# Comment on Food and Drug Administration Docket No. 2004N-0081, RIN 0910-AF47

## *Use of Materials Derived From Cattle in Human Food and Cosmetics*

On 14 July 2004, the Food and Drug Administration (FDA) published an Interim Final Rule titled *Use of Materials Derived From Cattle in Human Food and Cosmetics*. This rule prohibited the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE), in human food, including dietary supplements, and cosmetics. On 7 September 2005 FDA issued an amendment to this interim final rule to permit collection of the small intestine excluding the distal ileum and sought further comments.

New Zealand welcomes the opportunity to comment on the amendment to FDA Docket No. 2004N-0081. This submission, while supporting and commending FDA on the amendment, reiterates the position presented in New Zealand's original comments on the interim final rule when first issued, that there is no scientific justification for applying the interim rule to New Zealand given its widely acknowledged BSE-free risk status.

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 in 2003. New Zealand continues to strongly advocate that the world take a more rational risk-based approach to dealing with this disease of cattle, noting that it has only infected consumers in countries where the epidemic resulted in thousands of cattle cases and precautions to protect the human population had not yet been implemented effectively. 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 which we are battling with. This is a position New Zealand has firmly supported. There is a continued need for such a principled approach to ensure we can more 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 crucial in underpinning 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 remains concerned that the measures introduced by the interim final rule, which are directly in response to the discovery of BSE in North America, continue to be applied to New Zealand bovine products. New Zealand is not aware of any risk assessment of our BSE status being conducted by the United States. The measures applied by FDA are in excess of the relevant

international standard (OIE). Most of our trading partners acceptance of New Zealand's BSE-free status has meant that there are no SRMs associated with cattle born, raised and slaughtered in New Zealand.

While the FDA advised that the interim final rule was 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. With the exception of very small volumes from Australia, which is also widely recognised as being BSE free, New Zealand has not imported meat and bone meal from any country since the early part of the last century. Nor have we imported animal feeds containing such ruminant protein from any BSE affected country (including the United States and Canada). New Zealand has imported very few live cattle from the US and Canada, all of which are identified and officially monitored and controlled.

As a consequence of the integrated nature of international trade the continuing application of the FDA's 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, is having substantial adverse economic effects on New Zealand industries. These inappropriate negative impacts could easily be avoided.

## *Background*

While the interim final rule's stated intent was to protect the food and cosmetic supply from materials that may carry the risk of transmitting BSE, New Zealand remains concerned that the burden of many of the measures imposed are disproportionate to the actual risks involved. The US has only detected one indigenous case of BSE to date, hence there is an extremely low risk posed to US consumers by this disease. This raises the question of the extent of the measures introduced within the United States in response to such an extremely low risk.

We acknowledge the linkage between BSE of cattle and vCJD of humans, but note that 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 were being reported each week. Since 1986, nearly 200,000 British cows 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, fewer than 160 cases of vCJD have been recorded in that country. That is, fewer than 18 cases per

year, on average, and the evidence continues to suggest that the vCJD epidemic has peaked and is in decline.

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 as seen in the United Kingdom. In addition any possible exposure of the United States cattle population would at least be two or three orders of magnitude less than in the United Kingdom. The results to date of the United States Department of Agriculture surveillance and testing regimes support the fact that the United States is highly resistant to any proliferation of BSE and confirm the position formerly acknowledged by the Harvard-Tuskegee study of BSE.

## *Specific risk materials*

New Zealand continues to support the United States decision to classify as SRMs brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column and dorsal root ganglia from animals of age 30 months and over, and the tonsils and distal ileum of all cattle in populations where a case of BSE has been reported. 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. Current scientific knowledge indicates that exclusion of these tissues from animals of younger age would provide very little further mitigation of what is already an extremely low level of risk. New Zealand again urges the United States to take a scientific approach in recognizing that the exclusion of these tissues, from cattle of any age, is completely unwarranted in a country, such as New Zealand, demonstrated to be free from BSE.

## *Conclusion*

It is essential that the United States takes a science and risk-based response in respect of domestic BSE measures as this 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. Accordingly, New Zealand is concerned to see that the measures, which are directly in response to the discovery of BSE in North America, continue to be applied to New Zealand origin bovine products some 15 months after the interim final rule was issued. There is a continuing failure to apply the international standard (OIE) for BSE to exporting countries.

New Zealand requests that any subsequent measures adopted by the United States recognise the different BSE status or risk profile of bovine products from exporting countries. In doing so the United States would be giving appropriate regard to its obligations under the

WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

New Zealand has a well established and widely acknowledged freedom from BSE and other TSEs. The existing measures achieve the same level of human and/or animal health protection anticipated by this interim final rule. The imposition of unnecessarily prescriptive trade requirements are impediments to legitimate trade and create unnecessary and burdensome compliance costs.