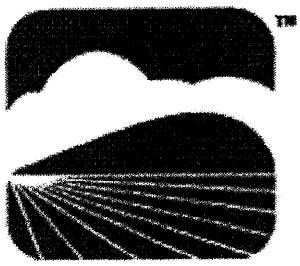
TAB 32



Land O'Lakes Farmland Feed

October 30, 2001

My name is Brad Gottula. I am the Director of Quality Assurance and Regulatory Affairs for Land O' Lakes Farmland Feed. Our company operates 95 feed manufacturing plants in 29 states in the U.S. and in the province of Ontario, Canada. In addition, our branded feed products are manufactured at over 200 locally owned cooperatives in North America. Our company supports the efforts by the FDA and other governmental agencies to prevent BSE from ever becoming a threat in this country. We appreciate the opportunity to respond and give our insight to several of the thought provoking questions that are the focus of this important hearing.

In regards to question 1: What additional enforcement activities, if any, regarding the present rule are needed to provide adequate public health controls? Are there other suggestions for ways to improve compliance with the rule?

We do not believe additional enforcement tools or measures are needed to enforce 21 CFR 589.2000 regulations that ultimately would provide improved safety and public health. The overall educational efforts that have been ongoing for the last 4 years need to remain a primary focus in order to make sure all feed manufacturers and animal producers are adequately informed and educated about this important rule. One of the biggest areas of confusion or inadequacy that has existed with this rule is that some feeders, small feed dealerships and non-FDA licensed feed manufacturers do not seem to understand all of the rule requirements and exemptions. This ultimately leads to non-compliance issues and misinformation as well

as confusion in the marketplace. Continued efforts to educate all entities that are the subject of this rule must be undertaken to improve understanding and compliance. An approach of using targeted inspections of firms who have not consistently proven to be adequately informed and in compliance, or of those firms who are actually rendering or using prohibited mammalian proteins may be an effective method to improve compliance with the requirements of this rule.

Question 3: Should the present FDA ban on the use of certain mammalian proteins in ruminant feed be broadened? If so, what should the new parameters of use be? Should the rule be broadened beyond ruminant feed? Beyond mammalian protein?

The present rule that bans the use of certain mammalian proteins in ruminant feed should only be broadened if compelling scientific evidence supports the fact that an ingredient or product may be a carrier of the BSE agent. Banning products based on anything other than scientific evidence leaves the feed industry and our customers prey to emotion and speculation that ultimately damages the credibility of our nation's animal feed and food supply. Suggestions to ban approved ruminant feed ingredients such as blood products, gelatin and milk products should be halted as scientific evidence from extensive studies done in Europe by the World Health Organization in 1995 have proven that blood products do not carry the BSE agent. Any revocation of an exempted or excluded product currently allowed under 21 CFR 589.2000 should and must be based on sound science. If compelling scientific evidence does not prove a product is a carrier of the BSE agent, it should be allowed or continue to be allowed as an approved feed ingredient for specific species of animals.

Question 4: Should FDA require dedicated facilities for the production of animal feed containing mammalian protein to decrease as much as possible the possibility of comingling during production?

Many feed companies including Land O'Lakes Farmland and Purina Mills have voluntarily made this decision either soon after the publication of the rule in 1997 or more recently. The voluntary stance many companies have adopted and that Land O'Lakes Farmland Feed supports, regarding not manufacturing ruminant feeds in facilities that utilize prohibited mammalian proteins, or to simply not utilize prohibited mammalian proteins in their feed mills, is working and there is little to any added benefit foreseen in making this a mandatory requirement with the absence of BSE in this country.

Question 5: Should FDA require dedicated transportation of animal feed containing mammalian protein to decrease as much as possible the possibility of comingling during transport?

From an efficiency standpoint, this will increase delivery costs and the operational challenges to effectively transport feed and feed ingredients. The recent enactment in South Dakota of specific transportation and handling regulations for delivery vehicles transporting ruminant feeds and feeds that may contain prohibited mammalian proteins will increase costs for feed manufacturers, dealers and customers because it is removing transportation efficiencies that feed manufacturers have utilized in a safe and efficient manner for many years. Today in South Dakota, two delivery vehicles may now be required to deliver a feed shipment, depending upon the type of feed that in the past was easily taken care of by one vehicle. At $1.40 per gallon for fuel for delivery vehicles that typically average 6-7 miles per gallon, this is very expensive for feed manufacturers and haulers, and these costs will be passed on to customers. In the case of prohibited mammalian protein ingredients that are delivered to feed manufacturing sites, we believe there may be some inherent benefit in having dedicated trailers and rail cars for these products as this will likely reduce potential cross contamination issues. However, additional costs will be incurred and passed on to manufacturers, dealers and customers.

Question 11: Should FDA change its rule to require labeling of protein- containing feed to specify what type(s) of mammal was used in the production of the protein, e.g. ``porcine MBM", ``bovine MBM"? AAFCO has utilized, and FDA has endorsed the use of the collective feed term concept in 35 states since the early 1970's. The concept is based on the sound nutritional principle that animals do not require any specific feed ingredients, but need nutrients that can be supplied by a wide range of ingredients. The benefits of these terms are many but primarily result in lower cost to the producer/customer, without any sacrifice in safety or nutrition. No other labeling concept has been nearly so successful in the feed industry.

Of the seven collective terms acting legally as definitions on feed labels, the one with the most current concern is "animal protein products." In 1998, AAFCO asterisked (*) all the feed definitions within this term which are prohibited/restricted in ruminant feeds as per 21 CFR, § 589.2000. The feed industry strongly supported this effort.

FDA requires firms to place the caution statement: **"Do not feed to cattle or other ruminants."** on any labels or labeling containing or likely to contain any substances prohibited in ruminant feed. This statement is the sole label indicator that a feed is likely to contain a restricted use protein product from the list of asterisked (*) products in the AAFCO animal protein product collective term. If a firm does not use the cautionary statement, it indicates the feed does not contain restricted use protein products.

Some regulatory officials believe that doing away with the "animal protein products" collective term would simplify regulatory obligations. This view is not necessarily correct, as, verification of the ingredients actually used in a feed formula requires review of formula records, regardless of whether a collective term is used. For example, if a firm were to use meat and bone meal on a label without the

collective term, verification would still be required in order to document the actual ingredient used is indeed the one on the label.

If AAFCO or FDA were to change the animal protein ingredient names to require species names, as is already voluntarily allowed, the names would be "porcine (or pork) meat and bone meal" and "bovine (or beef) meat and bone meal." If a firm chooses to use one of these names on a label with or without the cautionary statement, investigators would still be required to examine formulas and ingredient records to verify if, in fact, the correct product and ingredient name were used. Any changes made to the collective term or ingredient listings on feed labels must be based on a sound understanding that the change will result in better compliance, better regulation or better prevention of BSE. Moreover, a review of inspection data collected by FDA should clearly reveal that either there is widespread abuse of the term or serious misbranding to justify changing these ingredient names. That justification does not exist at this time.

Regulatory changes regarding the use of collective feed labeling terms will result in substantial costs to change feed labels and feed manufacturers and regulatory agencies must justify the costs from any benefits derived. Regulatory changes regarding changes in accepted feed labeling practices moves our industry further from having uniform feed labeling guidelines across state lines and further hampers effective and efficient business practices as mentioned earlier with the example in South Dakota and the additional regulations they have now implemented regarding feed labeling, handling and transportation. As the U.S. does not have BSE, it is difficult to justify this major change to feed labeling regulations.

Question 12: In order to make the statement clearer, should the required cautionary statement on the label of products that contain protein derived from mammalian tissues and that are intended for use in animal feed be changed to read: ``**Do not feed to cattle, sheep, goats, bison, elk, or deer.**''?

We do not believe changes are needed in the caution statement, as the statement is adequate to communicate the intended information provided people using the product look for the statement and read and follow the product label. Label changes cost the feed industry hundreds of thousands of dollars annually and changes of this magnitude must be weighed as to if they will result in improved compliance or more effective prevention of BSE. A change in the caution statement wording would be quite costly to the feed industry and would provide little if any added benefit to the feed customer and consumer who ultimately must pay for these changes.

Question 15: Regarding helping to increase compliance with the rule, what role, if any, should public or private certification programs play?

Certification programs can exist in a variety of forms. Affidavits and self-certification forms are and should be widely accepted as many companies are in compliance with this rule and have excellent documentation in their quality assurance and regulatory programs that prove this. FDA has recently updated their BSE Inspection Form to include an "Inspection Findings Summary" section in which when the inspection findings or Inspection Report is eventually shared with the firm that has been inspected, compliance or non-compliance with the BSE rule is documented. This should be ample proof to any feed customer or livestock buyer that the firm in question is in compliance with 21 CFR 589.2000. Fee based third party certification programs may be of interest to some companies but our view is that FDA must be cautious in whether or not it endorses such certification programs, as this may open the door to unfair competition in the marketplace by companies who would possibly leverage livestock buyers and food

companies to only purchase animals fed by third party certified feed manufacturers. Our firm belief is that state and federal BSE inspection programs are working and should continue to be the compliance indicator for the regulated industry. Funding should continue to be directed towards this end.

Land O'Lakes Farmland Feed appreciates the opportunity to share our views on this important feed regulation. We have worked diligently to inform our employees and customers of this rule's requirements and pledge to continue to do all we can to prevent BSE from threatening our nations feed and food supply. We would like to commend FDA for its scientific view of this important issue and urge that they continue to foster open dialogue and reason regarding this rule as it is evaluated as to its effectiveness. Thank You.

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