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RE: Docket No. 2004N-0264

Texas and Southwestern Cattle Raisers Association is a 127-year-old trade organization whose 12,800 members manage approximately 5.4 million head of cattle on 70.3 million acres of range and pasture land, primarily in Texas and Oklahoma.

We appreciate this opportunity to share with the Food and Drug Administration our perspectives on the proposals designed to evaluate the need for, benefits of, and implications for taking additional actions to prevent the amplification and spread of Bovine Spongiform Encephalopathy (BSE) in the United States.

As indicated by the FDA, the extensive list of questions in the Advanced Notice of Proposed Rule-Marking published in the Federal Register on July 14, 2004, are designed to surface and define the scientific basis for additional BSE prevention measures, the risk reduction impacts, and implication for the industry and the environment. Specifically the FDA requests comments and scientific information on several additional measures related to animal feed under consideration to help prevent the spread of BSE in the United States. Some of these measures include:

- removing specified risk materials (SRMs) from all animal feed, including pet food, in order to control the risks of cross contamination throughout feed manufacture and distribution and on the farm due to misfeeding;
- requiring dedicated equipment or facilities for handling and storing feed and ingredients during manufacturing and transportation, to prevent cross contamination;
- prohibiting the use of all mammalian and poultry protein in ruminant feed, to prevent cross contamination; and
- prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

It is important to mention that the TSCRA is very concerned that the FDA "has tentatively concluded that it should propose to remove SRMs from all animal feed and is currently working on a proposal to accomplish this goal." The core of our comments will challenge this assumption as it does not appear to be grounded in evidence, science, nor risk analysis.

For the reasons we detail in our comments, we do not believe that the current risk analysis data, coupled with an over 15-year history of proactive BSE prevention measures supports the FDA concluding that the SRM and other measures discussed in the ANPRM are necessary at this time.

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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] MBM in ruminant feed, practical difficulties of enforcement demand more pragmatic and effective solutions." The IRT implied that this conclusion is based upon epidemiological evidence from the United Kingdom.

The fact is, 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 UK and then applied unilaterally to the situation in the United States. Such an opinion of the IRT literally ignores the actions taken by the United States since 1989, 14 years of BSE surveillance data, existing FDA feed ban compliance data and a comprehensive risk analysis conducted by the Harvard School of Public Health Center for Risk Analysis.

We want to take this opportunity to summarize all of these elements that must go into the decision-making process, information apparently ignored or dismissed by the IRT.

#### **Risk Analysis and Reduction Measures Taken in the U.S. since 1989.**

The primary risk of BSE introduction into the United States relates to the importation of cattle from the United Kingdom (UK) prior to 1989. Animal Plant and Health Inspection Service records indicated they conducted a trace-back effort to locate each of the 496 UK and Irish cattle that were imported into this country between January 1, 1981, and July 1989. In 1996, personal communications with APHIS staff indicated that few of these animals came from farms in the UK that had cases of BSE. Thus, the risk that these imported cattle were exposed to BSE was analyzed to be low. At the same time, it was estimated that perhaps as few as two of these imported animals might present a BSE risk. An effort was made in 1996 and 1997 to depopulate all remaining UK cattle and to test them for BSE. None of these animals were found to have BSE as a result of this testing program. The U.S. Department of Agriculture also traced the location of any other cattle imported into the United States from other countries that subsequently had cases of BSE. Five head of cattle imported from other countries in Europe in 1996-97 were placed under quarantine and eventually depopulated and tested. None were found to have BSE.

In December 1997, the USDA expanded the list of countries identified as having or at risk of BSE including virtually all of Europe.

In 1990, a BSE surveillance program was implemented in the United States initially using samples of brain tissue provided from rabies-suspect cattle. The population of rabies-suspect cattle over 30 months of age continues to be an important contributor of samples for the BSE Surveillance program.

The BSE surveillance program in the United States exceeded the minimum standards for BSE surveillance set by the International Office of Epizootics which estimated the United States need only sample between 400-500 animals to provide a valid estimate of BSE

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prevalence. In 1999, an effort was made to increase the surveillance program in order provide a higher level of confidence in our assumptions that, even if the BSE agent had been introduced into the United States, the prevalence of the disease was very low and the FDA feed bans put in place in 1997 would effectively be reducing the risk of amplification and spread.

An assumption was made to design a surveillance program capable of identifying the disease if it existed at a level of 1/million cattle over 30 months of age. Assuming most of these cattle would be in the population of cattle that were disabled, diseased or dead, it was assumed that 45 cases of BSE (1/million, with 45 million cattle over 30 months of age) would be found in a population of 195,000 cattle as estimated by a survey conducted by the American Association of Bovine Practitioners. The USDA applied Cannon and Roe's formula to determine the sample size needed to be tested to detect disease at the estimated prevalence indicating that, nationally, a sample size of 12,500 was needed.

Since 1990, the U.S. targeted surveillance program has sampled more than 90,000 animals and has never identified a domestic case of BSE. This provides us confidence that if the disease is present at all, it is at a very low prevalence. This is important as this is one of the critical assumptions within the Harvard Center for Risk Analysis study. In the presence of data indicating the risk of BSE is low in the United States, it is impossible to understand how the IRT could compare the situation in the United States to that of the United Kingdom and consequently make recommendations for additional regulatory actions on that basis.

### **The Harvard Center for Risk Analysis Study Significance**

In April of 1998 the USDA contracted with Harvard University Center for Risk Analysis and Tuskegee University to conduct a comprehensive Analysis of the risk of BSE in the United States and the prevention measures that had been put in place.

The project took 3 years to complete and was revised in 2003. The model developed is easily the most comprehensive BSE model ever developed. It created an array of simulations built upon assumptions ranging from the initial prevalence of BSE in the United States prior to the 1997 FDA feed ban ( 1, 5, 10, 20, 50, 200 or 500) coupled with the effect of the FDA feed ban, including an assumption of less than 100 % compliance.

Harvard reports that in every scenario, there is too little BSE infectivity in the U.S. cattle system, coupled with a solid history of FDA feed ban compliance to perpetuate the disease. Harvard determined the U.S. was not only extremely resistant to the disease but if it had been introduced; it was on a steady path of eradication as a result of the fed bans.

**In light of this information, we strongly urge the FDA to share with us their analysis of the BSE risks, including any additional analysis conducted by the Harvard Center for Risk Analysis that details the risk/benefits and costs associated with the proposed set of options outlined in the ANPR.**

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### **The FDA Feed Ban Structure and 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.

### **International Review Team Report**

It is imperative that the FDA base its decisions to add additional regulations to prevent the amplification and spread of BSE on science and risk analysis.

In this regard, there are no data to suggest either the risk of BSE in the United States has changed since the FDA developed the 1997 feed regulations. In addition, FDA data on feed ban compliance is exemplary. Thus, our low BSE risk coupled with a high degree of feed ban compliance clearly indicates there is no risk based nor scientific justification to expand the BSE prevention measures to include removal of SRM's or other measures as detailed in the ANPR.

It appears the sole basis for this ANPR is the International Review Team (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 likely necessary in the United States to prevent the amplification and spread of BSE. 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.

It actually seems that the IRT predicated its recommendations upon data to be gathered as a result of the large, one time sample of the high risk cattle population that is being carried out at this time. Data from this expanded surveillance program must be used within the context of additional analysis using the Harvard model. This process and data utilization must be the foundation of our decision-making process. If the expanded surveillance program were to alter our BSE prevalence assumptions included in the Harvard BSE Risk Analysis and/or the surveillance program indicates there are cases of BSE born after the feed ban, then and only then would additional BSE prevention measures be appropriate for consideration.

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#### **FDA Feed Restriction Proposed in January 2004**

After a BSE-positive cow was detected in late December 2003, FDA announced its plans to publish interim final rules on BSE that would take effect immediately upon publication. For animal feed, FDA stated that the rule would eliminate the present exemption in the ruminant feed rule that allows mammalian blood and blood products to be fed to other ruminants as a protein source, ban the use of "poultry litter" as a feed ingredient for ruminant animals, and ban the use of "plate waste" as a feed ingredient for ruminants. In addition, FDA said that to further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed, the rule would require equipment, facilities, or production lines to be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.

**The TSCRA supports the requirement proposed in January that equipment, facilities, or production lines must be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.**

**The TSCRA supports a process to determine the risks associated with feeding broiler litter to cattle and FDA action if such an analysis indicates it represents a significant risk of BSE amplification and spread.**

**The TSCRA supports the FDA in conducting a risk analysis of the use of blood and blood products in cattle diets. If data indicate specific products pose an unacceptable risk then we would support prohibiting the use of those specific products. It appears the data does not support a complete prohibition of the use of all blood products to cattle.**

**The TSCRA also supports many of the actions taken in January by the USDA to protect public health and also those announced by the FDA on July 9, 2004 that prohibit 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. These high-risk cattle-derived materials include SRM's that are known to harbor concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months of age or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age. Prohibited high-risk bovine materials also include material from non-ambulatory disabled cattle, the small intestine of all cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. These measures aid in protecting public health and thus leave the discussions contained in the ANPRM as issues related to protecting animal health, but not of direct significance to public health which is fully protected through other, direct means.**

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### Summary

The TSCRA has and remains completely dedicated to following a science and risk analysis based program to prevent the introduction, amplification and spread of BSE. However, at this time, over 15 years of action, information and analysis indicates that there are no data to support the FDA altering the existing feed regulations.

In addition, even if this situation is altered, as a result of data provided by the expanded BSE surveillance program, a much narrower, defined SRM removal policy (brain and spinal cord only from animals over 30 months that pass antemortem inspection) would be an effective and far more cost effective means to reduce BSE risk. The data show that while the high-risk, cattle-derived materials from cattle over 30 months include: the brain, skull, eyes, and spinal cord, portions of the small intestine and tonsils from all cattle, restricting all of these from animal feed is not necessary.

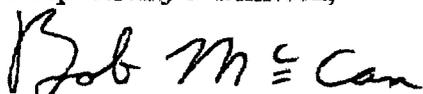
Consequently, the discussions relating to SRM removal from animal feeds are only related to the question of if additional measures are needed to further protect animal health. These additional measures would not significantly affect the already incredibly low BSE risk to public health.

Consistent with the basic premise of the Harvard Center for Risk Analysis BSE Risk Analysis, we see no evidence of a need to alter our FDA feed restrictions course at this time. If data indicate there is a need to do so, our analysis of risk reduction steps illustrates that a narrowly defined and targeted SRM removal policy would reduce risk by a small percentage.

Last but not least, we strongly encourage the FDA to avoid proposing any changes in the existing fed ban regulations unless the expanded BSE surveillance program provides evidence that such a change is needed based upon risk. In addition, any proposed changes should be subjected to the Harvard Risk Analysis Model to verify they would, indeed, reduce BSE risk.

We look forward to FDA responses to the data and information we and others have provided, including another opportunity to participate in a notice and comment rule-making process in the event FDA decides to publish a proposed rule related to this ANPRM.

Respectfully submitted,



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**FAX COVER**

**DATE:** August 13, 2004

**TO:** Food and Drug Administration, Division of Dockets Management

**FROM:** Crystal Bryant

**PAGES:** Seven

**SUBJECT:** Comments submitted regarding Docket No. 2004N-0264

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