

section 701(b) of the act authorizes FDA and the Department of Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent a letter to members of the public interested in food issues outlining the four provisions in title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see <http://www.cfsan.fda.gov/~dms/sec-ltr.html>). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held several meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, in order to solicit stakeholder comments. In response to these solicitations, FDA received numerous comments regarding section 305 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments received thus far along with the comments we receive during the public comment period on this proposed rule as we develop the final rule. Some of the significant comments FDA received on or before August 30, 2002, include:

- Defining farm to include typical post-harvesting operations, if all food is grown on the farm;
- Including food product categories in a format that satisfies both the requirements of the Bioterrorism Act and stakeholder concerns;
- Allowing facilities that handle most or all of the food categories listed to check "most/all" food product categories instead of requiring them to check every product category handled by the facility;
- Maintaining flexibility regarding qualifications for a U.S. agent;
- Including dates the facility is in operation, if its business is seasonal;
- Defining "facility" to include multiple buildings on a single site, or buildings within the same general physical location;
- Allowing a corporate headquarters or other central management to submit registrations for multiple facilities;
- Providing for both electronic and paper registration;
- Providing registration numbers instantaneously, if registration is done electronically;
- Requiring only trade names of facilities, as opposed to brand names of products the facility produces;

- Defining "food" consistent with the act's definition;

- Including a model of what the electronic registration screen would look like;

- Defining "timely updates" to mean within 30 calendar days of changes to information on the registration form; and

- Requiring facilities that begin to manufacture, process, pack, or hold food for consumption in the United States on or after December 12, 2003, to register before they begin such activities.

III. The Proposed Regulation

This proposed rule implements the food facility registration requirements in section 305 of the Bioterrorism Act. Together with the proposed rules implementing section 307 (prior notice), section 306 (recordkeeping), and section 303 (administrative detention) of the Bioterrorism Act, registration of food facilities will enable FDA to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Registration will provide FDA with information about facilities that manufacture, process, pack, or hold food for consumption in the United States. In the event of an outbreak of food-borne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be impacted by the outbreak.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA). For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. FDA has endeavored to make the registration process as simple as possible for both domestic and foreign facilities.

A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

- Owners, operators, or agents in charge of facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States must register the facility with FDA;
- Facilities covered under this rule must be registered by December 12, 2003;

- Domestic facilities must register with FDA, whether or not food from the facility enters interstate commerce;

- A foreign facility may designate its U.S. agent as its agent in charge for purposes of registering the foreign facility;

- Foreign facilities are exempt from registering if food from these facilities undergoes further processing or packaging by another facility outside the United States. The facility is not exempted from registration if the processing or packaging activities of the subsequent facility are limited to the affixing of a label to a package or other de minimis activity. The facility that conducts the de minimis activity also must register.

- The following facilities are also exempt from registering: Farms; retail facilities; restaurants; nonprofit food facilities in which food is prepared for, or served directly to, the consumer; fishing vessels not engaged in processing, as defined in § 123.3(k); and facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*);

- FDA strongly encourages electronic registration, which will be quicker and more convenient for both facilities and FDA than registration by mail.

B. General Provisions

1. Who Must Register Under This Subpart? (Proposed § 1.225)

As required by the Bioterrorism Act, the proposed rule applies to facilities engaged in the manufacturing/processing, packing, or holding of food for human or animal consumption in the United States. The proposed rule applies to both domestic and foreign food facilities. Individual homes are not subject to the regulation if the food that is manufactured/processed, packed, or held in the home does not enter commerce.

FDA is proposing in § 1.225(b) to require all domestic facilities that manufacture/process, pack, or hold food to register, whether or not the food from the facility enters interstate commerce. The Bioterrorism Act provides that "any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States" must register and defines "domestic facility" as "a facility located in any of the States or Territories." Therefore, FDA tentatively concludes that the statute requires all domestic facilities to