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December 16 , 2002

Dockets Management Branch (HRA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Reference: Docket No. 02N-0273

Dear Sir or Madam:

The current regulation (Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed) prohibiting the use of certain proteins in ruminant feed established at Sec. 589.2000 (21 CFR 589.2000) contains the stated objective:

“To prevent the establishment and amplification of the agent(s) of bovine spongiform encephalopathy (BSE) in the U.S. cattle herd through feed and thereby help minimize any risks from such agent(s) to animal or human health.”

The objective has been, and is being, met.

The agency requested information on five issues listed in the Advance Notice of Proposed Rulemaking:

1. Excluding Brain and Spinal Cord From Rendered Animal Products
2. Use of Poultry Litter In Cattle Feed
3. Use of Pet Food In Ruminant Feed
4. Preventing Cross-Contamination
5. Elimination of the Plate Waste Exemption

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I will reference the Harvard Risk Assessment published in November, 2001 (1).
The report states,

“Our analysis finds that the U.S. is highly resistant to an introduction of BSE or a similar disease. BSE is extremely unlikely to become established in the U.S. Similarly, if the disease does indeed occur spontaneously in cattle, as some have suggested, it would result in one to two cases per year with little spread.”

The above statements are conclusions of both the Harvard School of Public Health and Tuskegee University from their evaluation, which included addressing the five issues listed in the agency’s ANPRM. Although risk can never be established at zero, the risk analysis performed by the two institutions selected by the USDA concludes the risk of BSE in this country to be “extremely unlikely”, based upon the programs in place.

Based upon official compliance findings of the agency, and surveillance programs administered by USDA, the original regulation enacted in 1997 is meeting the stated objective. Therefore, any additional regulations relative to the five items listed in the ANPRM would serve no beneficial purpose.

Sincerely,



Kevin Custer
Vice President
American Proteins, Inc.
Chairman
Animal Protein Producers Industry

References

1. Harvard School of Public Health/Tuskegee University, Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, November 26, 2001