STATE OF CALIFORNIA GRAY DAVIS, *Governor*

DEPARTMENT OF FOOD AND AGRICULTURE

November 16, 2001

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Ms. Linda A. Grassie
Dockets Management Branch (HFA-305)
Animal Feed Rule Hearing
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Ms. Grassie:

Re: Docket Number 01N-0423

The California Department of Food and Agriculture (CDFA) welcomes the opportunity to provide comment on issues relative to animal proteins prohibited in ruminant feed pursuant to the Code of Federal Regulations Section 589.2000. CDFA applauds the Food and Drug Administration (FDA) (agency) for taking the initial action to establish this rule and pursue measures to prevent the occurrence of bovine spongiform encephalopathy and new variant Creutzfeldt-Jakob disease in the United States. It is essential that California maintain assurances for feed safety to the producers and continued consumer confidence in the food produced from animal agriculture. We support the agency's efforts to continue and improve the protection for the livestock industries and public health. Keeping the above as our goal, we would like to provide comments to the 17 questions listed in the October 5th *Federal Register* Notice. Our comments will correspond numerically to those in the October 5th notice.

1. Yes, the FDA can pursue additional compliance activities to assure protection of public health. The most efficient way to employ enforcement activities is to have a close working relationship with State Feed Control Officials. States like California that contract with the FDA to perform BSE inspections and re-inspections, coupled with routine surveillance, feed sampling and testing, and a voluntary feed quality assurance program result in a comprehensive compliance program for state licensed feed manufacturers. BSE inspections need to be expanded to on-farm operations and allied industries such as the transporters of feed commodities. The key to enforcement is immediate quarantine authority for the State Feed Control Official if there is even a suspicion of ruminant feed being adulterated with prohibited materials. Many states like California have such quarantine authority and with an established working relationship (Partnership Agreements) with the FDA, this authority can be an important enforcement tool.

2. A major area that is not effectively addressed is the large number of on-farm ruminant feeders. In California, there are numerous dairies consisting of a thousand cows or more that receive bulk lots of feed commodities they mix on farm. These operations have not all been inspected as we have with commercial feed mills in the state. We currently conduct BSE inspections on farms when we conduct drug residue investigations under separate contract with FDA. This, however, leaves a large portion of the ruminant feeders without any direct contact from the FDA or the State Feed Control Official. If we want to have thorough coverage to prevent the occurrence of BSE, then the on-farm production of feed needs to be addressed.

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3. Broadening the mammalian protein ban to include blood processed for animal feed should be considered. Other proteins from the carcass may be present as a contaminant in blood products and the use of blood in ruminant feed interferes with laboratory diagnoses important for compliance.

   Unless scientific evidence supports risk to other non-ruminant species and identifies proteins other than mammalian protein that could contain the BSE agent, no further additional ban or action should be taken. There is already a huge disposal issue in the livestock industry; therefore, any unnecessary ban on animal protein is not advised. The illegal dumping of animal carcasses is already an issue in rural areas of the country. This could not only enhance the potential for diseases already present, but may make it difficult for early detection of BSE.

4. & 5. Dedicated facilities would not be required if there was no common equipment used in the production or transportation of prohibited mammalian protein or products containing prohibited mammalian protein. It is possible for facilities to operate dedicated equipment if they wish to produce multi-species feeds. The option should be available for manufacturing facilities to determine if they want to use dedicated equipment to make ruminant feeds or produce only non-ruminant feeds in their facility. Dedicated transportation equipment would reduce the potential for contamination or commingling. A "zero tolerance" policy would result in dedicated facility and transportation equipment. This may not be a feasible option for the transportation industry. Therefore, guidelines for acceptable clean out of transportation equipment, with a mechanism to assure clean out has occurred, would be acceptable.

6. Licensing of rendering and other firms/facilities engaged in the production of animal feed containing mammalian protein would be duplicative of state requirements. The agency can be more effective by working closely with the appropriate state agency already having the authority to regulate such firms to identify and assure compliance with the prohibited mammalian protein rule.

7. The agency should evaluate the current exclusions in Sec. 589.2000(a)(1) and base decisions to revoke or change on valid scientific information along with practicality.

   We recommend that the agency look at how and where blood is collected at the time of slaughter. Samples of feed containing porcine blood examined via microscopy have found bone and hair. If bovine blood is collected in a similar manner, then there is concern that bone and perhaps other tissues (nerve) may also be in blood products. A complete ban of mammalian proteins from ruminant feed would be easier to enforce; however, the inclusion of plate waste in any ban would raise perceived concerns about the safety of food prepared for human consumption.

8. The agency should consider adding any substance that contains prohibited material to the list of prohibited material in ruminant feed. Poultry litter and related poultry waste products may contain prohibited material if they are used in the poultry feed. Poultry litter and processed poultry waste products may contain prohibited materials but are commonly used as a source of non-protein nitrogen for ruminants.

9. The precautionary statement exemption for labeling of pet foods should be removed. Pet foods are commonly recycled or added to ruminant feed by livestock feed manufacturers who are not aware that some pet foods contain prohibited material. Even pet foods that do not include prohibited material may be considered contaminated due to the lack of any clean out requirements for pet food facilities making products both with and without mammalian protein.

10. The length of time for retention of records must be based upon the intended purpose for which they are needed. If the agency needs to have records for future trace back of a BSE-infected animal, then the time frame may be several years. However, it may be impractical to require businesses to retain records for more than three years.

11. The agency should change the rule and require labeling of all animal protein products utilizing the AAFCO official name and source species definitions, for all feed that does not contain the warning statement.

12. Yes, the label cautionary statement should be clarified to state: "Do not feed to cattle, sheep, goats, bison, elk or deer." This would leave no doubt about which species are included in ruminants.

13. We are not aware of new developments for analytical methods to detect and identify prohibited mammalian proteins. While there are ELISA based methods that can detect mammalian proteins, they do not differentiate blood protein from other protein tissues. Sampling done now should employ microscopy to determine the presence of mammalian protein. This will at least determine whether feeds that do not have exempt materials added are contaminated with prohibited material.

14. If there is a genuine concern that there is willful non-compliance, any additional civil or monetary penalties must be severe to serve as a deterrent.

15. Public or private certification programs are helpful in educating firms about the requirements of the rule. Current private programs do not verify that a firm is following established procedures to assure the safety or quality of animal feed in the same way as the California feed safety/quality assurance program.

16. Imported animal feed must be produced under similar requirements as in the United States. Countries that have BSE must be restricted from exporting feed or other products containing prohibited material into the United States.

17. No comments.

The above comments are generated from staff familiar with the implementation of the prohibited mammalian protein ban and the industries impacted by the rule. If you have any questions regarding our comments, please contact Mr. Steven D. Wong, Branch Chief of our Agricultural Commodities and Regulatory Services Branch, at (916) 654-0574.

Thank you for this opportunity to assist in the development of national policy on an important issue having major impact to the agricultural industries of the state and to the well-being of our citizens.

Sincerely,

John M. Donahue, Director
Inspection Services

SW/gc

cc: Mr. William (Bill) Lyons, Jr., Secretary, CDFA
Ms. Valerie Brown, Deputy Secretary, CDFA
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