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The Food and Drug Administration (FDA) has published a proposed rule that would require registration of food facilities. 68 Fed. Reg. 5,378 (Feb. 3, 2003). Comments on this proposed rule must be submitted to FDA by **April 4, 2003**.^[1]

This proposed rule, together with a proposed rule that would require prior notice of food imports, are the first two of four anticipated proposed rules implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The Bioterrorism Act was passed in response to the events of September 11, 2001, and Title III of the Bioterrorism Act includes provisions designed to protect the U.S. food supply from acts of bioterrorism or intentional contamination.

This memorandum summarizes the food facility registration proposed rule. While reading this memorandum, it is important to keep in mind the following points:

- This proposed rule would affect large segments of the U.S. food industry, as well as many foreign food companies.
- While this proposed rule is mandated by Section 305 of the Bioterrorism Act, it goes beyond the provisions of the Bioterrorism Act in certain respects. For example, the proposed rule would require submission of information not provided for in the Bioterrorism Act. It is possible that FDA may have exceeded its statutory authority. The food industry may wish to raise this issue in comments to FDA, or bring a legal challenge to the final rule on these grounds.

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Purpose of Registration Requirement

The purpose of registration is to enable FDA, in the event of an actual or threatened bioterrorist attack, to determine the source and cause of the event and communicate quickly with potentially affected facilities.

Who Must Register

Under the proposed rule, the owner, operator, or agent in charge of every domestic or foreign facility that engages in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States must register with the FDA, unless exempt.^[2] A domestic facility must register whether or not the food from the facility enters interstate commerce.^[3] A foreign facility is required to have a U.S. agent; it may designate the U.S. agent as its agent in charge for purposes of registration.^[4] A “foreign facility” is any facility that is not located in a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

The proposed rule would define “food” as it is defined in section 201(f) the Federal Food, Drug, and Cosmetic Act (FFDCA) (21

U.S.C. § 321(f)). This is a very broad definition that includes, for example: shell eggs; raw agricultural commodities for use as food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging^[5] and other articles that contact food; dietary supplements; infant formula; beverages, including alcoholic beverages and bottled water; and live food animals, such as live cattle and hogs.

The proposed rule would define “facility” to mean “any establishment, structure or structures under one management at one general location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States.” Thus, a single food facility may consist of several contiguous buildings, provided they are under one management. Similarly, a single building may constitute more than one food facility if different parts of the building are under different management.

Who Is Exempt from Registration

The proposed rule would exempt the following types of food facilities:

- Foreign facilities, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. However, if the further manufacturing/processing (including packaging) by the subsequent facility is of a *de minimis* nature (e.g., adding labeling to packaged food), this exemption would not apply. In that case, both the last manufacturer/processor or packer and the subsequent facility conducting the *de minimis* activity would be required to register. In essence, the last foreign facility that truly manufactures/processes or packs the food would always be required to register. In addition, any subsequent facility located outside the United States that takes possession, custody, or control of the finished food for holding, storage, or other *de minimis* activities (e.g., labeling) prior to export to the United States would be required to register.
- Farms. The proposed rule would define “farm” as “a facility in one general location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both.” Examples include fruit orchards, hog farms, dairy farms, feedlots, and aquaculture facilities. The definition includes: (1) facilities that pack or hold food (e.g., harvested crops), provided all such food is grown or raised on that farm or is consumed on that farm; and (2) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. However, a facility that grows crops and/or raises animals and manufactures/processes food that is sold for consumption off the facility does not qualify for this exemption.^[6]
- Retail facilities. The proposed rule would define “retail facility” as “a facility that sells food products directly to consumers only.” This includes facilities that manufacture/process food in the facility solely for direct sale to consumers in that same facility. Examples include grocery and convenience stores, vending machines, and commissaries. Facilities, such as warehouse clubs, that sell both directly to consumers and to distributors and wholesalers would not qualify for this exemption. FDA is requesting comments on whether the retail exemption should also apply to food for animal consumption.^[7]
- Restaurants. The proposed rule would define “restaurant” as “a facility that prepares and sells food directly to consumers for immediate consumption.” Examples include cafeterias, lunchrooms, cafes, fast food establishments, food stands, taverns, bars, catering facilities, and hospital kitchens.^[8] The term “restaurants” also encompasses pet shelters, kennels, and other facilities that provide food to animals. Facilities that provide food to interstate conveyances (e.g., airplanes, passenger trains, cruise ships), rather than directly to consumers, are not restaurants and would not qualify for this exemption.
- Nonprofit food facilities in which food is prepared for or served directly to the consumer. The proposed rule would define “nonprofit food facility” as “a charitable entity that prepares, serves, or otherwise provides food to the public.” To qualify for this exemption, the entity must be exempt from paying income tax under the U.S. Internal Revenue Code. Examples include food banks, soup kitchens, and nonprofit food delivery services.
- Facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA). Facilities that are jointly regulated by FDA and USDA (e.g., facilities that slaughter both cattle and deer; facilities that process both meat and non-meat products) would be required to register.^[9]
- Fishing vessels, unless such vessels also engage in processing.

In the case of mixed-type facilities (*i.e.*, facilities that perform activities requiring registration and activities that are exempt from registration), FDA will not require registration if the activity requiring registration is merely incidental to the activity that is exempt from registration. An example of a mixed-type facility would be a farm that also manufactures/processes human food or animal feed for consumption offsite.

Registration Information

Registrants would be required to provide FDA with the following information:^[10]

- The name, full address, phone number, fax number, and E-mail address of the food facility;
- The name and address of the parent company (if the facility is a subsidiary of the parent company);

- Emergency contact information (including contact person's name, title, office phone, home phone, cell phone (if available), and E-mail address (if available));[\[11\]](#)
- All trade names used by the facility;
- The category of food manufactured/processed, packed, or held at the facility (using the food categories listed in 21 C.F.R. § 170.3);[\[12\]](#)
- For foreign facilities, the name, address, phone number, fax number (if available), and E-mail address (if available) of the U.S. agent; and
- A signed statement certifying that the registrant is authorized by facility to submit the registration and that all information submitted is true and accurate, together with the registrant's phone number, fax number (if available), and E-mail address (if available).

The registration form will also include, and FDA requests that registrants provide, the following optional information:

- A preferred mailing address. This would allow a facility's corporate headquarters to serve as the primary contact with FDA instead of the facility.
- The type of activity conducted at the facility (*e.g.*, processor/processor, repacker/packer, acidified/low acid food processor, contract sterilizer). This information would allow FDA to target communications relevant to only one type of activity (*e.g.*, a threat directed only to manufacturing facilities) to only those affected.
- Food categories not listed in 21 C.F.R. § 170.3 (*e.g.*, dietary supplements, infant formula, food for animal consumption).
- The type of storage, if the facility is solely a holding facility (*e.g.*, ambient storage, refrigerated storage, frozen storage).
- A food product category for "most/all food product categories," if the facility manufactures/processes, packs, or holds foods in most or all of the categories listed in 21 C.F.R. § 170.3.
- The approximate dates of operation, if the facility's business is seasonal.

FDA has published a Draft Food Facility Registration Form (Form 3537) and Cancellation of Food Facility Registration (Form 3537a). [Click here to view a draft of Form 3537 \(PDF\)](#)

Registration forms, and any information in those forms that would disclose the identity or location of a specific registered person, is not subject to disclosure under the Freedom of Information Act. FDA has stated, however, that it may share registration information with other federal and state government agencies. In the event that FDA does share registration information with other federal or state agencies, FDA's existing regulations require that the agency obtain a written agreement that such federal or state agencies would not make the shared information public.

Method of Registration

The proposed rule would provide for registration by both electronic and paper means. However, FDA strongly encourages electronic filing. In the case of foreign facilities, the U.S. agent may register electronically for them. Firms that register electronically will receive an instantaneous confirmation and facility registration number; the facility will be considered registered upon transmission of the confirmation and registration number, unless notified otherwise. Registration by mail may take weeks or months; FDA will consider the facility registered only when its information is entered into the registration system and the system generates a registration number. Electronic registrations will be able to be submitted 24 hours a day, 7 days a week, through a link on FDA's website. Electronic registration will not be accepted unless all mandatory fields are completed.

FDA expects to have both electronic and paper registrations systems operational at least two months before the statutory deadline of December 12, 2003. FDA will announce the exact date these systems will be operational in the final rule.[\[13\]](#) Registrations mailed to FDA before that date will not be accepted.

Facilities that currently manufacture/process, pack, or hold food for consumption in the United States must be registered by December 12, 2003. Facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003 must register before they begin such activities.

Companies that own multiple facilities will be able to submit registrations for all of their facilities.[\[14\]](#) There is no registration fee. All registration information must be in the English language.

Updates and Cancellations

If any registration information submitted to FDA (including optional information) changes, the facility would be required to submit an update, via the Internet or paper copy, to FDA within 30 calendar days of the change. FDA requests comments on this 30-day timeframe. FDA also is requesting comments on whether updates to optional information should also be required and whether doing so would discourage submission of optional information.

A facility canceling its registration must do so on a separate cancellation form, electronically or by mail. A cancellation of registration must include the following information: facility registration number; whether the facility is domestic or foreign; facility name and address; the name, address, and E-mail address (if available) of the individual submitting the cancellation; and a statement by the submitter certifying that the information submitted is true and accurate and that the submitter is authorized by the facility to cancel its registration.

FDA is seeking comments on the circumstances under which a firm's registration should be considered null and void and on the circumstances in which a registration should be revoked. FDA also seeks comments on the process for such determinations.

Consequences of Failure to Register or Submission of False Information

Failure to register a covered facility is a prohibited act under Section 301 of the FFDCA (21 U.S.C. § 331). FDA may bring a civil action in federal court to enjoin any person who commits a prohibited act (*i.e.*, to compel registration), or may bring a criminal action in federal court to prosecute a person who commits a prohibited act. In addition, under the Bioterrorism Act, FDA may seek debarment of any person convicted of a felony relating to the importation of food. For foreign facilities that fail to register as required, the Bioterrorism Act requires that food from an unregistered facility be held at the port of entry unless FDA directs its removal to a secure facility.^[15]

If a person submits false information, or if a person registers a facility without authorization to do so, the registration will be considered a materially false, fictitious, or fraudulent statement to the U.S. Government, subjecting the person to criminal penalties under 18 U.S.C. § 1001.

Relationship to Other Registration Requirements

This proposed registration requirement will be in addition to, not in place of, any other existing registration requirements that may apply to a food facility (*e.g.*, registration under 21 C.F.R. Part 108 related to emergency permit control). However, FDA is seeking comments on whether there are registration requirements under which facilities must submit duplicative information to more than one federal agency. If so, FDA seeks comments on ways, consistent with the requirements and purposes of the Bioterrorism Act, to minimize such duplication. In particular, FDA is interested in comments on whether it has authority to grant a partial or full exemption from the proposed registration requirement to facilities that have already registered with another federal agency, and whether the goals of the Bioterrorism Act can be met if FDA does not have complete registration information.

Impact on Small Businesses

FDA is unsure whether the proposed rule would have a significant economic impact on a substantial number of small businesses. FDA requests comments on the effect of the proposed rule on small businesses. In particular, FDA seeks comments on whether setting staggered compliance dates that would allow small businesses more time to comply would be consistent with Section 305 of the Bioterrorism Act.

Submitting Comments

[Submit Comments Electronically](#)

Submit Written Comments:

Submit written comments in duplicate [individuals may submit one copy] to: Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852 ATTN: Docket No. 02N-0276

[1] Comments on FDA's estimate of the cost of the proposed rule to industry must be submitted to the Office of Management and Budget's Office of Information and Regulatory Affairs by March 5, 2003.

[2] The proposed rule includes definitions of the terms "manufacturing/processing," "holding," and "packing."

[3] FDA is requesting comments on whether it has authority to exempt domestic facilities engaged only in intrastate commerce and, if so, whether it should exercise that authority. FDA tentatively concluded that the Bioterrorism Act does not permit such an exemption.

[4] The proposed rule would define "U.S. agent" as "a person residing or maintaining a place of business in the United States whom a foreign facility designates as its agent." A U.S. agent may be a business partner, broker, U.S. lawyer, or parent company. A U.S. agent cannot be a mailbox, answering machine, or service. The U.S. agent will act as the foreign facility's communications link to FDA. FDA will treat representations made by the U.S. agent as those of the foreign facility and consider information provided to the

foreign facility's communications link to FDA, FDA will treat representations made by the U.S. agent as those of the foreign facility and consider information provided to the U.S. agent as information provided to the foreign facility. FDA recommends that foreign facilities and their U.S. agents execute written agreements specifying the U.S. agent's responsibilities, but they need not submit a copy of this agreement to FDA.

[5] "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

[6] However, a facility that grows crops and/or raises animals and also manufactures/processes food and sells it directly to consumers (e.g., at a roadside stand) would qualify for the retail establishment exemption.

[7] It seems clear that distributors themselves, including "cash and carry" stores, would not qualify for this exemption, because they do not sell food directly to consumers only.

[8] Although not specifically mentioned by FDA in the preamble to the proposed rule, school cafeterias appear to qualify for this exemption. In addition, school foodservice programs, including central kitchens, would appear to qualify for exemption as nonprofit food facilities. A question might arise, however, if a school district's central kitchen sold food to another school district.

[9] While a meat or poultry slaughter or processing plant that is regulated exclusively by USDA would qualify for this exemption, a warehouse or distribution center that stores only meat and poultry products would not qualify for this exemption. That is because FDA and USDA share concurrent jurisdiction over meat and poultry products after they leave the processing plant (see 21 U.S.C. §§ 467f(b) and 679(b)).

[10] The information required by FDA in the proposed rule goes considerably beyond the information that the Bioterrorism Act authorizes FDA to require. The Bioterrorism Act authorizes FDA to require only the following information: the name and address of the facility; the trade names under which the registrant conducts business; and (when determined necessary by FDA through guidance) the general food category of any food manufactured, processed, packed, or held at the facility. In the preamble to the proposed rule, FDA cites Section 701(a) and (b) of the FFDC (21 U.S.C. § 371(a) and (b)) as statutory authority for requiring these additional items of information. Section 701(a) gives FDA authority to promulgate regulations for the efficient enforcement of the FFDC. Section 701(b) gives FDA and the Secretary of the Treasury authority to promulgate regulations for the efficient enforcement of the import provisions of the FFDC.

[11] The emergency contact person does not have to be located at the facility, but he or she must be accessible and able to respond in an emergency. A parent company may list an individual at corporate headquarters who has responsibility for responding to emergencies.

[12] For ease of use, the more common categories found in FDA's product code builder (www.fda.gov/search/databases.html) will be listed as the main categories on the registration form, followed by the food product categories in 21 C.F.R. § 170.3. FDA invites comments on whether use of its product code builder categories adequately addresses industry concerns that the product categories listed in § 170.3 are outdated and unworkable.

[13] If for some reason FDA is unable to publish a final rule by October 12, 2003, or if the electronic registration system is not completed by that date, the agency will publish a notice providing an address to which paper registrations should be sent.

[14] FDA has stated that companies registering electronically on behalf of multiple facilities will be able to do so without having to re-type redundant information.

[15] The proposed rule would define the "port of entry" as the port where the food first arrives in the United States; it may differ from the port where the food is entered for U.S. Customs purposes. The proposed rule contains detailed provisions governing secure storage at the port of entry of food from an unregistered foreign facility.