

Warehouses, Other Food-Handling Facilities Must Register With FDA Under New Regulations Aimed at Fighting Bioterrorism — Requirement Does Not Apply to Retail Stores

As N.G.A. has reported, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (known as the Bioterrorism Act) directs the Secretary of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To implement the Bioterrorism Act, the Food and Drug Administration has issued an interim final regulation, Registration of Food Facilities, which requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Under this interim final regulation, all affected facilities must register by December 12, 2003. Note that while warehouse/distribution facilities are among those establishments that are required to register, retail food establishments do not have to register. However, retail companies that own and operate a separate warehouse facility must register those facilities.

Retail food establishments, including supermarkets, delis, restaurants, etc., which sell food directly to consumers as their primary function (meaning that annual food sales directly to consumers are of greater dollar value than annual food sales to other buyers) are not required to register. This new FDA registration requirement applies to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the United States.

It is important to note that it is not just a company that must register, but each covered facility that must be registered. "Facility" means any establishment, structure, or structures under one ownership, at one general physical location. Warehouses or similar facilities that manufacture/process, pack, or hold food (other than retail establishments), including those operated by wholesalers or retailers, are among the facilities that must register.

Although N.G.A. does not completely agree with the scope of FDA's interpretation of the statute, the agency has decided that any facility operated by a retailer that holds food and is not a retail establishment must be registered. N.G.A. will be commenting on this issue and others during the 75-day comment period on this interim final rule, which closes December 24, 2003. FDA's stated purpose is that this facility registration information will help to determine the location and source of a potential or actual bioterrorism incident or an outbreak of food-borne illness. However, N.G.A. is concerned about the overly broad coverage that this rule could impose and will continue to work closely with FDA during the implementation phase. N.G.A.'s members are encouraged to submit their comments on the interim final rule to Mike Mason, N.G.A. Director of Public Affairs, at mmason@nationalgrocers.org, or by fax to (703) 516-0115.

Which Facilities Must Register

This new regulation pertains only to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the United States. Examples of "food" include: fruits and vegetables; raw agricultural commodities for use as food or components of food; canned and frozen foods; dairy products and shell eggs; beverages (including alcoholic beverages and bottled water); bakery goods, snack food, and candy (including chewing gum); fish and seafood; infant formula; dietary supplements and dietary ingredients; animal feeds and pet food; and live food animals.

Retail grocery stores are specifically excluded from registration requirements under the regulation. Note that while an establishment might manufacture/process, pack, or hold food, if its primary function is to sell food directly to consumers, including food manufactured or processed on-site, it is considered

a retail food establishment and is not required to register.

In addition, those wholesalers and retailers who operate tractor-trailers and other such vehicles should note that transport vehicles that hold food only in the usual course of their business as carriers are not required to register as food-handling facilities.

Other facilities not required to register include:

- Restaurants, i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. (Note, however, that facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers are not restaurants for purposes of the rule.)
- Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture, that is, facilities handling only meat, poultry or egg products.
- Food-contact substances and pesticides are not "food" for purposes of the interim final rule. A facility that manufactures/processes, packs, or holds a food contact substance or a pesticide is not required to register.
- Nonprofit food establishments, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States.
- Private residences of individuals, even though food may be manufactured/processed, packed, or held there.
- Non-bottled water drinking water collection and distribution establishments and structures, such as municipal water systems.
- Farms, i.e., facilities in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.
- Fishing vessels that harvest and transport fish.

Registration is required only once for each food facility. However, required registration information must be updated within 60 days if there are changes.

How to Register

The registration must be completed by the owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the United States, or an individual authorized by one of them. A domestic facility must register whether or not food from the facility enters interstate commerce. A foreign facility must designate a U.S. agent (for example a facility's importer or broker), who must live or maintain a place of business in the U.S. and be physically present in the United States, for purposes of registration. FDA will accept food facilities registration through the Internet, by surface mail (paper or CD-ROM), or by fax. For additional information, see FDA's website at www.fda.gov/furls.

- To register online: <http://www.cfsan.fda.gov/~furls/ovffreg.html>
- To download forms: <http://www.cfsan.fda.gov/~furls/papercd.html>.

FDA has set up a "help desk" to assist with registration, which will be available to answer questions from 7 a.m. to 11 p.m., U.S. Eastern Time, on business days beginning October 16, 2003. (In the U.S call 1-800-216-7331 or 301-575-0156; from elsewhere call 301-575-0156; fax questions to 301-210-0247; or e-mail questions to furls@fda.gov.) If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from FDA by calling 1-877-FDA-3882 (1-877-332-3882) or by mailing a request to: U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville MD 20857.

Completed forms should be mailed to the above address or faxed to (301) 210-0247. Also, registrations for multiple facilities may be submitted to FDA in CD-ROM format ISO 9660 (CD-R or CD-RW) data

format. These files must be submitted on a Portable Document Format (PDF) of Form 3537 and be accompanied by one signed copy of the certification statement that appears on the registration form. Each submission on the CD-ROM must use the same preferred mailing address in the appropriate block on Form 3537. There is no maximum number of registrations that may be submitted in this manner. However, each registration on a CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company. If the information does not conform to these specifications, FDA will not process the registration(s) and will return the CD-ROM for correction.

Required Information

Each registration must include the name, address, and phone number for the facility and its parent company (if applicable); the name, address, and phone number of the owner, operator, or agent in charge; all trade names the facility uses; applicable food product categories as identified in FDA's regulation, 21 CFR 170.3; a statement certifying that the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration. A foreign facility must also provide the name, address, and phone number of its U.S. agent. The foreign facility must also provide the emergency contact phone number for its U.S. agent unless the facility designates another person to serve as the emergency contact. A domestic facility must also provide an emergency contact phone number. In addition, FDA is asking for, but not requiring, certain optional information on the registration form. For example, some food products are not identified in the list of food categories at 21 CFR 170.3, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may be the focus of a food-related emergency, FDA said. If the information submitted to FDA changes, an update must be provided to FDA within 60 days.

The registration information will not be made available to the public. FDA said that, neither the list of registered facilities, any registration documents submitted under this regulation, nor any information derived from the list or the documents that would reveal the identity or location of a specific registered person is subject to disclosure under the Freedom of Information Act (FOIA).

Enforcement

Failure of a domestic or foreign facility to register, update required elements, or cancel its registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. However, the FDA has yet to issue an enforcement guidance, other than to say that it can bring civil or criminal actions against violators.

N.G.A. is encouraged that FDA has said it recognizes that a number of affected parties still may need assistance in understanding the rule's requirements and how to comply. FDA said it intends to issue a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. N.G.A. commends FDA for these efforts, and will work with the agency as it compiles an enforcement guideline that is both effective and fair to industry.

Important Warning on Firms Offering Registration

FDA has said it is aware that various firms may be offering their services to assist domestic and/or foreign facilities to register with FDA. The agency emphasized that these firms are not affiliated with FDA, nor has the agency contracted with any firms to register facilities. Also, there will be no registration fee.

Additional Comments

FDA is providing a 75-day comment period on specific issues related to this interim final rule. N.G.A. has worked with FDA throughout the rulemaking process, and is encouraged that the FDA has worked with industry and has taken steps to make its regulations workable. N.G.A. has emphasized to FDA that our industry's top priority is to ensure the security of the food supply for American consumers.

Wholesalers and retailers affected by the rule are encouraged to review the registration form and other

materials (see www.fda.gov/oc/bioterrorism/furls) and provide N.G.A. with your comments and assessment. Please provide this information to Mike Mason, N.G.A. Director of Public Affairs, who can be reached at (703) 516-0700, or mmason@nationalgrocers.org. N.G.A. will continue to work closely with FDA as it develops enforcement guidelines and further refines this interim final rule.

If you have questions or need additional information, contact Tom Wenning at publicaffairs@nationalgrocers.org.

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