

in *de minimis* manufacturing/processing would be inconsistent with the Bioterrorism Act language quoted in the response to comment 17.

(Comment 26) One commenter requests that FDA provide either a definition of “*de minimis*” or more examples of what constitutes *de minimis* activity, such as blending, sieving, particle size distribution, drying crops, and repackaging.

(Response) FDA has concluded that *de minimis* manufacturing/processing does not involve direct manipulation of food. Therefore, most of the activities included in the comment (blending, sieving, particle size distribution, and drying crops) are not *de minimis* because they manipulate food.

Regarding “re-packaging,” it is not clear whether this activity would contact the food itself or merely involve contact with outer materials that do not contact the food. If the re-packaging involves contact with the food itself, it would not be considered *de minimis*.

## 2. Farms

FDA did not receive any comments on “farm” as an exemption. Please see section III.E.6 of this document for changes FDA made to the definition of “farm.” FDA also addresses the comments we received on farms in section III.E.6 of this document.

## 3. Retail Facilities

FDA did not receive any comments on “retail facilities” as an exemption. In this interim final rule, we have changed the term “retail facility” to “retail food establishment” to be consistent with the statutory term. Please see section III.E.14 of this document for changes FDA made to the definition of “retail food establishment.” FDA also addresses the comments we received on retail food establishments in III.E.14 of this document.

## 4. Restaurants

Please see the definitions section III.E.13 of this document for changes FDA made to the definition of “restaurant.” FDA also addresses all but one of the comments we received on the “restaurant” exemption in section III.E.13 of this document.

(Comment 27) FDA did receive one comment specifically addressing the restaurant exemption. This comment states that although the proposed rule provides that restaurants are exempt from registration, it “continues to define when it is necessary for food facilities to register and provides an opportunity for the foreign facilities to designate a U.S. agent for registration. This language alone contradicts the exemption in

many circumstances within the restaurant industry. The intention of Congress was to exempt restaurants \* \* \* language must be incorporated to state that foreign facilities should not have the ability to designate a U.S. agent for registration.” This commenter also urges FDA to incorporate language in the interim final rule clearly stating that foreign facilities may designate a restaurant as a U.S. agent, while emphasizing that this designation does not remove the restaurant exemption from all restaurants.

(Response) FDA is not certain it understands this comment. This commenter appears to be concerned that the restaurant exemption would conflict with the U.S. agent requirement, if a foreign facility were to choose a domestic restaurant as its U.S. agent. FDA agrees that even if a foreign facility designates a domestic restaurant as its U.S. agent, the restaurant is still exempt from registration itself. In such circumstances, the restaurant can also be authorized by the owner, operator, or agent in charge of the foreign facility to register that facility. Regarding incorporation of language specifying that restaurants can be U.S. agents in the interim final rule, FDA believes that this change is not necessary because the interim final rule states that a U.S. agent is “a person (as defined in section 201(e) of the act (21 U.S.C. 321(e)).” This definition includes a restaurant.

## 5. Nonprofit Food Facilities

In this interim final rule, FDA has changed the term “nonprofit food facility” to “nonprofit food establishment” to be consistent with the statutory term.

(Comment 28) One commenter asks FDA to confirm that the commenter’s affiliates and their agencies are exempt as nonprofit food facilities. This commenter states that all of its food banks, food rescue organizations, and local agencies of its affiliates are required to be incorporated as nonprofit organizations that are exempt from paying income tax as defined by the U.S. Internal Revenue Code Section 501(c)(3) or “the equivalent.” The commenter states that its certified affiliate food banks and food rescue organizations provide food to the public through direct distributions and through distributions to local nonprofit section 501(c)(3), or equivalent nonprofit, agencies.

(Response) The interim final rule defines a “nonprofit food establishment” as “a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by

humans or animals in the U.S.” The interim final rule includes central food banks, soup kitchens, and nonprofit food delivery services as examples of nonprofit food establishments. In response to the comment, FDA is clarifying that to be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)). If the commenter’s establishments meet all aspects of the definition of nonprofit food establishment in this interim final rule, they would be exempt from registration.

Please see section III.E.10 of this document for changes FDA made to the definition of “nonprofit food establishment.”

## 6. Fishing Vessels

(Comment 29) One commenter states that the fishing vessel exemption will not achieve its intended purpose, due to the Bioterrorism Act’s reference to § 123.3(k), which FDA includes in the fishing vessel exemption. The commenter argues that incorporating the reference to § 123.3(k) into the proposed rule invalidates nearly the entire exemption, because harvested fish must be removed from the harvest vessel for any further processing. The exemption, therefore, would only exempt those fishing vessels that transfer harvested fish by brailing or pumping to offshore processing vessels. The exemption would not apply to fishing vessels that enter port and offload fish dockside. As a result of these restrictions on the exemption, the commenter requests that FDA “acknowledge the irony of this exemption” and consider requesting a technical amendment to the Bioterrorism Act to broaden the exemption.

(Response) The Bioterrorism Act (21 U.S.C. 350d(b)(1)) expressly references the Seafood Hazard Analysis Critical Control Point (Seafood HACCP) regulations (§ 123.3(k)) as part of the fishing vessel exemption. Accordingly, to the extent that the exemption for fishing vessels is limited, it is limited by Congress. Importantly, however, FDA notes that “dockside unloading” is included in the definition of “processing” (§ 123.3(k)) to cover waterfront facilities that unload vessels and pack the catch for shipment to buyers, not the vessels from which the catch is unloaded. (See 60 FR 65096, 65114 to 65115, December 18, 1995.) Thus, the comment is not correct that the only vessels that would be exempt are those that transfer fish by brailing or pumping to offshore processing vessels. Generally, vessels covered by the