NEW ZEALAND EMBASSY

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6 May 2004

FSIS Docket Clerk
Docket # 03-025IF, 03-038IF, and 01-033IF
Room 102
Cotton Annex
300 12th and C Street, SW
Washington DC 20250–3700

03-025IF
03-025IF-605
HE John Wood

Dear Sir/ Madam,

It is my pleasure to forward to you the enclosed New Zealand Government submission on the USDA's Interim Final Rules on Bovine Spongiform Encephalopathy (BSE), *(Federal Register 9 CFR Parts 301,309 et al [Docket No. 03-025IF, 03-038IF & 01-033IF].*

Yours sincerely,

John Wood

HE John Wood
Ambassador

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FSIS Docket Clerk
Docket # 03-025IF, 03-038IF, and 01-033IF
Room 102
Cotton Annex
300 12th and C Street, SW
Washington DC 20250–3700

Dear Sir or Madam,

NEW ZEALAND GOVERNMENT SUBMISSION ON FEDERAL REGISTER 9 CFR Parts 301, 309 et al [Docket No. 03-025IF, 03-038IF & 01-033IF]

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy Surveillance Program; Interim Final Rules and Notice

New Zealand has the following comments on both the immediate implementation of the interim final rule and the potential future maintenance of the sanitary measures contained therein.

New Zealand notes that the new measures contained in the interim final rule have been driven by the recent detection of BSE cases in both the United States and Canada, acknowledging the significant flow of both animals and animal by-products between the two countries. As such the United States is attempting to put in place appropriate additional controls to deal with a newly emerged level of hazard as opposed to a changed human health objective. In this regard, New Zealand notes that no cases of BSE have been detected in New Zealand, that it has previously completed, published and directly supplied to the United States a risk assessment supporting its BSE-free status, and that the risk factors identified above that exist between the United States and Canada are not applicable to the New Zealand cattle population.

There is a high level of international confidence in the BSE freedom status of New Zealand which has previously been acknowledged by most countries around the world including the United States, (both the USDA CFR 94.18 and the FDA's TSE advisory Committee), Canada and the EU (New Zealand has always been rated GBR 1, the lowest risk category). This high level of confidence has also been reflected by the actions of the international regulatory science community which has consistently contracted New Zealand to supply both the negative control cattle and sheep brains to validate TSE tests and negative control animals for TSE trials.

New Zealand has not seen any evidence presented to date by the United States which directly questions its current status, or which correlates the health status of its cattle population with that of either the United States or Canada or any other country which has reported cases of BSE. Accordingly, New Zealand asserts that the application of the additional measures contained in the interim final rule to imports from New Zealand is not scientifically supported, not consistent with the relevant international standard and is more trade restrictive than required to achieve the level of human health protection required by the United States.

New Zealand supports the application of both robust science and international standards to ensure BSE is handled in the most efficient manner while ensuring unnecessary trade restrictions are minimized. In particular, New Zealand notes that the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) requires such measures to be applied only to the extent necessary to protect human, animal or plant life or health, based on scientific principles and not maintained without sufficient scientific evidence; and an assessment of risk. The application of the additional measures to New Zealand, which is demonstrably free of BSE, is more trade restrictive than necessary to achieve the appropriate level of sanitary protection required by the United States and is without scientific justification. As such, New Zealand is concerned that the new measures are being applied inconsistently with the United States' obligations under the SPS Agreement.

New Zealand urges the United States to reapply to the regulation of beef its long-standing regulatory policy of advocating the use of risk based regulatory frameworks justified by science and the acceptance of international standards as the basis for best ensuring its regulations best achieve its human health objectives whilst minimizing unjustified restrictions on trade. We note that New Zealand and the United States are both strong advocates internationally of the importance of these principles as the best means for both protecting consumers whilst not unduly affecting the commercial opportunities of our importers and exporters.

In cattle populations with identified BSE cases, New Zealand supports the range of tissues to be included as "specified risk materials" (SRM), and the age of cattle selected; namely cattle 30 months of age or greater for all tissues, and the tonsils and distal ileum from all cattle. However, while endorsing the need to exclude this range of tissues in countries which have recorded the presence of BSE, New Zealand urges the United States to recognise that exclusion of such tissues is not scientifically warranted in a country such as New Zealand. The New Zealand cattle population is demonstrably free from BSE and cattle production systems and importation history are markedly different from that of the United States. New Zealand therefore urges the United States to apply the relevant international standard contained in the OIE Terrestrial Animal Health Code, Part 2, Section 2.3, Chapter 2.3.13, thereby recognising that the same or a greater level of protection of human health can be provided by well-documented BSE-freedom as published and previously directly supplied by New Zealand to the United States. New Zealand respectfully requests that the United States urgently issues an "Amended Interim Final Rule" to exclude any materials derived from cattle born, raised and slaughtered in New Zealand from the definition of "Specified Risk materials".

New Zealand recognises that in cattle populations with identified BSE cases certain classes of non-ambulatory cattle may be more likely to have BSE than other fully clinically normal animals. It needs to be noted, however, that the human health risk posed by such animals is extremely small and the overwhelming majority of such cattle in the United States are likely to pose no BSE risk whatsoever, and the simple exclusion of their SRM would adequately manage any residual risk. Because of animal welfare concerns, the current New Zealand standard does not allow non-ambulatory animals to be transported. However, cattle which have become non-ambulatory during transportation or lairage, and which are otherwise judged suitable for purpose at ante-mortem inspection may be processed as judged appropriate. Recognising its BSE-free status, New Zealand notes that there has been no scientific justification presented to justify New Zealand having to apply measures additional to those previously agreed to between the two countries. If an additional risk mitigation measure is deemed scientifically justified by the United States for BSE-free countries such as New Zealand, the condemnation of selected tissues such as the CNS, tonsils and distal ileum just for non ambulatory animals should be more than adequate to ensure the level of human health protection required by the United States.

FSIS requests comments on the potential implications, if any, of the so-called "atypical" BSE cases reported in Japanese cattle at 21 and 23 months of age. New Zealand endorses the comments by an OIE Expert Group convened in Paris, 4 December 2003. That group concluded that the available evidence did not justify any changes in current disease control methods nor in

measures taken to protect human health. The OIE expert group also concluded that the so-called "atypical" BSE cases were no cause for changes in the international standards for trade in cattle and cattle products.

We note that FSIS requests comment on whether or not it should modify rules to address the observation that, in rare instances, BSE has been confirmed in cattle younger than 30 months of age. As BSE in cattle has a median incubation period of 60 months, the 30 month cut-off for exclusion of SRM provides very strong protection of human health, given that fewer than 0.1% of BSE cases have been recorded in cattle under 30 months of age.

As docket number 03-025IF points out, the incubation period of BSE is believed to be inversely proportional to the dose of agent received. Much of the experimental data, where short incubation periods have been observed, are derived from studies in which very high doses were administered. In a situation such as exists in North America, where BSE is very rare and where measures to "dampen" its spread have been in place for a number of years, it is improbable that cattle are likely to be exposed to high doses of agent. Therefore, short incubation periods are unlikely in the United States, so a 30-month of age cut-off for SRM is adequate and appropriate.

Finally, as long as the United States accepts that the types of tissues which should be treated as SRMs varies with the status of the cattle population and/or country, New Zealand notes with approval that the final interim rule prohibits the use of SRM, regardless of whether the animal has been tested for the presence of BSE or not. Our experts endorse the comments on the limitations of the tests currently available. We are also pleased that the United States has resisted calls to test clinically normal animals at slaughter, as we believe such a measure would be wasteful, and achieve very little in the way of protecting human health. Further, we note that at least some calls for universal testing have come from parties with a direct financial interest in the sale and use of BSE test kits.

In conclusion, we note in the interim rule it is stated: "FSIS is taking this action in response to the diagnosis on December 23, 2003, by the United States Department of Agriculture of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington." This finding and the epidemiological factors involved are unrelated to the health status of the New Zealand cattle population.

New Zealand asserts that the United States has not presented any evidence which questions New Zealand's well established and internationally acknowledged freedom from BSE and other TSEs. Accordingly, New Zealand considers that no measures additional to those previously agreed between the two countries, as based on the current international standard, are necessary to achieve the same level of human and/or animal health protection anticipated by this interim final rule.

New Zealand is concerned that the new measures are being applied inconsistently with the United States' obligations under the SPS Agreement. Furthermore the imposition of unnecessary prescriptive trade requirements are impediments to legitimate trade and create unnecessary and burdensome compliance costs.

New Zealand respectfully requests that the United States urgently issues an "Amended Interim Final Rule" to exclude any materials derived from cattle born, raised and slaughtered in New Zealand from the definition of "Specified Risk Materials".