



Department of  
**AGRICULTURE  
FISHERIES &  
FORESTRY -  
AUSTRALIA**



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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
rm. 1061  
Rockville, MD 20852  
USA  
<http://www.fda.gov/dockets/ecomments>

### **Animal Proteins Prohibited in Ruminant Feed (HFA-305)**

Dear Sir/Madam

In my capacity as Australian Chief Veterinary Officer, I am writing to provide comment on the potential changes proposed by the United States (US) Food and Drug Administration (FDA) to its current regulation, 21 CFR Part 589, prohibiting the use of certain proteins in ruminant animal feed (HFA-305).

We understand the proposed changes to the regulation are designed by the FDA to add to the Bovine Spongiform Encephalopathy (BSE) quarantine and preventative measures already adopted by the US, and to further reduce the small risk that BSE will enter and become established in the US.

As part of this process, we understand comments are being sought from concerned parties on the strengthening of animal feed regulation and would appreciate the following comments from the Department of Agriculture, Fisheries-Forestry-Australia be considered on point 1 "excluding brain and spinal cord from rendered animal products".

Australia is a major exporter of bovine and bovine-derived products to over 150 markets worldwide. The USA is one of Australia's major markets for these products. Therefore these new regulations, if also applied uniformly for all imported products, regardless of the country of origin's health status, could potentially have a significant impact for Australian product, particularly rendered animal products.

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All available evidence shows Australia continues to be free from TSEs affecting farm and native animals, including BSE and scrapie. This most favourable disease status is maintained by:

- Strict quarantine to prevent the introduction of BSE
- Other preventative animal health measures, including ruminant feeding restrictions, to guard against its establishment
- Conformation equal to or beyond the relevant OIE and WHO recommendations
- Independent scientific review.

Up to this point in time, this favourable status has been recognised by Australia's trading partners, as demonstrated by their affording it derogations from their various BSE-related requirements and from requirements defined by the Office International des Epizooties (OIE) Animal Health Code (*code*) Chapter on BSE. Amongst other things the *code* allows for countries that meet the criteria for a BSE-free country not to be required to remove high-risk tissues, such as brain and spinal cord, from the production chain. As such the current FDA proposed changes run counter to established international precedents for low risk countries.

The processing methods employed by Australia's rendering industry are designed to address the animal health risks presented by the raw materials used.

- The rendering industry employs three main processing methods: dry batch rendering, continuous dry rendering, and continuous wet rendering.
- Consistency in addressing animal health risks is assured through official audit and industry QA programs.
- Legally, Australian rendered animal proteins must be produced in accordance with the *Australian Standard for Hygienic Rendering of Animal Products*.
  - The standard requires that all rendering plants implement ISO 9000 aligned quality management systems and HACCP plans which include processing parameters to control pathogens present in Australia (e.g. *Clostridium* spp. and *Salmonella* spp.).

It is also important to note Australia's laws on the feeding of animal material to ruminants go beyond the requirements of both WHO and OIE.

- Legislation was amended in 2001 to create an inclusive ban on the feeding to ruminants of all animal material (excluding gelatine, tallow and milk) as well as the feeding of MBM of any origin, including fish, poultry and feather meals.
- This approach is designed to simplify compliance and prevent recycling and amplification of the BSE agent derived from any real or theoretical source.

For the reasons stated above, the TSE risks posed by the MBM, tallows and stockfeeds produced in Australia can be regarded as negligible and therefore Australia would request consideration be given to providing low-risk BSE countries with a derogation from these proposed requirements.

Australia's National Health and Medical Research Council formed a principal committee, called the Special Expert Committee on TSEs (SECTSE), to provide independent scientific advice to government on issues relating to TSEs in humans and animals. SECTSE have made a thorough assessment of Australia's current ruminant feeding controls and believe they provide suitable protection for Australia's animal and public health status.

I would welcome the opportunity to be able to provide further information and comment, as Australia places great importance on BSE control and preventative measures adopted by its trading partners, that may in turn directly or indirectly impact on world markets for animals and animal products.

I take this opportunity to convey our highest considerations to the FDA and advise that we value the continued close working relationship of our respective services.

Kind regards

A handwritten signature in black ink, appearing to read 'Gardner Murray', with a small dot at the end of the signature.

GARDNER MURRAY  
Australian Chief Veterinary Officer  
and Executive Director

cc Philip Corrigan