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

October 16, 2003

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 is a major supporter of food safety and continues to be supportive of FDA efforts to assure the world's most nutritious, safe and affordable food supply. Representatives from our company, including myself, have met with agency representatives to convey our support for food safety and to pledge our ongoing efforts to enhance the safety and suitability of our products. We view CVM's effort as a review of all food safety programs in place today for the purpose of identifying where present programs need improvement and identify gaps where no programs exist and are needed to assure the continued safety of our food supply.

The Federal Register Notice (7/28/03) summary states: "The Food and Drug Administration (FDA) is announcing a meeting to discuss 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..." We at LOLFL are concerned that this stated mission does not include all industry segments in the feed safety chain, and thus does not encourage FDA to look at all aspects of the animal feeding chain, including ingredient producer, transportation and on farm practices that might compromise food safety.

Before we direct our comments to the discussion topics contained in the above referenced Federal Register, we would like to place emphasis on the need for appropriate regulation of all segments of the feeding industry. Today, current regulations cover medicated feeds (21 CFR 225), prohibited proteins (21 CFR 589.2000) and salmonella (21 CFR 500.35). Other than these regulations, there are no federal rules relative to feed safety. In addition, state feed laws tend to focus on enforcement of label guarantees (protein, fat and fiber).

We at LOLFL strongly believe that the FDA now has an opportunity to correct this unbalanced approach to food safety by establishing appropriate focus on all industry segments and reallocating resources to those industry segments in the food safety chain that currently have no food safety rules or enforcement. These other industry segments include ingredients, non-licensed feed mills, transportation of feed ingredients and on farm practices. The licensed feed mills have a feed safety bar in the medicated feed cGMP's (21 CFR 225) that are well understood and have served the industry well in providing safe feed for animals. Outside of the medicated feed cGMP's, there is no other recognized feed safety bar for the other industry segments.

This is also an opportunity for state and federal governments to work together in the feed safety process. Today, AAFCO is working on a Model Feed Process Control Program. We believe FDA should take an active role in this effort and make it part of CVM's total feed safety initiative. FDA should also work with state enforcement to make states a vital part of the feed safety process, redirecting resources for the public benefit.

Finally, a tremendous opportunity exists for government and industry to work together. LOLFL pledges to work with the agency to help further our common objective of continuing to provide the American consumer with the world's safest, most nutritious and most affordable food supply.

We now turn our comments to the topics on which the agency has requested industry input.

WHAT ARE THE STRENGTHS OF THE CURRENT FEDERAL AND STATE REGULATORY PROGRAMS FOR FEED SAFETY?

a. Medicated feed cGMP's (21 CFR 225) work very well and have a proven track record at the FDA licensed feed mills. We do not believe the value of cGMP's has been properly understood in the feed safety effort, domestically or internationally.

b. The BSE (21 CFR 589.2000) rule has worked very well in controlling the intentional use of mammalian tissue in ruminant feeds.

c. State feed control has helped in the feed safety initiative through the federal/state inspection program. However, only about half of the states participate. State feed programs tend to be economically focused.

WHAT ARE THE WEAKNESSES OF THE CURRENT FEDERAL AND STATE REGULATORY PROGRAMS FOR FEED SAFETY?

a. Enforcement is concentrated on the licensed feed mills, which are responsible for less that 13% of the animal feed fed to animals in the U.S.

b. No cGMP's or other feed safety guidelines are in place for animal feed ingredients, non-medicated feeds, transportation and on farm feed practices.

c. Assay tools are needed for monitoring and detecting feed safety hazards in feed ingredients. These include pathogens, dioxins, pesticides, etc. Today, these monitoring tools are very limited.

d. Lack of enforcement on unapproved feed ingredient additives is a weakness. Many feed additives that are marketed, and even advertised, nationally have not received FDA or state acceptance, recognition or official definitions.

e. Another weakness is the lack of effective feed safety guidelines (on farm) or oversight after feed leaves the feed mill and until the feed is consumed by animals. For example, pelleted feed is free of salmonella immediately following pelleting but has the potential for re-infection up to the time consumed by animals because of handling practices in distribution and feeding.

f. If the feeding of mammalian protein to ruminants can really cause BSE, then the potential for cross contamination must be better controlled. Separate facilities, especially at the rendering level, are needed to assure integrity of non-prohibited rendered product.

g. Government could provide regulatory/inspection-based incentives through such programs as an AAFCO/Industry/FDA jointly adopted Voluntary Self Inspection Program (VSIP) for feed mills. Such programs could help state and federal program resources from the presently heavily regulated licensed feed mill to other segments of the animal feeding industry. Existing industry-sponsored programs have been driven primarily by marketing opportunities and liability risks; however, no common compliance bar has been established. In the case of VSIP, a commonly understood compliance bar exists, relative to the medicated feed cGMP's.

WHAT ARE THE STRENGTHS AND WEAKNESSES OF CURRENT INDUSTRY FEED SAFETY PROGRAMS?

a. The present program only provides oversight for the large licensed feed mills, which are the most compliant of the food system. Oversight is needed for feed ingredients and the other segments of the feeding industry not presently subject to oversight.

b. The cGMP's have a compliance bar that is understood and recognized by the industry. Other so called feed safety programs lack this common bar.

c. The value of medicated feed cGMP's is not understood by those outside the feed industry. cGMP's are not being effectively promoted for food safety.

d. AAFCO has developed "Best Management Practices" for non-medicated feed and ingredient manufacturers. FDA should look into formalizing these practices in FDA regulations.

e. The U.S. feed industry is experiencing a proliferation of programs such as HACCP, HACCP-like, ISO, etc., which are confusing to the feed industry, regulatory bodies such as FDA and state regulators, and customers of the feed industry. A commonly understood bar is needed.

WHAT ARE THE POTENTIAL BENEFITS OF A COMPREHENSIVE, RISK-BASED FEDERAL FEED SAFETY PROGRAM?

a. Such a program could provide a common bar understood by all.

b. A program could be of value in world trade, to overcome trade barriers, while not contributing to domestic feed manufacturing safety, as present cGMP's are the most adequate means for regulating medicated feed. A new program may have more value for non-regulated feed articles such as feed ingredients.

c. A new program could bring proper food safety guidelines and enforcement to other segments of the feed industry that are not presently regulated. Today the focus is on the licensed feed mill. The 87% of feed fed, that is not presently regulated, could and should be brought under the same compliance rules.

WHAT COMPONENTS SHOULD BE INCLUDED IN AN AFSS?

a. Look at all segments of the feed industry. Don't reinvent regulation for large feed mills, but recognize the success of present programs.

b. Include cGMP's similar to the medicated feed cGMP's for other industry segments not presently regulated. Also, look at the non-medicated "Best Management Practices" developed by AAFCO. Be careful to allow needed flexibility for industry to identify feed safety issues and develop compliance programs.

c. Any feed safety risks incorporated into an animal feed safety system must be science-based, which may require a significant research component to identify specific hazards and the levels at which such hazards pose a risk to human or animal health.

d. If additional testing requirements are a requirement of an animal feed safety system, then accurate, inexpensive and rapid diagnostic tests (such as assays) that yield accurate, repeatable results must be developed and available for use in monitoring and detecting identified risks. These rapid tests need to be approved by FDA, and FDA should not allow manufacturers or suppliers to self-proclaim the accuracy or reliability results of these tests without exhaustive testing by FDA. State regulators should not be allowed to adopt these rapid tests as standards without FDA approval.

e. A federal animal feed safety system must be integrated seamlessly with state programs and be supported by state feed control officials.

f. An animal feed safety system should not be HACCP based in concept since feed manufacturers have a unique set of processing elements that do not conform to HACCP concepts used in other industries. A cGMP type policy is more appropriate and should be the foundation of any animal feed safety system.

WHAT IS THE POTENTIAL BURDEN (INCREASED COST AND MANPOWER) OF A COMPREHENSIVE, RISK-BASED FEDERAL FEED SAFETY PROGRAM, AND WHAT OPTIONS ARE AVAILABLE TO MINIMIZE THE BURDEN?

a. The challenge of on farm enforcement must be overcome.

b. New jurisdiction issues in feed ingredient rules and enforcement will arise.

c. Much greater cooperation among the states is required.

d. Introduction of programs like VSIP and other voluntary self inspection/compliance programs will help to free enforcement resources for other feed safety enforcement initiatives.

e. Foreign trade issues will arise due to the differences between cGMP's and HACCP.

f. A comprehensive, risk-based feed safety program calls for new assay tools that are very costly.

g. Feed industry operating costs will rise to meet additional demands of additional regulations – i.e., procedure modifications, record keeping, etc.

We at LOLFL appreciate the opportunity to comment. We are available to meet with the agency at any time to help with the feed safety initiative or to offer further comments on these important issues.

Sincerely,

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