



AMERICAN FEED INDUSTRY ASSOCIATION  
October 20, 2004

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

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

Dear Food and Drug Administration:

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 has nearly 600 corporate members that manufacture 75% of the nation's primary, commercial feed and is therefore, the largest feed trade group in the world. AFIA member products are regulated by FDA and development of a national AFSS would have substantial impact on our members' business operations and products. Therefore, AFIA makes these comments on behalf of its members.

AFIA applauds the agency for holding a public meeting in 2003 and continuing to dialogue with the public on this very large but important effort. AFIA's comments here will address FDA's March 31 *Federal Register* notice providing the agency's current thinking on definitions for "comprehensive" and "risk-based" and "Elements of an Animal Feed Safety System."

Comprehensive

The FDA's range for this definition is appropriate. For the first item, AFIA agrees that this range is what is needed and suggests combining this statement with the statement in #5, so that the new, succinct item would read as follows:

1. *it would apply to the whole range of feed products, including all ingredients and finished feed produced for food and non-food animals.*

Regarding the second item, AFIA believes it is important to recognize the statutory allowance for self-affirmation of generally recognized as safe (GRAS). So, the text should read as follows:

2. *use ingredients approved, generally recognized as safe, and/or recognized by an established regulatory agency...*

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AFIA would suggest changing item number three to reflect a better comprehensive concept as follows:

3. *cover the complete range and variety of facilities, equipment and distribution methods involved in animal feed production.*

Many feed safety concerns involve distribution methods and the commercial carriers utilized by large and small firms alike. State and federal feed control authorities spend little education, surveillance, compliance and enforcement time examining this industry.

AFIA again reiterates its support for both third-party certification/inspection programs, which allow governmental authorities to better utilize existing resources, if third-party programs are recognized. Also, research ongoing at Kansas State University has revealed that feed HACCP programs can effectively utilize this quality program to produce better and safer feed. This is yet another quality tool for firms to choose from in the feed safety toolbox. Thus, AFIA agrees with item number four regarding process control.

AFIA is concerned about moving from an overarching but basic feed safety program, to a more specific and resource-intensive HACCP program. We are concerned with the increasing number of HACCP or HACCP-type programs for which no standard is being met. AFIA believes K-State is building that standard and supports third-party certification and auditing of HACCP feed programs. The Facility Certification Institute (FCI) will begin offering audits and certification of HACCP programs before the year's end. AFIA believes FDA should recognize the programs as a powerful feed safety tool and consider such certified facilities as lower targets for inspections, as the audits and certification requirements would far exceed any federal regulatory requirements. AFIA is not in favor of mandatory government HACCP programs at this time.

AFIA concurs with FDA's view on number six. We support the risk-based definition provided by the agency, and this item adequately addresses the definition of "hazards." Inherent in these two definitions of comprehensive and risk-based is the scientific assessment necessary to determine the likelihood and degree of negative consequences that a new hazard poses. This is essential in determining the risk of a new hazard. We believe FDA has clearly elucidated these concepts in its definitions.

Regarding "...human and animal health issues,..." in number seven, AFIA believes the agency has a clear track record of addressing the former over the latter and will continue to do so, even though the statute does not provide a priority. This priority is determined by the agency's funding and/or other congressional mandates and those of the executive branch. We are pleased to see that the agency has addressed both issues, as many HACCP programs address only the human health issues. We believe K-State is utilizing prerequisite control points to address animal health issues; leaving critical control points to address human health issues. AFIA strongly asserts that both health areas must be addressed.

Regarding issue number eight, AFIA strongly believes in cooperation of regulatory agencies and has lobbied for increased funding in support of that goal. Furthermore, AFIA's

policy is to support national legislation for feed regulatory uniformity that would provide FDA with the authority to promulgate national feed regulatory standards for labeling, inspection, compliance and other areas, as appropriate. This legislation would use the Association of American Feed Control Officials' Model Feed Bill and Regulations as the national standard. Such legislation would preempt any state laws or regulations not in accord with FDA's national standard.

AFIA also supports self-inspection programs that have third-party oversight systems and urges the agency to acknowledge, support and accept these programs. Such support could be in the form of a compliance policy guide laying out the terms of such private certification programs that would allow the agency to reduce the number of inspections to facilities so certified. This would substantially increase the agency resources to focus on more facilities not otherwise being inspected. Nothing in such a guide would preclude the agency (or state) from conducting an inspection of any certified facility if permitted by law.

#### Risk-Based

Risk can simply be defined as "the probability that exposure to a hazard will lead to a negative consequence" (D. Ropeik and G. Gray in *Risk* p. 4. 2002. Houghton Mifflin Co., Boston). FDA's risk-based approach is more appropriately defined where the term "negative" is inserted before consequence, which term has no good or bad inherent in its definition. We would also support any language regarding education of the public and industry or non-regulatory approaches, as well.

#### Elements of an Animal Feed Safety System

Generally, this system offers a simple, basic set of requirements for feed safety. Much of it is included in AFIA's Safe Feed/Safe Food Certification Program, which is attached for review. AFIA believes each of the elements offers important considerations, but we would combine some and rename and align others for clarity. Also, as a general rule many of the items listed may not be appropriate at all stages of the feed industry. The SF/SF program lists in a number of places, "where" or "if" "appropriate." Also, there appears to be a mix of passive and active voice, and questions and statements, which should be corrected to a uniform document.

The first item, "Incoming Materials" is appropriate for both feed and ingredient suppliers. However, we would suggest either including a supplier selection program section or creating a section before incoming ingredients with such a name. This component is in the AFIA SF/SF Program.

The second section on "Processing/Manufacture" is comparable to the AAFCO Best Management Guidelines checklist. This format differs considerably from the rest of the document. We would suggest re-engineering this document to provide either a question type checklist or requirement statements.

Conclusions

AFIA believes FDA is moving in the right direction in making uniform a national Animal Feed Safety System (AFSS). However, much work is needed to bring on board all of the feed industry and its customers. The diverse nature of this industry will make it difficult to create a "one size fits all" type program. FDA has made an excellent start in creating an umbrella of issues to begin to address a national program.

AFIA wishes to convey to FDA in the strongest possible terms that voluntary, third party feed safety certification programs will continue to grow, and the agency should seriously study them as a way to partner in feed safety. This would reduce public input while maintaining a higher level of oversight and would free public resources to better monitor the highest risk industries. In fact, the voluntary self-inspection program (VSIP) created jointly by AAFCO and the feed industry allows for third-party certification. A certification program is required in the VSIP process. The Certifying Body (CB) in that process consists of AAFCO, a third-party, some of whose members may have inspection contracts with FDA, some not. This CB then provides oversight to a Certifying Organization (CO), which is responsible for the operation of the certification program. AAFCO has self-selected itself to be the CB. If a firm or facility utilizes a third-party certification program for feed safety, it should be accorded the same privileges of "relaxed" inspection as those facilities participating in VSIP.

AFIA appreciates the opportunity to offer these comments and to participate in the FDA's AFSS public meeting. We look forward to further participation at FDA's future AFSS meetings and providing input to make the safest feed system in the world even safer.

Sincerely,



Richard Sellers  
Vice President, Feed Control & Nutrition

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

attachments