October 2003

FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule - Registration of Food Facilities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (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 carry out the provisions of the Bioterrorism Act, FDA published, on October 10, 2003, 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***. In the event of a potential or actual bioterrorism incident or an outbreak of food-borne illness, facility registration information will help FDA to determine the location and source of the event and permit the agency to notify quickly facilities that may be affected. **Facilities can register online via the Internet, by completing a paper form, or submitting to FDA a CD-ROM with relevant registration information. The online registration system will be available for use on *October 16, 2003*. For assistance with online registration: in the U.S call 1-800-216-7331 or 301-575-0156; from elsewhere call 301-575-0156; or send a fax to 301-210-0247. Requests for assistance also may be emailed to furls@fda.gov. Beginning October 16, 2003, the Online Registration Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.**

This new regulation pertains *only* to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the U.S. Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals

- Animal feeds and pet food

Food contact substances and pesticides are not "food" for purposes of the interim final rule. Thus, a facility that manufactures/processes, packs, or holds a food contact substance or a pesticide is not required to register with FDA.

Who must register? 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 U.S., or an individual authorized by one of them, must register that facility with FDA by **December 12, 2003**. 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 U.S., for purposes of registration.

What types of facilities do not have to register?

- ***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.
- ***Transport vehicles that hold food only in the usual course of their business as carriers***.
- ***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. Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. The term "farm" also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and 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. A farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment.
- ***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. 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.
- ***Retail food establishments***, such as groceries, delis, and roadside stands, that sell food directly to consumers as their *primary function*, meaning that annual sales directly to consumers are of greater dollar value than annual sales to other buyers. An establishment that manufactures/processes, packs, or holds food and whose primary function is to sell food

directly to consumers, including food that the establishment manufactures/processes, from that establishment is a retail food establishment and 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 U.S. Central food banks, soup kitchens, and nonprofit food delivery services are examples of nonprofit food establishments.
- ***Fishing vessels*** that harvest and transport fish. Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
- ***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.

Do all foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S have to register? No. If a foreign facility that manufactures/ processes, packs, or holds food sends it to another *foreign* facility for further manufacturing/processing or packaging before the food is exported to the U.S., only the *second* foreign facility is required to register. **However**, if the second foreign facility performs only a *de minimis* activity, such as putting on a label, *both* facilities would be required to register. Also, any foreign facility that *packs or holds* food after the last foreign manufacturer/processor of the food must register.

How often must you register? Registration is required only once for each food facility. However, required registration information must be updated if it changes.

What does the registration number mean? It means that the owner of the facility has complied with this rule by registering with FDA. Assignment of the number does not convey FDA approval or endorsement of the facility or its products.

Is there a fee for registration? There is no fee for registration or for updates of any registration.

How can a facility register? Registrants must use Form 3537 to register or update a registration. Facilities may register online via the Internet at www.fda.gov/furls, which will operate 24 hours a day, seven days a week, beginning October 16, 2003. This web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. In addition to the online help registrants can access at www.fda.gov/furls, there is also an Online Registration Help Desk:

- 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
- Email questions to furls@fda.gov

Beginning October 16, 2003, these phone numbers will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from FDA by calling 800-216-7331 or 301-575-0156 or by mailing a request to:

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville MD 20857
USA

When the form has been filled out completely and legibly, it should be mailed to the above address or faxed to (301) 210-0247. Also, as noted immediately below, registrations for multiple facilities may be submitted to FDA on a CD-ROM.

Is there a mechanism for registering multiple food facilities at one time? FDA will accept multiple registrations submitted 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. FDA will process CD-ROM submissions along with mailed and faxed submissions in the order received.

Why does FDA encourage electronic registration? FDA encourages this mode of registration as the least costly and most efficient means for the facility as well as FDA. With electronic registration, all required information must be entered before the system will accept the submission. At that point, registrants will receive immediate confirmation of registration and a registration number. Paper registration will be a more costly and less efficient process to supply both FDA with the necessary facility information and facilities with their registration numbers. Further, paper registration may have a higher number of errors or omissions on the form, requiring additional time to complete the registration process.

What information is required? 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.

Is additional information requested? FDA is asking for, but not requiring, certain *optional* information on the registration form. The optional information will help us communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency. 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. Therefore, FDA encourages, but does not require, submission of the information identified as optional on Form 3537.

Is registration information available to the public? No. 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).

What if the submitted registration information changes? When a required element of a facility's registration information changes, e.g., change of operator, agent in charge, or U.S. agent, the owner, operator, or agent in charge, or an individual authorized by one of them, must submit an update to the facility's registration within 60 days of the change through the Internet at www.fda.gov/furls or through the paper update process.

What if a facility goes out of business? When a facility goes out of business, its registration must be canceled using Form 3537a, either through the Internet, at www.fda.gov/furls, or through the paper process.

What if a new owner acquires an already-registered facility? The former owner must cancel the facility's registration within 60 days of the change (using Form 3537a), and the new owner must re-register the facility using Form 3537. Both cancellation and re-registration may be completed through the Internet or through the paper process.

What happens if a facility does not register? 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. The Federal government can bring a civil action to ask a Federal court to enjoin persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act. If a foreign facility is required to register but fails to do so, food from that foreign facility that is offered for import into the U.S. is subject to being held within the port of entry for the article unless otherwise directed by FDA or the Bureau of Customs and Border Protection (CBP). FDA plans to issue enforcement guidance regarding the agency's policies regarding refusals of imported food

under section 801(m)(1) or holds of imported food under section 801(l). This guidance document will be available to the public, and FDA will publish a notice of its availability in the Federal Register.

Will additional comments be accepted on this interim final regulation? FDA is providing a 75-day comment period on specific issues related to this interim final rule. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days beginning in March 2004. Regularly updated information on this interim final rule and how to comment on it can be accessed electronically at http://www.fda.gov/oc/bioterrorism/bioact.html.

How will FDA enforce this interim final rule during the comment period? FDA will actively consider the exercise of its discretion in the enforcement of the Registration interim final rule while at the same time ensuring public health protection, both during initial implementation of the rule and thereafter. The Registration interim final rule takes effect on December 12, 2003 and covered entities are responsible for complying with the requirements in the rule at that time. FDA recognizes that a number of affected parties still may need assistance in understanding the rule's requirements and how to comply even after the extensive outreach and educational activities that FDA will be conducting before December 12th. Accordingly, for this and other reasons, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities in understanding the requirements and how to comply. FDA will shortly publish a notice of availability for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. This guidance, however, will not affect FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act. This policy will also not affect the ability of the Bureau of Customs and Border Protection to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

For further information: For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at http://www.cfsan.fda.gov/~furls/ffregfr.html.
