

August 10, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No: 2004N-0264

Dear Sir or Madam:

Founded in 1919, the National Restaurant Association is the leading trade association for the restaurant industry. The National Restaurant Association represents more than 65,000 members and over 310,000 restaurant outlets in 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands. The National Restaurant Association has always supported strong government food safety regulations to assure the highest standards in food safety and maintain high levels of consumer confidence. The restaurant industry has invested billions of dollars in the last decade to improve food safety nationally and around the world. Our efforts have clearly made a difference as evidenced by the CDC's recent 2004 report noting the declining rates of illnesses associated with meat products in the U.S. The strong consumer confidence we enjoy today regarding domestically produced beef must never be shaken by inadequate regulation or perceived food safety gaps.

We have a direct and vested interest in the federal measures to mitigate BSE risks in the U.S. and wish to submit formal written comments for the record concerning the Docket No. 2004N-0264, "Federal Measures to Mitigate BSE Risks: Considerations for Further Action", Federal Register: July 14, 2004, Volume 69, Number 134. We appreciate the opportunity to comment on the FDA Advanced Notice of Proposed Rulemaking (ANPRM) and are encouraged that the Agency has requested input regarding the food industry from a farm-to-table view of these proposed mitigation measures.

After the identification of bovine spongiform encephalopathy (BSE) in the second indigenous North American cow, the U.S. Department of Agriculture (USDA) responded rapidly to implement measures to protect public health and consumer confidence. Given what is known about the epidemiology and characteristically long incubation period of BSE, additional regulations from the Food and Drug Administration (FDA) are long overdue. Scientific and epidemiological findings provide more than ample support for further decisive actions regarding the FDA feed ban in the United States. These actions are imperative to prevent further recycling of the BSE agent within the North American cattle herd and a subsequent consumer confidence crisis. The elimination of BSE from the North American cattle herd would provide safer beef and pharmaceutical products and above all a fully confident national and world market for U.S. beef products.

We feel that the FDA must provide a more comprehensive and protective feed ban which includes absolute controls for specified risk materials (SRMs) and dead live stock. The food industry must be assured that the possibility of contaminated materials are fully removed from all animal feeds and that legal exemptions which allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued.¹

We are also concerned with the proposed definition of SRM's that FDA has used in this interim final rule for human food. We question what is meant by tissues "*closely associated with infectivity.*" FDA's description in the preamble to the ANPRM, on footnote 4, states that SRM's are "*ruminant tissues that have demonstrated infectivity at some point during the BSE incubation period.*" As a matter of government accountability and consistency we strongly recommend that the FDA coordinate fully with the existing USDA definition of SRM's and assure absolute clarity and consistence in the FDA definition of "specified risk materials" or SRM's. This will be a critical component to any consistent science base regulatory action to truly reduce the risk of BSE transmission in cattle.

SRMs, as defined by the USDA, are tissues which, in a BSE infected animal, are known to either harbor BSE infectivity or to be closely associated with infectivity. If SRMs are not removed, they may introduce BSE infectivity and continue to provide a source of animal feed contamination. Rendering has been shown to reduce infectivity but it will not totally eliminate the possibility of transmission. This is significant as research in the United Kingdom has shown that a calf may be infected with the BSE agent by the ingestion of as little as .001 gram of untreated brain material.

With the current feed ban, it is still possible for cattle to be exposed to BSE through:

1. Feeding of materials currently subject to legal exemptions (*e.g.*, poultry litter, plate waste)
2. Cross feeding (the feeding of non-ruminant rations to ruminants) on farms; and
3. Cross contamination of ruminant and non-ruminant feed

A number of authoritative bodies also agree with the position that removing SRMs and dead livestock from all animal feed would reduce the BSE risk within the U.S. significantly. We believe that the recommendations of the World Health Organization and others must be fully considered by the Agency in the development of these rules. To the extent possible we believe that scientific consistency with these rules and with previous international recommendations should be maintained.

¹ The exemption for milk and milk products from the existing feed ban should be retained, because there is no scientific evidence that BSE can be transmitted through milk.

Recommendations of the World Health Organization (WHO)

The World Health Organization (WHO) has issued the following recommendations for countries with BSE or those where a known exposure exists:

No part or product of any animal which has shown signs of a TSE should enter any food chain (human or animal). In particular:

- o All countries must ensure the killing and safe disposal of all parts or products of such animals so that TSE infectivity cannot enter any food chain.
- o Countries should not permit tissues that are likely to contain the BSE agent to enter any food chain (human or animal).

From the report of a WHO Consultation on Public Health Issues related to Human and Animal Transmissible Spongiform Encephalopathies WHO/EMC/DIS 96.147, Geneva, 2-3 April 1996.

Recommendations of the Harvard/Tuskegee BSE Risk Assessment

Executive Summary of the 2001 release:

“Specific pathways or practices that would contribute the most to the spread of BSE if it were introduced into the U.S. relate to compliance with the FDA feed ban and include misfeeding on the farm and the mislabeling of feed and feed products prohibited for consumption by cattle. The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if this disease were introduced into the U.S.”

“Our evaluation of potential risk mitigation actions highlights potential measures to further reduce the already low likelihood that BSE could spread to cattle or contaminate human food if it were to arise. Prohibiting the rendering of animals that die on the farm, possibly of BSE, removes a great deal of potential contamination in the animal feed chain and reduces average predicted cases of BSE following introduction of ten infected cattle by 77%. Implementation of a UK-style ban on specified risk material (e.g., spinal cords, brains, vertebral columns) from both human food and animal feed reduces the predicted number of BSE cases in cattle by 80% and the potential human exposure by 95%.”

“The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if the disease were introduced.” The base case scenario showed that the mean total number of ID50s (i.e., dosage sufficient to infect 50 percent of exposed cattle) from healthy animals at slaughter presented to the food/feed system was 1500. The mean total number of ID50s from adult cattle deadstock presented to the feed system was 37,000. This illustrates the risk of “4D cattle” (i.e., deadstock).

From the Harvard Risk Assessment, 2001, Appendix 3A Base Case.

Recommendations of the Subcommittee to the USDA's Foreign Animal and Poultry Disease Advisory Committee

An international panel of transmissible spongiform encephalopathy (TSE) experts appointed by Secretary of Agriculture Ann M. Veneman as a subcommittee to the Foreign Animal and Poultry Disease Advisory Committee issued a report in February 2004 which stated:

“... given the epidemiological evidence indicating that BSE agent was already circulating in ruminant feed prior to the feed ban in 1997, and the integration of the North American cattle and feed industries, strong consideration should be given to excluding all SRM from both the human food and animal feed supplies.”

“Considering the BSE situation in North America, the subcommittee believes the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent.”

From the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases' Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy, Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States, 2 February 2004, p. 8.

In conclusion, we urge the FDA to adhere to the advice of both international and domestic experts without undue delay. We strongly promote the additional FDA regulations prohibiting the inclusion of SRM's and dead livestock in feed for all animals. We further urge FDA to discontinue all of the exemptions to the existing feed ban (with the exception of the exemption for milk), which still allow the feeding of ruminant protein to ruminants. The National Restaurant Association strongly believes that maintaining consumer confidence with the highest level of food safety standards is critical at this time to eliminate the risk of BSE transmission in U.S. cattle.

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If the federal government and food industry work together to ensure the safety of the nation's beef supply, regulatory resources must be deployed effectively and efficiently. As such, the National Restaurant Association would like to offer our support in the development and promotion of scientifically sound FDA regulatory approaches to fully and consistently stop the spread of BSE in U.S. cattle. Thank you for the opportunity to submit these comments. Please feel free to call our Health and Safety Regulatory Affairs Department with any questions you may have regarding this issue, at (202) 331-5900.

Sincerely,



Steven F. Grover, R.E.H.S.
Vice President
Health and Safety Regulatory Affairs

cc: Steven C. Anderson, CAE, President and Chief Executive Officer
Mary Adolf, Chief Operating Officer, NRAEF
Lee Culpepper, Senior Vice President, Government Affairs and Public Policy