

August 13, 2004

VIA FAX 301/827-6870

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

RE: Docket No. 2004N-0264

Texas Cattle Feeders Association (TCFA) represents the cattle feeding industry in Texas, Oklahoma and New Mexico—an area that feeds over 7 million head annually, which is about 30% of the total fed cattle in the U.S.

We appreciate this opportunity to comment on the proposals designed to evaluate the need for taking additional actions to prevent Bovine Spongiform Encephalopathy (BSE) in the United States.

TCFA is very concerned with the July 9, 2004 FDA News Release that states, "FDA has reached a preliminary conclusion that it should propose to remove SRM's from all animal feed and is currently working on a proposal to accomplish this goal." The majority of our comments will challenge this assumption.

Current risk analysis data, plus the 15-year history of proactive BSE prevention measures, do not support FDA concluding that additional feed restrictions as discussed in the Advance Notice of Proposed Rulemaking (ANPRM) are necessary.

Prevention of BSE in the United States

Since 1989, Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the U.S. from countries where BSE is known to exist. In 1997, APHIS extended importation restrictions on ruminants and ruminant products to all of the countries in Europe.

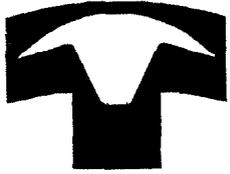
In 1997, FDA prohibited the use of all mammalian protein, with the exception of pure pork and pure equine protein from single species processing plants, in animal feeds given to cattle and other ruminants.

In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species.

The United States has had an active surveillance program for BSE since 1990. Historically, the sampling strategy was designed to detect one BSE-infected animal per million cattle and to take into account regional differences while striving for uniform surveillance throughout the country. Since 1993, BSE surveillance in the U.S. has met or exceeded international standards.

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In April 1998, USDA contracted with the Harvard Center for Risk Analysis (HCRA) at Harvard University and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk in the United States.

The Harvard-Tuskegee Study concluded that the U.S. is highly resistant to any proliferation of BSE or similar disease and that measures taken by the U.S. government and industry make the U.S. robust against the spread of BSE to animals or humans should it be introduced into this country.

The Harvard-Tuskegee Study further indicated that, if introduction of BSE had occurred via importation of live animals from the United Kingdom prior to 1989, mitigation measures already in place would have minimized exposure and begun to eliminate the disease from the cattle population.

In January 2004, USDA implemented additional restrictions to enhance BSE prevention in the U.S. These were the SRM rule prohibiting specified risk materials, the AMR rule prohibiting products produced by advanced meat recovery and the stunning rule prohibiting certain stunning devices.

In July 2004, FDA implemented a rule that prohibits the use of cattle-derived materials that can carry the BSE-infectious agent in human foods, including certain meat-based products and dietary supplements, and in cosmetics.

Compliance Data

To prevent the spread of BSE through animal feed in the United States, FDA implemented a rule in 1997 that prohibits the use of most mammalian protein in feeds for ruminant animals. The enforcement of the rule involves inspections of renderers, feed mills, ruminant feeders, protein blenders, pet food manufacturers, pet food salvagers, animal feed distributors, transporters, ruminant feeders and other entities. FDA reported on July 29, 2004, that the most recent inspection of the 2,901 active businesses handling prohibited materials that only 17 firms (0.6%) were classified as Official Action Indicated (OAI). These firms were mandated to implement corrective action and were promptly re-inspected.

The level of compliance demonstrated in these FDA reports is outstanding and well within the range of the set of assumptions utilized by the Harvard Center for Risk Analysis that determined the U.S. is extremely resistant to BSE, and if present, it is being eradicated as a result of the current feed restrictions.

Since the rules went into effect, it is clear that the firms have committed to implementing the regulation, and due to re-inspections, there are ever higher levels of compliance at the time of the follow-up inspection. BSE risks have continued to be reduced and no evidence exists that the disease prevalence exceeds the range of options evaluated in the Harvard study. These facts continue to point toward the effectiveness of the U.S. system and refute the need for additional BSE prevention measures to protect cattle health.

International Review Team Report

It seems the FDA is responding to a statement made in the International Review Teams (IRT) report, "While the science would support the feed bans limited to the prohibition of ruminant derived meat and bone meal in ruminant feed, practical difficulties of enforcement demand more pragmatic and effective solutions."

Decisions made to identify, control and eradicate diseases such as BSE can not be based upon the disease prevalence, feeding practices, regulations and other measures taken in the United Kingdom and then applied unilaterally to the situation in the U.S. Such an opinion of the IRT literally ignores the actions taken by the U.S. since 1989 to prevent BSE in the U.S.

It appears the sole source of information that has precipitated this ANPRM is the IRT report. It is important to note that the IRT did not provide a single reference or data set to support their assumptions that additional steps were needed to prevent BSE in the U.S. In fact, their assumption that additional actions were warranted based upon "epidemiological evidence in the United Kingdom" is inconsistent with the principles of risk analysis. These principles include that you must analyze risk within the given context of the country and its systems rather than simply extrapolate from existing data and experiences. This is exactly what the Harvard study accomplished.

Summary

TCFA remains dedicated to following a science and risk-analysis based program to prevent the introduction and spread of BSE. At this time, over 15 years of action, information and analysis indicates that there are no data to support FDA altering the existing feed regulations.

TCFA supports the requirement that equipment, facilities, and production lines must be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.

TCFA strongly opposes: (1) removing specified risk materials (SRM's) from all animal feed, including pet food, (2) prohibiting the use of all mammalian and poultry protein in ruminant feed, (3) prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feeds, and (4) prohibiting the use of meat and bone meal in all animal feeds.

Removing all SRM's and dead stock from all animal feed will cause economic dislocation throughout the livestock industry. Such action will likely require redesign of facilities and processes, increase disposal costs, may reduce the value of livestock and may necessitate closure of some facilities that cannot feasibly exclude SRM's from their raw material supply. The disposal of SRM's and all dead stock will also create significant environmental concerns that are unresolved.

We strongly encourage the FDA to avoid proposing any changes in the existing feed ban regulations unless the expanded BSE surveillance program provides evidence that such a change is needed based upon risk. Any proposed changes should be subjected to the Harvard Risk Analysis Model to verify they would, indeed, reduce BSE risk.

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FDA, USDA and the industry must remember and be proud of these facts: (1) The single cow identified with BSE on December 23, 2003, came from Canada. (2) USDA began implementing BSE prevention restrictions in 1989 and have added additional restrictions as appropriate. (3) U.S. surveillance testing has been in place since 1990. (4) The Harvard Center for Risk Analysis Study reported that the U.S. has implemented a robust program to prevent BSE in the U.S. (5) Public health exposure has been eliminated by restricting SRM's in human food and cosmetics.

In conclusion, it is imperative that FDA base its decisions to add additional regulations to prevent BSE on science and risk analysis. Therefore, TCFA opposes the additional feed restrictions outlined in this ANPRM.

Sincerely,



Richard McDonald, Ph.D.
President & CEO