



U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

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PROTECTING THE FOOD SUPPLY: FDA Actions on New Bioterrorism Legislation

Proposed Regulation: Registration of Food Facilities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) 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 by **December 12, 2003**. The first in a series of rules required by the Bioterrorism Act to permit FDA to respond quickly to a threatened or actual terrorist attack on the U.S. food supply, registration will assist FDA to determine the location and cause of a potential threat and permit the agency to quickly notify facilities that might be affected.

Who must register under the proposal? Owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States would be required to register the facility with the FDA. Domestic facilities will be required to register whether or not food from the facility enters interstate commerce. Foreign facilities that engage in the above activities also would be required to register unless food from that facility undergoes further processing or packaging by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities would be required to register.

Is there a registration fee? There is no fee associated with registration.

What facilities are exempted from registration? Exempt from registration are farms; retail food operations; restaurants; non-profit operations that prepare food for, or serve food directly to, consumers; fishing vessels not engaged in processing [as defined in 21 CFR 123.3 (k)]; and facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture.

What will happen if facilities fail to register by December 12, 2003? The Bioterrorism Act makes failure to register a prohibited act. The Federal government can bring a civil action in Federal court to enjoin persons who commit a prohibited act; or the Federal government can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. If foreign facilities fail to register and also attempt to import food into the U.S., the Bioterrorism Act requires that the food be held at the port of entry unless FDA directs that it be moved to a secure location. FDA is proposing that, when the food must be moved, the private parties involved (i.e., the owner, purchaser, importer, or receiver of the food) must arrange for moving it and promptly notify FDA of its location. The private parties would be responsible for any costs associated with moving or storage of the food.

What methods of registration are proposed? The FDA is proposing that registration may be electronic, via the Internet, or by paper through surface mail. However, the agency strongly encourages electronic registration because it will be faster and more convenient. The system the agency plans will be able to accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week. A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are filled in. Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations that FDA will have to enter manually.

When can facilities register? FDA plans to have both its electronic and paper systems in operation at least two months before the December 12, 2003, statutory deadline for registration. By October 12,

2003, FDA will publish in the *Federal Register* either the final registration rule or a notice of the address to which paper registrations should be sent, **if** either the final registration rule or the electronic system has not been completed by that date. Directions for obtaining mail registration forms will be included.

Registrations should not be sent to FDA before October 12, 2003. If mailed before that date they will not be accepted.

How many facilities are covered by this proposal? The FDA estimates that approximately 202,000 domestic and 205,000 foreign facilities will be required to register.

How to Comment on Proposed Regulations: Under U.S. law, proposed regulations are published in the *Federal Register* to provide interested parties with an opportunity to submit comments, e.g., suggestions to make the proposal more effective or less burdensome, questions regarding the agency's data or assumptions, submission of information the agency may not have, etc. FDA will consider all timely comments that it receives as it develops the final registration rule, which will be published in the *Federal Register*. Regularly updated information on this regulatory proposal and how to comment on it can be accessed electronically at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

Comments on this proposed regulation, Registration of Food Facilities (Docket Number 02N-0276), will be accepted for 60 days from the date it appeared in the *Federal Register*. Written comments on the proposal can be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can be sent electronically to www.fda.gov/dockets/ecomments. It is important to include the docket number when providing comments.