



LAND O LAKES[®]
Feed

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

August 27, 2004

RE: Docket No. 2003N-0312

**Discussion of Animal Feed Safety System: A Comprehensive Risk-Based Safety Program for the Manufacture and Distribution of Animal Feeds;
Request for comments:**

Land O'Lakes Farmland Feed LLC ("LOLFL"), together with its subsidiaries, is a major manufacturer and distributor of animal feed, including medicated feed, and therefore has a vital interest in the potential development of a comprehensive, risk-based animal feed safety system (AFSS) describing how animal feeds (individual ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from animals. 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 filed comments with CVM relative to the initial FR request for comment on October 2, 2003. Company representatives also attended a meeting on September 23-24, 2003, and were active in that meeting providing information requested by CVM representatives. LOLFL continues to believe that this is an extremely important initiative by CVM which we fully support. All statements and positions taken in our October 2, 2003 comments referenced above continue to be relevant and fully supported by our company. The following comments are to address those issues raised in your recent request for comment.

Under **COMPREHENSIVE, RISK-BASED, AND ELEMENTS OF AN ANIMAL FEED SAFETY SYSTEM**, LOLFL offers these comments of clarification. While we fully agree with the concepts, we believe directional clarification is needed. The agency resources should be directed to where there are presently no rules of guidance and/or where presently there are no oversight inspections.

COMPREHENSIVE

1. "It would apply to the whole range of feed products, including all ingredients and finished product."

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An Animal Feed Safety System should apply to all feed ingredients and final products. However, commercial feed products are presently subject to cGMP's and oversight inspections. Presently no cGMP's or oversight inspections apply to feed ingredients, or to most on farm mixing and feeding.

2. "Use ingredients approved and/or recognized by an established regulatory agency or entity whose members are charged with a responsibility of enforcing laws regulating the production, labeling, distribution, or sale of animal feeds."

We fully agree that all ingredients used in animal feeding should be approved ingredients. However this is not true today primarily because of a lack of enforcements by both states and FDA. We believe that, in this situation, the onus is on the agency to enforce the present feed rules and not permit the continued feeding of non-approved additives.

3. "Cover the complete range and variety of facilities involved in animal feed production."

All facilities should be included in the feed safety program. Today, only commercial feed mills using animal drugs are included in published rules and oversight inspections. We believe ingredient facilities and on farm mixing should be included in both appropriate feed rules and oversight inspections.

While the cGMP's are appropriate for the medicated feed industry, as they have been applied during the last half of the 20th century, the other industry segments must work with the agency in the development of rules that are appropriate for their food safety issues, as has been done for medicated feed. A one-size-fits-all approach will not be effective in the human food safety effort.

4. "Have the flexibility to be process or product-oriented, depending on the situation."

We fully support this direction. Many feed safety issues are not process related and are ingredient related such as dioxin, mycotoxins and various pesticides. While cGMP's are appropriate for the medicated feed industry, most other segments can use HACCP principles more effectively. Each industry segment must step up and work with the agency in this effort.

5. "Address feeds produced for food and non-food animals."

We certainly believe non-food animal feed products should be safe. However, from a public interest standpoint, consistent with agency resources, the priority and direction should be to address and establish an Animal Feed Safety System targeting food animals that become human food. Presently, tort laws

and liability issues are effective in helping to protect animal health. The agency has limited resources, which we believe are best used in targeting human food safety issues.

6. "Cover all known hazards, and be applicable to hazards not yet identified."

The action needed to assure human and animal food safety for a given hazard depends upon the nature of the hazard. A given program for one hazard may not have any relevance to another safety hazard. We believe each hazard must be addressed on its own conditions. A program should be applicable to hazards not yet identified. We believe the development of this program should focus on the known hazards, and minimal time should be spent on the hazards not yet identified. The definition of "hazard" needs critical consideration and should be science based relative to human feed safety concerns. Hazards need to be evaluated relative to food safety risks and addressed appropriately. A one-size-fits-all approach will not result in improved food safety but in increased compliance and enforcement administration costs.

7. "Address both human and animal health issues."

Again, we believe that human health issues should be the priority, and that animal health issues, while important, should not be addressed unless the animal health issue has an impact on human health.

8. "Acknowledge and coordinate regulatory authorities at all levels, including local, state, tribal and federal, involved in feed safety."

LOLFL strongly supports state feed inclusion in the federal feed safety program. Today, states play a very important role in animal feed safety. This is a very important resource for the Center for Veterinary Medicine (CVM) to use. LOLFL is concerned that the use of third party inspections is diminishing the important role FDA and the states play today in human and animal feed safety. We believe the public would be better served if the agency adopted VSIP, a program developed jointly by the feed industry, FDA and the states, that will continue the important oversight role of government, yet free resources of FDA and states for other important food safety issues. State and federal oversight has worked very well coupled with the cGMP's, and it's time to expand jurisdiction and rules to the other industry segments where oversight has not been established. LOLFL encourages careful consideration of adding additional regulations on FDA licensed feed mills, which are not the primary source of food safety problems today.

RISK-BASED

LOLFL fully agrees with the language of the Risk-Based section. However, we note deviations from that language in other sections attempting to regulate more than just food safety hazards, such as a program that will be applicable to hazards not yet identified. Further, there is concern that the feed safety focus will continue to be on the commercial feed mill, which already has regulations and enforcement.

LOLFL recognizes the need to also address perceived food safety hazards that impact the economics of agriculture, such as the BSE and Foot & Mouth disease scare that goes beyond known science. In those cases, LOLFL supports the agency's approach to food safety to date as well as its proposed approach moving forward.

The primary concern LOLFL continues to have in feed safety is that regulation and enforcement will continue to focus on the same segment of the feed industry, namely the commercial feed mill, and will not address other segments such as ingredients, transportation, and on farm users and mixers. Data supports that the commercial feed mill segment is an insignificant factor relative to food safety problems. Less than one percent of known illegal residues are caused by commercial feed mills.

ELEMENTS OF AN ANIMAL FEED SAFETY SYSTEM

“The following bullets are some basic elements of any animal feed safety system. Every feed and/or feed ingredient transporter, processor, distributor, and user should be incorporating these elements into their animal feed business process. The detail and extent to which any of these elements apply to a specific product or line of products will depend on the product itself, its use, the facility structure and equipment, and the distribution and feeding mechanism.”

LOLFL supports the above statement, but we wish to point out that existing rules are only published for the commercial segment of the above, and that enforcement is presently only on the commercial feed mill. We believe that, to be successful, rules and enforcement must be expanded to the other feed segments – and applied and enforced as aggressively as they have been for licensed commercial feed mills.

LOLFL also believes that the following sections support the value of the present medicated feed cGMP's (21 CFR 225), and the importance of their recognition as critical tools for feed safety. More emphasis needs to be placed upon the importance and contribution made by our present medicated feed rules in both domestic feed safety and international trade feed safety.

“1. Incoming materials-know what you are getting. (a. through f.)”

These guidelines are on target, but will vary in detail and thoroughness depending upon the incoming material and the feed industry segment. The present feed cGMP's (21 CFR 225) for the commercial feed mill adequately address incoming materials. LOLFL would encourage similar cGMP's for the other feed industry segments.

“2. Processing/Manufacture”

Again, for the commercial feed mill, 21 CFR 225 addresses these issues. LOLFL is in full agreement with these requirements, as currently written, and encourages their extension to the other industry segments where appropriate.

“3. Record Keeping”

These requirements are consistent with current medicated feed cGMP's, and LOLFL is fully supportive of their continued need and use for commercial mills. These requirements should be extended to the other feed industry segments where appropriate.

“4. Distribution/Transportation/Feeding”

We agree with all requirements of this section, but because the section is targeted solely to the commercial feed mill, we would include other requirements as follows:

- Have records of what transportation vehicle has been used, for and when. Have cleaning records showing when cleaned and how.
- Have records of which feed bins at a feeder's facility have been used, for and when. Feeding bins should be appropriately labeled at all times for appropriate identification of feed.
- Have records to identify all feed/feed ingredients received at a feeding facility, how used, and disposition of unused feed.

”5. Inspection/Audit/Corrective Action”

Again, while we agree with the requirements of this section, the requirements are targeted to the commercial feed mill. What types of audits and corrective action are needed for an ingredient supplier? These need to be focused on the ingredient and the nature of the ingredient production. What kinds of audits are appropriate for a feeder and what is the nature of corrective action in these instances? What about animal and feed ingredient recalls? The focus tends to be on a feed product recall. Our concern is that the language is targeted to the commercial feed product.

“6. Responsibilities”

Expand a. to read: “Determine responsible individuals for controls and corrective action throughout the receipt, transportation, process, distribution, feeding and marketing of feed ingredients, feed products and food animals.”

“7. Training”

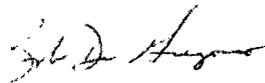
Discussion is on employees, but how about self-employed, such as many on farm mixers and feeders? Again, the language is targeted to the commercial feed mill, and this section needs to address ingredient suppliers, transportation, and on farm mixing and feeding.

LOLFL appreciates the opportunity to provide comment on the proposed outline for development of an Animal Feed Safety System. While we support the outline and approach, we are concerned that the focus will continue to be placed solely on one industry segment, the commercial feed mill. Control systems vary, but generally they have a number of common basic elements. These include the following elements: (1) A thorough analysis of manufacturing and distribution for each product (ingredient/feed product/animal), (2) identification of risks associated with the process and product, (3) identification and implementation of controls to effectively prevent identified risks, (4) employee training programs, (5) controls focused on critical steps, (6) assurances that such steps are accurately and consistently performed, and (7) record keeping and validation of the system.

We encourage CVM to handle these elements on an industry segment-by-segment basis. rather than through an industry-wide, one-size-fits-all approach. Each industry segment has very unique feed safety issues and challenges, and feed safety issues need to be addressed accordingly. Finally, the feed safety initiative will not be resolved by adding more regulation to the licensed mills that the FDA and states already regulate.

Again, LOLFL appreciates the opportunity to comment. Our staff is available to meet with the agency at any time to help develop the feed safety initiative or offer further comments on feed safety issues in general.

Sincerely,



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