



April 10, 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: Registration of Food Facilities; Docket No. 02N-0276

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) on the agency's proposed rule to require registration of food facilities. 68 Fed. Reg. 5378 (Feb. 3, 2003). The proposed rule is intended to implement Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).

IFDA is a trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 135 members include broadline and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than \$64 billion in food and related products to the fastest growing sector in the food industry. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

IFDA strongly supports the purposes of the Bioterrorism Act and of this proposed rule. However, we are concerned that the proposed rule goes considerably beyond the Bioterrorism Act in terms of the information registering facilities would be required to submit. The Bioterrorism Act requires only the name and address of the facility, the trade names used by the registrant, and (if FDA determines through guidance that it needs such information) the product category of the food manufactured/processed, packed, or held at the facility. From this humble beginning, FDA proposed a six-page registration form with 12 sections and numerous items of information. IFDA believes that, by requiring so much more information than the Bioterrorism Act, FDA has exceeded its statutory authority. If Congress had intended to authorize FDA to expand the scope of required information to this extent, it would have included language in the Bioterrorism Act indicating such

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an intent (*i.e.*, language authorizing FDA to require “such other information as the Secretary deems necessary”). Section 305 of the Bioterrorism Act contains no such language.

In addition, IFDA believes that the proposed rule could be improved, and its burden on the food industry mitigated, by making the following changes.

1. Facilities required to register under other federal or state registration requirements should not be required to submit duplicative information to FDA.

In the proposed rule, FDA “seeks comments on whether there are registration requirements under which facilities must submit duplicative information to more than one Federal agency.” 68 Fed. Reg. at 5386. If so, FDA requests comments on whether granting a full or partial exemption from the proposed registration requirement would be (a) within FDA’s authority under the Bioterrorism Act, and (b) consistent with the purposes of the Bioterrorism Act.

The vast majority of IFDA members’ facilities are already required to register with the U.S. Department of Agriculture (USDA) under the Perishable Agricultural Commodities Act (PACA) and the USDA regulations at 7 C.F.R. § 46.4. The PACA Application for License requires extensive information, including much of the information that FDA is proposing to require.¹ Some IFDA members that handle hazardous materials are required to register with the U.S. Department of Transportation, and many IFDA members are also subject to various state registration requirements. This means that a single facility may now be subject the three different registration requirements involving three different government agencies; the proposed rule would add a fourth.

IFDA believes that a facility should not be required to submit the same information to two federal agencies. In the case of facilities registered under PACA, FDA can and should obtain duplicative information from USDA. We therefore propose that FDA should exempt PACA-registered facilities from this proposed registration requirement.

2. The definition of “facility” should be revised to remove the reference to mobile facilities.

¹ PACA registration requires essentially all of the information required by Section 305 of the Bioterrorism, including names, trade names, and locations of the registrant’s facilities. Although PACA registration does not include the food product categories manufactured/processed, packed, or held at the facility, this information can be surmised from the other PACA registration information. PACA registration requires the registrant to indicate the type of facility it operates. If the registrant checks “wholesaler,” “processor,” or “commission merchant/growers’ agent,” this means it handles only perishable commodities as defined in PACA (*i.e.*, fresh and frozen fruits and vegetables of every kind and character). If the registrant checks any of the other facility types, then it is “full line” (*i.e.*, it handles most or all food product categories).

The proposed rule defines “facility” to include “a mobile facility traveling to multiple locations.” 68 Fed. Reg. at 5418. Neither the proposed rule nor its preamble explain what sort of mobile facilities FDA has in mind. We believe it is clear that Congress did not intend that the registration requirement should apply to trucks, rail cars, or shipping containers, even if these are occasionally used to store food on a temporary basis.

IFDA requests that the definition of “facility” be revised to remove the reference to mobile facilities. Alternatively, FDA should explain clearly what sort of mobile facilities would be subject to the registration requirement.

3. Emergency contact information should not require the name of an individual.

The proposed rule would require each registering facility to submit emergency contact information, including the contact person’s name, title, office phone number, home phone number, cell phone number (if available), and e-mail address (if available).

Because the contact person for a particular facility is likely to change frequently, IFDA suggests that the name of the contact person should not be required. Alternatively, the name of the contact person should be optional information. We believe that FDA will be able to reach the emergency contact person using that person’s title and other contact information; the name of a specific individual is not necessary.

4. The final rule should clarify that facilities that handle most or all food product categories may indicate this fact and are not also required to list each food product category.

The proposed rule would require that each facility list the food product category or categories it manufactures/processes, packs, or holds. The proposed rule also provides for a food product category of “most/all food product categories” as optional information. While it appears that a registering facility may check “most/all food product categories” instead of checking each individual food product category that applies, this is not clear.

Most IFDA members operate facilities, whether storage facilities or “cash-and-carry” stores, that handle a wide variety of food product categories. IFDA therefore requests that the final rule clarify that a facility may check “most/all food product categories” instead of checking the individual product categories listed on the registration form.

5. Registrants should not be required to update optional information.

The proposed rule would require that any change in registration information, including optional information, must be updated within 30 days after the change. FDA has requested comments on whether the requirement to update optional information may affect the submission of optional information. IFDA believes that the final rule should request, but not require, updates of optional information. If optional information is required to be updated, we think this may discourage submission of such information.

6. The final rule should provide for administrative and judicial review of agency decisions.

Under the proposed rule, food imports from an unregistered foreign facility would be refused entry and held at the port of entry until registration is completed. The proposed rule also contemplates that FDA may, under certain circumstances, revoke a facility's registration, thereby effectively prohibiting that facility from manufacturing/processing, packing, or holding food for U.S. consumption. The proposed rule does not provide parties adversely affected by such determinations any right of review.

IFDA believes that the final rule should provide for the reviewability of such determinations. There is a strong presumption in favor of the reviewability of agency decisions, both administrative review and judicial review, even where the governing statute does not expressly provide for such review. *See, e.g., Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). 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. Due process requires that the final rule provide for administrative and judicial review of FDA decisions to cancel a facility's registration or to refuse admission to food imports.

IFDA thanks FDA for this opportunity to comment.

Sincerely,



David French
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