

exemption both for retail food establishments (such as grocery stores) that sell or transfer some products to sources other than a consumer (e.g., to other grocery stores), and for direct selling entrepreneurs, as long as their primary function is to sell directly to consumers.

FDA further agrees that under the revised definition of retail food establishment, certain warehouse clubs may be exempt from registration, if, based on dollar volume of their sales, they sell food directly to consumers as their primary function.

In addition, FDA has determined that an establishment "attendant" to a retail operation, if located separate from the retail food establishment, is not a retail food establishment for purposes of this rule. This is consistent with the Conference Report for the Bioterrorism Act, which states that the term "retail" does not include warehouses that do not sell directly to consumers as their primary function (H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 133 (2002)).

Regarding FDA's use of the term "commissaries" in § 1.227(c)(11) of the proposed rule, FDA is clarifying that the term was intended to refer to establishments on military bases that sell food directly to consumers. As noted in the response to comment 74, FDA did not intend to include other types of commissaries, such as central kitchens for restaurants, within the restaurant exemption. To avoid confusion, the interim final rule deletes the word "commissaries" as an example of a "retail food establishment" because this term has multiple meanings. Regardless of what an establishment is called, it is exempt as a retail food establishment if—and only if—it meets the definition.

(Comment 77) Several commenters argue that "direct selling" or "multi-level selling" home-based distributors should be considered retail food establishments because their primary function is selling to consumers. However, because these salespeople also transfer products among themselves, they are not exempt under the proposed rule. The parent company's manufacturing and distribution facilities would be required to register. There are millions of direct selling entrepreneurs and registering them all would flood the registration system and not be meaningful. These salespeople are analogous to retail chain stores that sometimes need to transfer inventory between them.

(Response) As discussed in the response to comment 7, private residences of individuals are not facilities for purposes of this interim

final rule and, therefore, are exempt from registration. Accordingly, these home-based distributors are not subject to registration.

(Comment 78) One commenter asks FDA to clarify when operations of a retail food establishment cease to be incidental to the activities of the retail food establishment and cause the retail food establishment to become a mixed-type facility that must register. This commenter asserts that activities such as operating a juice bar, repackaging nuts or dried fruits received in bulk into smaller packages, or unpacking and displaying produce are good examples of incidental activities in a retail food establishment.

(Response) The revised definition of "retail food establishment" clarifies that such establishments may manufacture/process, pack, or hold food so long as the establishment's primary function is to sell from that establishment food that it manufactures/processes, packs, or holds directly to consumers. As noted, 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. Therefore, if the establishment's primary function is to sell food directly to consumers, repackaging nuts or dried fruit for sale directly to consumers and unpacking and displaying produce for direct sale to consumers are permissible activities. However, if an establishment's primary function is to sell food to distributors, but the establishment also conducts some minor sales directly to consumers, repackaging nuts for sale directly to these consumers does not cause the establishment to fall within the definition of "retail food establishment." Examples of manufacturing/processing that a retail food establishment might perform include making potato salad for sale at the delicatessen counter of a grocery store, filleting fish at a fish market, and cutting cheese from a large block into slices for sale directly to consumers based on the amount they request. Operating a juice bar would be exempt as a "restaurant" because it involves preparing and selling food directly to consumers for immediate consumption.

(Comment 79) Some commenters argue that retail food establishments should include retailers of animal food. They argue that the plain text of the statute does not have a limitation on the scope of the retail food establishment exemption and that because animal food is included in the proposed rule's definition of food, the exemption should

also apply to both. These commenters further argue that it would not make sense to hold animal food retailers to a standard higher than that for retailers of human food and note that pet food is offered alongside food for human consumption. Finally, these commenters assert that the failure to exempt pet food retailers would be to eliminate the benefit of the exemption for retail animal food facilities.

(Response) FDA agrees with these comments and advises that the definition of "retail food establishment" includes animal food retailers. FDA believes that this is consistent both with including animal feed as "food," as well as with the language of the Bioterrorism Act. The agency has amended the definition of "retail food establishment," however, to clarify that the term "consumers" does not include businesses. As a result, an establishment that sells animal food to pet owners and other individuals as its primary function is exempt as a retail food establishment. An establishment that sells animal feed to businesses, such as farms, as its primary function must register.

(Comment 80) One commenter asks FDA to clarify whether wholesale establishments are also included in the definition of "retail food establishment."

(Response) Wholesale facilities are not covered by the definition of "retail food establishment" because they do not sell food directly to consumers as their primary function.

(Comment 81) One commenter asks FDA to clarify whether retail co-ops are required to register in light of the proposed rule's statement that "FDA is proposing to require co-op facilities that manufacture/process, pack, or hold food, and that are not subject to the farm exemption, to register with FDA." The commenter states that "retail co-ops, aside from cooperative ownership, operate no differently than any other retail establishment."

(Response) FDA agrees that a retail food establishment that is cooperatively owned is exempt from registration if it sells food directly to consumers as the co-op's primary function. The establishment's primary function must be to sell food, including that manufactured/processed at the establishment, directly to consumers.

(Comment 82) Several commenters ask whether establishments supplying food to consumers via Internet or mail-order sales are covered under the definition of "retail food establishment."

(Response) Facilities selling food directly to consumers via the Internet or mail-order are covered under the