

process, pack, or hold food samples should not be considered “facilities” for purposes of FDA registration. The commenters note that R&D facilities typically hold food and often process it on a small scale, but this food is intended for research purposes and not for commercial sale or public consumption. The commenters explain that sample facilities distribute samples internally to employees and are not commercially distributed.

(Response) Under section 305 of the Bioterrorism Act, facilities are required to register if they manufacture/process, pack, or hold food for consumption in the United States. Therefore, R&D facilities and sample facilities that manufacture/process, pack, or hold food that is consumed in the United States, either by the facility’s employees or others are required to register. However, if R&D facilities and sample facilities manufacture/process, pack, or hold food and this food is not for consumption or actually consumed in the United States, the facilities are not subject to registration.

(Comment 68) One commenter takes issue with FDA’s inclusion of animal feed within the definition of food. This commenter states that in the legislative history of the Bioterrorism Act, Rep. Shimkus (R-IL) repeatedly states that the registration requirement is intended to apply to food for “human” consumption. The commenter also indicates that the Conference Report to the Bioterrorism Act states that the retail exemption applies to facilities that sell to the consumer “for human consumption,” stating that FDA took comments on this issue in the proposed rule. The commenter argues that because the recordkeeping, administrative detention, and prior notice parts of the Bioterrorism Act specifically refer to requirements regarding food for animals, as well as for humans, while the registration part of the Bioterrorism Act does not, FDA should limit the food definition to food for human consumption.

(Response) As discussed in the response to comment 58, the meaning of “food” in section 415 is ambiguous. Therefore, FDA may define “food” in a reasonable manner. As noted in the response to comment 66, sections 303, 306, and 307 of the Bioterrorism Act reflect Congressional concern with the health and safety of “animals.” In that response, FDA also explains why, logically, the standard in question (“serious adverse health consequences to human or animals”) need not appear in section 305 of the Bioterrorism Act. One important way in which to safeguard animals is to protect their

food supply. FDA believes that it is reasonable to include food consumed by animals in the definition of “food” and thus, to require the registration of facilities that manufacture/process, pack, or hold food for consumption by animals. Accordingly, the interim final rule’s definition of “food” in § 1.227(b)(4) includes food for consumption by animals.

8. Holding

FDA received many comments regarding whether facilities that hold products on a temporary basis are required to register as holders. Because these comments also questioned whether these units fit within the definition of “facility,” FDA has addressed those issues in comment 44 and its response.

(Comment 69) Several commenters request that FDA clarify who is required to register and pay the costs for storage if a manufacturer/processor sends food to a warehouse for holding under the manufacturer/processor’s name before export to the United States.

(Response) FDA interprets this question as applying solely to the warehouse, not the manufacturer/processor. Each facility that holds unprocessed food that will be imported into the United States in its unprocessed form for consumption in the United States must be registered with FDA, unless it is exempted by this rule. Additionally, each foreign facility that holds food destined for consumption in the United States subsequent to the last foreign manufacturer/processor must be registered with FDA, unless it is exempted by this rule. Consistent with the plain language of the Bioterrorism Act, the interim final rule places the responsibility of registering a facility on the owner, operator, or agent-in-charge of such facility. Although the interim final rule permits the owner, operator, or agent in charge to authorize an individual to register the facility, the facility’s owner, operator, or agent in charge retains the legal responsibility to ensure that the facility is properly registered with FDA. In the situation raised in the comment, whether the warehouse or the manufacturer/processor pays the cost of such storage is a private matter between the manufacturer/processor and the warehouse.

On its own initiative, FDA has made an editorial change in this section for clarity.

9. Manufacturing/Processing

(Comment 70) One commenter requests FDA to clarify whether commercial ripening of fruit fits within

the definition of “manufacturing/processing.” The commenter states that some cargo containers are equipped with technologies that artificially ripen fruit while in transit. The commenter states that “such technological advancements should not change the interpretation of what defines a facility under the rule,” and requests that FDA not consider this activity manufacturing/processing.

(Response) Because this activity involves “treating,” “modifying,” or “manipulating” food, it constitutes manufacturing/processing as defined by the interim final rule (21 CFR 1.227(b)(6)). The fact that these manufacturing/processing activities occur in a transport vehicle does not alter the fact that these activities are manufacturing/processing. Thus, a vehicle engaging in the artificial ripening of food while in transit is required to register.

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

10. Nonprofit Food Establishment

FDA received no comments on this issue. On its own initiative, FDA has made several changes in this section to be consistent with the legislative history for section 305 of the Bioterrorism Act (21 U.S.C. 415). FDA has also made several editorial changes in this section for clarity.

11. Packing

(Comment 71) One commenter asks FDA to differentiate between “packing” and “packaging.” The commenter states that although arguably the terms could be used interchangeably, they are in fact materially different. The commenter states that this distinction is especially important because FDA considers “packaging material” food under § 1.227(c)(4).

(Response) FDA agrees with the commenter and differentiates between these terms in the interim final rule. The interim final rule defines “packaging” (when used as a verb) as “placing food into the container that directly contacts the food and that the consumer receives.” (§ 1.227(b)(8)). FDA has redefined “packing” as “placing food into a container other than packaging the food” (§ 1.227(b)(9)). FDA notes that packaging material is no longer included in the definition of “food” as revised in this interim final rule.

(Comment 72) One commenter asks whether putting food into tote bins and bulk containers is considered “packing” for purposes of this rule.

(Response) Putting food into tote bins and bulk containers is “packing” as