FULL ASSESSMENT REPORT
SECTION 37

PROPOSAL P238

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)

NOTE: This Full Assessment was considered as a matter of urgency, under section 37 of the Australia New Zealand Food Authority Act 1991 and has been recommended to the Australia New Zealand Food Standards Council. ANZFA will conduct an inquiry into this Proposal as soon as practicable.
PROPOSAL P238
INTRODUCTION

Bovine Spongiform Encephalopathy (BSE), commonly known as “mad cow disease”, is a chronic degenerative disease affecting the central nervous system of cattle. It was first diagnosed in the United Kingdom in 1986 and to date over 180,000 cases have been confirmed in the United Kingdom. Over 1500 cases have now been reported in Europe, and recent developments indicate that BSE may be present but undetected throughout Europe. These concerns have arisen because of reports of BSE in native born cattle in countries outside the United Kingdom (for example, The Netherlands, Belgium, France, Portugal, Switzerland, Luxembourg) and of inadequate surveillance mechanisms in place in a number of countries.

Variant Creutzfeldt-Jakob Disease (vCJD), a rapidly progressive and fatal neuro-degenerative human disorder, was first diagnosed in the United Kingdom in 1996 and it is now accepted that it is caused by the transmission of BSE to humans. As a result, there is increasing concern about the potential exposure of Australian consumers to vCJD through the importation of beef products from European countries which have either a history of BSE or a substantial risk of BSE prevalence.

In 1996, Australia and New Zealand suspended the importation of British beef and beef products as a result of the incidence of BSE in cattle in the United Kingdom. On January 8, 2001 Australia and New Zealand introduced an immediate suspension of the importation of beef products and virtually all foods containing beef from 30 European countries. This suspension, introduced as an interim measure to protect the public against exposure to the BSE agent, was implemented under the Imported Food Control Act. ANZFA also initiated a voluntary withdrawal of imported European beef and beef-based products from distribution and retail outlets. A formal risk assessment of the importation of European beef products has been initiated, however an urgent amendment to the Australia New Zealand Food Standards Code under section 37 of the Australia New Zealand Food Authority Act 1991 is now required to provide a direct means of addressing the threat to human health. This Proposal will formalize these measures within the accepted bi-national food regulatory framework. These restrictions do not include milk and dairy products, gelatine, fats and tallow, collagen from bovine skins and hides, and non-beef flavourings, as current scientific evidence indicates these products present a minimal risk for transmission of the BSE agent.

On 5 January 2001, New Zealand enforced a six month Emergency Food Standard to suspend the importation of beef and beef products from 30 European countries.

Other countries (United States, Canada, Japan, Colombia, the Philippines and some European and certain Arab countries) have implemented restrictions on bovine-derived meat and meat products from European countries in response to the increasing incidence of BSE in European cattle herds.
OBJECTIVE OF THE PROPOSAL

This Proposal aims to achieve the following objectives, namely to:

- Recommend to the Australia New Zealand Food Standards Council an amendment to volume 1 and volume 2 of the Australia New Zealand Food Standards Code to require bovine meat and bovine-derived food ingredients to be derived from animals free from BSE to ensure continued protection of public health in Australia and New Zealand;

- Permit the Imported Food Program of the Australian Quarantine Inspection Service and the New Zealand Ministry of Health to enforce the above provision by the application of certification criteria;

- Allow additional time for ANZFA to undertake a formal assessment of the risk to human exposure to BSE through, inter alia, the importation of beef products from countries regarded as either BSE-infected or as having some uncertainty regarding their BSE status; and

- Ensure, by way of amendment to the Australia New Zealand Food Standards Code, that an identical requirement applies in both Australia and New Zealand, simplifying the administration of any necessary certification arrangements and eliminating the possibility that BSE-infected beef or beef products may be imported via Australia or New Zealand into the other country under the Trans Tasman Mutual Recognition Agreement.

IMPACT OF PROPOSAL

This Proposal will minimize the risk from BSE to the Australian and New Zealand populations and protect consumer confidence in the safety of imported bovine-derived meat and food ingredients. The Proposal will not disadvantage products from countries which can certify to the satisfaction of relevant Australian and New Zealand authorities that they are BSE-free.

As there are no cases of BSE detected in Australia to date, the practical impact of this proposal will occur at the import level only, and will primarily be carried out by ANZFA, AQIS and MOH (NZ), except for imported products which entered Australia prior to 8 January 2001.

SECTION 37 CONSIDERATION

It is proposed that this Proposal be considered as a matter of urgency, under section 37 of the Australia New Zealand Food Authority Act 1991 (the ANZFA Act), to omit a round of public comment and to make a recommendation to the Australia New Zealand Food Standards Council as soon as possible. The urgency is required because BSE may have been unwittingly imported into Australia and New Zealand, and currently the Food Standards Code is silent on the issue of a BSE-free requirement. This Proposal would protect the health of the community through provision of a mechanism for the importation of bovine-derived meat and food ingredients sourced from BSE-free countries or countries that can certify effective BSE control mechanisms.
BACKGROUND

BSE was first confirmed in cattle in the United Kingdom in 1986, however evidence suggests that the disease first occurred between 1980 and 1985. As of December 2000, there have been over 180,000 confirmed cases in the United Kingdom and 1500 cases in other European countries (Attachment 1). Affected animals display changes in temperament, coordination problems and decreased milk production. The accepted route of transmission of BSE in cattle is through meat-and-bone meal in animal feed contaminated with the BSE agent.

In 1996 the first cases of a new variant of Creutzfeldt-Jakob disease were reported in humans by the United Kingdom National CJD Surveillance Unit. BSE and vCJD are fatal brain diseases with unusually long incubation periods and are caused by a transmissible agent. There is no known cure.

Following the disclosure of the link between BSE and vCJD and the discovery of a large number of cases in the British herd AQIS decided, on ANZFA advice in 1996, to suspend the importation of British beef and beef products. This suspension is still in place with continued monitoring of the situation by ANZFA and AQIS. More recently, it has been established that European cattle herds have become infected with BSE, said to be due to consumption of BSE-contaminated feed imported from the United Kingdom. The number of reported cases appears to vary widely between countries. There has been almost no BSE reported outside Europe, and those cases that have occurred appear to have been related to the importation of British cattle.

The total number of European cases of BSE, although low by comparison with the incidence in the United Kingdom, is rising. The current information and the history of this epidemic, and the extensive movement within Europe of live cattle, meat products and animal feeds, suggest that the absence of reported cases in some parts of Europe might reflect the absence of a stringent surveillance system rather than the absence of the disease. Implementation and enforcement of an effective BSE control program in Europe has lagged behind that of the United Kingdom. The European Community has conducted an assessment of the incidence of BSE, and the surveillance measures in place to detect BSE, and as a result has certified only 6 countries worldwide as being in its safest Category 1 status1 (including Australia).

In response to the increasing incidence of BSE, The European Commission has implemented a series of Community- wide measures for BSE control:

- a ban on feeding mammalian meat and bone meal to all farm animals has been in place since 1996, however there have been a number of BSE cases in cattle born after implementation of feed bans in the United Kingdom, France and Switzerland indicating cross-contamination of feed with potentially BSE-contaminated ruminant meat and bone meal. As a result, from January 2001 a six month ban has been implemented in the European Community on the use of processed animal proteins as feed for all farmed animals;

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1 Argentina, Australia, Chile, Norway, New Zealand and Paraguay have a current geographical BSE-risk category of 1. Category 1 is defined as being highly unlikely that domestic cattle in these countries are (clinically or pre-clinically) infected with the BSE-agent.
introduction of the over thirty month (OTM) rule which prohibits the sale for human
consumption of beef from cattle aged over thirty months at slaughter; and

removal of animal tissue most likely to contain the BSE agent from the food chain
(specified risk material, SRM, which includes brain, eyes, tonsils, spinal cord, and
ileum of animals aged over twelve months and entire intestine of cattle of all ages)
which was introduced in October 2000.

Since 1997, the United States and Canada have included sheep and goats, as well as cattle in
the regulations on the importation of ruminants, ruminant-derived meat and meat products
and certain other ruminant products from countries in which BSE may exist. The current
regulations (CFR Parts 94 and 96, administered by the Animal and Plant Health Inspection
Service of the United States Department of Agriculture, APHIS) restricts imports from
countries and regions in which BSE is known to exist (Belgium, France, Great Britain,
Northern Ireland, Republic of Ireland, Luxembourg, The Netherlands, Oman, Portugal and
Switzerland) and also from countries which present a significant risk of introducing BSE due
to less restrictive import requirements and/or inadequate surveillance mechanisms compared
to the United States (Albania, Austria, Bosnia-Herzegovina, Bulgaria, Croatia, the Czech
Republic, Denmark, the Federal Republic of Yugoslavia, Finland, Germany, Greece,
Hungary, Italy, the former Yugoslav Republic of Macedonia, Norway, Poland, Romania, the
Slovak Republic, Slovenia, Spain and Sweden).

APHIS has advised ANZFA that once a country is listed under CFR94, the United States
does not use a certification process for implementation of the legislation as the United States
will not allow imports of ruminant derived meat and meat products. There are procedures for
requesting removal of restrictions, however currently there has not been any country removed
from the above list.

Canada restricts the import of all live ruminants and ruminant meat and meat products and
has additional controls for other ruminant by-products from countries not BSE-free. These
restrictions are substantially harmonised with the United States due to the large amount of
trade in animal feedstuffs and livestock and livestock products between the two countries.
Currently the only countries that would be eligible to export ruminant meat and meat
products to Canada are the United States, Australia, New Zealand, Argentina and Finland.
Products exempted from these BSE restrictions include milk and milk products, hides and
skins, gelatin and collagen made exclusively from hides and skins and protein-free tallow as
they are not considered to be a risk for transmission of BSE.

As from January 2001, Japan has introduced restrictions on imported beef and beef products
from the European Community as well as Switzerland and Liechtenstein.

In sum, the increasing incidence of BSE in the European herds leads to the conclusion that
European beef and beef products being imported into Australia and New Zealand may
contain BSE. In the current state of uncertainty, it would be prudent to amend the Food
Standards Code to require all beef and beef products to be BSE-free.
Utilising the Code would ensure that an identical food regulatory measure on BSE operated in both Australia and New Zealand. This is important in the context of the Trans Tasman Mutual Recognition Agreement (TTMRA) that provides, amongst other things, that products approved for sale in one country and can be sold in the other and would provide a mechanism of control over European beef and beef products already in Australia but not yet sold.

Amending the Food Standards Code is a relatively quick and simple mechanism that is not difficult to administer and minimises the possibility that BSE-infected product enters Australia or New Zealand under TTMRA.

This proposed measure is currently anticipated to only have a practical effect on the importation of European beef and beef products into Australia and New Zealand as currently both domestic herds are classified as BSE-free. Should this situation ever change, logically it will become a requirement for domestic beef and beef products as well. ANZFA intends keeping this matter under review.

**SCIENTIFIC ASSESSMENT**

BSE is a fatal brain disease of cattle resulting in a progressive degeneration of the nervous system. Epidemiological evidence indicates the cause of BSE in cattle is consumption of BSE-contaminated feed. Although cattle, sheep and goats are susceptible to BSE via oral experimental challenge, currently there is no evidence that natural BSE has occurred in sheep or goats anywhere in the world.

Creutzfeldt-Jakob Disease (CJD) is a rapidly progressive and ultimately fatal disorder of the central nervous system belonging to a group of disorders known as transmissible spongiform encephalopathies. In 1996 a new type of CJD was first described – it is now commonly known as variant CJD or vCJD. This variant of CJD differed from classical CJD in several aspects:

- early age of onset (average age of 29 years compared to 65 years for classical CJD, range 16 to 53 years);
- duration of illness. It takes on average 14 months between onset of clinical symptoms and death compared with 4 months with classical CJD; and
- atypical electroencephalogram appearance of vCJD. The brains of vCJD patients show other distinctive changes in addition to the classical spongiform changes seen in brains of classical CJD patients.

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5 Roberts, G.W. and James, S. 1996. Prion diseases: transmission from mad cows? Current Biol. 6(10), 1247-1249
As of December 2000, there have been 85 confirmed or suspected cases of vCJD in the United Kingdom (of which 82 have died), 3 cases in France and 1 case in Ireland. Scientific evidence indicates that classical CJD and vCJD are caused by different agents and epidemiological, pathological and molecular biological evidence strongly support a causal association between vCJD and BSE.\(^6\) It is generally accepted that transmission of vCJD to humans results from consumption of BSE-contaminated material.\(^7\) Both BSE and vCJD are characterized by the appearance of abnormal prion protein in neural tissues which accumulates within the brain, causing degeneration and eventual death. The minimum infectious dose, as well as the effect of repeated doses of the BSE agent on humans is not known, however feeding studies in cattle have shown that less that one gram of infected tissue is sufficient to cause BSE in all of the recipient cattle\(^8\).

Current scientific evidence indicates the BSE agent is extremely heat resistant (reported to withstand 138°C for longer than one hour), resistant to common sterilants, pH extremes and irradiation processes.\(^9\) The exact level of inactivation of the BSE agent by processing is uncertain. Scientific evidence has shown that severe heat treatment of infected material by 133°C at 3 bars for 20 minutes will not completely eliminate the BSE agent but will reduce infectivity by a factor of one thousand.\(^10\) However normal cooking and industrial food processing of products sourced from BSE-contaminated material would not affect the level of infectivity. During the canning process of a meat product, the internal temperature of the product usually remains below 100°C, although the applied temperature may reach 120° C or greater\(^11\).

The tests currently available for detection of the BSE agents will determine if a detectable level of the abnormal prion protein is present in brain tissue of cattle at slaughter. The European Commission has approved three rapid antibody-based tests (Biorad, Prionic and Enfer tests). Currently there is not a test available for detection of BSE early in infection and as such testing programs are targeted at animals over thirty months of age. These rapid tests have only been validated for use on brain tissue and for post-slaughter examination. There are no tests that can be used on processed meat products, therefore the BSE infectivity of such products can only be established by testing the animal that the product is derived from.

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\(^6\) Bruce, M., et al. 1997. Transmissions to mice indicate that new variant CJD is caused by the BSE agent. Nature 389, 448-450

\(^7\) Statement to United Kingdom Parliament by Secretary of State for Health 20 March 1996

\(^8\) Final Opinion of the Scientific Steering Committee on the Oral Exposure of Humans to the BSE Agent: Infective Dose and Species Barrier (Adopted 14 April 2000)


\(^11\) Board, P.W. 1977 Determination of thermal processes for canned foods. CSIRO Division of Food Research Circular No. 7.

The introduction of rapid diagnostic tests and their application in screening programs will potentially uncover cases that otherwise would remain undetected. This has been demonstrated in France recently with 40 cases reported following implementation of an active surveillance program. Although improved surveillance will impact on control of the BSE epidemic in Europe, the movement of significant quantities of beef and beef products throughout the European Community necessitates effective enforcement mechanisms for control of specified risk materials, as recently demonstrated by the detection of 40,000 kilograms of beef containing spinal cord material exported to Ireland from Germany.

The current scientific evidence, as outlined above, demonstrates:

1) the link between BSE and vCJD;
2) the increasing incidence of bovine BSE in Europe identifies a more widely spread problem than was seen in 1996;
3) the concerns of inadequate surveillance and control of movement of meat products;
4) that bovine animals have been infected with the BSE agent through BSE-contaminated feed whereas current available evidence indicates that BSE has not been naturally transmitted to sheep and goats; and
5) that current scientific evidence indicates that milk and milk products, hides and skins, gelatin and collagen made exclusively from hides and skins and protein-free tallow are not considered to be a risk for transmission of the BSE agent.12 This evidence is currently being reviewed in the United Kingdom and the United States.

On the basis of the evidence available, an amendment to Volume 1 and Volume 2 of the Food Standards Code that bovine meat and bovine-derived food ingredients must be derived from animals free from BSE is justified to ensure continued protection of public health;

PUBLIC CONSULTATION

Under subsection 37(3) of the ANZFA Act, ANZFA is required as soon as practicable to hold an inquiry into the provision as adopted.

REGULATORY IMPACT ASSESSMENT

Regulatory Impact Analysis

The Authority is required, in the course of development of regulations suitable for adoption in Australia and New Zealand, to consider the impact of various options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

Identification of affected parties

1. Governments in Australia and New Zealand
2. Consumers in Australia and New Zealand
3. Manufacturers, producers, importers and retailers of food products
Options

Option 1— Discontinue current interim measure of import restrictions and take no further action

Benefits

• There is no benefit to consumers in not providing a mechanism for protection of the public from possible exposure to the BSE agent and the consequent health threats.

• There would be the administrative saving to government and industry of not having to adopt, administer and comply with a certification regime to ensure that beef and beef products were BSE-free.

Costs

• The cost to government of not implementing some mechanism to protect public health and protect consumer confidence in the safety of bovine-derived meat and food ingredients incorporated into domestic food production would be the potential legal and moral liability of failing to protect the Australian and New Zealand public, with consequent loss of public confidence in the safety of the food supply and in the legislative and administrative mechanisms to protect that food supply, as experienced in the United Kingdom and documented in the Phillip’s report.

• The potential substantial public health costs incurred in the event of a significant outbreak of vCJD cases.

• The cost to consumers is the threat to public health and safety as a result of potential exposure to the BSE agent.

• The cost to industry is the loss of consumer confidence in the safety of imported bovine-derived meat and food ingredients incorporated into domestic manufacture and as a result, significant economic losses.

Option 2 – Maintain current import suspension without an amendment to the Food Standards Code

Benefits

• Other than saving the minor cost of making an amendment to the Food Standards Code, there are no benefits to government, consumers and industry by not formalising the interim measures within the accepted bi-national food regulatory framework

Costs

• The cost to government is of a potential challenge under the World Trade Organisation Agreement on Sanitary or Phytosanitary Measures (‘the SPS Agreement’) against a measure which appears on its face to be discriminatory.
Option 3 – Make a recommendation to the Australia New Zealand Food Regulation Ministerial Council for an amendment to Volume 1 and Volume 2 of the Food Standards Code that bovine meat and bovine-derived food ingredients from European countries must be derived from animals free from BSE to ensure continued protection of public health

Benefits

- The benefit to government, consumer and industry would be confidence in the safety of imported bovine-derived meat and food ingredients that have been sourced and manufactured within the European countries.

Costs

- The cost to government, consumers and industry would be the threat of exposure to the BSE agent arising from potentially BSE-infected bovine-derived meat and food ingredients being sourced from countries other than the European countries and then processed in the European countries and exported. The European country concerned could not certify that the bovine-derived meat and food ingredients were BSE-free. There is also the potential exposure from the BSE agent contained in European bovine-derived meat and food ingredients which were exported to a non-European country, processed in that country and exported to Australia and New Zealand as a product of that country. As there are no tests available to detect the BSE agent in a processed food, it would be quite possible for BSE to enter the Australian and New Zealand food supply under either scenario.

- The potential of a challenge under the SPS Agreement on the basis that measures were being applied differentially between Europe and other countries.

Option 4 – Make a recommendation to the Australia New Zealand Food Regulation Ministerial Council for an amendment to Volume 1 and Volume 2 of the Food Standards Code that bovine meat and bovine-derived food ingredients must be derived from animals free from BSE to ensure continued protection of public health

Benefits

Government  The Proposal would provide the regulatory basis for the implementation of measures to reduce the potential risk to consumers resulting from exposure to all products potentially infected with the BSE agent.

Consumers  This Proposal would minimize the risk from BSE to the Australian and New Zealand population and enhance consumer confidence in the safety of imported bovine-derived meat and food ingredients.

Industry  Improved confidence in the safety of imported bovine-derived meat and food ingredients incorporated into domestic manufacture would help protect industry from economic loss.
Costs

Government  Enforcement of certification
Industry  Compliance costs of certification –see above
Consumers  The above costs may be passed on to consumers but these should be minimal given the small proportion of Australian and New Zealand consumed foods containing imported beef ingredients that is at risk of BSE infectivity.

On balance, Option 4 appears to be the best way forward.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements, including the SPS Agreement. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards that may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

An amendment to volume 1 and volume 2 of the Food Standards Code that beef and beef products must be derived from animals free from BSE to ensure continued protection of public health will effect trade issues for sanitary or phytosanitary reasons. Therefore a notification to the WTO under the SPS Agreement is required, highlighting the urgency of the amendment in relation to the increasing incidence of BSE in European countries.

CONCLUSION

An urgent amendment should be made by the Australia New Zealand Food Standards Council to volume 1 and volume 2 of the Food Standards Code to the effect that beef and beef products must be derived from animals free from BSE to ensure continued protection of public health. There is still scientific uncertainty associated with most aspects of BSE and as a result the current Proposal is aimed at risk reduction in light of current knowledge and as such will need to be reassessed as new scientific evidence becomes available.

ATTACHMENTS

1. Number of reported cases of BSE worldwide*(excluding the United Kingdom) as at 7 December 2000 (source: Office of International des Epizooties, 2000)

2. Draft amendments to Volume 1 and Volume 2 of the Food Standards Code.
Number of reported cases of BSE worldwide*(excluding the United Kingdom) as at 7 December 2000 (source: Office of International des Epizooties, 2000)

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*Cases are shown by year of confirmation.

(a) No cases were confirmed in Ireland before 1989. All the cases reported by Ireland to the OIE have been in female animals, apart from one imported 5-year old bull which was confirmed positive in 1989. There have been no cases reported to date in young male animals, i.e. steers or bulls.

(b) France: includes 1 imported case (confirmed on 13 August 1999).

(c) Imported case(s).

(d) Belgium - data as of 30 November 2000;
Denmark - date of detection of the case: 20 January 2000 - date of confirmation of the case: 25 February 2000;
France - data as of 30 November 2000 - Clinical cases=59; cases detected within the framework of the research programme launched on 8 June 2000=37;
Germany - date of confirmation of the case: 26 November 2000;
Ireland - data as of 15 August 2000;
Liechtenstein - date of the last confirmation of a case: 30 September 1998;
Luxembourg - data as of 30 November 2000;
Netherlands - date of the last detection of a case: 10 March 1999;
Portugal - data as of 23 November 2000;  
Spain - data as of 7 December 2000;  
Switzerland - data as of 10 November 2000 - Clinical cases=17; cases detected within the framework of the investigation programme=14 (new surveillance system since 1 March 1999).
DRAFT VARIATION TO THE FOOD STANDARDS CODE

To commence: On gazettal

The Food Standards Code is amended by –

(1) inserting immediately following subclause 7(1) in Standard C1 in Volume 1 -

(2) Subject to subclause (3), bovine meat and food ingredients derived from bovines must be derived from animals free of bovine spongiform encephalopathy.

(3) Subclause (2) does not apply to –

(a) collagen from bovine skins and hides (including sausage casings produced from this type of collagen;)
(b) bovine fats and bovine tallows;
(c) gelatine sourced from bovines; and
(d) milk and other dairy products sourced from bovines.

(2) inserting immediately following clause 10 in Standard 2.2.1 in Volume 2 -

11 Meat and meat products must be derived from cattle free of bovine spongiform encephalopathy

(1) Subject to subclause (2), bovine meat and food ingredients derived from bovines must be derived from animals free from bovine spongiform encephalopathy.

(2) Subclause (1) does not apply to –

(a) collagen from bovine skins and hides (including sausage casings produced from this type of collagen; and
(b) bovine fats and bovine tallows; and
(c) gelatine sourced from bovines; and
(d) milk and other dairy products sourced from bovines.