

of the FD&C Act. Articles that are refused for inadequate prior notice cannot be entered under any form of Customs entry. Those articles may only be entered after adequate prior notice has been given.

(Comments) Several comments express concern about the impact of refusal and holding at the port or secure storage on the quality, value, and marketability of perishable fresh and frozen foods.

(Response) FDA expects that the changes in the interim final rule, in particular the shortened timeframes, will mean fewer refusals. In addition, since FDA will make every effort to review prior notices for refused articles within these same timeframes, those responsible for submitting prior notice have the ability to have the refusal removed in a matter of a few hours. This, too, significantly reduces the impact of the interim final rule on perishables. Finally, FDA also intends to provide guidance to its staff on implementing and enforcing the prior notice requirements, both during the initial transition period and after that period ends.

FDA agrees that appropriate storage and holding conditions must be considered for perishable and frozen foods refused for inadequate prior notice. This means that if the article of food arrives in frozen condition and has been transported under frozen conditions, the facility used for holding the product must provide adequate frozen conditions.

(Comments) Some comments express concern that there are insufficient facilities at the U.S./Mexico ports to handle the potential refusals during the produce season. One commenter disagrees with FDA's statement in the preamble to the proposed rule that "U.S. Customs has identified a well-established network of storage facilities that are secure." The comment pointed out that there is no infrastructure of secure facilities at all ports. A comment noted that there are few facilities at remote East and West ports along the U.S./Canadian border that have temperature controlled environments and are available around the clock. Another comment noted that there generally is a lack of bonded cold storage facilities at borders and at airports. One comment asks for information on the infrastructure of storage facilities that would provide sanitation and temperature controls, as well as security controls, including security against theft and accidents. Some comments ask that FDA publish a list of the secure facilities and the costs

that FDA authorizes for the refused food.

(Response) FDA expects that the changes in the interim final rule, in particular the shortened timeframes, will mean fewer refusals and thus less need for storage for refused articles of food. Nevertheless, FDA and CBP agree that the different ranges of storage available at different ports need to be addressed. However, this issue needs to be addressed in light of the determination, reflected in § 1.283(a)(2)(i), that food refused under section 801(m)(1) of the FD&C Act has "general order" status. Under customs laws and regulations, general order merchandise must generally be held in a general order warehouse (19 CFR 127.1). Customs regulations also empower the port director, if merchandise requires specialized storage facilities that are unavailable in a bonded facility, to direct the storage of the merchandise by the carrier or by any other appropriate means (see 19 CFR 4.37(f), 122.50(f), or 123.10(f)). Additionally, fruit and other perishables may be held by the port director in a bonded cold-storage warehouse for a reasonable period, if it is probable that entry will be made at an early date (19 CFR 127.28(c)).

FDA and CBP believe that general order storage qualifies as secure facilities for purposes of the Bioterrorism Act, as it is subject to the requirements set out at 19 CFR part 19. In particular, 19 CFR 19.9 contains controls that will ensure that refused food will be adequately controlled while in storage and will not be released from general order storage without CBP authorization.

(Comments) Several comments ask for clarification on secure facilities. Comments ask whether a general-purpose warehouse in a FTZ or a secure facility operated by the importer of record would be considered a secure facility under the rule. Another comment suggests that a clear chain of custody and fiduciary responsibility is required when products are impounded. The comment recommends that appropriate and sufficient impound storage facilities must be available before enforcement begins.

(Response) As set out previously, food refused under section 801(m)(1) of the FD&C Act must be held in accordance with CBP's regulations on general order merchandise.

(Comments) One comment suggests that if there is a failure to submit adequate prior notice, the goods should be allowed to move to the port of destination.

(Response) The prior notice is required to be submitted to and confirmed by FDA before the article of food arrives at the port of arrival. Food refused because of inadequate prior notice must be held within the port of entry for the article unless directed by CBP or FDA. Thus, refused food may be permitted to move to the port of destination.

iii. *Movement of refused food (§ 1.283(a)(2)(iii)).* (Comments) One comment objects to making the carrier responsible by regulation for movement of refused food. One comment suggested that FDA should be responsible for movement of refused foods.

(Response) As set out in the preamble to the proposed rule (68 FR 5431 to 5432), we do not believe that section 801(m) of the FD&C Act mandates that the government take physical control of refused food. Rather, it limits the locations where refused food can be held and to whom it can be delivered. Accordingly, FDA proposed that the carrier or the person who submitted the prior notice arrange for the movement of the refused food. FDA has decided to remove this limitation in the interim final rule. Since we have removed limitations on who can submit, submitters may now be foreign firms that may have difficulty arranging to move food from overseas. We have concluded that we should not impose any limitations on who may arrange for the movement of refused foods. The interim final rule, § 1.283(a)(2)(iii), does maintain the requirement that movement of refused food occur under the appropriate CBP custodial bond. The interim final rule further provides that refused food must be taken directly to the designated facility, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee. Failure to observe these conditions will be a violation of the bond and may result in the imposition of liquidated damages.

b. *Segregation of refused foods (§ 1.283(a)(3)).* (Comments) Some comments state that FDA should release to the owner or importer all of the other food or nonfood items in the shipment that are not affected by the inadequate prior notice, in mixed or consolidated shipments, if one or more food items has been refused because of inadequate prior notice. One comment points out that shipments might contain sealed containers of different foods from different sources. One comment asks for clarification on how refused products will be segregated from products that may continue when the products are on a truck or in a rail car. The comment points out that this is a concern for less-