

Editorial: Development of Australia's response to bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease

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On 18 July 2001, the Australian government announced details of a permanent system of categorisation and certification designed to ensure that all beef products entering Australia for human consumption are free from the dangers of bovine spongiform encephalopathy (BSE). Details of the certification system will be published in a later edition of *Communicable Diseases Intelligence*.

The certification regime is the latest measure announced with the objective of ensuring Australia remains free of animal transmissible spongiform encephalopathies (TSEs) and to reduce the risk of variant Creutzfeldt-Jakob disease (vCJD) amongst the human population.

Australia has had two historical incidents of animal TSEs. In 1952 an imported herd of sheep was found to have scrapie. The herd was quarantined without any further spread of the infectious agent. In 1991, a cheetah in a zoo in Broome was discovered to have feline spongiform encephalopathy. This incident was attributed to exposure to infected meat and bone meal (MBM), before the animal was imported into Australia.

In 1966 Australia banned any further importation of MBM, except from New Zealand, to reduce the risk of foot and mouth disease. The ban also had the effect of protecting Australian cattle from any subsequent exposure to the BSE epidemic that emerged in the United Kingdom (UK) in the 1980s. Subsequently, Australia imposed restrictions on the importation of live cattle, semen and embryos from the UK. When BSE spread into mainland Europe in the 1990s, these restrictions were extended to all known BSE-affected countries. Australia is also fully compliant with the animal testing requirements of the Office International des Epizooties (OIE).

Variant CJD, first recognised in 1996 and attributed to eating BSE infected beef and beef product, has been a major tragedy for many families in the UK and Europe. With the announcement of a possible case of vCJD in Hong Kong, it can only be a matter of time before other countries with high numbers of travellers to and from the UK and continental Europe, such as Australia, begin reporting cases. Australians are amongst the most travelled people in the world.

There is still major uncertainty about many aspects of BSE and vCJD — particularly about the science, the control measures and the effectiveness of public health responses.

We do not know if vCJD is transmissible through human blood and blood products. The preliminary report by

Houston et al in the *Lancet* in August 2000 helped prompt Australia to defer blood donors who had spent 6 months or more in the UK. In the meantime, Australia continues to monitor blood donor deferral policies globally, while awaiting confirmation of the Houston finding.

There are now emerging reports of possible treatment regimes. At this time it is far too early to tell how effective these treatments may be, or indeed whether they will be effective in the long term. Australia will continue to monitor the situation with great interest.

If the ultimate size of the UK BSE epidemic (e.g. over the next 40 years) were known, an assessment of the risk to other exposed populations could be given. Knowledge of the epidemic size would allow calculation of the expected number of vCJD cases for a given number of contaminated animals in the food chain. It is likely to be 5-10 years before the size of the UK epidemics can be estimated with any more precision. With BSE epidemics still emerging in other European countries, an accurate quantification of risk for humans cannot be given.

Control measures introduced in the UK, and subsequently into other BSE-affected and at-risk countries, have reduced the entry of BSE-contaminated material into the human food chain. Nevertheless, there are continuing uncertainties.

- BSE is asymptomatic for most of its course and the point at which various tissues become potentially infectious has not been established.
- The minimum size of an infectious dose for humans and the cumulative dose response relationship is unknown.
- It is not known whether all mechanisms of transmission have been identified, especially as some cases of BSE continue to be detected in cattle born after the imposition of control measures in the UK.
- The lympho-reticular system is recognised as the site of early replication of prions, although the infectivity of these tissues in the early stages of infectivity is still under study.
- The precise amount, destination and end-use of exports of possibly infective meat and bone meal is still uncertain.
- The degree of compliance with control measures, particularly in countries at an early stage of the BSE epidemic, remains unclear.
- Many of the countries that are recorded as having received potentially infective MBM are not fully compliant with OIE requirements and thus may not be in a position to detect an emerging BSE epidemic.

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There are still about 1,000 new cases of BSE detected each year in the UK, despite the MBM ban having been in force and closely monitored for compliance for some years.

Previously, BSE could only be diagnosed at autopsy. Pre-symptomatic diagnosis is now possible by immunochemical testing of brain tissue at the time of slaughter. However, there are still no reliable tests available to detect BSE early in the incubation period. The tests currently approved for use in cattle down to the age of 30 months in the European Union, have been evaluated by comparison with inoculation experiments in mice. Although there are reports of positive results in younger animals, the testing regimes have still to be validated at younger ages. The tests for diagnosis of BSE, currently in use throughout Europe, are now being validated to ensure they are equally sensitive and specific in Australian cattle breeds.

There are still no validated tests available to detect BSE-contamination in processed foods and meat products at the end of the human food chain. Therefore, the traditional method of ascertaining the level and extent of threat from an imported foodborne disease to the Australian population — namely by testing at the point of entry — cannot be applied.

As BSE has continued to spread throughout the UK and Europe, the risk from non-food exposures has also come under increasing examination. In 2000, Australia's Chief Medical Officer, Professor Richard Smallwood, convened a group of experts to examine the safety of some vaccines derived from master seeds which include bovine products — some of which are from BSE affected countries. That group reported in November 2000 that these vaccines should remain on the market as they posed negligible, risk from BSE contamination.

The Therapeutic Goods Administration (TGA) is taking a proactive approach to ensure that any potential risk of exposure to BSE through medicines and medical devices is minimised. In line with other international regulatory agencies, the TGA is continuing to require that animal derived ingredients used in the manufacture of new products submitted for approval, should be sourced from BSE-free countries. Where this is not possible, evidence

needs to be provided as to the product's safety from BSE risk. TGA is also continuing an extensive review of existing products to identify and remove any potential risks of exposure to BSE.

As the magnitude of potential exposure to BSE became more apparent, Australia's National Health and Medical Research Council established a Special Expert Advisory Committee on Transmissible Spongiform Encephalopathies (SECTSE) to provide independent scientific advice to government on the animal and human risks for Australia.

Since its establishment, SECTSE has been examining a number of areas of potential risk to the Australian population and animal industries. The committee has also advised on a proposal to undertake a comprehensive survey of blood donors which will describe travel profiles of blood donors for use in risk assessments and policy development. The survey should be completed by the end of 2001.

SECTSE is also keeping itself fully informed of risk assessments being undertaken within the Department of Health and Aged Care, the Australia New Zealand Food Authority and the Department of Agriculture, Fisheries and Forestry — Australia (AFFA).

CJD is not currently a notifiable disease in Australia. Since 1993, the Commonwealth has funded the Australian National CJD Case Registry, based at the Department of Pathology in the University of Melbourne, to undertake national surveillance of human TSEs, provide diagnostic assistance for physicians and advise on infection control issues. In 2000, this role was broadened to include surveillance and diagnostic testing for vCJD.

Contingency planning is an important aspect of any national response to an emerging disease threat. AFFA has contingency plans in place should a case of BSE be detected in Australia. A vCJD response plan is also close to finalisation should a case of vCJD be detected in Australia.

Australia's Infection Control Guidelines are also being reviewed and will be made widely available upon publication. SECTSE is examining the need for additional guidance on infection control issues for vCJD, and will be issuing those separately.