



American Proteins, Inc.

4705 Leland Drive  
770-886-2250 Phone

Cumming, GA 30041  
770-886-2296 Fax

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August 10, 2004

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

From: Kevin Custer  
Vice President

Regarding: 21 CFR Part 589  
Federal Measures To Mitigate BSE Risks:  
Considerations for Further Action  
Advance Notice of Proposed Rulemaking  
Docket No. 2004N-0264  
Regulatory Identification No. (RIN) 0910-AF46

Dear Sir/Madam:

Since 1988 I have worked with FDA on risk reduction evaluations/programs relative to BSE. I have always admired the scientific approach the agency took towards the rule making process. For the first time in sixteen years I am concerned with the agencies approach.

2004N-0264

C62

Based upon official compliance findings of the agency, and surveillance programs administered by the USDA, the original regulation enacted in 1997 is meeting the stated objective. Therefore, no benefits would be derived from additional regulations.

Although I disagree with the agency's direction relative to this ANPRM, I commend the continued efforts to prevent the establishment and amplification of this disease, and remain, at your service.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Custer". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Kevin Custer  
Vice President  
American Proteins, Inc.  
Chairman  
Committee on Feed Safety  
United States Animal Health Association  
Past Chairman of the Board  
Animal Protein Producers Industry  
Past Chairman of the Board  
Fats and Proteins Research Foundation



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CbZ

The current regulation (Substances Prohibited From Use in Animal 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.

We have not diagnosed an indigenous bovine with BSE. The bovine of Canadian origin, which was diagnosed on December 23, 2003, is a testament to the success of our programs, not a call for additional regulations.

If one condenses the referenced ANPRM, the agency is asking for information relative to seven issues:

1. Removal of SRM's from all animal feed and pet food
2. Prohibition of poultry litter in ruminant rations
3. Require dedicated lines and transport for prohibited material
4. Prohibition of all mammalian and avian meat and bone meal in ruminant rations
5. Prohibition of material from dead and non-ambulatory bovines in all animal feed and pet food
6. Prohibition of ruminant blood, and blood products, in ruminant rations
7. Prohibition of plate waste in ruminant rations

The Harvard Risk Assessment published in November 2001 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.”**

Based upon official compliance findings of the agency, and surveillance programs administered by the USDA, the original regulation enacted in 1997 is meeting the stated objective. Therefore, no benefits would be derived from additional regulations.

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