AMERICAN FEED INDUSTRY ASSOCIATION

February 4, 2003

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0273 – Substances Prohibited From Use In Animal Food Or Feed; Animal Proteins Prohibited In Ruminant Feed; Advanced Notice Of Proposed Rulemaking

Dear Sir/Madam:

The American Feed Industry Association (AFIA) is the national trade association for feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers and other firms which supply goods and services to the feed industry. AFIA's nearly 600 corporate members manufacture 75% of the nation's primary, commercial feed. AFIA members are subject to the current regulation (21 CFR § 589.2000). AFIA offers these comments on behalf of its members.

AFIA believes the current rule is more than adequate in light of the near zero risk of BSE being introduced in the U.S. and, in fact, AFIA supported FDA's final rule as a regulation going further than justified by current science for a country free of BSE, like the U.S. Compliance with the current rule is nearing 100% which is and should be the feed industry's goal. AFIA fully supports FDA's efforts to annually inspect 100% of the firms handling the restricted use proteins regulated under the rule.

No new risks or verifiable science support the proposed changes set forth in the ANPRM. In fact, as the Harvard BSE Risk Assessment indicated, if BSE were to occur in the U.S., the disease would not be able to sustain itself because of the current measures in place. Not only would the proposed changes result in no appreciable reduction in the risk of BSE occurring or proliferating in the U.S., the proposed changes would likely take away valuable resources that are needed to ensure full compliance with the current BSE feed rule.

Rigorous enforcement of the current feed rule will result in greater risk reduction than any or all of the proposed changes discussed in the ANPR. To that end, we urge the agency to continue to educate the regulated industries about the rule, continue active surveillance, assure compliance if violations are discovered, take vigorous enforcement actions against violators and continue the agency's cooperation and support of state inspection programs.

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1501 Wilson Blvd., Suite 1100, Arlington, VA 22209
Tel: 703/524-0810 FAX: 703/524-1921 E-mail: afia@afia.org www.afia.org

With regard to the individual areas of concern and specific questions, AFIA offers the following comments:

1. Excluding Brain and Spinal Cord from Rendered Animal Products

It is unclear why FDA would propose to remove these products from all rendered animal products in the absence of BSE in the U.S. Other than ruminants, no food animals have exhibited BSE. Any expansion of this exclusion (beyond the current rule's prohibition of use in ruminant feed) must be based on sound science, the lack of which indicates no expansion should be adopted.

2. Use of Poultry Litter in Cattle Feed

AFIA is concerned with any FDA attempt to regulate a feed ingredient not in commerce, such as an on-farm practice, although AFIA is not aware of widespread sales of poultry litter to food animals. Where is the authority to regulate any such non-commercial products?

3. Use of Pet Food in Ruminant Feed

AFIA is aware of the concern expressed to the agency by the Pet Food Institute regarding any requirement to label pet food with the cautionary statement "Do not feed to cattle or other ruminants.". AFIA members are in full agreement with the conclusion by PFI that such statements would have a serious negative repercussion on consumer perception and purchases of such products. If the rationale for labeling such products is that some venders are in violation of this rule by distributing to ruminants feeders salvage/distressed pet food, which is required to be labeled with the cautionary statement, AFIA would submit that the existing labeling rule should be enforced instead of requiring labeling of entire categories of individual consumer products. The failure to enforce this provision is not a rational basis to require more labeling, which will likely be similarly ignored by the alleged violators.

4. Preventing Cross-Contamination

AFIA believes that nearly all feed firms in the U.S. manufacturing ruminant feed have eliminated restricted use protein from their ingredient inventory, except those few firms manufacturing feed and pet food. According to FDA's compliance report, these few firms are in compliance with the current rule as provided for in the rule's preamble. AFIA is unaware of any risk information or studies of carryover that support the establishment of a safe level. The feed industry's voluntary efforts have resulted in a nearly perfect compliance record. AFIA continues to believe efforts to mandate dedicated feed mills and vehicles would result in disruption of industry structure, while providing far less risk prevention than enforcing the current rule. The

absence of a scientifically safe carryover level and validated test method lead AFIA to conclude that, at this time, there is no scientific or legal basis to support a regulatory safe level for cross-contamination or any requirement for dedicated facilities.

5. Elimination of Plate Waste

From a public policy position, it is illogical for FDA to ban products from ruminant feed that USDA has deemed safe for human consumption. AFIA is also aware that neither Canada nor Mexico have this exemption and that continued use of plate waste presents a miniscule risk—based on very low volume of use in the industry—from certain neurological tissues entering the feed supply.

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AFIA believes FDA has been diligent in carrying out its responsibilities to reduce, as much as possible, the risk of BSE being introduced and amplified in the U.S. This country's risk of BSE in domestic cattle is not zero, nor can it ever be, but our risk today is the lowest it has ever been, at least since the disease was first recognized as a threat to the U.S. cattle herd. AFIA pledges its continuing commitment to a goal of 100 percent compliance, and our cooperation in assuring that federal and state agencies have the necessary resources to achieve that goal.

AFIA continues to strongly support the efforts of the non-profit Facility Certification Institute (FCI) to augment federal/state surveillance and compliance investigations. In the two years of existence, nearly 600 inspections have been completed of feed and ingredient firms for compliance with the BSE feed rule. A new certification program in animal plasma and hemoglobin began early in 2002 and all of this industry's plants are certified by FCI.

Later this year, FCI expects to announce the availability of a new program—Certified Transport Program (CTP)—which will focus on both common and private carriers. Interest in this program is very high. The CTP will cover not only the BSE feed rule, but will implement much of the spirit of the Safe Food Transportation Act of 1990, which AFIA believes the U.S. government's failure to implement has left a gaping hole in this country's food safety net. Until that act is implemented and rules finalized, the industry must step up to the plate and implement a strong, voluntary transportation certification program, one which will put into effect an additional layer of food safety protection.

AFIA is pleased to partner with FDA in a cooperative venture to develop an educational video about truck cleanout to prevent the carryover of any restricted use protein into ruminant feed. AFIA's members tell AFIA staff that this area of potential contamination continues to be the major compliance concern with this rule in the absence of a sensitive, reliable bovine protein test acceptable to FDA.

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AFIA appreciates the opportunity to comment

Sincerely,

Richard Sellers
Vice President, Feed Control & Nutrition