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EMBASSY OF AUSTRALIA
WASHINGTON DC

19 December 2005

Docket number 2002N-0273

Docket Clerk
Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852
USA

Dear Sir or Madam

AUSTRALIAN GOVERNMENT SUBMISSION ON DOCKET NUMBER. 2002N-0273

SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Thank you for the opportunity to comment on the Proposed Rule (amendments to 21 CFR Sec. 589.2000 and a new Sec. 589 2001). Australia notes that Sec 589.2000 has not extended to the operation of ruminant feeding restrictions in countries currently supplying beef and beef products to the United States (US) i.e. arrangements in such countries have at various times since 1987 differed from those detailed in Sec 589.2000. Australia's initial assessment, confirmed by informal discussions with FDA officials, is that new provisions of Sec 589.2000 and Sec 589.2001 will not change this situation, and that the proposed provisions would not apply to Australia's legislated ruminant feeding restrictions. If however this assessment is incorrect, then Australia would question whether the proposed US measures could be said to be based on a risk assessment and whether they are not more trade restrictive than required. Australia notes that the application of this proposed rule to the operation of ruminant feeding restrictions in countries which are *BSE free/negligible risk*, and which are supplying beef and beef products to the US, such as Australia, would have serious economic and environmental consequences for such countries.

In light of the above assessment, the comments provided below are restricted to Australia's concerns with the Proposed Rule in regard to its effect on Australian exports to the US of animal food or feed, or ingredients of animal food or feed. These comments are consistent with those already provided in response to FSIS and FDA Interim Final Rules on BSE and the FSIS/APHIS/FDA Advanced Notice of Propose Rulemaking on BSE.

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The Australian Government applauds the US intention to adopt BSE measures that are consistent with World Organisation for Animal Health (OIE) guidelines and current scientific knowledge, such as the regulation of meat and bone meal and tallow containing more than 0.15% insoluble impurities. However, OIE recommends against the application of measures to trade in bovine products from countries that are *BSE free* or represent a *negligible BSE risk*. Australia meets all relevant OIE requirements for a *BSE free* or a *negligible risk* country. Accordingly, it is our view that the application of the proposed BSE measures to imports of Australian animal food or feed, or ingredients of animal food or feed, is not warranted on scientific grounds, nor is it consistent with current OIE guidelines. We note that the US proposed measures do not appear to contain provision for regionalisation. In particular, the measures fail to recognize the concept of disease-free areas. Australia requests that such considerations be included in the Proposed Rule. This would provide an appropriate avenue for recognition that Australian beef and feed products present a negligible health risk in relation to BSE and would provide a basis for exemption of Australia from the application of certain measures, detailed below.

It is our position that Australia's *BSE free/negligible risk status*, coupled with existing BSE risk management measures, provides highly effective safeguards that are sufficient to meet the health objectives apparently represented by the FDA Proposed Rule.

Australia's claimed *BSE free/negligible risk status* is supported by scientific and technical evidence. The Australian Government's conservative approach to disease risk management during the past forty years has provided additional assurance of freedom from important animal diseases, including BSE. Relevant risk management measures adopted by Australia include:

1. In 1966, Australia banned meat and bone meal (MBM) imports from all countries except New Zealand (NZ). (Note: NZ adopted similar policies).
2. In 1988 Australia banned further importation of live cattle from the UK and Ireland. Similar action has been taken in regards to other countries (i.e. those approved as sources of livestock).
3. The Australian Government traced all cattle imported from the UK and Ireland between 1980 and 1988. There were 131 cattle in all. Those cattle still alive were put into quarantine surveillance for life and cannot enter the animal or human food chain.
4. Biosecurity Australia's risk assessment ("*The likelihood that bovine spongiform encephalopathy (BSE) established in the Australian herd as a result of the importation of cattle from the UK and Europe (1980 to 1991)*") released in November 2001 concluded that the overall likelihood of BSE establishment was negligible.
5. Similar tracing and quarantine surveillance measures have been undertaken in relation to the small number of cattle imported from other countries that subsequently reported BSE.
6. BSE surveillance on clinically suspect cattle was implemented from 1990. A coordinated national surveillance program for BSE was implemented with effect from 1997 in accordance with the OIE *Code*.
7. In 1996, Australian livestock industries adopted a voluntary ban on feeding ruminant derived MBM to ruminants – this ban was legislated in 1997 and was refined in 1999 to ban the feeding of mammalian-derived materials to ruminants.
8. From 1998, the Australian Government has audited renderers and stock feed manufacturers to verify the effectiveness of the ruminant feed ban. A national audit program was implemented in 2002.
9. In 2000 the European Commission (EC) confirmed that in its view Australia is a Geographical BSE Risk level 1, meaning that it is highly unlikely that BSE exists in clinical or pre-clinical form in Australia.
10. In 2001 the feeding of all animal protein, including poultry and fish meals, to ruminants was banned (milk, tallow and gelatine may still be used in ruminant feed) in accordance with the OIE Code.

11. In 2003, Australia commenced the TSE Freedom Assurance Program (TSEFAP). This program ensures the coordination of all TSE-related activities and programs, including for surveillance, research, feed ban compliance and lifelong quarantine of imported cattle.

Australian agricultural authorities have worked closely with public health agencies since the early 1990s on policies and programs to keep BSE out of Australia. Currently, a National Health and Medical Research Council Committee — the Special Expert Committee on Transmissible Spongiform Encephalopathies — advises the government on BSE-related issues. Australia continues to review and update its BSE strategies in light of advice from this Committee and in response to scientific developments around the world.

In relation to the FDA Proposed Rule published in October 2005 in docket number 2002N-0273, Australia provides the following specific comments.

The US requirement that certain specified risk materials (SRMs) be excluded from the feed chain for all animals should not be applied to Australia. While SRMs may pose a greater risk than muscle cuts in countries potentially affected by BSE, Australia meets requirements for a *BSE free/negligible risk* country. We recommend that certain SRMs derived from Australian cattle not be excluded from the non-ruminant animal food chain on account of BSE risk. As such, we request that the FDA Proposed Rule not be applied to imports of Australian origin bovine protein intended for use in non-ruminant animal feeds.

In support of this request we note that the EU laws governing animal by-products (Regulation 1774/2002) allows imports of animal feed such as meat and bone meal from Australia, intended for use as ingredients in pet food (for non-ruminant animals) without the removal of SRMs. We also note that 9CFR§94.18 does not include Australia in the list of regions affected by BSE, or as a region which has less restrictive import restrictions or inadequate surveillance for BSE. Australia also understands that Canada does not intend to apply similar restrictions to imports of Australian animal food or feed, or ingredients of animal food or feed.

Australia recognises the right of the US to implement measures for imported animal food or feed, or ingredients of animal food or feed, in order to achieve its appropriate level of protection (ALOP). However, in the case of Australian animal food or feed, or ingredients of animal food or feed, the US' ALOP is achieved by Australia meeting the requirements for a *BSE free/negligible risk* country. Accordingly, we request amendments to the US FDA Proposed Rule to allow for the recognition of regions as *BSE free* or *negligible BSE risk* in accordance with OIE guidelines. This would then allow for the exemption of Australian animal food or feed, or ingredients of animal food or feed, from the Proposed Rule on the basis that Australia is a region that is *BSE free* or of *negligible BSE risk*, consistent with the relevant OIE standard.

Yours sincerely

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