

inspected these facilities that provide food to interstate conveyances and considers them processors, rather than restaurants.

Because the proposed rule also applies to facilities that manufacture/process, pack, or hold food for animal consumption in the United States, by analogy, the term "restaurants" also includes pet shelters, kennels, and veterinary facilities in which food is provided to animals.

l. *Retail facility.* In § 1.227(c)(11), the proposed rule defines a retail facility as "a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The term includes facilities that not only sell food directly to consumers, but that also manufacture/process food in that facility solely for direct sale to consumers from that same facility."

The Bioterrorism Act does not limit the retail facility exemption to human food. However, the legislative history to the Bioterrorism Act states that the retail exemption applies to food for "human" consumption. Therefore, FDA is taking comments on whether the retail exemption should also be applied to food for animal consumption.

The proposed rule would also require facilities that sell both directly to consumers and to distributors and wholesalers to register. Examples of these facilities are warehouse clubs. Because such facilities do not sell food directly to consumers only, they do not meet the definition of a "retail facility."

m. *U.S. agent.* FDA is proposing in § 1.227(c)(12) to define a 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." This definition is consistent with FDA's drug, biologics, and device registration regulations found in parts 207, 607, and 807 (21 CFR parts 207, 607, and 807), respectively. In order to ensure that the U.S. agent is available to assist FDA in contacting foreign facilities, the proposed definition of U.S. agent also specifies that the U.S. agent "cannot be in the form of a mailbox, answering machine, or service, or other place where an individual acting as the foreign facility's agent is not physically present." FDA also is proposing to have the U.S. agent's responsibilities include acting as a communications link between FDA and the facility, such that FDA will treat representations provided by the U.S. agent to FDA as those of the foreign facility, and will consider information FDA provides to the U.S. agent as the equivalent of providing the same

information or documents directly to the foreign food facility. As noted previously, FDA also is proposing to allow the U.S. agent to register on behalf of the foreign facility. FDA recommends that the U.S. agent and facility enter into a written agreement specifying the U.S. agent's responsibilities. The facility does not need to submit a copy of the agreement to FDA as part of its registration. If the foreign agent registers a facility without authorization from the facility, FDA will consider the registration to be a materially false, fictitious, or fraudulent statement to the U.S. Government under 18 U.S.C. 1001.

n. *You or registrant.* FDA is proposing in § 1.227(c)(13) to define "you" or "registrant" as "the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States." FDA is proposing to use "you" or "registrant" throughout the proposed rule for easier readability.

C. Procedures for Registration of Food Facilities

1. When Must You Register? (Proposed § 1.230)

The Bioterrorism Act requires facilities subject to its requirements to be registered with FDA no later than December 12, 2003. Proposed § 1.230 would require facilities that currently manufacture/process, pack, or hold food for consumption in the United States to be registered by December 12, 2003. FDA is proposing that facilities that begin to manufacture/process, pack, or hold food for consumption in the United States on or after December 12, 2003, must be registered before they begin such activities. This also would apply to facilities engaged in seasonal activities that may not be operating in December, 2003. Before these facilities could begin to manufacture/process, pack, or hold food for consumption in the United States after December 12, 2003 (or resume operations after this date), they must be registered with FDA.

FDA is planning to have both its electronic and paper registration systems operational at least 2 months before the statutory deadline of December 12, 2003. FDA will announce the exact date these systems will be available for registration in the final rule. On or before October 12, 2003, FDA will publish in the **Federal Register** either a final rule setting forth the final registration requirements, or a notice providing an address to which paper registrations should be sent, if either the final rule or the electronic system for accepting registrations has not been completed by that date.

Registrations should not be mailed to FDA before publication of that document in the **Federal Register**. Registrations mailed to FDA before the date announced in the **Federal Register** publication will not be accepted.

2. How and Where Do You Register? (Proposed § 1.231)

Although FDA is proposing to allow registration by either electronic or paper means, FDA is planning to devote most of its resources earmarked for registration to building and maintaining an electronic food facility registration system. The majority of facilities, both in the United States and abroad, have access to the Internet, either within their companies or through public libraries, copy centers, schools, or Internet cafes, as well as through a foreign facility's U.S. agent if the facility makes such arrangements. If the U.S. agent does not have Internet access onsite, the agent may register the facility electronically from a local library or other public facility that offers Internet access either free or for a relatively small fee. In this manner, all foreign facilities would be able to obtain an automatic electronic confirmation of registration and the facility's registration number similar to domestic facilities that register electronically.

Registering electronically will benefit both facilities and FDA. FDA will be able to accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week through a link on FDA's Internet Web site. Electronic registration also will enable a facility to be registered more quickly than registering by mail, since obtaining confirmation of registration and the facility's registration number online should be instantaneous once a facility fills in all required fields on the registration screen. In contrast, registration by mail may take several weeks to several months, depending on the efficiency of the mail system and the number of paper registrations that FDA will need to enter manually into the system. Registrations received by mail will be processed in the order in which they are received.

Regarding the electronic Internet-accessible system, the registrant will be able to fill out the entire form online. In order to ensure that the form is filled out completely, the electronic system will not accept a registration submission until all of the mandatory fields are completed. Because FDA intends to allow companies the option of filing registration forms on behalf of one or more of their facilities, FDA will give the registrant the option of completing additional registration forms for other