



ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS, INC.

February 13, 2003

Commissioner Mark B. McClellan, M.D., Ph.D. (HF-1)
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Commissioner McClellan:

On behalf of the Association of American Feed Control Officials (AAFCO), I wish to comment on the potential changes to the existing rule prohibiting the use of protein from certain mammalian tissues to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States cattle herd. These comments are to further emphasize those submitted by AAFCO in response to the solicitation for the advance notice of proposed rule making dated November 4, 2002, issued under sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, and 371) and under the authority of the Commissioner of Food and Drugs. 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, Costa Rica, the United States Department of Agriculture, and the Food and Drug Administration are members of AAFCO.

Occurrences of BSE, during the last few years have had devastating effects in other parts of the world where the risk had previously been determined to be relatively low. Members of our association continue to conduct the majority of the inspections of the commercial feed manufacturing establishments in North America for compliance with the requirements of regulations designed to prevent spread of BSE through feed. AAFCO is committed to achieving 100% compliance with the federal rule as defined in Title 21, Code of Federal Regulations, Part 589.2000, prohibiting the feeding of protein from certain mammalian tissues to cattle and other ruminants.

Two issues of main concern within AAFCO include the feeding of poultry litter to ruminants and the exemption of the required cautionary statement on pet food labeling.

Poultry Litter

During preliminary discussions with FDA, prior to the implementation of 589.2000, AAFCO had expressed concern over the feeding of poultry feeds to ruminant animals. Those concerns have not changed. Banning the inclusion of poultry litter in cattle or other ruminant feed will eliminate another potential source of incidental exposure of ruminant animals to prohibited protein from certain mammalian tissues. There is potentially significant spillage of poultry feed in poultry feeding operations, which may be a source of prohibited mammalian protein. The litter potentially containing this prohibited mammalian protein may be minimally processed or not processed at all before inclusion into ruminant animal feeds. Model regulations for processed animal waste products as animal feed ingredients have been developed by AAFCO, but it is up to the individual States to adopt these regulations. These regulations would apply to commercial feeds, again as defined by the individual States and in many instances would not apply to ruminant feeding practices found on the farm.

Secondly, AAFCO is not aware of any scientific evidence that would support the inactivation of the BSE agent after passing through the monogastric digestive system of poultry or through current methods of processing poultry litter.

While consideration must be given to poultry litter that does not contain prohibited material, it is imperative that any regulations developed to ban the inclusion of this material are practical and enforceable. A partial ban of poultry litter feeding (e.g., allowing feeding of poultry litter, which does not contain prohibited material) would be unenforceable and is not recommended.

Pet Food Exemption

Employees of feed manufacturing establishments have been educated to recognize prohibited protein from certain mammalian protein from certain mammalian tissues on the basis of the labeled caution statement. Since packaged pet food is exempt from the caution statement established in 21 CFR 589.2000, there is concern that material from broken bags, left over materials and even intact pet food containers are not being recognized as containing or potentially containing prohibited material and could be incorporated into cattle or other ruminant feed.

Animal producers and purchasers of animal feed also need the label statement to recognize products which contain or may contain prohibited material and should not be fed to cattle or other ruminants.

The Pet Food Institute has done an excellent job educating their industry members on the proper handling and disposition of salvaged/distressed pet food at the manufacturing level. However, there still appears to be a concern with the handling and disposition of salvaged/distressed pet food at the retail and wholesale distribution level. A number of pet food manufacturers have stated that once their products leave their distribution system that these products are no longer in their control. The concern is not limited to the retail and wholesale distribution of pet food but all food that contains

or may contain prohibited mammalian protein, including salvaged/distressed human food. In general, the retail and wholesale distributors are unaware of federal and state feed labeling requirements, and most likely, not aware of the required cautionary statement for salvaged/distressed pet food. Labeling pet food that contains or may contain prohibited mammalian protein with the BSE caution statement would address some of the issues in the retail and wholesale distribution sector. Additional controls will be needed to address the handling and disposition of salvaged/distressed human food that contains or may contain prohibited mammalian protein in the retail and wholesale distribution sector that may be fed illegally to cattle or other ruminants.

Requiring the BSE caution statement on pet food that contains or may contain prohibited protein would improve enforcement and compliance. Employees of the feed manufacturing sector, the retail and wholesale distribution sector and on-farm producers would be able to recognize that these products are clearly not intended for cattle or other ruminants. Additionally, show cattle may be fed pet food during their show preparation. It is apparently a fairly common practice to feed a high protein, high-energy supplement to "finish" the calf and give it a "slick" coat. Pet food meets the criteria.

A BSE regulatory program should not withhold information from distributors, feed manufacturers and customers, especially when some of the customers are livestock producers. Accurately labeling feed that contains or may contain prohibited mammalian protein to reflect that the pet food is not intended for cattle or other ruminants will help ensure that these products are handled and used appropriately in all sectors. The current success of FDA's BSE rule is due in part to aggressive educational efforts by all sectors and a strong regulatory response. The negative economic consequences of labeling pet food with the caution statement should be addressed by educating the purchasers of these products, not by dismissing or ignoring this potential problem.

On behalf of the Association of American Feed Control Officials I would like to provide the above comments for your consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ali Kashani".

Ali Kashani, Ph.D.
AAFCO President

AK:mw
cc: AAFCO Board of Directors