



Australian Government

Department of Health and Ageing

**RURAL AND REGIONAL AFFAIRS AND
TRANSPORT REFERENCES COMMITTEE**

**SENATE INQUIRY INTO THE POSSIBLE IMPACTS
AND CONSEQUENCES FOR PUBLIC HEALTH,
TRADE AND AGRICULTURE OF THE
GOVERNMENT'S DECISION TO RELAX IMPORT
RESTRICTIONS ON BEEF**

SUBMISSION

DEPARTMENT OF HEALTH AND AGEING

NOVEMBER 2009

Background

1. In 2001 Australia put in place measures to protect the Australian population from Bovine Spongiform Encephalopathy (BSE) contamination, including a ban on beef imports from countries reporting any BSE cases and those countries exposed to high risk factors. The Australian domestic food safety policy on “*Bovine Spongiform Encephalopathy (BSE): Human Health Requirements For The Importation Of Beef And Beef Products*” (BSE policy) is reflected in requirements set out in the Australia New Zealand Food Standards Code *Standard 2.2.1 – Meat and Meat Products*.
2. There have been considerable advances in the scientific understanding and management of BSE since 2001. In 2005 the World Organization for Animal Health (the OIE) agreed to amend the standard and adopt a three category country classification system assessing countries as either ‘negligible’, ‘controlled’ or ‘undetermined’ BSE risk.
3. The Department of Health and Ageing (DoHA) commissioned expert reviews of the science which were carried out in 2005 and 2006. Given the time that had elapsed and the advances that have been made in the management of BSE since the scientific evidence was reviewed in 2006 in relation to BSE it was decided that it would be prudent to update the science in this area in 2009.
4. DoHA works closely with other Australian Government Departments and Agencies to minimise the potential risk to humans from BSE through contamination of food supplies, blood supplies, medicines and therapeutic devices.
5. Food Standards Australia New Zealand (FSANZ) is an independent bi-national organisation. FSANZ's role is to protect the health and safety of the people of Australia and New Zealand by maintaining a safe food supply. It identifies food that should not be sold in Australia due to an unacceptably high BSE related risk and identifies restrictions that need to be put in place on the importation of food containing beef and beef products from countries at risk.
6. Australian Quarantine Inspection Service (AQIS) provides quarantine inspection services for the arrival of international passengers, cargo, mail, animals and plants or their products into Australia, and inspection and certification for a range of animal and plant products exported from Australia. Its role is to implement Government policies designed to keep Australia BSE free.

Review of Australia’s BSE policy

7. In mid 2009, DoHA commissioned Professor John Mathews, an eminent scientist with 40 years experience as an epidemiological researcher, to review the current scientific evidence on BSE particularly in relation to food and the flow on implications to human blood, human blood products and other human therapeutic goods. Professor Mathews’ review updated and re-examined the scientific evidence used to inform Australia’s BSE policy to reflect any advances in scientific knowledge since the last update to the review in 2006.
8. The final report ‘*Review of Scientific Evidence to Inform Australia’s Policy on Transmissible Spongiform Encephalopathies (TSEs)*’ (Mathews Report) concluded that the overseas epidemic of variant Creutzfeldt-Jacob Disease (vCJD) is declining, and that beef imports from “controlled risk” or “negligible risk” countries, with appropriate certification,

would lead to only a negligible increase in risk for vCJD in Australia. A copy of the Mathews Report is at Attachment A.

9. Furthermore the independent review indicates that it is possible to import beef from countries that have reported cases of BSE and maintain a high level of protection for the Australian public, provided the appropriate risk mitigation strategies are put in place.

10. The Mathews' Report concluded that:

- Over the last five years the evidence for more effective control of the global BSE epidemic has strengthened. Passive and active surveillance, carried out in accordance with OIE guidelines and European Community legislation, has shown that numbers of BSE-affected cattle are falling year by year in virtually all affected countries;
- The amount of BSE-infected material entering the human food chain in "controlled BSE risk" countries such as the UK is now very small because of the decline in BSE, the removal of brain and other specified risk materials (SRMs) from carcasses, and the detection and destruction of infected animals;
- The risk of future food-borne transmissions leading to human vCJD is very small, if not negligible, even in the UK, where previously the risk was greatest; and
- An estimate of the absolute risk to Australians from UK beef imports, if this was to be allowed, is found to be 40 million times less than the risk from road accidents.

11. The National Health and Medical Research Council's (NHMRC) Transmissible Spongiform Encephalopathies Committee (TSEAC) peer reviewed the Mathews Report in September 2009 and supported the findings of the report. Australia's Chief Medical Officer, Professor Jim Bishop, was also consulted.

Impact of changes on the BSE import policy for beef and beef products

12. Australia has changed its BSE food safety policy for imported beef and beef products, effective 1 March 2010, to allow the importation and/or sale of beef and beef products under agreed conditions from countries that have reported cases of BSE. This change to the BSE policy has moved from an exclusion system to an assessment system whereby the human health risk from beef and beef products from all countries is evaluated.

13. Australia's policy on BSE and imported food safety takes into account the international standard for BSE developed by the World Organisation for Animal Health (OIE). Rather than directly adopt the OIE standard, however, Australia has chosen to base its import conditions on a science-based risk assessment of applicant countries using the OIE's risk assessment methodology.

14. Any country wishing to export beef to Australia will need to apply to FSANZ and undergo an assessment to determine whether the beef and beef products from a country represent a risk to the health of Australian consumers and what import conditions would need to be imposed by Australia before beef and beef products could be imported. This process and import conditions are outlined in Australia's *Bovine Spongiform Encephalopathy (BSE): Requirements for the importation of Beef and Beef Products for Human Consumption – Effective March 2010*.

15. The assessment requirements relate to a wide range of factors, such as animal health, surveillance, feeding and slaughter practices. This comprehensive assessment will determine the BSE risk category to which a country belongs and therefore the certification that must

accompany each consignment of beef and beef products imported into Australia. Transitional arrangements will apply for countries already approved to export beef to Australia.

16. Any country that does not meet the assessment requirements will not be able to export their products to Australia.

Impact on other health policies

17. Australia has put in place a number of measures to prevent BSE and vCJD, including strict controls and restrictions on imports of live animals, genetic material and animal feedstuffs; stringent requirements to safeguard against exposure to the BSE agent via imported beef or beef products; a ban on feeding meat and bone meal to ruminant animals; a national BSE surveillance program in cattle; the assessment of therapeutic goods that use bovine materials during production; and the deferral of blood donations from people who lived in the UK for a cumulative period of six months or more between 1980 and 1996 or who received a blood transfusion or injection of blood or blood products while in the UK from 1980 onwards, irrespective of their length of stay.

18. Food safety: The change to Australia's imported BSE food policy will not affect the Food Standards Code and *Standard 2.2.1 – Meat and Meat Products* which requires that beef and beef products imported into Australia be derived from animals that are BSE free. Australia has in place a risk based assessment system to ensure that all beef and beef products entering Australia are derived from animals free from BSE. This measure is administered by the Australian Quarantine and Inspection Service (AQIS) and informed by advice from Food Standards Australia New Zealand (FSANZ). This standard applies to imported as well as domestically produced food.

19. Blood supply: The blood supply is protected through a decision by all Australian Health Ministers to defer blood donations from anyone who lived in the United Kingdom for a cumulative period of six months or more between 1980 and 1996 or who received a blood transfusion in the United Kingdom from 1980 onwards, irrespective of their length of stay. The Australian Red Cross Blood Service investigates any potential risk to the blood supply from a donor with suspect CJD. The National Blood Authority's National Blood Supply Contingency Plan considers the risk of any significant threat to the blood supply, including due to contamination from vCJD.

20. Medicines and therapeutic devices: The Therapeutic Goods Administration's (TGA's) role is to regulate and ensure the safety, efficacy and quality of therapeutic goods in Australia. The TGA monitors restrictions on the importation of biological materials that may contain Transmissible Spongiform Encephalopathies (TSEs) used in the production of therapeutic goods and has an ongoing assessment process for new products to minimise the potential risk of exposure to TSEs. The Office of Devices Blood and Tissues evaluates TSE safety of all therapeutic goods in accordance with the policy specified in the TGA Approach, which includes the TGA Supplementary Requirements for minimising the risk of transmitting TSEs (referred to as TGA Supplementary Requirements).

21. Under certain circumstances therapeutic goods containing bovine materials from USA and Canada are allowed if BSE safety is demonstrated through appropriate risk assessments. Circumstances of such consideration include shortage of critical medicines, although the TGA policy does not recommend such use of bovine materials. However, TGA currently

does not allow bovine materials of any infectivity category to be sourced from UK, Portugal and Ireland.

Consultation

22. DoHA undertook a targeted two stage consultation process with stakeholders. The first stage involved those organisations that could assist with the scientific review (the TGA, FSANZ and the National Health and Medical Research Council).

23. The second stage of consultation was with those stakeholders who have an interest in any change to the BSE policies including the National Blood Authority, Australian Red Cross Blood Service, the Royal College of Pathologists Australia, the Australia New Zealand Society of Blood Transfusions, the Haematology Society of Australia and New Zealand, CSL Limited, the Australian Bone Marrow Donor Registry and AusCord Blood Bank Network. The Australian Medical Association and the Creutzfeldt-Jakob Support group were unable to attend but were provided with information from the meeting. No contentious issues were raised during the consultations.

Conclusion

24. Ongoing reviews of scientific evidence and monitoring of local and global developments have been crucial in effective management of the transmissible spongiform encephalopathies (TSEs), BSE and vCJD in Australia. The most recent analysis shows that the potential risk to human health from BSE through contamination of food supplies, blood supplies, medicines and therapeutic devices can be managed provided there are appropriate risk mitigation strategies in place.