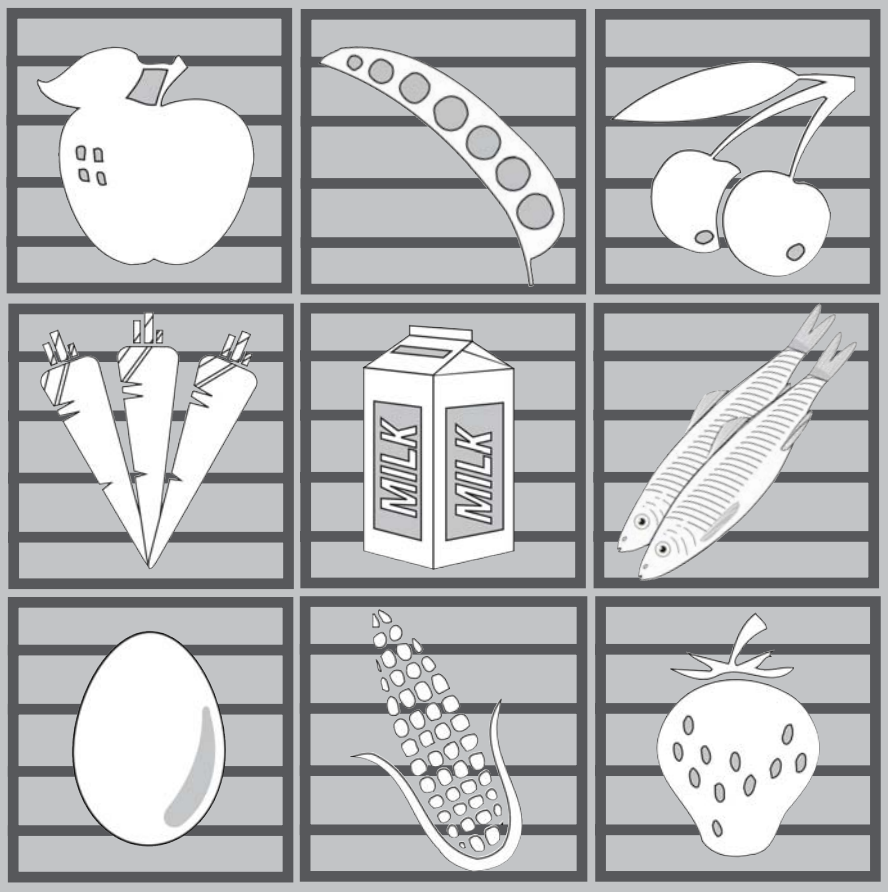
Protecting the U.S. Food Supply

U.S. Food and Drug Administration

U.S. Department of Health and Human Services

What You Need to Know About

ADMINISTRATIVE DETENTION OF FOOD



The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

November 2004

U.S. Food and Drug
Administration

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and Human Services

This guidance document is a restatement of the Food and Drug Administration's (FDA's) current requirements for the new food bioterrorism legislation and is presented in simplified format and language. As guidance, it is not binding on either FDA or the public. FDA notes, however, that the regulation that is the basis for this booklet establishes requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulation at 21 CFR Part 1, Subpart K, in addition to reading this booklet.

INTRODUCTION

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

The Bioterrorism Act authorizes an officer or qualified employee of FDA to 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 that the article of food presents a threat of serious adverse health consequences or death to humans or animals. FDA has now issued its Administrative Detention final rule with procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. This final rule also describes the process for appealing a detention order.

The authority in section 303 of the Bioterrorism Act to detain administratively an article of food took effect on June 12, 2002, and immediately upon enactment of the Bioterrorism Act. The procedures specified in the final rule that FDA would use to detain food administratively took effect on July 6, 2004.

Purpose of this Booklet

This booklet was created to inform food manufacturers, processors, packers, transporters, importers, and exporters about a new FDA bioterrorism regulation that is in effect. It contains important information that may affect your firm.

The information in this booklet also appears online at:
http://www.fda.gov/oc/bioterrorism/bioact.html.

About Administrative Detention: The New Food Bioterrorism Regulation

Section 303(a) of the Bioterrorism Act adds section 304(h) to the Federal Food, Drug, and Cosmetic Act. This provision authorizes FDA to detain an article of food, if there is credible evidence or information that indicates the article presents a threat of serious adverse health consequences or death to humans or animals.

Why Administrative Detention Is Required

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 that is 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 to prevent the quality of the food from being adversely affected, if held longer than seven 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 Act, if the officer or qualified employee has credible evidence or information indicating that the article of food 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 Director of the FDA District where the detained article of food is located, or an official senior to such director. A directory of FDA District Offices can be found at: **www.cfsan.fda.gov/~dms/district.html**.

What information must FDA include in the detention order?

The final rule requires the detention order to include the following:

- Detention order number
- Hour and date of the order
- Identification of the detained article of food
- Detention period
- Statement that the article of food identified in the order is detained for the period shown
- Brief, general statement of the reasons for the detention
- Name of the authorized FDA representative who approved the detention order
- 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?

No, 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's 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 one 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 that is subject to a detention order, the final rule requires FDA to send the seizure recommendation to the Department of Justice within four 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 from 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 two 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 four 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 the appeal requests a hearing, and FDA grants the request, then for both perishable and non-perishable foods, the hearing will be held within two calendar days after the date the appeal has been filed.

When does FDA have to issue a decision on an appeal?

FDA must confirm or terminate the detention order within five calendar days after an appeal is filed and after providing an opportunity for an informal hearing.

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's 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, when 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. This permits the agency to bring such food under FDA control.

By comparison, 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, illegal additives, or residues;**
- **Is properly labeled**

If FDA determines that refusal under section 801(a) appears appropriate, FDA, as stated 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."

At this time, we *do not* foresee frequently using administrative detention under section 304(h) to control the movement of imported food subject to section 801. When FDA determines that it is appropriate to bring imported food under FDA control using the authority of section 304(h), the standard for administrative detention of imported food will be the same as it is for other food. That is, 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 Bioterrorism Act. The FDA procedures for administratively detaining foods that are specified in the final rule took effect on July 6, 2004, 30 days after the rule was published in the *Federal Register*.

How to Get More Information

Information on FDA's actions involving the Bioterrorism Act is available online at **http://www.fda.gov/oc/bioterrorism/bioact.html**.

For more information, go to:

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