



AMERICAN FEED INDUSTRY ASSOCIATION

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April 4, 2003

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

Re: Registration of Food Facilities; Docket No. 02N-0276

Dear Sir/Madam:

The American Feed Industry Association (AFIA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on food facility registration. 68 Fed. Reg. 5378 (Feb. 3, 2003).

AFIA is the national, not-for-profit trade association for feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers, and other firms that supply goods and services to the feed 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 purposes of the proposed rule, and of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) that it is implementing. However, we believe that some minor changes and clarifications would help minimize the burden of the registration requirement on the food and feed industries without compromising the goals of the registration system.

1. The exemption for retail facilities should be extended to include retail facilities that sell animal feed and/or pet food.

In the preamble to the proposed rule, FDA requests comments on whether the exemption for "retail facilities" should apply to retail outlets that sell food for animal consumption. According to FDA, the legislative history of the Bioterrorism Act states that the exemption applies only to food for "human" consumption. 68 Fed. Reg. at 5383. FDA should not be reaching to legislative history when Congress' intent is plain from the language of the statute itself. Whatever the legislative history says, the Bioterrorism Act contains no limitation upon the scope of "retail establishments." The final regulation should follow the unambiguous language Congress enacted and the President signed into law, not the views expressed in legislative history. *See e.g., HUD v. Rucker*, 535 U.S. 125, 132 (2002) (reference to legislative history is inappropriate when the text of the statute is unambiguous).

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Such a construction is also sensible. If retail stores that sell food for human consumption are exempt, retail facilities that sell food for animal consumption (e.g., feed stores, farm stores, pet food stores) should also be exempt. It is perverse and nonsensical to hold feed stores and pet food stores (or the thousands of stores that sell both human and animal food) to a higher standard and greater regulatory oversight than stores that sell food for human consumption alone.

Retail establishments that sell both human and animal food are ubiquitous. Indeed, it is the rare establishment that **does not** also sell cat or dog food for the convenience of its customers. To reach beyond the plain language of the statute and require retail establishments that sell food for animal consumption to register will virtually gut the congressionally mandated retail establishment exemption.

2. AFIA agrees with FDA's distinction between retail establishments that sell only to consumers and those that sell to wholesalers or distributors

FDA proposes extending its retail establishment exemption only to those facilities that sell directly to consumers. Those that also distribute to distributors and wholesalers would be required to register. 68 Fed. Reg. at 5383. AFIA supports this sales/distribution distinction to determine which entities must register.

In the animal feed business, it is the common practice for dealers (i.e., "retailers"), to purchase and distribute animal feeds to consumers. In some instances they purchase commercially prepared animal feed, and distribute it directly to customers. In other instances the dealer may be a "mix and grind" operator – that is, it grinds and mixes the feed, bags it, and sells the animal feed to the customer. These practices are analogous to retailers, such as grocery stores, who make sandwiches, cook meat, mix salads, and mix and bake breads and desserts. Both the grocery store and the animal feed dealer mix a food product and sell it from that establishment to customers. AFIA believes such dealer operations, including "mix and grind" dealers, should be exempt from the registration. On the basis of the operations conducted, there is no basis for distinguishing these types of retail practices from those conducted by exempt retail grocery and convenience stores.

3. AFIA agrees that facilities that manufacture/process feed for distribution to contract growers should not be exempt.

The preamble to the proposed rule provides that the farm exemption does not apply to facilities that manufacture/process feed for distribution to contract growers to be fed to animals being raised on the contract growers' farms. 68 Fed. Reg. at 5382. AFIA agrees that such facilities should not be exempt. Feed mills that manufacture feed for distribution to contract growers are in direct competition with the commercial feed industry, such as AFIA's members. AFIA believes there is no reason, and Congress could not have intended, to exempt these facilities.

4. The final rule should clarify the definition of “facilities.”

AFIA requests that the final rule clarify the definition of “facilities” on several bases. First, AFIA takes issue with FDA’s registration requirement for a “mobile facility” that travels to “multiple locations, that manufactures/processes, packs or holds food for consumption in the United States.” Proposed 21 C.F.R. § 1.227(c)(2). The proposed definition does not clearly exclude trucks, truck trailers, rail cars, airplanes, and vessels. These vehicles do not have a fixed locale, travel to multiple locations, and temporarily hold the food they are transporting. If Congress had intended to expand the common sense definition of “facility” and require registration of every transportation vehicle carrying food in and into the United States, it would have so stated. The final rule should explicitly exclude transportation vehicles, even if used for temporary storage, from the definition of “facilities.”

Additionally, the final regulation should clarify that the temporary “holding” of food in one’s home, on one’s farm, or in temporary storage does not convert that locale into a “facility,” thereby triggering the registration requirement. The proposed definition of “facility” in section 1.227(c)(2) seems to suggest that any location where food is “manufactured/processed, packed, or held” becomes a facility.

In the feed business, it is not uncommon for sales personnel to have animal feed and feed ingredients on hand for sales calls and product deliveries. Incidental to their sales responsibilities, they must store product on their own property or in some type of public storage. If Congress had intended to require registration of any home, farm, storage locker, or feed bin, that might hold animal feed, it would have so stated. The burdens upon individuals to generate this registration information, and the burdens upon FDA to collect and absorb such information, would be overwhelming.

Last, some animal feed manufacturers have sales personnel who travel to customers in trucks and hand mix feed to order. AFIA does not take issue with the registration of the plants from where an animal feed manufacturer does business, if they otherwise meet the definition of “facility” that manufactures, packs, processes, or holds food. AFIA does take issue with requiring registration of these individual traveling trucks and mixers. The operations are akin to transportation vehicles and to retail establishments, such as grocery stores, that bake, cook, or prepare product for distribution at that establishment.

5. FDA should ensure the security of registration information and the registration system.

AFIA believes it is essential that the new registration system be secure. If any person with access to a facility’s registration number can access that facility’s registration and alter registration data, the registration data will be worthless. Since registration numbers will be required to be

provided to other firms (e.g., for purposes of compliance with the prior notice requirement), the registration number alone should not be sufficient to access the system. FDA should design the system so that only authorized persons can access and change a facility's registration information.

6. Facilities should be allowed to submit registration information in the form of an electronic data file.

AFIA believes that the registration system should allow the submission of electronic data files in place of entering the data into FDA's system. For large companies with many different facilities, it would not be feasible to require manual entry of the information into the registration system. Allowing companies to submit electronic data files with registration information, such as in an Excel spreadsheet, would significantly decrease the burden on both the agency and the companies.

7. The criteria for revoking a facility's registration should be limited to those relevant to the purposes of the Bioterrorism Act.

The proposed rule requests comments on the circumstances in which a facility's registration should be revoked by FDA, and the procedures that should apply to such a revocation. Revocation of a facility's registration will effectively prohibit that facility from manufacturing/processing, packing, or holding food for consumption in the United States.

Given the serious consequences of revocation, AFIA believes that it should be reserved for extreme situations that indicate the potential for bioterrorism, intentional contamination, or other criminal activity. In all other situations, FDA has a range of other enforcement tools that the agency should employ before seeking revocation. For example, if a food product manufactured by a facility is adulterated or misbranded, FDA's first recourse should be to request a recall. If the facility refuses to recall the product, then FDA should initiate a seizure or injunction action in federal court. Revocation should only be pursued as a last resort. In addition, AFIA believes that a facility facing revocation should be afforded appropriate due process protections consistent with the property rights involved. Specifically, revocation should require an adjudicative hearing in accordance with the Administrative Procedure Act (5 U.S.C. § 554).

8. If an imported food is refused admission because it is from an unregistered foreign facility, there should be procedures for the review of this and other similar FDA determinations.

Under the proposed rule, if a foreign facility that is required to register fails to do so, food from the unregistered foreign facility may be refused admission and held at the port of entry until registration is completed. If FDA directs removal of such food to a secure storage facility, the owner, purchaser, importer, or consignee must arrange for storage of the food in an FDA-designated

secure facility; must notify FDA of the location; must move the food to the secure facility under bond; and must bear the transportation and storage expenses. The proposed rule does not provide any right for parties adversely affected by a refusal of admission to challenge that determination.

AFIA believes there must be some mechanism for review of such determinations and others, including those related to revocation of a firm's registration. There is a strong presumption in the law in favor of reviewability of agency decisions, even where the governing statute does not expressly provide for such review.

It is the rare instance in which an aggrieved party may not seek judicial review of an agency action. The Administrative Procedure Act states that judicial review shall apply to agency action "except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). The courts have held that "there is virtually a presumption in favor of judicial review unless a contrary purpose is fairly discernable in the statutory scheme." *Hayes Intern. Corp. v. McLucas*, 509 F.2d. 247 (5th Cir. 1975) (citing *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967)). The absence of express statutory language authorizing judicial review is not enough to overcome this presumption of reviewability. Agency action typically is found to be non-reviewable only if there is a showing of "clear and convincing evidence" of a legislative intent not to allow review. *Abbott Laboratories*, 387 U.S. at 140 (citing H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946) ("To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.")).

While the Bioterrorism Act does not expressly provide for review of agency decisions, there is no evidence in the statute or its legislative history to overcome the presumption in favor of review. Accordingly, the final rule should provide a mechanism for review of agency registration – related decisions, both administrative review within FDA and judicial review in court.

9. FDA should limit when updates to registrations are required

FDA proposes to require that any change in the information contained in a facility registration be provided to FDA in a facility registration update within 30 days of the change. This proposed requirement is unnecessarily burdensome. AFIA proposes that, at a minimum, changes to optionally provided information need only be reported to FDA annually. Moreover, AFIA notes that the data elements that are most likely to change, and frequently, are those requiring identification of a particular contact person. AFIA suggests that the final rule eliminate this detailed identification of personnel by name; the registration will already have the facility's contact information, including main phone number. Alternatively, AFIA suggests that FDA permit the identification of several emergency contacts, including a primary contact, and back up contacts, and require updating that information only if all of the emergency contacts have changed.

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We appreciate this opportunity to comment.

Respectfully submitted,

A handwritten signature in black ink that reads "Richard Sellers" followed by a stylized flourish or initials.

Richard Sellers
Vice President, Feed Control and Nutrition