

Comments on:

Food and Drug Administration Docket No. 2002N-0273 RIN 0910-AF46.

Substances Prohibited From United States in Animal Food or Feed; Proposed Rule

New Zealand welcomes the opportunity to comment on FDA docket no. 2004N-0273, *Substances Prohibited From United States in Animal Food or Feed: Proposed Rule*.

Introduction

New Zealand has closely followed the events since the United States announced its first case of BSE in 2003. As with previous submissions on BSE-related interim final rules, amendments to interim final rules, and proposed rules, New Zealand continues to strongly advocate that the world take a rational risk-based approach to dealing with this disease of cattle, noting that it has only infected consumers where the disease was epidemic and no precautions were taken to protect the human population. Regulatory reactions and decisions around the world need to be commensurate with the real risk selected hazards pose to our consumers relative to the other diseases we are battling.

This is a position New Zealand continues to firmly support. Such a principled approach is needed to ensure we can most appropriately focus and apportion resources on those areas most likely to significantly improve and protect the health of our populations.

The United States has a key role in leadership with respect to domestic BSE measures by applying science and risk-based responses. Such an approach is crucial in securing appropriate international standards. If the United States itself does not demonstrate this approach then the international community will be less prepared to adopt risk-based standards. Accordingly, New Zealand is concerned to see any measures, which are directly in response to the discovery of BSE in North America, being applied to New Zealand bovine products. New Zealand has not seen any evidence in this proposal, as with other BSE-related measures, of the United States and its agencies (including FDA) taking into consideration its WTO obligations under the SPS Agreement. It appears that the proposed measures, as has previously been the case, will be applied to all trading partners regardless of their country BSE status.

FDA has advised that the proposed rule is in response to recommendations of the International Review Team (IRT) in 2004 with respect to actions that could be taken to

provide additional and meaningful human or animal health benefits in light of the North American experience. FDA has stated that the proposed measures are intended to strengthen existing safeguards designed to help prevent the spread of BSE in United States cattle. New Zealand contends that as another year has passed since the IRT assessment was conducted, and reported, results of the USDA Animal and Plant Health Inspection Service (APHIS) targeted testing programme have provided further support for the effectiveness of the earlier safeguard measures implemented in the United States.

New Zealand again notes that its disease status has not changed. Nor does our cattle population share a common risk profile with that of the United States. We have not imported animal feeds containing ruminant protein from any BSE affected country (including the United States and Canada) that could pose a risk to our status, and we have imported only a negligible number of live cattle from the United States and Canada all of which are identified and officially controlled. While New Zealand maintains that additional measures as proposed are unnecessary and disproportionate to the risk posed or the degree of risk reduction they will give, we are pleased that FDA has weighted the options and is proposing measures that are least burdensome to the United States industry thereby minimising potential environmental problems. These proposed measures, as with previous BSE-related measures, would however place an unwarranted burden on industry in BSE free countries such as New Zealand.

Internationally, the scientifically accepted definition of “Specified Risk Materials” (SRMs) has been qualified by animal species, tissue type, age and most importantly country status. According to the relevant international standard (OIE), as applied by most of our trading partners, New Zealand’s widely accepted BSE-free status has meant that there are no SRMs associated with cattle born, raised and slaughtered in New Zealand. This is further supported by the European Unions classification of New Zealand as GBR 1.

As a consequence of the integrated nature of international trade, the application of additional measures as outlined by FDA’s Proposed Rule to demonstrably BSE free countries such as New Zealand, even for a transitional period, is unwarranted and has the potential for substantially adverse economic affects on New Zealand industries, in particular complying with the separation requirements of processing facilities as proposed for the amendment to 21 CFR part 589.2001.

Background

New Zealand acknowledges the linkage between BSE of cattle and vCJD of humans but would like to note that many of the measures that have been put in place by the United States on an interim basis, and the additional measures as outlined in this proposed rule, are disproportionate to the actual risks involved.

Evidence accumulated since 1996, when vCJD was first reported, strongly indicates that it is not easy for humans to become infected with vCJD. At the peak of the British BSE epidemic well over 700 clinical cases of the disease in cattle were being reported each week. Since 1986, nearly 200,000 British cattle have been confirmed with BSE and epidemiological modeling suggests that perhaps 1 to 2 million additional BSE-infected animals may have entered the human food supply in the United Kingdom. Despite that level of exposure, only about 150 cases of vCJD have been recorded in that country to date. That is, a little more than 20 cases per year on average, and the evidence suggests that the vCJD epidemic has peaked and is in decline (<http://www.cjd.ed.ac.uk/vcjdq.htm>).

The United States has applied substantial BSE-measures. It is extremely unlikely that a country such as the United States, which has applied anti-BSE measures with increasing stringency for several years, could experience a BSE epidemic in cattle as seen in the United Kingdom. In addition to any possible exposure of the United States cattle population at least being two or three orders of magnitude less than in the United Kingdom, anti-BSE measures have been applied with increasing stringency for several years. This response fully reflects the SPS principle that measures put in place to mitigate a food-borne risk should be proportionate to the risks involved. The United States Department of Agriculture's (USDA) current surveillance programme has demonstrated the presence of BSE but at a very low incidence in the United States. The Harvard-Tuskegee risk assessment has demonstrated that BSE is not capable of sustaining an epidemic in the United States, and will die out under the current programmes already in place, even without the imposition of further measures. There may be a low probability of further BSE cases being detected in the United States, but any risk these pose to animal or human health is probably negligible.

International Review Team Recommendations

New Zealand commented in an earlier submission (Food and Drug Administration Docket No. 2004N-0264, RIN 0910-AF46) on the recommendations made by the International Review Team (IRT) with regard to preventing potentially infective material being fed to cattle and thus amplifying and recycling BSE. New Zealand believes that as with measures imposed elsewhere in the food chain, all mitigation measures imposed at the producer level should be proportionate to their ability to reduce risk. The IRT stated that the current United States ruminant-to-ruminant feed ban is inadequate. New Zealand continues to disagree with this conclusion. Given that the United States has been enforcing a ruminant-to-ruminant feed ban for several years, we believe that analogies with the European situation, where measures were not implemented until a BSE epidemic was well established, are scientifically unsound.

We do not agree with the IRT's assertion that SRMs must be excluded from all animal feed, including pet food. Application of such measures should only be considered for countries

where there is a significant BSE prevalence present in cattle, and be consistent with those specified by OIE. What is appropriate is that the response should be proportionate to the likely prevalence of BSE in the United States itself. The surveillance programme run by the United States Department of Agriculture since 1990 was designed to detect BSE at an incidence of one case per million adult cattle. This incidence is lower than that detected in most European countries during their BSE epidemic. These important facts lend some weight to discounting the IRT's assertion to exclude SRMs from all animal food and feed.

Further, measures to minimize amplification and recycling of BSE were in place in the United States long before the imported case was detected in Washington. The original Harvard-Tuskegee study concluded that, under existing conditions, a BSE epidemic could not sustain itself in the United States. The exclusion of any SRMs from feed intended for swine, poultry, horses and aquaculture, and from pet food, is therefore scientifically unsound and unnecessary.

For similar reasons we disagree with the IRT's recommendation to ban all mammalian and poultry protein from ruminant feeds. Even if current compliance is less than 100 percent, the BSE challenge in the United States is likely to be so small as to constitute a negligible risk in the face of current measures. New Zealand contends that extension of current food and feed restrictions would be disproportionate.

Clarification sought

New Zealand seeks clarification of a point in the proposed rule. The proposed rule prohibits "...mechanically separated beef that is derived from the materials prohibited by this proposed rule." The proposed rule specifies only brain and spinal cord. Does this mean that beef recovered by advanced meat recovery systems from vertebral column from which spinal cord has been removed is permissible?

Conclusion

A science- and risk-based response from the United States with respect to domestic BSE measures is crucial in securing appropriate international standards. It is unlikely that the international community will be prepared to adopt risk-based standards if the United States does not demonstrate and take leadership in such an approach. Actions taken by the United States in relation to BSE will likely set a precedent and have impact in relation to other diseases.

Internationally, the scientifically accepted definition of “Specified Risk Materials” (SRMs) has been qualified by animal species, tissue type, age and most importantly country status. The United States BSE-related interim final rules and this proposed rule specifically declaring certain bovine tissues from selected ages and classes of cattle as adulterants regardless of whether they are truly SRMs, are having substantial economic effects for New Zealand and in international trade in general. New Zealand’s widely accepted BSE-free status has meant that our major trading partners have accepted that there are no SRMs associated with cattle born, raised and slaughtered in New Zealand. This is further supported by the European Unions classification of New Zealand as GBR 1.

New Zealand further notes that there has been no change to our recognised status with regard to BSE. Additionally, the New Zealand cattle population does not share a common risk profile with that of the United States. There is no scientific basis for applying measures additional to those based upon the current international standard, and as previously agreed between the two countries. If the measures already in place are further perpetuated by the implementation of proposals under this Notice, New Zealand would have to substantially change its whole human and animal consumption by-product processing system, even though there has been no change in available science or in our animal health status. The imposition of unnecessarily prescriptive trade requirements are impediments to legitimate trade and create punitive costs on the meat industries of other countries such as New Zealand.

New Zealand is concerned that the proposed measures being canvassed by this Notice of Proposed Rulemaking will further perpetuate measures that are being applied to New Zealand bovine products by both FSIS and FDA which have no sound or scientifically justified basis.

New Zealand would like to see the United States address the issue of equivalence under any future BSE-related measures that might be introduced by FDA, FSIS or APHIS thereby giving due regard to its obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).