



AMERICAN FEED INDUSTRY ASSOCIATION

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February 17, 2006

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:

The American Feed Industry Association (AFIA) participated in the public meeting held April 5-6, 2005 to discuss FDA's proposed Animal Feed Safety System (AFSS). We offer these comments as follow-up to that discussion and in response to requests for comments from participants at that meeting.

AFIA is the national trade association for livestock and poultry 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 more than 75% of the nation's primary feed. AFIA member products are regulated by FDA and development of a national AFSS would have substantial impact on our members' business operations, their product manufacturing, availability, and our customer product options and choice.

AFIA applauds the agency for holding the second public meeting and the format utilized. However, we reiterate our request to receive the questions to be asked at the breakout sessions in advance, so that the industry can provide well-researched and informed comments.

Contamination Reporting

The opening presentations on FDA contaminant findings, presented by Dr. Dan McChesney and others, concern AFIA due to the assertions the feed industry should have prevented such contaminant concerns, i.e. three dioxin incidents, if a system similar to the proposed Animal Feed Safety System AFSS were in place. The design and thrust of these presentations appeared more to justify the creation of an AFSS program than to provide legitimate insight into contaminant mitigation. AFIA reminds FDA that the Government Accountability Office (GAO, and formerly the General Accounting Office) report in September 2000 reported: "Almost no human illnesses have been traced

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to animal feed in the United States.”¹. By any measure of concern – including FDA’s pursuit of its basic purpose, i.e. to protect human health, the agency has not made a compelling case for pursuing such a comprehensive system, one that currently carries a very heavy price tag. Three incidents of dioxin since 1996 do not denote an industry out of control.

Voluntary Industry Programs

The FDA presentations also appear to take no notice of industry voluntary efforts to bolster existing agency oversight. AFIA has worked diligently for several years to develop its Safe Feed/Safe Food Certification Program, soliciting FDA and the Association of American Feed Control Officials (AAFCO) input. This voluntary program, with guidelines created by the industry from the best information currently available, is being embraced by the feed industry at a fast rate. Over 400 facilities have committed to participate in the program and 114 have already received certification.

AFIA also wishes to reiterate and remind the agency of its support for both third-party certification/inspection programs, allowing governmental authorities to better utilize existing resources. Also, research ongoing at Kansas State University and Texas A&M University reveals that feed HACCP programs can effectively utilize this quality assurance program to produce better and safer feed. This should be viewed as expanding the number of tools available to companies to choose from their feed safety toolbox. AFIA continues to partner with both universities in encouraging the industry to partake in HACCP training.

In light of the industry’s historical record of safety and quality compliance, these emerging industry programs, the implications of feed safety as a contributor to human health problems as demonstrated by the GAO report, AFIA believes FDA could best use its scarce resources by focusing resources on other areas of concern, such as import inspections.

AFIA’s Overall Concerns with AFSS

The following are overall concerns about the development of the AFSS in general:

Risk-based Approach

AFIA is increasingly concerned about the agency’s discussion and justification for what FDA apparently believes to be a risk-based approach to feed safety. The scientific presentations in Omaha did not make a strong case for the “bottom up” approach to feed safety. Most disturbing was that an apparent lack of scientific data and/or adequate risk assessment on any given hazard or contaminant or combination, forces the agency to make risk determination based on the “gut feeling of experts.” This is wrong.

¹ Government Accounting Office (GAO), *Food Safety: Controls Can Be Strengthened to Reduce the Risk of Disease Related to Animal Feed*. Report GAO/RCED-00-255, September 2000.

Regarding microbes and microbial concerns in feed, these are dynamic issues, far from settled, and issues where the research seems to indicate a lack of feed concerns (Davies, 2004).² AFIA believes that absent a sound, scientific microbial risk assessment in feed detailing confirmed high levels of risk to animals or humans, FDA cannot and should not proceed with determining all salmonellae are generally hazards in feed. The issues of infectious dose, pathogenic strains and serovars/serotype determination make this issue one that begs for further research rather than following the "gut feeling" of experts, when experts of equal standing do not agree.

AFSS Magnitude

FDA has provided insufficient detail making it difficult to grasp the depth of all operations that an AFSS program will attempt to cover. It is obvious FDA contemplates a broad program, and the training for surveillance/enforcement of such a program is quite daunting. AFIA is forced to compare such a proposed regulatory program to the current regimen for regulating medicated feeds, and reminds FDA this long-standing program lacks uniformity among the district offices and commissioned state officers performing investigations required by law. The resources to hire the necessary manpower and train both state and federal investigators will be substantial. Due to the diversity of the industry and locations (both on and off farm), continuing training will be necessary. AFIA is concerned that federal budget constraints for at least the next two years will not provide adequate resources to provide that training, thereby contributing to an even greater expected training shortage and lack of uniformity of inspections.

Guidance vs. Regulatory Program

Given the limitations listed above, the ambition of the program and existing hurdles to be overcome, it seems prudent that any AFSS program envisioned by the agency would benefit – at least initially -- from being imposed as a guidance program for the regulated industry. Cooperative agreements with industry for voluntary programs and guidance programs for mandated regulations have been quite successful (e.g. BSE education video, GTI for dioxin, etc.). AFIA would support providing industry with Guidance To Industry (GTI) type documents for effective distribution by the regulated industries.

On-farm vs. Off-farm

AFIA's members are both commercial and non-commercial operations, representing all types of vertical integrators, including poultry, beef and pork producers. Included in these types of operations are farms where the feed-supplying firm owns the animals, but not the grow-out facilities, but also where the company owns both the animals and the production facilities. This diversity challenges FDA and state inspectors with myriad inspection issues.

AFIA urges a strong FDA outreach program to the on-farm industries, historically not central to either FDA or state inspection programs. Without direct outreach, AFIA believes FDA and the

² Davies, P., et al. 2004. The Role of Contaminated Feed in the Epidemiology of Control of *Salmonella enterica* in Pork Production. Food Borne Pathogens and Dis., 1:204-215.

states performing inspections under an AFSS regulatory program will by default and convention rely on frequent visits to easily located commercial and large integrated feed mills, perpetuating the current inequity of inspection. Data available to the agency demonstrate that feed mills closer to resident posts/district offices are inspected with greater frequency than those more distant or more difficult to reach. If such a purely regulatory program were to be adopted, as contemplated by AFSS, AFIA believes history will repeat itself in that on-farm operations will receive significantly less attention—a situation resulting in more feed being mixed on-farm. FDA must better engage the groups representing on-farm feed production. AFIA believes the agency is not receiving adequate input from this segment of the feed industry.

AFIA is currently cooperating with the National Pork Board (NPB) in such an effort through its Safe Feed/Safe Food Certification Program. An independent random survey of 200 medium to medium large pork producers found many of the producers are mixing feed on-farm, with 9% of those mixers expecting to buy more feed equipment in the coming year. Of these, nearly one-fourth are interested in participating in a pilot safe feed program, and the majority wish to have a pilot available in either an online or CD-ROM format. AFIA is developing over 150 training modules for an online training program through funding provided by the NPB. A survey of the largest 50 producers is ongoing and will likely find those operations receiving, but not purchasing feed, from integrated feed mills. Partnering with organizations such as these national producer groups and their largest and more innovative members represents a better way of reaching on-farm producers with feed safety information.

Conclusion

AFIA strongly believes a voluntary program, one with strong direction from the marketplace offers a much better chance of reaching the regulated industry and achieving the government-industry mutual goal of safer feed than a mandated regulatory program that will be no doubt under-funded as more pressing issues require funds to be allocated elsewhere. The history of producing safe feed, GAO's report, the lack of dedicated funds, the need for on-farm mixer outreach will all lead to a regulatory program, that if adopted, will have insufficient funding and for training and comprehensive outreach to the affected industries.

AFIA appreciates the opportunity to offer these comments and to participate in the FDA's AFSS public meetings. We look forward to further participation by FDA in AFIA's feed safety guideline outreach and a continuing discussion of third-party certification recognition.

Sincerely,



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