



January 15, 2004

Lester M. Crawford, D.V.M, PhD.  
Deputy Commissioner of Food and Drugs, HF-1  
The U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

On behalf of the Association of American Feed Control Officials (AAFCO), I wish to comment on the current regulation 21 CFR 589.2000, to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States cattle herd. AAFCO is an international association with membership consisting largely of state feed control officials responsible for administration of state laws, rules, and portions of the Food, Drug and Cosmetic Act pertaining to the distribution of commercial feed and feed ingredients for livestock, poultry and other animals, including pets. All fifty states, Puerto Rico, Canada, and Costa Rica are members of AAFCO.

AAFCO has provided comment to the agency, when provided the opportunity, through the previous Federal Register Notice and Advance Notice of Proposed Rulemaking mechanisms. The responses were respectfully submitted October 31, 2001 and January 27, 2003.

The following proposed action items are more than ever a great concern to AAFCO and its members:

- Some of the current exclusions deserve further scientific review. There is considerable debate concerning blood products, plate-wastes, tallow, and poultry litter. FDA should add to the list of prohibited material in ruminant feed (i.e., add to the definition of “protein derived from mammalian tissues”) poultry litter and other recycled poultry waste products. The concerns of poultry litter is not only the prohibited protein that goes through the digestive tract of the bird, but also the unconsumed feed containing prohibited protein that is found in the litter through feed spillage.
- Since the United States Department of Agriculture is adopting regulations prohibiting specific high-risk materials like the brain, spinal cord, dorsal root ganglia DRG, distal ileum, and the trigeminal ganglia and other tissues found in the head (e.g., eyes) from use in human food, we believe FDA should also prohibit the use of the specific high-risk materials from

food-producing animals. The European Commission Health & Consumer Protection Directorate-General Scientific Steering Committee has stated that the brain, the spinal cord, the dorsal root ganglia respectively represent 64.1%, 25.6%, and 3.8% of the total infective load in a BSE infected animal. Therefore removing this material from rendering process would reduce the infectivity of the rendered BSE animal by 93.5%. Removal of the remainder of the head and the distal ileum would further reduce the possible infectivity of the rendered product. If scientific experiments have shown certain species of food producing animals not to be susceptible to BSE by the oral route, then the high-risk materials should be allowed to be fed to these animals. Provided the rendering industry makes provisions for processing and distributing the material in such a way that high-risk material cannot contaminate product distributed for food producing animals that are susceptible to BSE.

- The intent and the objectives of 21 CFR 589.2000 are better achieved when dedicated facilities or dedicated mixing and conveyance equipment within facilities are used. When a facility making ruminant feed does not handle prohibited material, the chance of commingling, contamination and accidental mixing or human errors may be minimized. This statement is based on our facility inspection experience. The current rule specifies that materials containing or that may contain any amount of prohibited mammalian protein must be labeled with the cautionary statement. At this time, it is difficult to assure that current flushing and sequencing procedures are adequate to eliminate with 100% certainty “any amount” of the BSE causative agent(s). We are not aware that the agency has established an acceptable tolerance for prohibited protein in ruminant feed. The potential for accidental mixing warrants the consideration that ruminant feeds and ingredients intended for ruminant feeds be processed and assembled in a facility or by equipment within a facility dedicated to only handling non-prohibited materials for ruminant feed production. This requirement is viewed as a positive step in preventing the amplification of BSE in the United States.
- Requiring dedicated transportation of animal feed containing prohibited mammalian protein is viewed as another positive step in preventing the amplification of BSE in the United States. State feed regulatory agencies have very limited authority over the transportation system. The cleaning of transportation equipment between delivery of various commodities and feed ingredients appears to get limited attention. Feed production facilities advise sequencing loads of animal feed for distribution within reason. In addition, feed manufacturers flush their distribution equipment when sequencing is not possible. This could be a prohibitive, resource intensive activity to observe and determine if distribution equipment is actually being cleaned to eliminate “any amount” of BSE causative agent(s). The agency should consider the development of GMPs for the transportation sector to provide regulatory authority, not only for the BSE issue but also for all potential contaminants in animal feed. At a minimum, the agency

should develop and mandate a validated cleanout method and record-keeping system for the transportation industry to use. If feed manufacturers use dedicated facilities to manufacture ruminant feed, many of the trucks operated by the feed manufacturers will essentially become dedicated. However, trucks *and* rail cars used by commercial transportation firms that haul many ingredients to the manufacturers may not be dedicated. The transportation providers, their equipment and employees may be difficult to find, educate and regulate and will require a coordinated effort with federal Department of Transportation.

- The exemption of the “caution” statement on pet food products can and does lead to confusion and misunderstanding in certain segments of the feed and feeding industry. This statement is made based on several concerns. The first concern is in regard to use of salvage pet food product. Broken bag product is being picked up from establishments handling pet products. This product is being further processed and may be used in other animal diets. Although much of this product is making its way into swine feed, on occasion there is concern that some product is being diverted for distribution to ruminant animals. The second concern is in regard to the storage of packaged dry pet food at feed manufacturing establishments and on-farm. Animal producers, employees of feed manufacturing establishments and purchasers of animal feed have been educated to recognize prohibited protein materials on the basis of the labeled caution statement. Since packaged pet food is not required to contain the caution statement established in the rule, there is concern that material from broken bags, left over materials or even intact pet food containers are not being recognized as prohibited material and could be incorporated into ruminant feed. In addition, pet food may be a source of imported animal proteins. The agency should reconsider the current exemption for pet food to be labeled with the caution statement.
- To improve compliance with the rule, more frequent inspection and coordinated re-inspection is recommended for the feed manufacturing sector. Inspection and compliance with the current rule should be expanded to include allied industries. The agency must expand compliance inspections to the livestock producer level. This could be accomplished with the assistance and coordination of the state animal health officials. Border inspections need to be strengthened to prevent the importation of feeds or feed ingredients not complying with the rule. Although it is important to continue to educate, it is time to start increasing enforcement activities. State and federal application of enforcement activities using the AAFCO Enforcement Guidelines should be considered. Infraction severity and associated regulatory action should be evaluated and applied consistently.

AAFCO is committed to continuing to provide a forum to discuss the possibilities of providing additional safeguards through state animal feed regulations, inspections and labeling, which could assist in the protection against BSE and further protect human and

animal health. Several committees will be deliberating at the AAFCO mid-year meeting, in Fort Worth, TX to discuss current AAFCO definitions, lack of on-farm state inspection authority and the current FDA feeding ban regulation.

Additional up-to-date information can be found at the following websites:

[www.usda.gov](http://www.usda.gov)

[www.fda.gov](http://www.fda.gov)

[www.aafco.org](http://www.aafco.org)

Sincerely,

A handwritten signature in black ink that reads "Ben L. Jones". The signature is written in a cursive style with a large initial "B" and "J".

Ben Jones  
AAFCO President  
Office of the Texas State Chemist  
P. O. Box 3160  
College Station, TX 77841  
(979) 845-1121  
Fax: (979) 845-1389  
Email: [ben-jones@tamu.edu](mailto:ben-jones@tamu.edu)