



American Proteins, Inc.

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November 21, 2005

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

**From: Kevin Custer
Vice President
American Proteins, Inc.**

**Regarding: Docket No. 2002N-0273
Federal Register/Vol. 70, No. 193/October 5, 2005
21 CFR Part 589
Substances Prohibited from Use in Animal Food or Feed
Proposed Rule**

Dear Sir or Madame:

The Proposed Rule would remove the following materials from all animal feed:

- 1. Brain and spinal cord from cattle 30 months of age and older**
- 2. Cattle not inspected and passed for human consumption (includes cattle not inspected and passed for human consumption by the appropriate regulatory authority, nonambulatory cattle and fallen cattle)**
- 3. Mechanically-separated beef**
- 4. Tallow**

This document will address items 1. and 2.

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The current regulation, published as a final rule in 1997, (Substances Prohibited From Use in Animal 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”.

USDA began sampling bovine brain stems in 1990. From 1990 through June 2004, ~80,000 samples were analyzed, all negative for BSE. From June 2004 through November 1, 2005, over 500,000 samples were analyzed. One positive sample was reported in June 2005. Compliance within the affected industries is +98%. The Harvard Risk Assessment (published in 2001 and 2003) states, “Our analysis finds that the U.S. is highly resistant to an introduction of BSE or similar disease. Similarly, if the disease does indeed occur spontaneously in cattle, as some have suggested, it would result in on to two cases per year with little spread”.

The above facts are a testament to the success of the current regulation, industry effort, and government/industry commitment, not a call for additional regulations.

The current feed ban and unprecedented industry compliance, result in SRMs, being under the control of FDA. Regulations that remove SRMs, and dead stock, from the feed chain would eliminate control of this material, and likely lead to inappropriate disposition, resulting in negative consequences relative to the environment, animal, and human health.

Additionally, I am concerned that if SRMs and dead stock are removed from Meat and Bone Meal, it will only be a short time until customers of ours who purchase Poultry Product Meal require that poultry mortality (DOA's and farm mortality) be removed from that product. We currently process ~3,500,000 lbs per week of poultry mortality (182,000,000 lbs per year) in our rendering facilities located in Georgia and Alabama. Inappropriate disposition of part, or all of this material would be a certainty.

The U.S. has firewalls, cooperation and commitment that work to prevent the establishment and amplification of BSE. A small reduction of a risk that is almost non-existent is not justified based upon the negative, unintended consequences that would result from the Proposed Rule being published as a Final Rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin Custer", with a stylized flourish at the end.

Kevin Custer
Vice President
Technical Services