

the status of refused food, and to provide a mechanism for FDA review after refusal. In the interim final rule, FDA identifies the consequences and procedures for the following situations:

1. Inadequate Prior Notice (No, Inaccurate, or Untimely Prior Notice)

Unless immediately exported with CBP concurrence, an article of food that is refused for inadequate prior notice shall be held in accordance with § 1.283.

2. Status and Movement of Refused Food

- A refused food is considered general order merchandise under section 490(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1490(a)).
- The refused food must be moved under an appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal. If the food is held, it must be taken directly to the designated location within 48 hours, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

3. Segregation of Refused Foods

If a refused food is part of a shipment that contains other articles, the refused food may be segregated from the rest of the shipment within the port of arrival or at the hold location if different.

4. Costs

Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

5. Export After Refusal

A refused food may be exported with CBP concurrence and supervision (unless CBP or FDA has administratively detained or seized the article under other authority).

6. No Post-Refusal Submission or Request for Review

If no prior notice submission or request for FDA review is submitted in a timely fashion after a food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

7. Food Carried by or Otherwise Accompanying an Individual

For food that is not for personal use, if the article of food is refused because prior notice is inadequate or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the article may be held at the port or exported. If the individual cannot make arrangements for holding or export, the food may be destroyed.

8. Post-Refusal Prior Notice Submissions

If an article of food is refused for no or inaccurate prior notice, the prior notice must be submitted or corrected and resubmitted to FDA and confirmed by FDA for review.

9. FDA Review After Refusal

After refusal, only the submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(5) and § 1.277, or whether the prior notice submission is accurate. The interim final rule also sets out procedures and timeframes for the review process.

10. International Mail

In the case of food arriving by international mail, if prior notice is inadequate or if the PN Confirmation Number is not affixed, the article will be held by CBP for 72 hours for FDA inspection and disposition. If refused and there is a return address, the parcel may be returned to sender. If there is no return address or the food in the shipment appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel back to the sender or, if there is no return address, destroy the parcel, at FDA expense.

11. Prohibitions on Delivery and Transfer

A refused article of food may not be delivered outside of the port where the article is held and may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or secure facility until FDA has examined the prior notice, determined the adequacy of the prior notice, and notified CBP and the transmitter that the article is no longer

refused. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

12. Relationship to Other Admissibility Provisions

A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.

*I. What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (Section 1.284 Proposed as § 1.278)*

The interim final rule provides that failure of a person who imports or offers to import an article of food to submit prior notice is a prohibited act under section 301(ee) of the FD&C Act (21 U.S.C. 331(ee)) and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

*J. What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under 21 CFR Part 1, Subpart H? (Section 1.285)*

The interim final rule also sets out the consequences concerning what happens at the border to food from facilities that are not registered as required under section 415 of the FD&C Act and 21 CFR part 1, subpart H. These are similar to provisions in the interim final rule for dealing with food that is refused for inadequate prior notice.

Table 1A of this document shows the information required by sections 1.281(a), (b), and (c). For clarity, the table also identifies under what circumstances certain information is not required, e.g., registration numbers when the article of food is imported or offered for import for transshipment, storage and export, or further manipulation and export.

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