated solution is sterilized by UHT treatment of at least 138°C for at least four seconds.<sup>59</sup> It is likely that the filtration and sterilization processes also remove some BSE infectivity, in the unlikely event that any should be present by this stage of production.

### **Experimental studies**

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<sup>53</sup> Schrieber R, Seybold U (1993) Gelatine production, the six steps to maximum safety. In *Transmissible Spongiform Encephalopathies – Impact on Animal and Human Health*. Edited by F Brown. *Developments in Biological Standardization*. Volume 80. Karger, Basel: 195- 198.

<sup>54</sup> Mr Steve Ford, Purchasing Manager, Gelita New Zealand Ltd. Personal communication with Stuart MacDiarmid, 5 April 2005.

<sup>55</sup> Prusiner SB, Groth DF, McKinley MP, Cochran SP, Bowman KA, Kasper KC (1981) Thiocyanate and hydroxyl ions inactivate the scrapie agent. *Proceedings of the National Academy of Sciences USA*, 78. 4606-4610.

<sup>56</sup> Schrieber R, Seybold U (1993) Gelatine production, the six steps to maximum safety. In *Transmissible Spongiform Encephalopathies – Impact on Animal and Human Health*. Edited by F Brown. *Developments in Biological Standardization*. Volume 80. Karger, Basel: 195- 198.

<sup>57</sup> Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39. 329-338.

<sup>58</sup> Mr Steve Ford, Purchasing Manager, Gelita New Zealand Ltd. Personal communication with Stuart MacDiarmid, 5 April 2005.

<sup>59</sup> Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39. 329-338.

Relatively recently, the results of experimental studies have been published confirming risk assessments made earlier. An accurately scaled down laboratory process was developed to measure the effect of gelatine manufacturing processes on BSE infectivity. The experiment used crushed bones and intact calf vertebral columns. The crushed bone was smeared (“spiked”) with mouse brain infected with the 310V strain of mouse-passaged BSE. The same brain was injected into the spinal cord of the vertebral columns. The 301V strain of BSE was selected because it has a high infectivity titre and is one of the most heat-resistant TSE strains.<sup>60</sup>

The BSE infectivity of the spiked starting material was  $10^{8.4}$  mouse intracerebral ID<sub>50</sub> /Kg. Clearance factors of  $10^{2.6}$  and  $10^{3.7}$  ID<sub>50</sub> were demonstrated for the first stage of the acid and alkaline processes (see above) respectively. The complete acid and alkaline processes both reduced infectivity to undetectable levels, giving clearance factors of  $\geq 10^{4.8}$  ID<sub>50</sub> for the acid process and  $\geq 10^{4.9}$  ID<sub>50</sub> for the alkaline.<sup>61</sup>

The level of infectivity used in the experiments reflect worst-case conditions. The experiment did not take into account the very large effect of dilution of raw materials referred to above. Even if a BSE-infected animal contributed a vertebral column to an industrial batch of raw material, the concentration of BSE prion in the batch would not be as great as achieved by the “spiking” described in the experimental study.

## Conclusions

In the years since the public health risk posed by BSE was first recognized, much has been learned about the disease. It is now clear that humans are relatively difficult to infect by mouth and that the BSE epidemic is largely under control internationally. This means that any batch of raw material used to produce gelatine is highly unlikely to contain sufficient BSE to be able to infect humans consuming products made from it. Further, recent experimental studies have confirmed what was long suspected; namely, the described chemical processes used in the manufacture of gelatine are sufficient to inactivate any BSE infectivity which might have been present in the raw material from which the gelatine is made, even under “worst case” conditions.

Gelatine produced by modern industrial processes can thus be considered to pose no BSE risk to consumers, regardless of the source country from which it is derived.

## Acknowledgment

I thank Dr. Uwe Seybold, DGF Stoess AG, Eberbach, Germany and Dr David Taylor, SEDECON 2000, Edinburgh, Scotland for their critical review of this paper.

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<sup>60</sup> Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39. 329-338.

<sup>61</sup> Grobber AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatine. *Biotechnology and Applied Biochemistry*, 39. 329-338.

## **Appendix 5: Membership of Review Team**

### **Project Leader**

Dr John Hellstrom, Consultant

### **Project Team**

Ministry of Health

Dr Alison Roberts  
Manager Public Health Medicine

Ministry of Foreign Affairs & Trade:

Keawe Woodmore  
Specialist Negotiator, SPS Issues  
Trade Negotiations Division

New Zealand Food Safety Authority:

Dr Stuart MacDiarmid  
Principal Advisor (Food-Borne Zoonoses)

Neil McLeod

Senior Programme Manager (Market Access: Asia-Pacific)  
Trish Ranstead

Policy Analyst (Policy)

Hilary Eade

Programme Manager (Technical Standards – Imports)

Clare Stynes

Programme Manager (Import Systems)

## **Appendix 6: Terms of Reference**

### **Project purpose**

To review new scientific knowledge and experience concerning BSE and the risks to human health, and propose modifications to the New Zealand BSE Measure as appropriate.

### **Project strategy**

The review will be carried out by a project team made up of NZFSA, Ministry of Health and Ministry of Foreign Affairs and Trade staff with relevant technical, operational, trade and policy skills and knowledge. The project team will be lead by an independent person who has a sound knowledge of relevant national and international issues.

The project team will:

- Review new scientific knowledge and experience with BSE concerning the risks to human health and document its findings,
- Make recommendations on appropriate changes to the current New Zealand BSE Country Categorisation Measure to take account of the new scientific knowledge and experience with BSE, that are consistent with developments occurring in review of the OIE *Terrestrial Animal Health Code* BSE Chapter,
- Consult with appropriate experts within New Zealand, and
- Provide a report to NZFSA which documents the review team's findings and recommendations.

Stakeholders will be informed of and update on progress of the review.

### **Benefits**

New Zealanders effectively protected from exposure to the BSE agent in imported bovine food products for human consumption through the application of sanitary measures that are necessary and appropriate.

### **Project objectives**

1. New scientific knowledge and experience with BSE concerning the risks to human health documented.
2. Changes to the current New Zealand BSE Country Categorisation Measure to take account of the new scientific knowledge and experience with BSE, that are consistent with developments occurring in review of the OIE *Terrestrial Animal Health Code* BSE chapter recommended.
3. Recommendations and proposed modifications to the New Zealand BSE Country Categorisation Measure have science community support.

### **Final Deliverables**

1. Documented review of new scientific knowledge and experience.

2. Report recommending proposed changes to the NZ BSE Measure.
3. Support of New Zealand BSE expert scientific group community.
4. Support of other stakeholders – specifically MoH and MFAT.

### **Inclusions**

- Communication about the project

### **Exclusions**

- Animal health issues associated with BSE
- Development, consultation and implementation of a modified New Zealand BSE Country Categorisation Measure

## **Appendix 7: Terms of reference of the Inter-departmental Advisory Group**

### **Role**

The role of the Inter-departmental Advisory Group (IDAG) is to:

1. Provide advice from the perspectives of the members' organizations.
2. Assure assimilation of the work and the status of the work of the review in these organizations and with the relevant science community.
3. Deal with sensitive issues as they arise.
4. Provide comment on draft papers.

### **Membership**

- Tony Robinson, MORST – in connection with the Ministerial Advisory Committee on BSE;
- Mark Jacobs, Ministry of Health;
- Derek Belton, Biosecurity New Zealand;
- Mark Trainor, Ministry of Foreign Affairs and Trade.

### **Role of the Chair**

- Raise issues from the working group.
- Apprise IDAG of progress/process so far.
- Seek feedback on particular points and, where appropriate, request feedback through members' networks.

### **Role of the Project Manager**

- Provide secretariat.
- Co-ordinate views and feedback.
- Annotate view and feedback and, where necessary, take them to the Steering Group for a view on what to do with them.