

defined in the interim final rule (§ 1.227(b)(9)), because it is “placing [food] into a container other than packaging the food.”

12. Port of Entry

(Comment 73) Several commenters ask that the definition of “port of entry” be modified so that it is consistent with the U.S. Customs definition, which is “the port at which Customs entry is made for the shipment of imported food for consumption in the United States. This port may be different than the Port of Arrival, which is defined as the first port at which the carrier transporting the merchandise arrives.” A commenter states that creating a new definition of “port of entry” is contrary to Congress’s intent, which it may be presumed was based on Congress’s awareness of Customs’ definition of the term.

One commenter states that two Federal Government agencies having two definitions for the same term is potentially troublesome, and “lays the groundwork for confusion and conflict regarding where and when proper declaration is required.” Another commenter states that FDA’s proposed definition of “port of entry” will create substantial hardship for an importer of the food, who is usually located in close proximity to the inland port and is better equipped to handle compliance or clearance issues locally. The commenter states that, under FDA’s proposed definition of “port of entry,” imports would be subject to review by two separate FDA Districts, that of the port of arrival and that of the port of entry. This would greatly increase FDA’s workload. The commenter also indicates that FDA’s proposed definition of “port of entry” would create substantial problems if a foreign facility fails to register, because there is no provision in the statute for FDA to issue a refusal of admission that would enable the importer to export the goods, or any provision for the goods to be designated as general order status. In this case, the importer could not file a consumption entry, after which FDA could issue a refusal of admission under 21 U.S.C. 381(a), because a consumption entry cannot be filed until the goods have arrived at the inland port.

These commenters also argue that FDA’s concern that allowing food to be shipped inland before verifying registration could result in loss of government control over the food is inconsistent with the statutory objective. This objective is to prevent food imports from being released from Customs’ control until FDA has had an opportunity to screen the shipment and determine if it presents a risk of

bioterrorism. The commenter explains that, under Customs’ regulations, all food transported in bond to an inland port of entry is subject to Customs’ legal control until a consumption entry is filed and a permit for release is issued. Even if cargo is bound for consumption entry in an inland port, the cargo is still subject to detention or inspection by Customs or FDA at the port of arrival. One commenter states that a revised definition of port of entry would also assist express carriers, who are required to hold a shipment in their control until all regulatory agencies have released it.

(Response) As discussed in detail in response to comment 151, this interim final rule does not include a provision regarding consequences for failure to register on imported food. Because the definition of “port of entry” is only relevant to the consequences of failure to register when attempting to import food, we have removed the definition of “port of entry” from this interim final rule. FDA has defined the term “port of entry” in the interim final rule on prior notice of imported food published elsewhere in this **Federal Register**.

13. Restaurants

(Comment 74) One commenter asks FDA to specify that commissaries that are a single source of food for large populations via large chain restaurants should not be exempt from registration as restaurants.

(Response) FDA agrees with the commenter that facilities, such as commissaries or central kitchens that provide food to restaurants that subsequently serve the food to customers, are not restaurants. The proposed definition of restaurant is limited to establishments that prepare and sell food directly to consumers for immediate consumption. Although central commissaries prepare food that is eventually served to consumers, these facilities do not do so directly. Accordingly, FDA is clarifying in the interim final rule that commissaries, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers are not restaurants and thus, are required to register with FDA.

(Comment 75) Several commenters agree with FDA that the restaurant definition (and therefore, the exemption) should include pet shelters, kennels, and veterinary facilities. One of these commenters requests that FDA include these facilities in the interim final rule itself, as opposed to the preamble.

(Response) The preamble to the proposed rule stated that, by analogy, pet shelters, kennels, and veterinary

facilities were included in the restaurant exemption. FDA received no comments disagreeing with this approach. For clarity, the interim final rule’s definition of restaurant expressly includes pet shelters, kennels, and veterinary facilities.

On its own initiative, FDA has made several editorial changes in this section for clarity.

14. Retail Food Establishment

The interim final rule substitutes the statutory term “retail food establishment” for the term “retail facility,” which was used in the proposed rule.

(Comment 76) Some commenters state that the definition of retail facility as “a facility that sells food products directly to consumers only,” should be revised to delete “only.” This is based on the following arguments: 148 Cong. Rec. H2858 specifies that retail food establishments include those facilities “attendant” to retail operations; because the proposed definition of retail food establishment included commissaries, distribution facilities for grocery stores, which are also attendant facilities, should be included as well; the legislative history makes several references to retail as “sale to consumers as its primary function,” warehouse clubs should be included in the definition of retail facility, based on this language at 148 Cong. Rec. H2726: “[Retail] does not include a warehouse that does not provide articles of food directly to a retail consumer as its primary function * * *.”

(Response) FDA agrees in part with these comments. Accordingly, we have revised the definition of retail food establishment to eliminate the restriction that such facilities must sell only to consumers to be considered a retail food establishment. This interim final rule defines “retail food establishment” as “an establishment that sells food products directly to consumers as its primary function. A retail establishment may manufacture/process, pack, or hold food if the establishment’s primary function is to sell from that establishment food that it manufactures/processes, packs, or holds directly to consumers. A retail food establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “‘consumers’ does not include businesses. A ‘retail food establishment’ includes grocery stores, convenience stores, and vending machine locations.” This change preserves the retail