AMERICAN FEED INDUSTRY ASSOCIATION

July 8, 2003

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

Re: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0277

Dear Sir or Madam:

The American Feed Industry Association (AFIA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on establishment and maintenance of records. 68 Fed. Reg. 25,188 (May 9, 2003).

AFIA is the national, not-for-profit trade association for animal feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers, and other firms that supply goods and services to the animal feed and pet food industry. AFIA's nearly 600 corporate members manufacture 75 percent of the nation's primary commercial feed. Because AFIA members would be subject to the proposed rule, AFIA offers these comments on their behalf.

AFIA strongly supports the purpose of ensuring the safety and traceability of animal feeds, the goal of the proposed rule and of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). However, certain aspects of the proposed rule are of concern to AFIA's members. Some of the proposed requirements will burden AFIA members unnecessarily without furthering the goals of the Bioterrorism Act.

We urge FDA to make the following changes in the final rule and otherwise clarify certain outstanding issues:

1. FDA exceeds its authority under the Bioterrorism Act.

In the proposed rule, FDA exceeds the records access authority Congress granted to the agency. The Bioterrorism Act gives FDA access to records for the purpose of "determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to

humans or animals." 21 U.S.C. § 350c(a). Congress plainly set out the purposes for the records authority in the Bioterrorism Act: 1) "determining whether the food is adulterated;" and 2) determining whether the suspect food "presents a threat of serious adverse health consequences." 21 U.S.C. § 350c(a). Congress granted FDA records access under these limited circumstances to allow the agency to trace the distribution of foods that meet this standard and to permit their recovery.

Congress only authorized record keeping and access requirements that accomplish these objectives and meet these standards. Yet, the records access provisions FDA proposes do not acknowledge these explicit limitations Congress wrote into the Bioterrorism Act. If the final rule fails to incorporate these express limits, FDA will have most certainly exceeded its statutory authority and violated the Administrative Procedure Act.

2. All animal foods and pet foods not subject to the BSE Rule should be exempt.

FDA proposes to exempt from the record keeping provisions entities who manufacture, process, pack, transport, distribute, receive, hold, or import food for non-food producing animals if those entities are not already subject to the record keeping provisions of the FDA regulations prohibiting animal protein in ruminant feed (21 C.F.R. § 589.2000, the "Bovine Spongiform Encephalopathy [BSE] Rule") FDA asks whether this exemption should be broadened. 68 Fed. Reg. at 25,191-92. AFIA believes the exemption should be broadened to include all animal feeds and pet foods, unless otherwise covered by the BSE Rule.

In AFIA's view, the likelihood of a bioterrorist attack through animal feed or pet food is very remote. Moreover, the risk of harm to humans if animal feed or pet food is used as an instrument of bioterrorism is also very remote. There is no sound reason for forcing animal feed and pet food companies to comply with these burdensome requirements when the risk of serious adverse health consequence or death to humans or animals is so low.

Certainly, FDA has the flexibility to tailor the record keeping requirements to particular industries and to balance the burdens of record retention against the likelihood of harm. Congress' grant of authority to FDA to establish record keeping requirement was not mandatory -- FDA "may by regulation" establish requirements regarding record keeping. *See* 21 U.S.C. § 350c(b). Where the authority itself is conditional, greater care is warranted before FDA may impose burdens upon the animal feed and pet foods that are themselves at such low risk.

The most serious food-borne disease that can arise from tainted animal feed, Creutzfeldt-Jakob (CJD) or vCJD (CJD-variant), has been associated with the consumption of foods produced from BSE infected animals. BSE is already covered by its own, more specific rule, 21 C.F.R. § 589.2000, which already mandates record keeping. As BSE is a serious and fatal disease for which there is no known cure, AFIA believes it is appropriate to require entities that already must comply

with the BSE Rule to also comply the record keeping rule. However, to the extent there are conflicts between the two rules, the BSE Rule should govern.

3. Record keeping requirements should be consistent with existing record keeping requirements.

In establishing and implementing the record keeping requirements, FDA should look to the existing requirements already in place for certain foods. For instance, currently, FDA imposes record keeping obligations upon medicated feed operations. 21 C.F.R. Part 225. These regulations require medicated feed operators to maintain, among other things, master record file and production records, complaint files, and distribution records for not less than one year. 21 C.F.R. Part 225, Subpart E. Feed mill operators are already familiar with these regulations and their requirements. AFIA urges that FDA keep the bioterrorism record keeping requirements consistent with those already applicable to medicated feed operations.

As it finalizes the record keeping rule, FDA should look to these existing record keeping regulations. These regulations strike an appropriate balance of allowing FDA the access to information it needs for traceback and enforcement, without unduly burdening businesses. FDA should seek a similar balance as it implements this record keeping provision.

4. FDA needs to establish and publish internal procedures for implementing the records access requirements.

The proposed rule does not address the confidentiality of records FDA inspects. The Bioterrorism Act requires FDA to "take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that" FDA obtains. 21 U.S.C. § 350c(c). Although the FDA's access to records was self-effecting, without the need to promulgate regulations, FDA has not yet addressed how it will protect the records it could access. FDA should remedy this shortcoming immediately and issue a guidance on the procedures it will follow to protect records.

Additionally, the proposed rule does not set out the parameters for FDA's exercise of its records access authority. The Bioterrorism Act, among other things, specifies that FDA may receive access to records only upon presentation of a written notice. 21 U.S.C. § 350c(a). The request for records access must be made by an officer or employee designated by the Secretary, Health and Human Services. The proposed rule repeats the Bioterrorism Act's procedural requirements, but does not elaborate upon them. FDA should address the written notice and other procedural requirements, either in the final rule, or in a guidance.

5. FDA should clarify the definitions of "nontransporter" and "transporter."

FDA proposes establishing different record keeping requirements for transporters and nontransporters. A "transporter" is a domestic person who has possession, custody, or control of food for the sole purpose of transporting such food; a "nontransporter" is a person who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation. Proposed 21 C.F.R. § 1.328. Not surprisingly, many nontransporters own trucks or other vehicles and transport food as an incidental part of their operations. For example, many AFIA members deliver feed by truck to their customers. These entities should not be classified as transporters for their distribution practices are incidental to the other nontransporter activities -- holding, processing, packing, importing, or receiving animal feed or pet foods. AFIA asks FDA to clarify that under such circumstances, a nontransporter's incidental shipment and delivery operations will not result in a requirement that the entity must comply with both the transporter and nontransporter parts of the final rule.

6. AFIA supports the proposed rule's treatment of electronic records.

Proposed 21 C.F.R. § 1.360(f) provides that the maintenance of electronic records is acceptable. AFIA supports this provision. FDA further proposes to exempt electronic records an entity establishes or maintains to satisfy the bioterrorism record keeping requirements from the requirements of 21 C.F.R. Part 11, electronic records and electronic signatures. As FDA recognizes, it would be very burdensome to require that records that must be maintained under the bioterrorism rule also comply with part 11. Without such an exemption, entities would likely have to create costly new systems to comply with both rules. 68 Fed. Reg. at 25,199.

7. FDA should be flexible in the product identification requirements.

Under the proposed rule, a nontransporter must retain the "lot or code number or other identifier" of each article of food it receives or sends "to the extent this information exists." Proposed 21 C.F.R. § 1.337(a)(4). It is not clear what "other identifiers" would satisfy this requirement, and it is not clear under what circumstances such information will be deemed to "exist." Requiring product identification by lot number could be highly burdensome. Not all animal feed and pet food manufacturers and processors assign lot numbers to their products. When a manufacturer or processor does assign lot numbers, what constitutes a lot number and where and whether it appears on the product package all vary tremendously. Also, a single shipment or pallet of product may contain food or feed from multiple lots. AFIA suggests that FDA be flexible in implementing the product identity requirement, by, for instance, allowing identity and tracing of product by purchase orders or other similar types of documentation.

FDA proposes that manufacturers be able to identify the specific source of each ingredient that was used to make every lot of finished product. 68 Fed. Reg. at 25,106. FDA acknowledges

the difficulties in matching the source of incoming ingredients to lots of finished product because, among other things, manufacturers typically rely on multiple suppliers for ingredients and do not dedicate bulk storage facilities such as silos and tanks by supplier. These practices are extremely common in the animal feed industry. AFIA does not see how a typical animal feed manufacturer would be able to identify the source of ingredients in a finished animal feed product without completely reconfiguring its manufacturing and storage operations and establishing dedicated facilities segregated by supplier.

FDA states that such massive overhauls of existing processes are not the intent of the record keeping rule. However, FDA further states that manufacturers must capture that information which is "reasonably available." AFIA requests clarification from FDA and assurances that under the practices such as those described above, records matching bulk stored, commingled ingredients to individual lots of finished product are not reasonably available.

8. FDA should give record keepers more time to produce records in response to a written request.

The proposed rule sets very short time frames within which companies are required to make records available to FDA in response to a written request. Requested records must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours of a request, if made at any other time. Proposed 21 C.F.R. § 1.361.

Such short timeframes can be extremely onerous, and indeed, compliance with them may be impossible. Many AFIA members use off site records storage facilities that are not automatically available on a 24/7 basis. Even a 4-hour deadline during normal business hours (or an 8-hour deadline outside of normal business hours) may not feasible. AFIA suggests that FDA incorporate a "reasonableness" standard within its time limits that recognizes the good faith efforts of an entity to acquire the requested records as soon as possible.

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AFIA thanks FDA for this opportunity to comment on the proposed rule.

Sincerely,

Richard Sellers/dah

Richard Sellers
Vice President -- Feed Control and Nutrition
American Feed Industry Association