



LAND O LAKES® Feed

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

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Docket No. 2004N-0264
Regulatory Identification No. (RIN) 0910-AF46

Land O'Lakes Farmland Feed LLC ("LOLFL"), together with its subsidiaries, is a major manufacturer and distributor of animal feed. LOLFL also works with cooperative feed manufacturers and dealers marketing brands, such as LAND O LAKES® Feed and Purina Mills products, and other independent businesses manufacturing and selling animal feed who are stakeholders in the U.S. food safety system. LOLFL manufactures many species of animal feeds and, therefore, is and will be impacted by the BSE rules as are the suppliers of many of the animal feed ingredients used by LOLFL and the customers of LOLFL animal feed products. The proposed changes under consideration may and can have a significant impact to present animal feeding systems by altering economics of feed ingredients, animal feed product formulations and thus their costs, animal feeding practices, and the consumption of animal products by humans both within the United States, and through exports of United States animal products.

In 1997, FDA established several "firewalls" to protect against the spread of BSE to the United States, and within the United States even though BSE has not originated here. The firewalls established in 1997 are viewed by most industry participants as being effective in helping to assure the continued freedom that our beef industry enjoys from the threat of BSE and the continued confidence of our beef consumer. However, because of cases (separate single cases, one in Canada, one in Washington State, both of Canadian origin) in North America which are discussed in the above referenced document, and the increasing pressures from foreign countries which make up the bulk of our export trade, the agency is considering additional prevention safeguards to the existing firewalls within the United States.

LOLFL commends FDA and USDA for the proactive approach both agencies continue to take in assuring the safety of our beef supply in the United States while continuing to support science and a risk-based approach in the establishment of regulatory policies for BSE control in this country. LOLFL strongly believes that it is very important to wait until USDA completes its current expanded BSE surveillance program, which is to test over 260,000 animals for BSE, before additional firewalls which have the potential for major disruption of our present animal system, to be enacted. USDA's stepped-up testing program has less than 16 months to go. Data from this additional testing will provide the agencies with information needed to assess the extent of BSE potential in this country, if indeed there is any. Further, this will also provide additional time to collect needed facts

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as to the costs of SRM removal and the extent of SRM removal that could and/or should be done on an economical basis without adversely impacting our present animal system.

However, LOLFL is concerned that today we have potential weakness in the present firewalls established in 1997, which we believe need to be strengthened to assure the continued success of these firewalls. The present weaknesses could be strengthened now, without establishing new firewalls, until completion of the USDA animal testing, and the gathering of additional economic impact information on SRM removal. These weaknesses are as follows:

- There is a real potential for cross contamination of feed ingredients that might be used in ruminant animal feeds at renders that continue to handle prohibited material, and other feed ingredients in the same facility. LOLFL believes that separate facilities should be required for renderers that manufacture prohibited material, so that any other ingredients that they render can not be used in ruminant animal feed. We do not believe that a program of clean out is the best way to assure against the potential for human error in the contamination of a non-prohibited material feed ingredient from these facilities.
- Feed manufacturers that handle prohibited material in the manufacture of feeds should not be manufacturing ruminant feeds and, therefore, separate facilities should be required as noted above for renderers. Again, LOLFL does not believe that clean out practices are adequate in assuring against human error in the cross contamination of ruminant feeds with prohibited protein.
- LOLFL believes that dedicated trucks and rail cars should be required for the handling of prohibited protein. We can not trust clean out practices in the use of the same truck or rail car for handling of both prohibited material, and other ingredients that may be used in ruminant feeds. The potential for human error is too great.
- LOLFL strongly believes that prohibited material should be restricted to sale and used only by those licensed by FDA to handle prohibited material. We believe a license, similar to that required for users of Category II, type A drug sources, should be required for anyone to purchase prohibited material from a renderer who is licensed to render prohibited material. Provisions for the license should include record keeping of those who purchase the material, so that all prohibited material can be traced to the ultimate feeder. Further, LOLFL strongly believes that oversight mandatory inspection should be part of the licensing requirement, from the renderer all the way to the end user/feeder.

LOLFL believes that these changes to the existing firewalls will assure compliance with the intent of FDA's 1997 rule, as USDA and FDA are completing the stepped up BSE animal testing and gathering of economic data and need for SRM removal. LOLFL further believes that additional firewalls may be needed to help assure continued safety, such as partial or full SRM removal. LOLFL believes that those in the best position to

review the economics and the impact of such actions should be the decision makers as to the need for additional firewalls as discussed in the above referenced advance notice of proposed rulemaking. LOLFL believes that USDA and FDA are the best positioned for these types of decisions. We also believe that such additional measures may need to be coupled with the suggested strengthening of the existing firewalls to ensure that the objectives of the 1997 BSE rule are indeed fully realized.

We have not addressed the specific questions in our comments as we believe they are best left to those who can and will provide data in response to the questions. It is our thinking that the agency will evaluate all data provided and come to the appropriate conclusions as to the direction of additional firewalls needed. Our thoughts in these comments are to strengthen the existing firewalls. However, in regard to question number 12, we would like to respond with our concern.

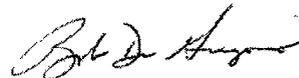
12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

LOLFL believes there is no scientific justification for banning avian and/or other mammalian (porcine or equine) meat and bone meal from ruminant feed since these materials have never been shown to harbor BSE infectivity nor are they in any way connected with BSE or it's transfer. We believe that the present firewalls, strengthened as we suggest in our comments, are consistent with the findings of the Harvard Center for Risk Analysis study for assurance of continued freedom from BSE infection in this country.

LOLFL believes that any such ban would totally disrupt the present animal feeding system based on an increase in the costs of protein sources available to the ruminant feeder, the limited ingredient alternatives for animal nutrition needs, nutritional and production issues that will adversely impact the animal producer, and the disposal and disease issues associated with this alternative.

Again, LOLFL appreciates this opportunity to comment. Our staff is available to meet with the agency at any time to clarify any of our comments and/or assist the agency in anyway we can in the mutual objective of preventing the establishment or spread of BSE in the United States.

Sincerely,



Robert M. DeGregorio, President
Land O'Lakes Farmland Feed LLC