

canned food, aquatic products, and fruit exporting enterprises. One of these commenters states that under the Warehouse Act, USDA performs regular, unscheduled inspections of these grain storage facilities; therefore, USDA, not FDA, is the most appropriate federal agency to respond to threats affecting these facilities. The other commenter states that fruit exporters have already registered with USDA.

(Response) FDA believes that this interim final rule implements the intent of Congress as expressed in the Bioterrorism Act. The statute does not include exemptions from the registration requirement for the types of facilities listed in the comment, and the comment identifies no other basis for the exemptions proposed.

*E. Comments on "What Definitions Apply to This Subpart?" (Proposed § 1.227)*

1. The Act

There were no comments on this issue.

2. Calendar Day

There were no comments on this issue.

3. Facility

(Comment 34) Several commenters recommend exempting temporary storage units, public storage facilities, and bulk storage facilities from the definitions of "facility" and "holding," because many of these storage facilities are not staffed, so it would be very difficult for FDA to get in touch with these facilities in the event of a bioterrorist attack or other food-related emergency. In addition, the commenters state that many of these holding facilities only hold goods for several hours; therefore, the contents of the facility are continually changing and would require constant updates.

(Response) The interim final rule maintains the definition of facility as proposed although FDA has clarified that "facility" does not include a transporter that holds food only in the usual course of its business as a carrier, private residences of individuals, and nonbottled drinking water collection and distribution establishments and their structures. The Bioterrorism Act does not exempt facilities based on the period of time during which they hold food. In terms of contacting facilities that are not staffed, the interim final rule requires facilities to provide an emergency contact who is accessible 24 hours/day, 7 days/week. (For foreign facilities, FDA will consider the U.S. agent the emergency contact, unless the

facility designates someone else, as provided in § 1.227(b)(13) and § 1.233(e).) This person does not have to be located at the facility, but does need to be accessible to FDA in case of an emergency.

(Comment 35) One commenter cites case law to argue that FDA has authority to provide for an additional *de minimis* exemption because the burdens of regulating very small facilities will yield trivial or no value. The commenters suggest that FDA change the definition of facility to exempt these storage buildings.

(Response) The Bioterrorism Act does not exempt facilities based on their size. Furthermore, many storage facilities, including temporary storage facilities, may be a target of terrorist attack. Therefore, having the registration information for these facilities can facilitate FDA's response to such an attack.

(Comment 36) Several commenters state that the proposed rule is not clear as to whether transport vehicles hauling food are "mobile facilities." These commenters argue that vehicles used to hold food such as rail cars, tanker trucks, river barges, refrigerated/freezer spaces on ships, truck terminals, marine terminals, and freight forwarders should be exempt from registration. One commenter asserted that the intent of the "holding" definition is to "capture those facilities which hold large quantities of food items for extended periods of time, pending some other action such as movement to a subsequent facility for processing," and states that products being held are "deliberately held under physical control, *i.e.*, restrained from movement." In contrast, "transportation of food items means deliberate movement of those items, under specific arrangements as defined in a bill of lading covering the movement, which would delineate the shipper, consignee, date of movement, details of the shipment, liability for freight charges, and many other elements of transportation." The commenter asserts that based on this distinction, transportation providers who are engaged in the movement of goods from a shipper to a consignee, should be exempt from registration.

(Response) FDA has clarified in § 1.227(b)(2) of the interim final rule that a "mobile facility" means a mobile manufacturer/processor, packer, or holder. In addition, the interim final rule provides that a vehicle used to transport food is exempt from registration unless it manufactures/processes, packs, or holds the food beyond the usual course of its business

as a carrier. This is consistent with the legislative history of the Bioterrorism Act, which states that "facility" does not include trucks or other motor carriers, by reason of their receipt, carriage, holding, or delivery of food in the usual course of business as carriers (H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 134 (2002)). However, stationary facilities that serve to assist transporters, such as truck or marine terminals or freight forwarders, are required to register because they hold food. If a railcar is used as a grain storage bin for a manufacturing plant, it would be akin to a silo, and as such, the railcar would be "holding" food, not transporting it. Thus, the railcar would be a facility that must be registered. As indicated in comment 36, the Bioterrorism Act does not exempt facilities based on how long they hold food.

(Comment 37) One commenter asks whether trucker-dealers, who purchase and take title to grain from producers, and hold the grain in a transportation conveyance until it can be sold to another processor, storage facility, or end user, are mobile facilities.

(Response) Based on the comment, FDA believes that trucker-dealers are mobile facilities, because they are holding grain in a transportation conveyance beyond the usual course of business as carriers.

(Comment 38) Several commenters state that requiring registration of mobile facilities that manufacture/process food is impractical for fishing vessels that process fish. These commenters state that these vessels have a home port designation but no fixed or permanent address; therefore, they would be required to continually update their registrations based on where the vessel was located in the ocean.

(Response) Registration requires a facility to provide sufficient information to enable FDA to contact the facility if FDA receives information about a bioterrorist threat or other food-related emergency, as well as for routine communications. FDA understands that a mobile facility does not have a fixed address. However, the Bioterrorism Act provides that the owner, operator, or agent in charge of a facility must register the facility; therefore, for mobile facilities such as vessels, the owner or operator of the facility usually has a fixed address and may include that fixed address on the registration.

(Comment 39) Several commenters request that FDA change the proposed definition of facility from being in "one physical location" to allow registration to be by firm, instead of by facility.