

- FDA will state in the detention order the location and any applicable conditions under which the food is to be held.

- FDA may direct that the article of food be moved to a secure facility, if appropriate. An article of food moved to a secure facility remains under detention before, during, and after such movement.

- FDA may approve a request for a limited conditional release of a detained article of food for purposes of destruction, movement to a secure facility, preservation of the detained article of food, or any other purpose that FDA believes is appropriate. An article of food transferred under a limited conditional release remains under detention before, during, and after the transfer.

- Any transfer of a detained article of food in violation of a detention order is a prohibited act.

- Any person who would be entitled to be a claimant for the article of food, if seized, may appeal a detention order and, as part of that appeals process, may request an informal hearing. If a hearing is granted, an FDA Regional Food and Drug Director (RFDD) or another official senior to an FDA District Director will serve as the presiding officer of the hearing.

- The proposed rule includes appeal and hearing timeframes for both perishable and nonperishable detained articles of food.

- *Perishable food:*

- An appeal must be filed within 2 calendar days of receipt of the detention order.

- If a hearing is requested in the appeal, and FDA grants the request, the hearing will be held within 2 calendar days after the date the appeal is filed.

- FDA's decision on appeal will be issued 5 days after the appeal is filed.

- *Nonperishable food:*

- A notice of intent to file an appeal and to request a hearing must be filed within 4 calendar days of receipt of the detention order.

- An appeal must be filed within 10 calendar days of receipt of the detention order.

- If a hearing is requested in the notice of intent and appeal, and FDA grants the request, the hearing will be held within 3 calendar days after the appeal is filed.

- FDA's decision on appeal will be issued 5 days after the appeal is filed.

- The proposed expedited procedures for certain enforcement actions with respect to perishable foods require FDA to send a seizure recommendation to the Department of Justice within 4 calendar

days after the detention order is issued, unless extenuating circumstances exist.

- Confirmation of a detention order by the FDA presiding officer is considered final agency action.

B. General Provisions

1. What Definitions Apply to This Subpart? (Proposed § 1.377)

Proposed § 1.377 describes the definitions that apply to this subpart and states that the definition of terms that appear in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart.

Proposed § 1.377 also defines specific terms used in the proposal.

- *Act* means the Federal Food, Drug, and Cosmetic Act.

- *Authorized FDA representative* means the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director. FDA's Office of Regulatory Affairs (ORA) is responsible for FDA's field operations and compliance related functions. The ORA field organization is divided into regional offices, which are headed by RFDDs. The regions are broken down into district offices, which are headed by District Directors. An RFDD is an FDA official senior to an FDA District Director.

- *Calendar day* means every day shown on the calendar. This term includes weekend days.

- *Food* has the meaning given in section 201(f) of the act. That definition is: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. These examples include, but are not limited to: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

- *Perishable food* means food that is not heat-treated; not frozen; and not

otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions. This perishable food definition has been modeled after the current RPM definition of "perishable commodity". Examples of perishable foods include, but are not limited to, fluid milk (but not ultrapasteurized); live fish, lobster, crab, other crustaceans, shellfish; and fresh fruits and vegetables.

We decided to use the RPM definition of "perishable commodity" as the basis for the definition of "perishable food" because the RPM definition is commonly used and understood by both industry and FDA. Furthermore, we believe this definition is appropriate in light of the 5-day (maximum) deadline for FDA to issue a decision on an appeal of a detention. Under the proposed deadlines for appeals involving the detention of a perishable food, FDA would issue a decision on an appeal prior to the expiration of the 7-day period. We believe the timeframes proposed here offer the best protection to appellants and products.

We invite comments and supporting data on how to best define "perishable food" for the purposes of this proposed rule.

- *We* means the U.S. Food and Drug Administration.

- *Working day* means any day from Monday through Friday, excluding federal holidays.

- *You* means any person who receives the detention order or that person's representative.

2. What Criteria Does FDA Use to Order a Detention? (Proposed § 1.378)

Proposed § 1.378 states the criteria FDA would use to order a detention. These criteria are taken directly from section 303 of the Bioterrorism Act. FDA may order a detention of an article of food that is found during an inspection, examination, or investigation under the act if an officer or qualified employee of FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals.

The Bioterrorism Act articulates a standard of "credible evidence or information" for determinations of whether the evidence or information indicates that an article of food presents a threat of serious adverse health consequences or death to humans or animals. "Credible evidence or information" is an evidentiary standard that in simplest terms means evidence