U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

Protecting the Food Supply

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FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA'S New Food Bioterrorism Regulation Final Rule: Administrative Detention

Section 303(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) adds section 304(h) to the Federal Food, Drug, and Cosmetic Act to authorize FDA to detain an article of food for which there is credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals. This authority is self-executing and provides an added measure to ensure the safety of the nation's food supply. The Bioterrorism Act also requires FDA to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. FDA has now issued a final rule that includes these expedited procedures for perishable foods as well as procedures describing how FDA will detain an article of food and the process for appealing a detention order.

What food is subject to the regulation? The definition of food used in the final rule references the definition of food in section 201(f) of the Federal Food, Drug, and Cosmetic Act. It includes food and beverages for human and animal consumption. Food regulated exclusively by USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act is not covered by the administrative detention regulation. All other food is subject to this regulation whether or not it enters interstate commerce.

What constitutes "perishable food?" FDA defines perishable food as 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 calendar days under normal shipping and storage conditions.

What criteria does FDA use to order a detention? An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the Federal Food, Drug, and Cosmetic Act if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.

Who approves a detention order? The final rule requires a detention order to be approved by the District Director of the district where the detained article of food is located, or an official senior to such director.

What information must FDA include in the detention order? The final rule requires the

detention order to include the detention order number; the hour and date of the order; identification of the detained article of food; the detention period; a statement that the article of food identified in the order is detained for the period shown; a brief, general statement of the reasons for the detention; the name of the authorized FDA representative who approved the detention order; and the address and location where the article of food is to be detained and the appropriate storage and transportation conditions.

How long may FDA detain an article of food? The detention period cannot exceed 30 days.

Where and under what conditions must the detained article of food be held? The final rule requires the detained article of food to be held in the location and under the conditions specified by FDA in the detention order. The detention order must require the removal of the detained article of food to a secure facility, as appropriate.

May a detained article of food be delivered to another entity or transferred to another location? The final rule states that an article of food subject to a detention order may not be delivered to another entity, such as its importers, owners, or consignees. Detained food may not be transferred from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article or the detention period expires, whichever occurs first. A "request for modification of a detention order" for a detained article of food may be approved for destroying the article of food, moving the detained article of food to a secure facility, maintaining or preserving the integrity or quality of the article of food, or for any other appropriate purpose. It is important to note that the existence of an appropriate customs bond required by Customs law and regulation does not prohibit movement of a detained article of food at FDA's direction.

What labeling or marking requirements apply to a detained article of food? A detention order may require that the detained article of food be labeled or marked as detained. The FDA tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative. This marking is different from the marking that FDA may require under section 308 of the Bioterrorism Act for food refused admission into the United States.

What expedited procedures apply when FDA initiates a seizure action against a detained perishable food? If FDA initiates a seizure against a perishable food subject to a detention order, the final rule requires FDA to send the seizure recommendation to the Department of Justice (DoJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.

Who receives a copy of the detention order? FDA will issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different form the owner, operator, or agent in charge of the place where the article of food is located, then FDA will provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily. If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

Who is entitled to appeal? Any person who would be entitled to claim the detained article of food if it were seized may appeal the detention order to the Secretary.

What are the requirements for submitting an appeal? For perishable food, an appeal must be filed within 2 calendar days of receipt of the detention order. For non-perishable 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, with the requirement that the actual appeal be filed within 10 calendar days of the receipt of the detention order.

Will a hearing be held if an appeal is made? The final rule states that, if a hearing is requested in the appeal, and FDA grants the request, then the hearing will be held within 2 calendar days after the date the appeal has been filed for both perishable and nonperishable foods.

When does FDA have to issue a decision on an appeal? Within 5 calendar days after such an appeal is filed, and after providing opportunity for an informal hearing, FDA must confirm or terminate the detention order.

When does a detention order terminate? If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order, or that person's representative. If FDA fails to issue a detention termination notice and the detention period expires, the detention order is deemed to be terminated.

What is the difference between an import detention and administrative detention?" Our authority to detain food administratively under section 304(h) of the Federal Food, Drug, and Cosmetic Act is separate and distinct from our authority to refuse admission of imported food under section 801(a) of that act, even though refusal under section 801(a) is preceded by an action referred to as "detention and hearing."

In section 304(h), Congress gave FDA the authority to detain food administratively where we have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals so that we can bring such food under FDA control.

FDA's evaluation of imported foods under section 801(a) largely focuses on whether the article of food appears to have been safely produced, packed, and held; contains no contaminants or illegal additives or residues; and is properly labeled. If FDA determines that refusal under section 801(a) appears appropriate, FDA, as set out in its regulations, gives written notice to the owner or consignee (see 21 CFR 1.94(a)). In guidance dating back many years, FDA refers to this written notice as the notice of detention and hearing.

We do not, at this time, foresee frequently using administrative detention under section 304(h) to control the movement of imported food subject to section 801. When FDA determines it is appropriate to bring imported food under FDA control using the authority under section 304(h), the standard for administrative detention of imported food will be the same as it is for other food, i.e., we must have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

When do the administrative detention requirements take effect? The administrative

detention authority in section 303 of the Bioterrorism Act took effect immediately upon enactment of the Act. The procedures FDA will follow for administratively detaining food that is specified in the final rule take effect 30 days after it publishes in the Federal Register.
