NATIONAL CATTLEMEN'S BEEF ASSOCIATION

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Advanced Notice of Proposed Rule-Making Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

Comments Submitted by

the

National Cattlemen's Beef Association

to the

Food and Drug Administration-Center for Veterinary Medicine
Regarding Docket No. 02N-0273
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Submitted by

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Producer-directed and consumer-focused, the National Cattlemen's Beef Association is the trade association of America's cattle farmers and ranchers, and the marketing organization for the largest segment of the nation's food and fiber industry.

We appreciate the Food and Drug Administration Center for Veterinary Medicine publishing the advanced notice of proposed rule-making (ANPR) (Docket No. 02N-0273) regarding substances prohibited from use in animal food or feed. The issue of Bovine Spongiform Encephalopathy prevention is of the utmost importance and concern to the nation's cattle producers. As such, we have been involved in reviewing measures to prevent this disease since it was first identified in 1985. We remain committed to taking the necessary, science and risk analysis based steps to prevent the introduction, amplification, or spread of this disease in the United States. We also have been instrumental in encouraging other beef producing countries around the world to take the steps necessary to prevent the disease in their cattle herds.

We believe the existing FDA animal feed regulations are appropriate given the low level of risk that BSE will occur in the U.S. Our goal is not to change the regulations, but to achieve 100 percent compliance with the existing regulations. According to FDA, compliance with the BSE feed rule (21 C.F.R. § 589.2000) has been excellent. In fact, the coalition is unaware of any other FDA rule or program even approaching a near 100 percent compliance rate.

BSE prevention in the U.S. involves multiple programs that can best be described as a "triple firewall" strategy. This includes: (1) a ban on the importation of ruminants and ruminant products from countries with BSE; (2) a statistically sound and comprehensive animal surveillance program to continually monitor for the presence of the disease; and (3) ruminant feeding restrictions to prevent the amplification and spread of the infective agent in the unlikely event BSE occurs in our domestic cattle. The current BSE feed rule, as part of this triple firewall strategy, is more than adequate to meet the objectives stated in the preamble to the final rule.

In this regard, we find the ANPR to be incomplete and perhaps behind the times as a tool to evaluate the true scope and nature of BSE risk and the measures necessary to mitigate those risks. In this regard, the ANPR focuses on risk within the United States which is relevant, but not of the highest concern from a risk analysis perspective. These comments seek to illustrate the nature of the BSE threat and to refocus our collective efforts on the highest priority mitigating measures.

The risk of the BSE threat being in the United States has been declining at an increasing rate. The risk was arguable highest in the early 1990's as imported cattle from the United Kingdom were present in the United States. If these cattle carried the BSE agent we faced the risk of the disease being identified as was the case in Canada in 1993. The next level of risk relates to if one or more UK cattle carrying the BSE agent were to have introduced the agent into the feed supply for cattle. This action would initiate the amplification stage of BSE as the disease, theoretically could silently spread to other cattle. It is unclear when this risk would have peaked, but arguably if the BSE agent were present we would probably have had one or more cases of the disease by 1998.

The United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) BSE surveillance program, coupled with the very noteworthy symptoms of this disease, means that if the disease was or had been in the United States, it would have been identified. We support the extensive and expanded BSE surveillance program as it is essential to "prove" beyond a reasonable doubt that BSE is not present in the United States. We firmly believe the surveillance program effectively demonstrates that the disease did not become established in the United States prior to the 1997 FDA regulation "Substances Prohibited From Use in Animal

Food or Feed; Animal Proteins Prohibited in Ruminant Feed (21 CFR 589.2000) was put in place.

Today, as documented by the FDA-CVM, compliance across the rendering, feed, and cattle production sectors with the 1997 feed restrictions is arguably the most effective of any FDA regulatory program. This is the result of having the full support of all sectors and the outstanding technical support of the FDA and aggressive compliance actions taken by both FDA officials and state officials working on behalf of the FDA. Thus, the potential for BSE to be amplified in the cattle population and spread has been nearly eliminated by this regulation in general and aggressive industry compliance and FDA and state regulatory action in particular.

Therefore, actions to expand the regulatory scope to include exclusions of brain and spinal cord from rendered animal products, prohibit the feeding of poultry litter to cattle, labeling pet food "Do not feed to ruminants", or eliminating plate waste exemptions are not necessary. In fact by expanding the regulatory focus the FDA and state officials efforts would be diverted from the real issue which compliance with the existing feed restrictions. Since the disease is not evident in the United States by all reasonable certainty, these measures are useless and possibly counter productive if they divert human resources from the real issues.

This leads us to what are the "real" issues?

The fact is, the spread of BSE in other countries, such those in the European Union, or Japan, is due to one simple fact. The disease was introduced to the countries through the importation of feed ingredients of ruminant origin or cross contaminated with ruminant proteins contaminated with the BSE agent. This fact, coupled with the failure of these countries to have in place and fully enforced feed restrictions, like those promulgated by the FDA in 1997, lead to the classic case of introduction, amplification, and spread of the disease.

Therefore, the FDA-CVM needs to rethink risk reduction strategies and carefully evaluate how to prevent the introduction of the BSE agent in imported feed and food items from other countries around the world, including the possibility of transshipment of such items and mislabeling.

In this regard, the FDA has indicated they have developed or will have the capacity to use sensitive pcr or eliza linked diagnostic tools that could be used to test imported feed ingredients to ensure they do not contain prohibited proteins.

We must ensure that there every effort is taken to prevent the introduction of the BSE agent into the United States. This must be our highest priority. The next highest priority is full enforcement of the existing regulations.

To this end, we feel it is imperative that the FDA meet with APHIS and officials from the newly formed Department of Homeland Security (DHS) to develop a strategy to prevent the introduction of the BSE agent into the United States. We feel the FDA can and should be a significant partner with APHIS and DHS in verifying that imported feed and food items are from the countries as labeled and are the substances as delineated on the shipping manifest and that they do not contain any prohibited ingredients.

Relative to the issue of cross-contamination, we obviously take this issue seriously, and although we find no evidence that that BSE agent is in any of our feed ingredients in the United States, prohibited or not, minimizing cross contamination is of importance. We encourage you to work closely with the feed industry to identify the appropriate strategies to minimize cross contamination.

In closing, we want to reiterate how impressive the FDA and state officials have been in achieving the level of compliance we have with the 1997 prohibited feeds regulations. Every sector from rendering to feed manufacturing, cattle and dairy production, and pet food fully supports achieving 100 percent compliance with the existing regulations. The Harvard risk assessment and real world data from the United Kingdom demonstrate our regulations, if enforced, will effectively prevent the amplification and spread of BSE if it were ever introduced to the U.S. We also believe there is abundant data to indicate the disease was not introduced to the United States nor does it currently exist here. Therefore, full compliance with the existing regulations must continue to be a primary focus of the FDA. There is no compelling reason to expand the current feed restrictions. However, there is a great need for the FDA to develop a strategy, in concert with APHIS and DHS to ensure the BSE agent is not introduced in imported feed or food items to the United States. This is the greatest need today and tomorrow We look forward to working with you as well as APHIS and DHS to make sure our border security systems will protect us from the introduction of the BSE agent.

Thank you for this opportunity to comment on the advanced notice of proposed rule-making.

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