

Bioterrorism Act and this interim final rule (which is consistent with the proposed rule) provide that a facility must be registered if it is engaged in manufacturing/processing, packing, or holding food for consumption in the United States. Second, both the Bioterrorism Act and the interim final rule (as did the proposal) provide that foreign facilities are exempt from registration if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. Finally, because the registration requirement is facility-based, an exporter is required to register only if it is the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States, and the facility is not subject to any of the listed exemptions. This is consistent with the specific language in the Bioterrorism Act.

(Comment 11) One commenter asks FDA to clarify whether registration applies to "bulk grain handling facilities which exist for the purpose of export and domestic shipments."

(Response) It is not clear from the comment what activities the bulk grain handling facility conducts. If "bulk grain handling" means storing grain in bulk, the facility is required to register with FDA if the grain will be consumed by humans or animals in the United States, because the facility is engaged in "holding" food. Similarly, if "bulk grain handling" is synonymous with the activities of a feedmill, the facility is required to register with FDA because feed mills manufacture/process, pack, and hold feed for animal consumption. The discussion under the definition of "retail food establishment" provides further clarification.

(Comment 12) One commenter has several questions related to who is required to register: Is the registration requirement limited strictly to commercial shipments? How does registration affect United States travelers who bring varying quantities of goods into the United States?

(Response) The registration requirement applies to facilities that manufacture/process, pack, or hold food for consumption in the United States. Thus the requirement is tied to: (1) Facilities, and (2) food that will be consumed in the United States. The Bioterrorism Act, therefore, does not limit the registration requirement to commercial shipments. However, travelers who bring foods into the United States on their person or in their baggage are not facilities under this rule, and thus, they are not required to

register. FDA notes that travelers may nevertheless be subject to prior notice if they are carrying or otherwise are accompanied by food that is not for personal use (*i.e.*, for consumption by themselves, family, or friends, and not for sale to anyone.)

(Comment 13) A commenter asks what is the responsibility of foreign governments owning facilities that hold food? Also, what is the responsibility of a country through whom goods of concern may be trans-shipped?

(Response) The registration requirement applies to facilities that manufacture/process, pack, or hold food for consumption in the United States. Thus the requirement is tied to: (1) Facilities, and (2) food that will be consumed in the United States. There is no exemption in the Bioterrorism Act or this interim final rule for facilities that manufacture/process, pack, or hold food that happen to be government-owned. Accordingly, such government-owned facilities are required to register if they meet the other requirements of registration.

A country through which foods may be trans-shipped on their way to the United States has no responsibility regarding registration, as the registration requirement applies to facilities that manufacture/process, pack, or hold food. Under the Bioterrorism Act, the responsibility to register is on the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption by humans or animals in the United States.

(Comment 14) A commenter primarily engaged in exporting products from the United States asks FDA to clarify whether such an exporter is required to register if the foreign country or foreign buyer rejects food being exported from the United States, and the food is returned to the United States.

(Response) Where food exported from the United States is rejected and returned to this country, the owner, operator, or agent of any facility that manufactures/processes, packs, or holds the food is required to register if the food will be consumed in the United States. FDA is assuming in comment 14 that no foreign facility other than the exporting facility manufactures/processes, packs, or holds the food before it is returned to the United States.

(Comment 15) One commenter asks FDA to clarify whether domestic grain handling, and feed manufacturing facilities engaged solely in exporting bulk or processed agricultural commodities to other countries are exempt from the registration requirement.

(Response) A facility is only required to register with FDA if the food manufactured/processed, packed, or held in the facility is for consumption or is actually consumed in the United States by humans or animals.

(Comment 16) One commenter asks "[w]hat happens if [an] exporter cannot get [the foreign] manufacturer to register, and does not have all of the necessary information to do it himself?" The commenter asks whether the exporter "will not be permitted to send the shipment resulting in lost sales to his company."

(Response) The response to comment 17 addresses which foreign facilities are required to register with FDA. If the manufacturer/processor in the above scenario (or a packer or holder) is required to register but fails to do so, the Bioterrorism Act provides that food shall be held at the U.S. port of arrival or in a secure facility until the facility registers (21 U.S.C. 381(l)). However, the provisions of the prior notice interim final rule (which is published elsewhere in this issue of the **Federal Register**) that address product under hold provide for export of such products.

FDA has made some editorial changes in this section for the purpose of clarity.

D. Comments on "Who is Exempt From This Subpart?" (Proposed § 1.226)

In the interim final rule, the title of this section has been changed to "Who does not have to register under this subpart?"

1. Foreign Facilities

(Comment 17) A commenter asks which foreign facilities would be required to register in the case of raw agricultural commodities, such as cocoa beans, which may be dried, (in some cases) fermented, blended with beans from other farms, packed into bags, fumigated, weighed, graded, and stored in one or more warehouses before being exported to the United States.

(Response) The Bioterrorism Act states that a foreign facility must register if food from such a facility is exported to the United States for consumption in this country "without further processing or packaging outside the U.S." Therefore, a foreign facility is only required to register if it manufactures/processes the food without further manufacturing/processing of the food by another foreign facility prior to export to the United States. The foreign facility is required to register even if there is a subsequent facility that further manufactures/processes the food if the activities of the subsequent facility are merely of a *de minimis* nature. A foreign facility must also register if, prior to