



NEW ZEALAND EMBASSY

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WASHINGTON

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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Dear Sir/Madam

Federal Measures to Mitigate BSE Risks: Consideration for Further Action
Docket number: 2004N-0264

Thank you for the opportunity to comment on the Advance notice of proposed rulemaking on additional measures under consideration in relation to bovine spongiform encephalopathy (BSE).

Please find enclosed the New Zealand Government's comments which detail a number of concerns we have. In particular, New Zealand is concerned that the new measures are being applied to New Zealand bovine products and that the interim final rules specifically declare certain bovine tissues from selected ages and classes of cattle as adulterants regardless of whether they are truly SRMs. This has a substantial and unnecessary negative economic effect for New Zealand and international trade in general.

⁵ New Zealand's widely accepted BSE-free status has meant that our major trading partners have accepted that there have previously been no SRMs associated with cattle born, raised and slaughtered in New Zealand. 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.

New Zealand has always advocated for a more rational risk-based approach to dealing with this disease, given it only infects consumers where the disease is epidemic and no precautions have been taken to protect the human population. A science and risk-based response from the United States will be a crucial factor in securing appropriate international standards and in setting a precedent where BSE is found in other countries and in relation to other diseases.

Yours sincerely

Ian Hill
Charge d'Affaires

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2004N-0264

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Comments from New Zealand on: Food and Drug Administration Docket No. 2004N-0264 RIN 0910-AF46.

New Zealand welcomes the opportunity to comment on FDA docket no. 2004N-0264. New Zealand has closely followed the events in the United States and around the world since the United States announced its first case of BSE late last year. New Zealand has and continues to strongly advocate that the world take a more rational risk-based approach to dealing with this disease of cattle, noting that it 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 with. This is a position New Zealand has firmly supported. Such a principled approach is urgently 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.

A science and risk-based response from the United States in respect of domestic BSE measures is also going to be 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 itself does not demonstrate this approach. Accordingly, New Zealand is concerned to see that the new measures, which are directly in response to the discovery of BSE in North America, are also being applied to New Zealand bovine products. 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.

While the FDA has advised the interim final rule is in response "to the finding of an adult cow that tested positive for BSE in the State of Washington", it is important to note that New Zealand's 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 US and Canada all of which are identified and officially controlled.

As a consequence of the integrated nature of international trade the application of the FDA's new interim final rule (specifically the declaring of certain bovine tissues from any country as adulterants regardless of whether they are truly SRMs), to demonstrably BSE free countries such as New Zealand, even for a transitional period, is having substantial adverse economic affects on New Zealand industries.

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 US on an interim basis are disproportionate to the actual risks involved.

Evidence that has 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 Harvard-Tuskegee study has shown that the United States is currently highly resistant to any proliferation of BSE, even without the imposition of further measures.

Sanitation measures

On page 42292 comment is sought on the need for additional measures that might be required to prevent cross contamination of carcasses. While not relevant to New Zealand, we note that cleaning and sanitation procedures that are already in place will remove protein material that potentially could be a source of cross contamination, or at least dilute them significantly to the extent that further measures would be unnecessary in a situation where there are multiple risk mitigating measures already implemented. The halving of carcasses and the implementation of the above measures to prevent contamination with spinal cord on the slaughter floor and in the boning room are an integral part of these practices.

International Review Team

On page 42293 FDA requests comments on recommendations made by the International Review Team (IRT) to prevent potentially infective material being fed to cattle and thus amplifying and recycling BSE, should it be present. 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 disagrees. 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 program 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 are important facts lend some weight to discounting the IRT's assertion to exclude all SRMs from all animal feed.

Further, measures to minimize amplification and recycling of BSE were in place in the United States long before the single imported case was detected in Washington. The Harvard-Tuskegee study concluded that, under existing conditions, a BSE epidemic could not sustain itself in the United States. The exclusion of 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 suggests that extension of current feed restrictions would be disproportionate.

Animal surveillance

New Zealand believes that the BSE surveillance program previously in place in the United States was appropriate, as demonstrated by the detection of the BSE case in Washington in December 2003. New Zealand also believes that the massive 12 to 18 month enhanced surveillance program currently being undertaken is an appropriate way to determine the likely BSE prevalence in the United States and whether risk management policies need to be adjusted. New Zealand agrees with the position that the United States has taken in

resisting demands for universal testing of all clinically normal cattle at slaughter, as such testing is scientifically unjustified and would contribute nothing to food safety.

Guidance and strategy

New Zealand notes that the United States has proposed to the OIE a science-based approach to BSE and trade issues, with a new “minimal risk” BSE classification. New Zealand strongly supports such an initiative, believing that rather than the current five categories of BSE status specified in the OIE’s *Terrestrial Animal Health Code*, a simplified system of three categories would properly protect animal and human health without raising unjustified barriers to trade. However, international acceptance of such a simplified system, with “minimal risk” being the most favourable category, is going to depend heavily on an international recognition and acceptance that BSE is not the major threat to human health that was feared when vCJD first appeared in epidemic form in the United Kingdom in 1996, nor is BSE a disease that can spread and establish easily.

A science-and risk-based response from the United States in respect of domestic BSE measures is going to be 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 itself does not demonstrate this approach.

Comments on specific questions

Question 1: In New Zealand, a BSE Expert Science Panel which includes technical expertise from across Government meets periodically. There is also a TSE Steering Committee that includes key regulators and operates under the New Zealand Food Safety Authority. New Zealand also has a BSE Liaison Group, which is not a technically specialised committee, but rather a group broadly representative of producers, consumers, government departments and other stakeholders. This committee brings in specialized expertise appropriate to particular BSE issues as they arise. The objective in having such groups is to monitor and provide fora for discussion with regard to TSE-related activities internationally and their likely impact on New Zealand in spite of our TSE free status.

Question 2: New Zealand disagrees with the IRT’s premise that it is difficult or not possible to separate small intestine from the intestine as a whole. The demarcation is clear and exclusion of the entire intestine is wasteful and unnecessary. The New Zealand opinion is supported by changes to the *Terrestrial Animal Health Code* by the OIE’s Terrestrial Animal Health Standards Commission at its June 2004 meeting.

Question 3: New Zealand’s views have been explained above.

Question 4: The list of tissues considered to be cattle SRMs should be the same for human food and animal feed. The list must be qualified by tissue

type, age and the level of risk presented in a country. Clearly, those tissues most likely to contain the BSE agent must be excluded from the rations of ruminants. Because of the strong evidence linking BSE to vCJD, the same tissues should be excluded from human food. However, especially in a country such as the United States, where BSE is rare, the exclusion of cattle SRMs from feed intended for swine, poultry, horses and aquaculture, and from pet food, is unnecessary and wasteful. This applies more so to a country which is “BSE-free”.

Question 6: Should the United States deem it necessary to prohibit cattle SRMs from all animal feed, a position that New Zealand considers to be excessive in view of the very low risk that exists in the United States, some permanent form of visible denaturing and labeling would be necessary to distinguish such material. Appropriate record keeping would be an integral part of such a measure. Any measures applied must take into consideration the level of risk of BSE that exists in a specific country.

Question 7: New Zealand has no comment, other than to suggest that impacts would be major and out of proportion to the health risks they purport to mitigate.

Question 8: New Zealand is not aware of any scientifically published data on the extent of direct human exposure to animal feed including pet food. Refer to our earlier comments with regard to the extremely low level of risk to humans when the incidence in the cattle population is as low as it is in the United States.

Question 9: Systems can be introduced to ensure that cross contamination is prevented during processing and manufacture without the need to move to dedicated facilities. These include adequate cleaning and sanitation of equipment and facilities, and controls with regard to the categories of animal and animal products processed, with separation and identification of the different classes of material produced. For example, the exclusion of animals of uncertain disease status or from animal disease control programmes. The need for storage and transportation separation depends on the security of packaging materials used and appropriate labelling to minimise to the greatest extent possible the risk of cross contamination. Any more stringent measures involving feed manufacturing for non-ruminant animals would not be cost effective when measured against that actual risk.

Question 10: Adverse economic and environmental impacts would result, for example from the building of new facilities, and additional transportation costs. These would be significant and out of proportion to the health risks the measures purport to mitigate. For example, requiring dedicated transportation would be unnecessary if packaging materials were secure.

Question 11: New Zealand reiterates that we are not in agreement with the findings of the IRT report that such measures are necessary in a country such as the United States where measures such as the ruminant-to-ruminant

feeding ban have been in place for many years and the risks are as low as they are.

Question 12: New Zealand has commented above that we consider such a measure extreme in the United States context. Such bans have been adopted in Europe because, in the experience of European regulators, cross contamination sometimes occurs and because the test method commonly used in Europe (microscopic examination for bone spicules) is unable to distinguish between mammalian, ruminant and avian meat and bone meal. Such an extreme measure may have been appropriate in Europe, where a widespread BSE epidemic was well established before risk mitigation measures were put in place. However, such a ban would be excessive in the United States, where BSE is a rare disease and where, as the Harvard-Tuskegee study has demonstrated, an epidemic of the disease is unlikely to occur. Furthermore, we understand that the United States has access to testing methods which overcome the limitations of microscopic examination for bone spicules.

Question 13: Our previous answers address this point. Such a measure would be disproportionate to the risk being managed.

Question 14: Unless an alternative method for safe, profitable use of the raw material becomes available, what is currently a valuable resource would become a waste product with adverse economic and environmental impacts. The impact would be significant and out of proportion to the health risks this measure purports to mitigate.

Question 15: BSE infectivity has been detected in a restricted range of bovine tissues. The majority of bioassays on bovine tissues, including blood, have failed to detect infectivity, even in clinical cases of BSE. An OIE expert ad hoc group, meeting in Paris 15-16 April 2004, concluded that the information available indicated that bovine blood and blood by-products would be safe, subject to stunning having been carried out in accordance with Article 2.3.13.15 of the *Terrestrial Animal Health Code*. Stunning methods currently used in the United States comply with Article 2.3.13.15.

Question 16: If SRMs, the tissues which have been demonstrated to contain BSE infectivity, are excluded from human food, plate waste cannot contain BSE infectivity. Banning the feeding of plate waste thus seems scientifically unjustified.

Question 17: As stated previously, New Zealand does not consider that SRMs should be prohibited from use in all animal feed, in view of the very low risk that exists in the United States. Given that BSE is very rare disease in the United States, and the Harvard-Tuskegee study has shown that it is unlikely to establish even before the implementation of measures in 2004, the banning of the use of poultry litter seems unwarranted, whether or not SRMs are excluded from all animal feeds.

Question 19: There is no such information.

Question 20: Where appropriate, SRMs could be removed from non-ambulatory disabled cattle. For BSE-free countries, which by definition have no SRMs, the issue is not relevant. In BSE affected countries, removal of SRMs from dead stock destined directly for rendering would be much less feasible.

Question 21: If the United States continues with only a ruminant-to-ruminant feeding ban then there are test methods available to detect the presence of ruminant protein in such feed. Otherwise, we know of no method where by this can be determined.

Question 22: We are unable to provide details at this time, but it is considered it would be economically significant.

Question 28: FDA should definitely include exemptions to any new and existing requirements to take into account future developments or test methods that would establish that feed does not present a BSE risk to ruminants. BSE risk mitigation measures must be science-based and, as such, must be subject to amendment and revision as scientific knowledge increases and new technologies become available.

Question 32: Measures based upon existing good hygienic practice including carcass separation during slaughter and dressing up until the time SRM materials can be satisfactorily managed, should be sufficient.

Question 33: As for Question 32.

Question 34: It would be entirely consistent with the United States' international obligations for FSIS to provide an exemption for BSE-free countries or countries with some other demonstrated low risk designation.

Question 35: Where the disease and/or risk status of a country has not changed associated with the findings of the cases of BSE in the United States and Canada then the FDA should exempt these previously BSE-free accepted countries from the provisions of the SRM rule. Standards applied must be risk-based and should be based on the international standard of the OIE. The United States has explicitly stated in both interim final rules that they have been initiated in direct response to an identified case of BSE in the United States. In neither interim final rule has the United States justified how the consequent change in the United State's BSE status directly affects New Zealand's previously accepted status on which trade has progressed for many years. The United States and NAFTA had an explicit policy of only trading in products from ruminants where an appropriate assessment had been made that the country was free of BSE. New Zealand is of the opinion that the United States should continue to allow trade from these countries until they have conducted and further concluded that the risk status of these countries has changed.

Question 36: Refer our answer to question 35. In other situations the FSIS would need to determine the status of third party evaluations and therefore establish whether FSIS needs to conduct its own evaluation whether in part or in full.

Conclusion

A science- and risk-based response from the United States in respect of domestic BSE measures is going to be 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 this approach. Actions taken by the United States in relation to BSE will have a precedent impact in relation to other diseases. In light of this New Zealand is pleased to see that questions around equivalence have been raised in this Notice.

New Zealand also notes that in considering the application of any further measures to mitigate the risks of BSE, the United States needs to give due regard to its obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

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 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 have previously been no SRMs associated with cattle born, raised and slaughtered in New Zealand.

New Zealand is concerned that the proposed measures being canvassed by this Advanced 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 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.