

register, whether or not they engage in interstate commerce. Moreover, having a central database of all domestic facilities producing food would greatly assist FDA in limiting the effects of a food-related emergency covering several States. Nonetheless, because FDA recognizes that this is an important and controversial issue, the agency is seeking comment on whether the agency has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and, if so, whether FDA should use that authority. FDA also seeks comment on how many intrastate facilities are not covered by one of the exemptions from the registration requirement (e.g., the farm or retail exemption). Finally, FDA invites recommendations on what screening questions the agency could ask to enable the owner, operator, or agent in charge of a facility to easily determine whether the facility is an interstate or intrastate facility.

For both domestic and foreign facilities, FDA is proposing in § 1.225(a) and (b) that the owner, operator, or agent in charge, register the facility. FDA is also proposing in § 1.225(c) that the U.S. agent may register a foreign facility if the foreign facility has designated the U.S. agent as its agent in charge. If a foreign facility wants to designate its U.S. agent as its agent in charge for purposes of registering, FDA recommends that the facility and U.S. agent enter into a written agreement authorizing the U.S. agent to register the facility and specifying the U.S. agent's other responsibilities. There are other roles in the course of business that an agent in charge may fill. A formal written agreement between the facility and its U.S. agent would provide clarity for both. Because the proposed rule would require the U.S. agent to reside or maintain a place of business in the United States, allowing the U.S. agent to register the foreign facility will give foreign facilities reliable access to electronic registration that some facilities might not otherwise have. For example, within the United States, Internet access is readily available to members of the public at many local libraries and certain places of business (e.g., photocopying centers).

This process will allow a foreign facility to be registered much more quickly than requesting a paper registration form from FDA by mail, waiting to receive the registration form in the mail from FDA, completing the registration form and sending it to FDA by mail, waiting for FDA to enter the information manually into the electronic registration database—which

could take several weeks to several months depending on the number of paper registrations FDA has received previously—and awaiting a response from FDA by mail that contains the confirmation of registration and the facility's registration number.

2. Who is Exempt From This Subpart? (Proposed § 1.226)

In § 1.226, FDA is proposing to exempt several types of facilities from the registration requirement. First, as noted previously, FDA is proposing in § 1.226(a) to exclude foreign facilities, “if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States.” In other words, foreign facilities involved in the initial stages of manufacturing/processing food are not required to register if another facility further manufactures/processes or packs the food produced at that facility outside the United States.

This exemption would not apply to facilities if the “further manufacturing/processing” at the subsequent facility is of a de minimis nature, such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. The facility conducting the de minimis activity would also be required to register. This proposal is based on FDA's tentative conclusion that the statute's exclusion of labeling and “similar activity of a de minimis nature” from the definition of “further processing and packaging” applies only for purposes of the definition of “foreign facility.” FDA tentatively concludes that this limitation does not apply to the term “processing” as used elsewhere in the registration provision of the Bioterrorism Act. Accordingly, facilities that label food or engage in similar activities would be required to register as processors. FDA requests comment on this interpretation of the Bioterrorism Act.

The following are examples of which foreign facilities would be subject to, or exempt from, the registration requirement, based on the activities they perform:

(1) A foreign facility would be required to register if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.

(2) A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be required to register, unless the further manufacturing/processing

entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register.

(3) The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be required to register, even if the food subsequently is held or stored at a different facility outside of the United States. FDA is proposing to require these manufacturers/processors to register because the Bioterrorism Act exempts a foreign facility from registering only if another facility subsequently processes or packages the food.

(4) Facilities located outside the United States that take possession, custody or control of finished foods for holding, packing, and/or storage prior to export to the United States, would be required to register.

Even though the last processors and packagers of food are required to register under the proposed rule, the Bioterrorism Act also requires foreign facilities that pack and/or hold food subsequent to the processing and packaging process to register with FDA. Requiring registration of foreign facilities that conduct a significant activity with respect to the food, starting with the last manufacturer/processor involved, and ending with the last facility before the food is shipped to the United States, is consistent with the Bioterrorism Act, and ensures that FDA has contact information for foreign facilities whose operations would be expected to affect food exported for consumption in the United States. This requirement achieves a balance between protecting the U.S. food supply, and not unduly burdening foreign facilities.

Consistent with the Bioterrorism Act, FDA also is proposing in § 1.226(g) to exempt certain fishing vessels from the registration requirement. These vessels include “those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel.” However, consistent with the Bioterrorism Act's reference to § 123.3(k), the proposed rule provides that “those fishing vessels otherwise engaged in processing fish, which for purposes of this section means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding