

export to the United States, it packs or holds food after the last foreign manufacturer/processor of the food. Under these provisions, the last facility that manufactures/processes the cocoa beans, and every facility that subsequently engages in packing or holding the beans, as well as any facility that subsequently engages in *de minimis* manufacturing/processing (such as labeling) of the cocoa beans, is required to register.

(Comment 18) Several commenters argue that registration of foreign facilities should be limited to the last holder of the goods, since it would be difficult for many facilities further up the distribution chain to find a U.S. agent.

(Response) FDA is denying this request due to the registration requirement provided in the Bioterrorism Act for foreign facilities that manufacture/process, pack, or hold food. See the response to comment 17 for these specific requirements.

(Comment 19) A commenter requests clarification on whether registration applies to foreign port facilities such as warehouses or storage and inspection facilities belonging to private companies. Another commenter asks whether brokers, warehousemen, or traders who take possession of food before it is exported to the United States need to register.

(Response) As noted, the registration requirement of the Bioterrorism Act is facility-based and has no exemption from registration for port storage and inspection facilities if these facilities are used to hold food. Therefore, foreign port storage and inspection facilities must be registered with FDA if they manufacture/process, pack, or hold food for consumption in the United States. Similarly, a broker, warehouseman, or trader who takes possession of food before it is exported to the United States is required to register if the broker, warehouseman, or trader is the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

(Comment 20) One commenter states that all foreign processors, holders, and manufacturers throughout the foreign distribution chain should be required to register.

(Response) FDA is denying this request due to the registration requirement provided in the Bioterrorism Act for foreign facilities that manufacture/process, pack, or hold food. See the response to comment 17 for these specific requirements.

(Comment 21) One commenter states that, in its application to foreign

facilities, FDA should revise its definition of "holding" to "provid[ing] storage of food products and neither engag[ing] in the manufacturing nor processing of the food products, except for incidental services that do not involve unsealing of the primary food container."

(Response) FDA declines to change "holding" to include "incidental services that do not involve unsealing of the primary food container." This change would blur the distinction between manufacturing/processing and holding because activities that do not involve unsealing of a food container could be considered *de minimis* processing, as opposed to holding. See the response to comment 17 for specific registration requirements for foreign facilities.

(Comment 22) Some commenters involved in the production of food that either has a long shelf life or long production phase ask whether they are required to register with FDA if they do not know the eventual export destination at the time of production. For example, for vintage wine, the eventual destination of the wine (*i.e.*, whether the wine is for consumption in the United States) is generally not known at the time of production. Other commenters state that for similar reasons, registration should not be required of foreign "collection points," which receive products from a large number of suppliers, then distribute or sell them at auctions.

(Response) Under this interim final rule, an owner, operator, or agent in charge must register its facility only if the food manufactured/processed, packed, or held at the facility is for consumption in the United States. In the response to comment 17, FDA has clarified the registration requirements for foreign facilities that manufacture/process, pack, and hold food. That discussion is also relevant to this comment. Although the destination of some food produced abroad is not known at the time of its production, FDA believes that producers and distributors of these products are likely to have an idea of the eventual destination, based on prior sales and promotional activities. Because the Bioterrorism Act generally prohibits food from an unregistered foreign facility from being delivered for distribution in the United States until the facility is registered, FDA recommends that the owners, operators, or agents in charge of facilities producing these types of food register their facilities if they reasonably believe their foods may be consumed in the United States.

(Comment 23) One commenter states that, for commercial confidentiality reasons, foreign traders may not wish to reveal the identity of the packer or producer to the importer, and that the registration requirement would interfere with this confidentiality.

(Response) FDA acknowledges that for some entities, the registration requirements may result in some alterations of their past business practices. However, the Bioterrorism Act imposes certain requirements on the importation of food for consumption in the United States, including registration of foreign and domestic food facilities. It is incumbent on these facilities to make the necessary arrangements to comply with the Bioterrorism Act if they wish to continue to import food into the United States.

(Comment 24) Some commenters request that foreign facilities should be exempt if they export food solely to their own subsidiaries in the United States. These commenters state that these foreign facilities send finished or semifinished goods or raw materials to their subsidiaries in the United States for further processing. The commenters argue that, under these circumstances, the foreign parent company should not have to register; however, under the proposed rule, not only the final processor, but also all of its suppliers, would be required to register.

(Response) FDA is denying this request because the Bioterrorism Act does not authorize an exemption from registration for facilities that export solely to their subsidiaries in the United States. Moreover, it appears that the commenter misunderstands the requirements that apply to foreign facilities. Under both the proposed rule and this interim final rule, suppliers of food need not register if another foreign facility subsequently manufactures/processes the food before it is exported to the United States, unless the subsequent facility is conducting *de minimis* activities, such as labeling. In the latter situation, both facilities would have to register.

(Comment 25) Several commenters request further clarification regarding the "*de minimis*" provision. Some commenters request that FDA exempt foreign facilities engaging in *de minimis* activity. In fact, one commenter mistakenly states that the proposed rule exempts foreign facilities if a facility subsequent to them conducts *de minimis* activity.

(Response) Please see the response to comment 17 regarding the registration requirements as applied to foreign manufacturers/processors. An exemption for foreign facilities engaged