



AMERICAN FEED INDUSTRY ASSOCIATION
October 24, 2003

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

Re: Docket No. 2003D-0312 (Animal Feed Safety System)

Dear Food and Drug Administration:

The American Feed Industry Association (AFIA) participated in the public meeting held September 23-24, 2003 to discuss FDA's proposed Animal Feed Safety System (AFSS). We offer the following comments as a follow-up to that discussion and in response to the questions raised in the *Federal Register* notice of July 28, 2004 (at FR 44344-44345).

AFIA is the national trade association for feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers and other firms which supply goods and services to the feed industry. AFIA's nearly 600 corporate members manufacture 75% of the nation's primary, commercial feed. AFIA member products are regulated by FDA and development of a national AFSS would have substantial impact on our members' business operations and products.

AFIA applauds the agency for holding the public meeting and the format utilized. However, there were several problems with the breakout session which should be corrected for any future meetings. First, the questions to the breakouts should be distributed well ahead of the sessions to facilitate intra-company discussion and development of well-reasoned comments.

Second, one concern raised by several industry members in several different groups involved the use of HACCP-like principles and follow-up questions. It was difficult for the higher number groups (4, 5, and 6) to answer the questions posed for the HACCP-like principles presented without having detailed information about what hazards and critical steps were recommended by the other groups or by a detailed specific facility plan. Although many hazards in the feed manufacturing process are generally known, a risk-based hazard analysis should be performed for each feed type and/or ingredient type to determine what critical steps need to be developed to control each hazard. It is difficult to answer questions about assuring control of critical steps or recordkeeping and verification without the essential information concerning hazards and critical steps.

Regarding the questions posed in the *Federal Register* notice of July 28, 2003, AFIA offers the comments on each question as follows:

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1. What are the strengths of the current Federal and State regulatory programs for feed safety?

AFLA believes the current state/federal program is an adequate deterrent that promote feed safety, and that this country has the highest standard of feed safety in the world. In fact, feed safety in the USA is the "gold standard" for the world. Efforts by the Association of American Feed Control Officials and CVM's university approach to training have greatly reduced non-uniformity of inspections in the USA. Over several decades, the AAFCO model bill and regulations approach has led to greater uniformity. AFLA has been a regular promoter of this model approach and has, in fact, been actively involved in writing, reviewing and promoting the model bill in over 20 states in the last decade. The state laboratories are a great national asset and should be cooperating on a regional basis to maximize their efforts and investment. Regular assays of contaminants, animal drugs and other items can be an effective deterrent.

Consumer confidence in the meat industry is extremely high, as it is with our customers, the producers. Tissue residues from feed are very rare and usually reported by FDA as less than one percent.

2. What are the weaknesses of the current Federal and State regulatory programs for feed safety?

After years of working to assure uniformity, resources, inspections and interpretation are not where they should be in a national program. There are a number of areas with lack of uniformity between state and federal programs, e.g. BSE feed rule inspection and enforcement. Some states are not doing inspections in this area. There seems to be a lack of awareness of how a feed regulatory program will impact feed safety—which should be all states' number one priority. Not all states have adequate training for inspectors in this area. As mentioned earlier, states need to regionalize their feed laboratories to enhance their capabilities and multiply their resources. Some states do no drug or contaminant testing. There is a serious lack of resources to totally cover all feed produced with inspections. If the USA adopts the current draft Codex Alimentarius "Code of Good Animal Feeding Practices," a strengthening of regulatory programs will likely be required.

3. What are the strengths and weaknesses of current industry feed safety program?

Strengths: *AFLA believes the efforts of trade and industry groups represent a major effort to promote feed safety. State land grant universities, led by Kansas State University's efforts, have provided the impetus and knowledge base for producing the safest feed in the world. The US feed industry has a myriad of programs to draw upon and uses many practical quality and feed safety programs to assure safe feed.*

AFLA and other groups have been very supportive of regulatory efforts for the BSE feed rule by assuring states are actively involved, assuring adequate funding and tirelessly advocating for 100% inspections and 100% compliance. As an adjunct to the first line of inspection, AFLA created the Facility Certification Institute to perform third-party,

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independent inspections of feed mills and ingredient suppliers and to supply these facilities with a certification certificate to present to their customers, who, in turn, present it to the packing facility. FCI will continue to offer these services and is branching out into ingredient inspections and certifications and, possibly, HACCP certification in the near future.

AAFCO's approach to voluntary "Best Management Practices" through its guidance document and checklist is being promoted by several trade groups. AFIA believes this program provides the basis for a minimum food safety standard that industry should embrace. It is based on sound, practical reasoning and, at a minimum, should be utilized by all facilities. We believe it offers the great opportunity for government and industry to promote food safety, and adequate time and educational opportunities should be allowed for all industry to utilize it. We urge AAFCO and FDA to work with the local and national trade organizations in promoting this consensus model of feed safety, and AFIA pledges its support to working with government regulators at all levels to disseminate this program.

According to those knowledgeable of international commerce, the USA feed industry has the best quality and safest ingredients in the world. Our agricultural base is diverse, stable and able to meet a wide range of demands for safe products. This type of marketplace drives competition that forces a higher playing field, even where regulation is low or inefficient. Customers demand quality products. Firms utilize a number of communication tools to advise customers of product quality, content and directions for use—all which promote safety. New technologies are being advanced to promote feed safety, including ISO, HACCP, and audit procedures.

Weaknesses: There are varying levels of understanding and resources of the importance of feed/food safety at smaller facilities in spite of AFIA and other groups' efforts. In some areas, such as dioxin contamination, there is not clear understanding of risks associated with food/feed safety. Microbial adulteration in feed is not the subject of research to document hazards to animals or humans, in spite of pronouncements by some in government.

4. What are the potential benefits of a comprehensive, risk-based Federal feed safety program?

Most importantly, such a risk-based program would provide minimum safety guidelines for all feed, ingredient and pet food manufacturers. However, this would not necessarily have to be a federal program, as industry guidance or codes of practice would accomplish the same goal with much lower costs. Such a program, either industry or Federal, would decrease the requirements or costs not related to feed/food safety in federal/state programs. This would allow for redirection of these related costs to areas of feed/food safety. AFIA strongly believes that state feed control resources should first be directed to feed/food safety; however, most state resources are heavily invested in economic analyses.

Such a program could easily conform to the expected global consensus being reached on the Code of Good Animal Feeding via the Codex Alimentarius. It would make firms' products more attractive for export markets.

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For those firms that have adopted wide-ranging and comprehensive feed safety programs, the benefits, both financially and in customer satisfaction, have been excellent. Some firms have documented cost savings related to implementation of feed safety programs and experienced growth in product marketing.

A federal program should have in place the scientific identification and quantification of risks associated with feed safety. AFIA understands the FDA is interested in a risk-based feed safety program and whole-heartedly endorses such a concept. However, such a risk-based approach is lacking in many areas, such as some contaminants, microbial concerns and others. FDA should fund risk studies to support any Federal feed safety program.

5. What components should be included in an AFSS?

This program should be a scientifically based system that recognizes the different feed matrices and processes. It should be a risk-based approach with strong education of industry, the public and regulators. It should have even application to all industry sectors and have appropriate compliance incentives, which should be part of an education program. It should be enforceable and have a strong cost-benefit evaluation associated with it. There should be an on-going risk assessment to strengthen the program. Independent, third party certification programs should be encouraged and supported by such a program, utilizing regulatory discretion for those facilities participating in a federally recognized program. Such discretion would free resources to focus on more serious areas of concern.

One possibility is have FDA develop voluntary standards for certain types of programs that firms would need to meet before claiming such a program is utilized, such as for HACCP. Alternatively, the agency could recognize a third-party certification program that is accredited to certify for a particular standard.

6. 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?

Potential burdens: In the absence of a level-playing field, there will be a push toward more on-farm mixing and less commercial feed. There will be education costs for researching, promoting and understanding the risks. There is a serious lack of enforcement resources for any national and/or state program. Obviously, there will be a cost to the consumer for any mandatory program. Very small businesses will likely fare poorer in any mandatory program, as they grapple to make sense of such a program, compliance and consequences.

Options: There should be a reallocation of resources so that food safety is the highest priority in all areas of feed control. FDA's acceptance and recognition of third-party certification programs and development of a regulatory discretion guide would allow agency resources to be shifted to serious areas of concern. The private sector is paying for private certification on an increasing basis. Conservatively, over 15% of all feed produced in the USA is privately certified by some independent, third-party.

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AFIA appreciates the opportunity to offer these comments and to participate in the FDA's AFSS public meeting. We look forward to further participation by FDA in AFIA's food safety guideline development and in discussion of third-party certification endorsements.

Sincerely,



Richard Sellers
Vice President, Feed Control & Nutrition

c: Dr. Stephen F. Sundlof, CVM Director
Dr. George Graber, Director, Division of Animal Feeds, CVM



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PAGES INCLUDING THIS COVER SHEET: 6

Comments:

Attached are comments to Docket No. 2003D-0312 Animal Feed Safety System on behalf of the American Feed Industry Association. The electronic filing system for this docket would not allow comments on all the questions and attempts to add the answers to all questions in the first box were rejected. Therefore, I am faxing the comments to the docket.

Regards,
RS
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