



**LAND O LAKES®  
Feed**

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

February 28, 2005

**RE: Docket No. 2003N-0312**

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

Land O'Lakes Purina Feed LLC ("LOLPF"), 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. LOLPF 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.

LOLPF 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. In addition, LOLPF submitted comments dated May 4, 2004, in response to the agency's request for comments called Discussion of Animal Feed Safety System. LOLPF continues to support all statements and positions taken in these previous submissions to the agency. The following comments are to address those issues raised in your recent request for comment.

## **DRAFT FRAMEWORK OF THE FDA ANIMAL FEED SAFETY SYSTEM**

### **COMPONENT #1. INGREDIENTS AND THE APPROVAL PROCESS**

LOLPF certainly supports CVM's development of a "Compliance Policy Guide" (CPG) that would explain the relationship between FDA and AAFCO and reinforce present policy whereby FDA recognizes ingredients defined in AAFCO's Official Publication (OP) as acceptable for use in animal feed. In addition, a regulation articulating this policy would also be helpful. However, today FDA has by regulation adopted the collective terms defined by AAFCO. Further, in practice, CVM is a partner with AAFCO in the addition of any new ingredients, or changes to existing ingredient definitions in

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AAFCO's OP. We believe the shortcoming of the system has been and continues to be the lack of enforcement rather than an understanding of policy.

Many ingredients included in animal feed today have not passed one of the hurdles (ingredient has an AAFCO definition, or is listed by FDA regulation, or has been established as GRAS under FDA rules, or has been the subject of an advisory opinion (formal or informal) and no action is being taken against them by either states or CVM. There are many examples of ingredients without official status, but enjoying tacit approval because of a lack of Federal and State enforcement.

The state feed control officials have expressed concern that when they attempt to take action against the marketing of non-approved additives, they do not receive the support of FDA in the enforcement process. Therefore, we believe that the Gap should direct its attention to enforcement of the present laws and improve their language, if needed, for proper enforcement.

## **COMPONENT #2. LIMITS FOR ANIMAL FEED CONTAMINANTS**

Gap 1:

... The AFSS Team will use this risk information to develop a risk-based approach for 1) determining which feed contaminants present the greatest risk to animal and human health and 2) deciding how such risks can be prevented or controlled.

The ranking of risks from potentially hazardous contaminants in animal feed is a very difficult and perhaps an impossible task. When done, it will give the public a false sense of security considering the dynamics of contaminants. Today, the tolerance for contaminants is zero. We believe agency resources would be better used, and the public better served, in the establishment of cGMP's for ingredient suppliers. cGMP's, and oversight inspections, would better assure the safety of the ingredients. We see the process that would be put into place as proposed in this Gap as an expensive scheme to define contaminants and require testing by the feed manufacturer for compliance with such defined contaminants. Ingredient risk changes constantly, and therefore, the focus should be on the purity of a particular ingredient. cGMP's have worked very well for feed manufacturers over the years and should be adopted upstream and downstream from the feed mill.

Gap 2:

Considering that the present tolerance is zero unless otherwise established by regulation, and that the EU has established many tolerance and action levels, we do not see the problem as a lack of guidance for harmful levels. We do, however, believe that quick and accurate tests are needed, but we do not see this solution as helping in the immediate future. The problem is lack of knowledge that the contamination was in the ingredient. Testing continues to be expensive, if a test exists at all, thus limiting the amount of testing, even if tolerances are established. The remedy today is keeping the contaminant out of the ingredient initially.

We see the real issues as the need for increased focus of the agency to enforce present laws on the marketing of non-approved ingredients, the inefficiency of the present ingredient approval process, and the lack of oversight inspection over ingredient manufacturers and distributors. Today there are no guidelines for the safe manufacture and distribution of feed ingredients to establish an industry standard, and there should be. AFFCO has established a guide (Best Management Practices) that can be applied to ingredient manufacturers, but it has not been embraced by the ingredient industry, nor have any oversight inspections been established. We suggest the above concern be identified as the Gap in Component #2.

Gap 3:

We would support the continued close working relationship of FDA with USDA relative to “improving methods of preventing, coordinating responses to, and investigating terrorist incidents involving the deliberate contamination of feed or feed ingredients with an exotic animal disease.”

**COMPONENT #3. PROCESS CONTROL FOR THE PRODUCTION OF FEED INGREDIENTS AND MIXED FEED**

We believe that the identified Gap is not correct. The Gap is focused solely on the medicated feed industry. The Gap recognizes the medicated feed cGMP's but believes a broader approach is needed that includes HACCP.

Enforcement of feed safety has been and continues to be focused on the medicated commercial feed industry. This industry segment is now recognized as providing less than 30% of the feed fed to food animals, and has a very safe track record for providing safe and effective products to the animal feeding industry.

We believe that, to move forward with HACCP on this industry segment, will formalize more requirements adding cost without providing a safer product to the animal feeder.

The animal feeder is not willing to pay for additional safeguards that he does not see as beneficial to his feeding practices. This will only result in more feed being made on farm, and in integrated facilities by-passing the present enforcement programs.

As we have said before, it is very important for the agency to extend feed safety programs up and downstream from the commercial feed manufacturer. This means ingredient suppliers and animal feeders. To continue to add cost to this one industry segment, which is already regulated and already providing a safe product, will result in the removal of this industry segment from our economy. This has been happening for the past 25 years, making the commercial feed industry less and less of a player.

AAFCO has been working on guidelines for non-medicated feed, ingredients, and on farm activities, which are the industry segments not presently regulated. We believe FDA can strengthen this process by moving toward formalizing these requirements presently in AAFCO's "Best Management Practices Guidelines." However, this must be coupled with enforcement and oversight inspections. CVM can free up inspection resources through the implementation of VSIP, a program that was developed by FDA/AAFCO/ and industry to help address this situation and provide for more complete oversight by freeing agency resources from medicated feed mill inspections.

The answer is not to add more rules on the medicated feed manufacturer. The addition of more regulations on the medicated feed manufacture is no longer the solution for safer feed, considering the commercial feed mill is not the only primary player in the feeding cycle today, and has a safe track record with less than 1% of residues today coming from commercial feed mills.

#### **COMPONENT #4. REGULATORY OVERSIGHT**

We strongly believe that using the BSE inspection model for the feed safety enforcement approach will not achieve its purpose—since 90% of the present BSE inspections are completed at commercial feed manufacturing locations which hold medicated feed licenses. This would make the commercial feed mill the focus point, and then move upstream or downstream for problems.

There are several concerns with this model.

- The commercial feed mill is no longer the major player in the feed source for food animals.
- Most problems occur on farm, and not because of the commercial feed mills.
- Commercial feed mills cannot be the enforcer for ingredient suppliers. Many small mills do not have the resources for analytical controls and other receiving inspection monitoring tools needed for formalized HACCP controls. Such food safety issues should be controlled through appropriate cGMP's placed upon the ingredient segment themselves. Appropriate cGMP's need to be developed for this industry segment, then adequate enforcement by state and federal inspections should help assure compliance.

- On-farm continues to be where most feed safety issues occur. Presently there are no applicable rules or oversight inspections, unless they are part of the medicated feed licensing program, and then inspections are rare. The agency needs to address this industry segment without linking it back to commercial feed manufacturers.

Land O'Lakes Purina Feed LLC totally supports Gaps #2 & #3 in all respects. We pledge to support the agency in any way we can in this effort.

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, LOLPF 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,

A handwritten signature in black ink, appearing to read "F. Palacios", with a long horizontal flourish extending to the right.

Fernando Palacios  
Executive Vice President  
Land O'Lakes Purina Feed LLC