



AMERICAN FEED INDUSTRY ASSOCIATION

September 8, 2008

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

Re: FDA Docket 2008-D-0381 “Draft Guidance for Industry Voluntary Third-Party Certification Programs for Food and Feed”

Dear Sir/Madam:

The American Feed Industry Association (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 more than 450 corporate members manufacture 75% of the nation's primary, commercial feed. AFIA represents all aspects of the total feed industry.

AFIA strongly supports FDA's efforts to recognize voluntary industry food/feed safety programs, and especially industry third-party certification systems that are independent. AFIA's Safe Food/Safe Feed (SF/SF) Certification Program was launched in September 2004 and provides a voluntary opportunity for feed, pet food and ingredient manufacturers to apply for certification and have their programs reviewed by outside, third-party inspectors to determine if the facility's feed safety program meets the guidelines established by the feed industry. If the program meets the guidelines, the facility may become certified and authorized to use the SF/SF certification logo.

AFIA applauds the quick issuance of this draft Guidance for Industry (GFI) which will allow better allocation of FDA's resources to those areas that are of higher risk in the food and feed industries by allowing firms that are third-party certified to be inspected less frequently where FDA recognizes such programs. AFIA believes that its program should qualify for FDA recognition, as the SF/SF program meets or exceeds FDA's requirements in all aspects of FDA's law and regulations.

As the only third-party, industry feed safety program operating in the U.S., AFIA has considerable interest in FDA's draft GFI. This letter provides our comments on the program and raises several issues of concern. Generally, AFIA supports the draft GFI but is concerned about the likely effect of the overly restrictive nature of the guidance on AFIA's SF/SF program. Recognizing that, as a practical matter, guidance criteria are often treated as *de facto* “requirements” by both industry and the agency, AFIA urges FDA not to adopt a “one size fits all program,” as many of the criteria may not fit the SF/SF program. Further comments on specific aspects of the draft GFI are presented below.



2101 Wilson Blvd., Suite 916, Arlington, VA 22201
Tel.: 703/524-0810 FAX: 703/524-1921 E-mail: afia@afia.org www.afia.org

General Comments

Although FDA notes that agency “recognition” of these types of programs will likely be a website listing, AFIA suggests that FDA also consider other types of recognition, such as mentioning the programs in warning and information regulatory letters to firms; allowing letterhead taglines such as “FDA recognized;” signing letters or memoranda of agreement regarding the program; and other novel ways of promotion. One of FDA’s main goals should be encouraging firms to enter recognized programs. FDA could also provide grants for training and development of inspection staff or recognized certifying organizations.

On a more elemental note, the final GFI should make clear the clearance or application process for recognition. Such things as what is needed, who does one apply to, what should be provided the agency for the review, will the agency rely more on the auditing organization than agency inspections, should be clearly addressed in the final GFI.

In the draft GFI, FDA provides little information in the way of timelines to achieve recognition or development of a final GFI. The agency should provide timelines in a *Federal Register* or website/e-mail notice before or at the same time as the publication of a final GFI. This would provide interested organizations time to prepare for providing the necessary information to receive recognition.

FDA’s Center for Veterinary Medicine leadership has made public announcements regarding allocation of feed inspection resources based on a risk ranking or risk profile of facilities. AFIA applauds this effort and urges the agency to include in that risk profile the consideration of whether a firm is participating in a recognized third-party feed safety program or not.

AFIA is concerned about the numerous guidance “requirements” in the draft GFI. It appears many of these are more related to the food industry than the feed industry. Some of these issues are addressed below in other areas, but AFIA urges the agency to not create a “one size fits all” recognition program, as many issues, such as inspector education and training, would make it difficult to find qualified inspectors due to the stringent education and training requirements in the draft GFI.

Certification Process

The draft GFI notes that before a firm/facility is certified, the management of that firm/facility should certify that it has no pending regulatory issue(s) with the agency. We are aware that some district offices send a type of “close-out” letter following a FDA Warning Letter. Our industry officials do not receive this letter from all districts and not regularly from the same district. AFIA suggests the agency require these letters from the districts to make the system uniform. This is the only method where firms will know they have complied with FDA’s requests. FDA should clarify in the final GFI what is acceptable evidence of compliance evidence that a pending regulatory issue has been resolved.

AFIA believes the GFI should be amended to require firms to notify the certification organization within a short timeframe of the receipt of any verbal/written notifications of non-

compliance from any state or federal feed regulatory agency. Failure to do so under the SF/SF program is grounds for decertification.

Other amendments to the GFI regarding maintaining or obtaining certification should include notification of change of ownership, which under the SF/SF program results in a new inspection, as AFIA tells firms that the SF/SF certification is not an asset of any firm, and must be surrendered when the firm is sold unless the firm can pass a new inspection.

Attributes for Third-Party Certification Programs

AFIA contracts with an organization that provides inspection services to SF/SF and makes the decision regarding whether a facility receives certification or not. AFIA suggests the agency detail the criteria for an auditing oversight firm. FDA should also address what would occur if an auditing firm applies for recognition as a certifying organization.

FDA does not state the frequency of inspections by the certification organization. AFIA believes the agency should include some guidelines of frequency of inspection based on risk rankings or other criteria. The SF/SF program inspects each facility biennially using unannounced inspections. However, more specifically, AFIA suggests FDA consider requiring biennial inspections with annual reviews written by plant management and submitted to the certifying organization and subject to spot inspection.

Similarly, AFIA requests the agency describe under what circumstances and frequency the certification organization should collect samples and analyze them. If this should be done on a regular visit, FDA should detail what the organizations should use in determining a sampling and analysis plan. AFIA believes that a review of a firm's sampling and analytical history from certified results of a recognized laboratory (with permission to contact that laboratory) would provide as good or better review of the firm's risk management program.

Regarding qualifications of inspectors for the certifying organization, AFIA believes the guidelines in the draft GFI are too restrictive, as the inspectors contracted by AFIA may not meet all these requirements for education, but have considerable relevant expertise based on experience. AFIA suggests FDA amend the section on education and experience to accept inspectors with a combination of education and experience that can be demonstrated by testing or by observation during joint inspections. Similarly, the joint inspection guideline of 10 joint inspections may be unnecessary if the inspector has adequate experience and demonstrates expertise after the first 2-3 joint inspections. This should also be altered.

Training of inspectors should be related to their experience of the industry in which they are inspecting. In the feed industry there are fewer processes that can lead to feed safety problems, as feed manufacturing is much less detailed than for food, and there are less sanitation requirements as well. This justifies less training than as suggested in the draft GFI. FDA should note such a bifurcation in this section, as well as other sections where it is appropriate to separate what is needed for a feed program versus a food program.

Regarding timeframes for records, AFIA recommends that records maintained by the certification organization be no longer than the longest one required in any FDA processing predicate rules for that industry. In the case of the feed industry, GMP records are required to be

maintained, as a practical matter, for a maximum of only two years. Extensions beyond such time require very costly filing and maintenance resources with little expected benefit.

The draft GFI says the certifying organization is required to notify FDA of any product with the potential for serious adverse health consequences or death for humans or animals. This will soon be required by the Food and Drug Administration Amendments Act of 2007 for registered facilities, and AFIA believes this is the responsibility of the facility's management. Notification for such products that have not left the operation would provide no protection to the public. AFIA believes firms with a requirement to notify FDA should do so, and the certifying organization's inspector should instead focus on gaining corrective actions for any processes out of control.

Regarding conflict of interest guidelines, AFIA is concerned that these may preclude the recognition of programs like AFIA's SF/SF program due to the overly stringent requirements in the draft. The agency should clarify the provisions regarding reimbursement of travel expenses and the like, to allow the firm to pay the certifying organization, which in turn pays the inspector. Also, FDA should make clear that it expects the rates for each firm with similar products to be the same (except for firms outside the US). The SF/SF program charges a uniform fee for all domestic inspections; it also requires a fee for reinspecting an out of compliance facility.

Finally, FDA asks to be notified of any changes to the certification program. This is a reasonable request, as the SF/SF program requires notification of any changes to a certified facility's processes. However, FDA does not provide a mechanism for this notification, nor does it indicate if it will approve or disapprove of the changes or leave that decision to an oversight auditing organization. AFIA suggests FDA clarify this section to provide more guidance on what is to be provided and what FDA will do with the information.

AFIA is very supportive of this effort to provide guidance to voluntary industry certification programs and urges FDA to proceed expeditiously to further detail the process an organization can use to be recognized by FDA. The long-term benefits to the agency and the public are certainly clear, as more oversight by FDA recognized groups will further reduce risks from feed hazards.

Thank you for the opportunity to submit comments on this very important plan for the feed and food industries.

Sincerely,



Richard Sellers
Vice President for Feed Regulation and Nutrition