

Land O'Lakes Purina Feed LLC

December 12, 2005

0775 5 DEC 15 P2:01

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

Docket No. 2002N-0273
Regulatory Identification No. (RIN) 0910-AF46
Substances Prohibited From Use in Animal Food or Feed

Land O'Lakes Purina Feed LLC ("LOLPF"), together with its subsidiaries, is a major manufacturer and distributor of animal feed. LOLPF also works with cooperative feed manufacturers and dealers marketing brands, such as LAND O LAKES® Feed products and Purina Mills® products, and other independent businesses manufacturing and selling animal feed who are stakeholders in the U.S. food safety system. LOLPF manufactures animal feeds for multiple species and, therefore, is and will be impacted by the BSE rules as are the suppliers of many of the animal feed ingredients used by LOLPF and the customers of LOLPF animal feed products. The proposed changes under consideration may have a significant impact to present animal feeding systems by altering economics of feed ingredients, animal feed product formulations and thus their costs. While LOLPF fully supports the Food and Drug Administration's (FDA) proposed action and its efforts to maintain our present healthy, nutritious and affordable food supply, we also provide the following comments relative to the proposed rule changes.

In 1997, FDA established several "firewalls" to protect against the spread of BSE to and within the United States. To further strengthen these firewalls, FDA has proposed additional measures prohibiting "high risk" cattle materials from being utilized in animal and ruminant feed. Although these new prohibitions will strengthen the 1997 firewalls, we would further support:

- Dedicated facilities/equipment/transportation
- Control over the sale, distribution and use of prohibited material

The following are our concerns:

Dedicated facilities/equipment/transportation as it relates to cross contamination.

- LOLPF believes that while the potential of infectivity in prohibited material is greatly reduced by removal of SRM's, the concern for cross contamination continues to be very real and may result in a weakened compliance with the existing 1997 rules. The agency has noted that a smaller amount of infectivity, as low as 0.01 gram of brain tissue from a BSE infected animal, can cause BSE. As such, this needs to be addressed or further clarified by FDA in the final rule.

02N-0273

P.O. Box 64281 • St. Paul, MN 55164-0281
1080 County Road F West • Shoreview, MN 55126

C 422

- Some producers, users and feeders of prohibited material (ruminant meat and bone meal) may believe that ruminant meat and bone meal and other previously prohibited ingredients are now safe for use in animal feed which could lead to cross contamination. Dedicated facilities/equipment (including truck and rail) would eliminate the potential for human error in any clean out procedures for renderers and feed manufacturers that handle such material.

Control over the sale, distribution and use of prohibited material.

- Due to the potential of favorable economics driving the use of prohibited material, LOLPF strongly believes that prohibited material should be restricted to sale and use only by those licensed by FDA to handle prohibited material, similar to that required for users of Category II, type A drug sources. In addition, mandatory inspection should be part of the licensing requirement, from the renderer all the way to the end user/feeder.

In addition, we fully support the agency's proposed action for record keeping for those responsible for SRM removal.

Without the recommended additions, we believe the beef industry would be subjected to a higher level of risk than should be tolerated. The agency estimates that 124 of 5,100 feed mills (which we believe does not include many non-registered feed mills), and 41 out of 235 renderers, handle both prohibited material and ruminant feed/feed ingredients. We are concerned more mills and renderers will handle both prohibited material and ruminant feed and feed ingredients if the historical concern is perceived to be lessened.

LOLPF recognizes the value and breadth of our industry partners and endorses NGFA's response with the following clarifications:

- NGFA believes the dedicated facility for handling of prohibited material should be voluntary while we believe it should be a mandatory requirement of food safety;
- NGFA recommends licensing for the manufacture of prohibited material and removal of SRM's while we believe licensing should be applicable to all who manufacture or use.

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

Sincerely,



Fernando Palacios
President
Land O'Lakes Purina Feed LLC