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[Docket No. 02N–0275]

RIN 0910–AC38

Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that provides procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals ("administrative detention"). The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which authorizes the use of administrative detentions and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order.

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**].

DDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Marquita Steadman, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–827–6733.

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I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of the Food and Drug Supply), Subtitle A (Protection of Food Supply), section 303, which amends section 304 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334 *et seq.*) by adding paragraph (h) to provide that 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. This provision also requires the Secretary of Health and Human Services (the Secretary) to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order. Section 303 of the Bioterrorism Act also amends the act by adding a new prohibited act as paragraph (bb) to section 301 of the act (21 U.S.C. 331)

The major components of section 303 of the Bioterrorism Act are as follows:

• *Criteria used to trigger an administrative detention*: Amends section 304 of the act to authorize 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 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.

• *Approval required*: The Secretary, or an official designated by the Secretary, must approve the detention order. An "official designated by the Secretary" means the District Director of the district where the detained article of food is located, or an FDA official senior to such director.

• *Period of detention*: The detention period will be for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary to enable the Secretary to institute a seizure or injunction action.

• *Required rulemaking*: The Secretary must by regulation provide for procedures for instituting certain enforcement actions on an expedited basis with respect to perishable food subject to a detention order.

• *Security of detained article of food*: The detention order may require that the detained article of food be labeled or marked as detained. The order must require the removal of the detained article of food to a secure facility, as appropriate.

• *Appeal procedure*: Any person who would be entitled to claim the detained article of food if such article were seized may appeal the detention order to the Secretary. Within 5 days after such appeal is filed, after providing opportunity for an informal hearing, the Secretary must confirm or terminate the detention order. The appeal process terminates if the Secretary institutes an action for seizure or injunction regarding the article of food involved. Confirmation of a detention order is considered a final agency action.

• *Prohibited act*: Amends section 301 of the act making it a prohibited act to transfer a detained article of food in violation of a detention order, or to remove or alter any mark or label required by the detention order to identify the article of food as detained.

Section 303 of the Bioterrorism Act also includes a provision authorizing temporary holds at ports of entry that will not be addressed in this proposed regulation, but through separate guidance that FDA plans to develop and issue. The temporary hold provision authorizes FDA to request the Secretary of Treasury to institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if 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, and FDA is unable immediately to inspect, examine, or investigate such article. FDA has received comments on the temporary hold provision in the public docket (Docket No. 02N–0275). FDA plans to consider these comments in developing guidance on the temporary hold provision.

FDA is proposing to amend title 21 of the Code of Federal Regulations (CFR) by establishing a new subpart to part 1 (21 CFR part 1) consisting of subpart K entitled "Administrative Detention of Food for Human or Animal Consumption." In this proposed rule, we describe the procedures for how FDA will detain an article of food and the process for appealing a detention order. We also address procedures for instituting on an expedited basis certain enforcement actions with respect to detained perishable foods. This proposed rule also makes a conforming amendment to part 16 (21 CFR part 16) entitled "Regulatory Hearing Before the Food and Drug Administration." Although the statutory requirements in section 304(h) of the act are self-executing and are currently in effect, FDA is issuing this regulation to further refine aspects of the administrative detention requirements.

The administrative detention process described in this proposed rule is modeled after FDA's medical device administrative detention regulation found

at § 800.55 (21 CFR 800.55). FDA believes that this process has been effective and efficient for medical device administrative detentions and should also work well for administrative detentions of food. In addition, using the medical device regulations as a model will be helpful to the agency as field offices are familiar with this detention process and training will not need to be as extensive.

Section 303 of the Bioterrorism Act provides for an opportunity for an informal hearing as part of the appeal process. The regulations in part 16 set out FDA's informal hearing procedures and provide that its procedures apply when the act or FDA regulations provide for an opportunity for a hearing and no specific hearing regulations exist (see § 16.1(b)). Proposed § 1.403 states that any informal hearing held on an appeal of a detention order will be conducted in accordance with part 16 except as noted therein.

Although section 303 of the Bioterrorism Act requires FDA only to promulgate regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order, FDA also is proposing in this regulation to describe the procedures for how FDA will detain both perishable and nonperishable articles of food and the process for appealing a detention order. If FDA did not establish other requirements for the process for appealing a detention order in this proposed regulation, it would be difficult for FDA to meet certain requirements in section 303 of the Bioterrorism Act. For example, section 303 of the Bioterrorism Act requires FDA, after providing an opportunity for an informal hearing, to confirm or terminate a detention order within 5 days after the date of appeal. Two of the requirements in this proposed rule would be to impose a deadline for filing an appeal and a limitation on the length of the informal

hearing (see proposed §§ 1.402 and 1.403). These proposed requirements are intended to ensure that FDA meets section 303's timing requirements. FDA is proposing to codify the procedures for how FDA will detain an article of food to clarify our procedures for the public and to follow FDA's model for the administrative detention of medical devices that has its procedures codified at 21 CFR 800.55. FDA is proposing to incorporate these provisions in a regulation instead of a guidance document to make them enforceable since guidance documents are not binding.

FDA wants to make clear that this proposed rule does not implement section 801 of the act (21 U.S.C. 381), despite its use of the term "detention". As explained in this preamble, this proposed rule implements section 303 of the Bioterrorism Act, which amends section 304 of the act. This amendment grants FDA the authority to detain food upon credible evidence or information of a threat of serious adverse health consequences or death to humans or animals. FDA has had similar authority for medical devices under section 304(g) of the act since 1976, and usually refers to this authority as "administrative detention" (§ 800.55). Section 801(a) of the act provides that FDA shall refuse the admission of any article of food that has been imported or offered for import that appears, among other things, to be adulterated or misbranded under the act, based on physical examination or otherwise. Under section 801(a), before FDA refuses admission to an article that appears violative, importers are provided with a notice of hearing on refusal of admission, which notifies them that the article may be subject to refusal of admission, and provides them with an opportunity to introduce testimony and establish that the article is fully in compliance with the act (§ 1.94). FDA refers to this administrative process concerning imports as detention (see "FDA

Regulatory Procedures Manual" (RPM), chapter 9). Because of the authorities available to FDA and the U.S. Customs Service to control imported food subject to section 801(a) of the act, FDA does not expect to frequently use administrative detention under section 303 of the Bioterrorism Act to control such imported food.

Section 304(h) of the act, as added by section 303 of the Bioterrorism Act, provides that :

> An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

This language does not include a limitation similar to that in section 304(g) of the act that provides for administrative detentions of devices during inspections conducted under section 704 of the act, a provision of the act that has an interstate commerce component. In addition, the prohibited act related to administrative detention of food, section 301(bb) of the act, unlike some other prohibited acts in section 301, does not include an interstate commerce component. Therefore, FDA tentatively concludes that all food would be subject to administrative detention under section 304(h) of the act, whether or not the food enters interstate commerce. Because a bioterrorist threat involving food or other food-related emergencies would have the same effect on the public health regardless of whether the food had originated from an out of State source, FDA believes that administrative detention should apply to all food, whether or not the food was in interstate commerce. FDA recognizes, however, that section 304(h) of the act is not clear in this regard.

For example, section 304(h) includes references to certain enforcement provisions of the act, such as section 304(a) of the act, an enforcement provision that includes an interstate commerce requirement. Because this is an important and controversial issue, the agency is seeking comment on whether its tentative conclusion that it has authority to administratively detain food in intrastate commerce is correct and, if so, whether FDA should use that authority. FDA also seeks comments on the amounts and types of food that would only be in intrastate commerce.

This proposed rule complies with section 315 of the Bioterrorism Act entitled "Rule of Construction," which states that nothing in title III of the Bioterrorism Act, or an amendment made by title III, shall be construed to alter the jurisdiction between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services under applicable statutes and regulations. Accordingly, this proposed rule does not apply to food regulated exclusively by the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). However, food that is jointly regulated by FDA and USDA would be subject to this proposed rule. An example of a food that is jointly regulated by FDA and USDA is frozen TV dinners containing both meat and fish.

In addition to section 303 of the Bioterrorism Act, which amends the act as described previously in section I of this document, FDA is relying on section 701(a) of the act (21 U.S.C. 371(a)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to members of the public interested in food issues outlining the four provisions of title III of the Bioterrorism Act which require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see http://www.cfsan.fda.gov/~dms/sec-ltr.html). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held several meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter in order to solicit stakeholder comments. In response to these solicitations, FDA received a number of comments regarding section 303 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we have received so far with the comments we receive during the public comment period for this proposed rule in developing the final rule.

Some of the significant comments FDA received on or before August 30, 2002, include the following:

- The regulations should apply to all foods within FDA's jurisdiction, (e.g., processed food, fresh agriculture, and dietary supplement products).

- The written notice of detention should describe the article of food that has been detained, the quantity of the food, its location, and the basis for the detention. A written notice of detention also should include a written explanation of the appeal right and information that will enable a person entitled to appeal to understand how to file such an appeal.

• FDA's regulations should ensure that if a detained article of food is moved to a secure facility, the food will be maintained under temperature, humidity, and other conditions that will maintain the value and quality of the food.

• A period of 24 to 48 hours from the time of request to the time of holding a hearing is the appropriate timeframe given the short life of many perishable foods.

• Any regulations with respect to detention of food should specify how disputes and resolutions will be handled in order to help prevent spoilage of detained food.

• When an appeal against the detention is filed, FDA should deal with it expeditiously within a fixed period of time to minimize the impact on private businesses.

• An appellant should be entitled to file a written statement of his or her position. The findings of the Secretary after the hearing should be set forth in writing since the Bioterrorism Act provides that the Secretary's decision is "final agency action" under the Administrative Procedure Act, which is judicially reviewable.

• A sanction should be imposed if the detained product is moved before the detention period has expired or has been terminated.

III. The Proposed Regulation

This proposed rule implements the administrative detention provision in section 303 of the Bioterrorism Act. If the regulation is made final as proposed, administrative detention, together with the proposed rules implementing section 305 (registration), section 306 (recordkeeping), and section 307 (prior notice) of the Bioterrorism Act, will enable FDA to act quickly in responding

to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement. For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. The criteria FDA would use to order a detention are taken directly from the Bioterrorism Act and are the same for both domestic and foreign articles of food.

A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

• An officer or qualified employee of FDA may order the detention of domestic or imported food for up to 30 days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.

• The FDA District Director in the district in which the article of food is located or an FDA official senior to such director must approve a detention order.

• FDA may require that the detained article of food be labeled or marked as detained with official FDA tags or labels. 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.

• A violation of a detention order or the removal or alteration of the tag or label is a prohibited act.

• 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 or information that is "worthy of belief or confidence; trustworthy." See Webster's Unabridged Dictionary (1998 ed.) (definition of "credible"). Although various statutes and regulations use this or a similar standard, and courts have invoked or applied the standard of credible evidence or information in a large number of decisions, no precise definition of the standard exists. Instead, determinations of what constitutes credible evidence or information have been made on a case-by-case basis. Likewise, FDA has administered evidentiary standards under other provisions of the act (see e.g., section 304(g)) on a case-by-case basis without further defining those standards in regulation. We believe that a similar approach here is appropriate. In applying the credible evidence or information standard to administrative detention, FDA may consider a number of factors including, but not limited to, reliability, reasonableness, and the totality of the facts and circumstances.

The officers or qualified employees of FDA who may order a detention include, but are not limited to, FDA field investigators, other government employees commissioned or deputized by FDA, and FDA employees who have security clearance to receive national security information. An "authorized FDA representative" as defined in proposed § 1.377, would have to approve a detention order before the FDA officer or qualified employee may order a detention.

3. How Long May FDA Detain an Article of Food? (Proposed § 1.379)

Proposed § 1.379 sets forth the period of administrative detention, (i.e., the length of time an article of food may be detained), consistent with the

requirements of section 303 of the Bioterrorism Act. The period of administrative detention must be a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless it is determined that a greater period is required either to seize the article of food or to institute injunction proceedings. The Bioterrorism Act provides that FDA may detain food for up to 10 additional calendar days if necessary to enable FDA to institute a seizure or an injunction action. Proposed § 1.379 incorporates this authority. An example of when FDA envisions using this authority is when the results of confirmatory testing or other evidentiary development is not complete. The authorized FDA representative, defined in proposed § 1.377, may approve the additional 10 days of detention at the time the detention order is issued, or at any time within the initial 20-calendar-day period, by amending the detention order.

Proposed § 1.379 states that the entire detention period may not exceed 30 calendar days in total. This proposed section also allows the authorized FDA representative, in accordance with proposed § 1.384, to approve the termination of a detention order before the expiration of the detention period. FDA intends to proceed as expeditiously as possible to resolve all issues involved with particular administrative detentions.

4. Where and Under What Conditions Must the Detained Article of Food be Held? (Proposed § 1.380)

Proposed § 1.380(a) requires you to hold the detained article of food in the location and under the conditions specified by FDA in the detention order. Use of appropriate storage conditions, such as temperature, humidity, and other conditions may be necessary to protect the safety and wholesomeness of the detained article of food. This proposed requirement is consistent with

the legislative history of the Bioterrorism Act (see H. Conf. Rept. No. 107–481, at 131 (2002)).

In proposing § 1.380(a), we also considered the experience that States have had with embargoes. As described in comments from States familiar with embargoing food on behalf of FDA or on their own initiative, States have ordered food embargoed and have provided requisite conditions that must be maintained while the food is embargoed, e.g., segregation from other products in the same warehouse.

In proposed § 1.380(b), the detained article of food must be moved to a secure facility if FDA determines that such movement is appropriate. FDA's determination of whether it is appropriate to require movement of a detained article will depend, in part, on whether we believe there is danger of the detained article entering the stream of commerce. FDA will make such determinations on a case-by-case basis considering several factors, including the adequacy of security where the detained article is located, and the ability to prevent the movement of the food. For example, if it appears likely that the detained food would be diverted, we would require the food to be moved to a secure facility. However, if the storage conditions are such that there appears to be no danger of the detained article of food moving into the stream of commerce, we would decide to keep the article of food detained at its current location.

There may be instances where we relocate the detained article of food to a secure facility. For example, FDA may not be confident that parties involved will adhere to a detention order. Rather than risk losing control over the detained article of food, FDA would relocate the detained article of food. There

may be other situations where FDA decides to relocate the detained article to a secure facility.

Proposed § 1.380(b), also states that a detained article of food remains under detention before, during, and after movement to a secure facility, if FDA has requested such movement. As such, we will also state in the detention order any applicable conditions of transportation of an article of detained food. This may include determinations that the article to be removed to a secure facility must be moved under certain conditions. Similar to determinations of whether to require that food be removed to a secure facility, determinations of the appropriate conditions of transportation will be made on a case-by-case basis.

Proposed § 1.380(c) requires you to have received a limited conditional release under proposed § 1.381(c) before you move the detained article of food to a secure facility.

Proposed § 1.380(d) requires you to ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement to the secure facility. This requirement applies until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

Proposed § 1.380(e) provides that the movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act. This proposed provision is consistent with the statutory language in section 303 of the Bioterrorism Act.

5. May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location? (Proposed § 1.381)

Proposed § 1.381 describes whether an article of food subject to a detention order can be delivered to another entity or transferred to another location. Proposed § 1.381(a) states that a detained article of food may not be delivered to another entity under the execution of a bond. Similarly, this proposed section also states that an article of food detained under section 303 of the Bioterrorism Act may not be delivered to any of its importers, owners, or consignees under section 801(b) of the act. The provisions found in this proposed paragraph are consistent with section 303 of the Bioterrorism Act, and are designed to keep foods that present a threat of serious adverse health consequences or death from moving in commerce.

Proposed § 1.381(b) prohibits, except as provided in proposed § 1.381(c), the transfer of a detained article of food within or from the place where it has been detained, or from the place to which it was moved, until an authorized FDA representative releases the article of food under proposed § 1.384 or the detention period expires under proposed § 1.379, whichever occurs first. This provision is necessary to ensure that the article of food subject to a detention order is not released into commerce.

Proposed § 1.381(c) provides that an authorized FDA representative may approve, in writing, a request for a limited conditional release of the detained article of food for any of the following purposes:

1. To destroy the article of food,

2. To move the detained article of food to a secure facility as described in the detention order,

3. To maintain or preserve the integrity or quality of the article of food, or

4. For any other purpose that the authorized FDA representative believes is appropriate in that case.

A limited conditional release of a detained article of food will be considered only in rare circumstances and only for the purposes described. We do not envision authorizing a limited conditional release under many circumstances because any movement increases the risk of inappropriate or unauthorized movement of detained articles of food into commerce. In order to decrease the chance of detained articles of food moving into commerce, the food should not be moved unless absolutely necessary. However, we recognize there may be cases where some movement is necessary. For example, it may be necessary to take steps to preserve the article of food until the detention is resolved, e.g., movement of a detained article of food from refrigerated storage to a freezer. This proposed section would allow such action in those limited circumstances that the agency finds appropriate.

As noted below, an article of food subject to a limited conditional release is still subject to detention and the requirements of this proposed rule.

Proposed § 1.381(d) requires you to submit a request for a limited conditional release in writing to the authorized FDA representative who approved the detention order. Your request must state the following:

- Reasons for movement;
- Exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred;
- Explanation of how the new address and location will be secure, if FDA has directed that the article of food be detained in a secure facility; and

• Explanation of how the article of food will be held under any applicable conditions described in the detention order.

If your request is for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food. Under "Federal Rules of Civil Procedure," Supplemental Rule C(6)(a), a person who asserts an interest in or right against property that is the subject of a seizure action in federal court must file a verified statement identifying the interest or right. The purpose of this requirement is to minimize the possibility that the detained article of food would be released for destruction to a person without the proper ownership or proprietary interest in the food.

Proposed § 1.381(e) states that a detained article of food remains under detention before, during, and after the transfer under a limited conditional release. Accordingly, we will prescribe applicable transportation conditions to an article transferred under a limited conditional release. This section also provides another security measure to prevent the detained article of food from moving into commerce. That is, we also require FDA supervision of all transfers of detained articles of food made under a limited conditional release, unless FDA declines such supervision in writing. If FDA declines such supervision, you will be required to immediately notify in writing the authorized FDA representative who approved the limited conditional release, that the article of food has reached its new location, and the specific location of the detained article of food within the new location. Such notification may be in the form of a fax, e-mail, or other form agreed to by the authorized FDA representative.

Proposed § 1.381(f) requires you to ensure that any tags or labels required under proposed § 1.382 accompany the detained article of food during and after movement. If FDA labels or marks the detained article of food under proposed § 1.382, this proposed provision would require that the tags or labels remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the approving official.

Proposed § 1.381(g) provides that the transfer of an article of food in violation of a detention order issued under proposed § 1.393 is a prohibited act under section 301 of the act. This proposed provision is consistent with the statutory language in section 303 of the Bioterrorism Act.

6. What Labeling or Marking Requirements Apply to a Detained Article of Food? (Proposed § 1.382)

Proposed § 1.382 describes the labeling or marking requirements that apply to a detained article of food. This proposed section states that the officer or qualified employee of FDA who issues the detention order may label or mark the detained article of food with official FDA tags or labels that include the following information:

- A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;
- 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;
- A statement, consistent with the statutory language in section 303 of the Bioterrorism Act, that the violation of a detention order or the removal or

alteration of the tag or label is a prohibited act under section 301 of the act, punishable by fine or imprisonment or both; and

• The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

Any label or mark of detention will be attached as appropriate given the circumstances. In some instances, the mark or label may be attached to the food container, while in other instances, the mark may be fastened to a packing container. Where the agency cannot mark or label a container or packing container, a mark or label may be attached to accompanying documents. FDA may use other means of marking or labeling as appropriate or necessary. Once the detained article is released, or the detention period expires, FDA would remove, or authorize the removal of, the required labels or tags, as described in proposed § 1.384. Accordingly, we would not expect the proposed labeling and marking provision to impair the future ability to distribute or market the article of food if the detention order is terminated.

7. What Expedited Procedures Apply When FDA Initiates a Seizure Action Against a Detained Perishable Food? (Proposed § 1.383)

Section 303 of the Bioterrorism Act directs the Secretary to issue procedures for instituting certain judicial enforcement actions on an expedited basis with respect to perishable food subject to a detention order. This provision directs FDA to issue procedures for instituting on an expedited basis seizure actions under section 304(a) of the act, or injunction actions under section 302 of the act (21 U.S.C. 332), or both. We have concluded that it is appropriate to focus on procedures to institute seizure actions on an expedited

basis because a seizure is the most efficient judicial action for rapid control of a violative article of perishable food.

Proposed § 1.383 describes FDA's procedure for sending a seizure recommendation under section 304(a) of the act to the Department of Justice (DOJ) for a perishable food (defined in proposed § 1.377) subject to a detention order. We propose to send the seizure recommendation to DOJ within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day when the government is open for business, we will advise the DOJ of our plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For example, if a detention order is issued on a Wednesday, the fourth calendar day would be the following Sunday. Because Sunday is non-working day, we would advise the DOJ of our plans to recommend a seizure action on Friday and would send the recommendation as soon as practicable on the following Monday.

For purposes of this proposed section, extenuating circumstances include, but are not limited to, instances when the results of confirmatory testing or other evidentiary development require more than 4 calendar days to complete.

Proposed § 1.383 is designed to accelerate the procedure for seizure recommendations and takes into account the 7-day timeframe in the proposed definition of "perishable food." As noted previously in section III.B.7 of this document, we have focused our implementation of this provision of section 303 of the Bioterrorism Act on seizure recommendation procedures. Use of injunctive relief may be appropriate in some circumstances involving detained perishable foods. However, expedited procedures for instituting injunction

actions would not accelerate the judicial control of a particular violative article of perishable food as much as expedited procedures for seizure actions.

We invite comment on this or other procedures that would address concerns about expedited enforcement actions with respect to perishable food.

8. When Does a Detention Order Terminate? (Proposed § 1.384)

Under proposed § 1.384, an authorized FDA representative will issue a detention termination notice releasing the detained article of food if FDA decides to terminate a detention order or the detention period expires. FDA will issue the detention termination notice to any person who received the detention order or that person's representative. FDA also will remove, or authorize the removal of, the required labels or tags attached under proposed § 1.382. If FDA fails to issue a detention termination notice and the detention period expires, the detention order is deemed to be terminated.

C. How Does FDA Order a Detention?

1. Who Approves a Detention Order? (Proposed § 1.391)

Proposed § 1.391 requires that an authorized FDA representative approve a detention order. As defined in proposed § 1.377, an "authorized FDA representative" is an FDA District Director in whose district the detained article of food is located or an FDA official senior to such director. For example, an RFDD is an FDA official senior to an FDA District Director. This is consistent with the approval requirements found in section 303 of the Bioterrorism Act. We are proposing that if prior written approval of a detention order is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. We believe allowing for oral approval of a

detention followed by written confirmation allows for efficient implementation of the administrative detention provisions.

For example, the investigator may be at a manufacturing plant located a great distance away from the district office and may determine that a detention is warranted. Instead of losing valuable time driving back to the district office to get a written signature in cases where a fax machine is not close by, the investigator may telephone the authorized FDA representative to get an oral approval. The authorized FDA representative would subsequently confirm the oral approval in writing by sending written confirmation to the investigator. In other circumstances where there is risk of the product moving to another location, we would want to detain the product immediately and an oral approval of the detention order may be prudent, followed by confirmation in writing. These examples illustrate some situations where oral approval may be necessary, but do not constitute an all inclusive list.

2. Who Receives a Copy of the Detention Order? (Proposed § 1.392)

Proposed § 1.392(a) requires FDA to 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 location of the food, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

Proposed § 1.392(b) would subject common carriers of articles of food to these administrative detention provisions. 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 would be required to provide a copy of the

detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if FDA can determine their identities readily.

3. What Information Must FDA Include in the Detention Order? (Proposed § 1.393)

Proposed § 1.393(a) requires FDA to issue the detention order in writing, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals. The written detention order serves as notice of the detention and provides notice that the persons with ownership rights to the detained article of food have the right to request an informal hearing.

Proposed § 1.393(b) requires the detention order to include the following information:

1. The detention order number;

2. The date and hour of the detention order;

3. Identification of the detained article of food;

4. The period of the detention;

5. A statement that the article of food identified in the order is detained for the period shown;

6. A brief, general statement of the reasons for the detention;

7. The address and location where the article of food is to be detained and the appropriate storage conditions;

8. Any applicable conditions of transportation of the detained article of food;

9. A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless subject to a limited conditional release under proposed § 1.381;

10. The text of section 304(h) of the act and §§ 1.401 and 1.402 of this chapter;

11. A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in proposed § 1.403;

12. The mailing address, telephone number, e-mail address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located; and

13. A statement indicating the manner in which approval of the detention order was obtained, i.e., orally or in writing.

D. What Is the Appeal Process for a Detention Order?

1. Who is Entitled to Appeal? (Proposed § 1.401)

Under proposed § 1.401, any person who would be entitled to be a claimant for such article of food, if seized under section 304(a) of the act, would be able to appeal a detention order. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C(6)(a) to the "Federal Rules of Civil Procedure."

2. What Are the Requirements for Submitting an Appeal? (Proposed § 1.402)

Proposed § 1.402 describes the requirements for submitting an appeal. As required by section 303 of the Bioterrorism Act, as part of your appeal, you may request an opportunity for an informal hearing. Proposed § 1.402(a) will

require you to submit your appeal in writing to the FDA District Director in whose district the detained article of food is located using the contact information provided in the detention order. We propose to allow you to submit your appeal in person, by mail, e-mail, or fax.

The timeframe for filing an appeal is determined by whether the detained article of food is perishable or nonperishable. If the detained article of food is perishable, as defined in proposed § 1.377, you would be required to file your appeal and request for a hearing within 2 calendar days of receipt of the detention order.

If the article of food subject to the detention order is nonperishable, you would be required to file a notice of intent to request a hearing within 4 calendar days of receipt of the detention order. The notice of intent would enable the agency to determine whether resources should be allocated to preparing for a regulatory hearing. If you do not file a notice of intent by day four, you do not receive a hearing. However, without filing a notice of intent by day four, you may still file an appeal without a hearing request. Whether or not you are requesting a hearing, your appeal involving a detained nonperishable food must be filed within 10 calendar days of receipt of the detention order.

We are using calendar days for the bifurcated deadlines for filing appeals to provide the most expeditious procedure for perishable food, and to provide a consistent approach for counting days. We are asking for comment on whether there are other ways we should be counting days for filing appeals, while adhering to the statutory deadline of 5 days for FDA to issue a decision on appeal (for both perishable and nonperishable food).

Proposed §1.402(b) provides that your request for an appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food. Under "Federal Rules of Civil Procedure," Supplemental Rule C(6)(a), a person who asserts an interest in or right against property that is the subject of an action must file a verified statement identifying the interest or right. The meaning of "verified statement" under Supplemental Rule C(6)(a) is governed by the local federal district court rules in which the detention takes place, and usually means that the statement must be accompanied by an oath or affirmation attesting to the statement's veracity.

Proposed § 1.402(c) provides that the appeal process would terminate if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act regarding the detained article of food.

Proposed § 1.402(d) describes the requirements for requesting an informal hearing as part of the appeals process. Your request for a hearing must be in writing and be included with your appeal. You may appeal a detention without requesting an informal hearing; however, if you want an informal hearing, you must include your request when you file your appeal. This proposed section describes the timeframes for holding the hearing if FDA grants your request for an informal hearing (see § 16.26 regarding denial of hearing). If the detained article of food is perishable, the hearing would be held within 2 calendar days after the date the appeal is filed. If the detained article of food is nonperishable, the hearing would be held within 3 calendar days after the date the appeal is filed. The quick timeframes for holding the hearing are necessary to ensure that FDA can adhere to the statutory requirement to issue a decision on appeal within 5 calendar days after the appeal is filed. FDA notes that under this proposal, the timeframes for perishable and nonperishable appeals will not be

significantly different in instances where an appeal is filed immediately upon receipt of a detention order. For example, if you file an appeal and request for a hearing on the same calendar day (day one) the detention is ordered for a perishable food, the hearing would be held by calendar day three, and the decision on appeal could be issued as early as calendar day three but no later than calendar day six. If a nonperishable food was detained in the same example, the hearing would be held by calendar day four, and the decision on appeal could be issued as early as calendar day four but no later than calendar day six.

We are requesting comment on the timeframes for holding the informal hearing.

3. What Requirements Apply to an Informal Hearing? (Proposed § 1.403)

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA would conduct the hearing in accordance with part 16, with the following exceptions:

• The detention order under proposed § 1.393, rather than the notice under § 16.22(a) of this chapter, would provide notice of opportunity for a hearing under this section and would be part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

• A request for a hearing under this section must be addressed to the FDA District Director in whose district the detained article of food is located in accordance with proposed § 1.402(a).

• The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart. Rather, the timeframes in proposed § 1.402(a) apply.

• The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart. Instead, the timeframes in proposed § 1.402(c) apply.

• Proposed §1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information.

• Proposed § 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., RFDDs or other officials senior to District Directors, who preside at hearings under this subpart.

• Under proposed § 1.403(f), the presiding officer may require that a hearing conducted under this section be completed within 1 day, as appropriate.

• Ordinarily under part 16 hearing procedures, the presiding officer issues a report and recommended decision and the Commissioner of Food and Drugs issues a final decision. However, under proposed § 1.403(g), the presiding officer will issue the final agency decision.

As described previously, the informal hearing requirements in part 16 state that its procedures are to be used when the act or FDA regulations provide for an opportunity for a hearing and no specific hearing regulations exist (see § 16.1(b)). Section 303 of the Bioterrorism Act provides for an informal hearing opportunity, but does not provide specific provisions for the informal hearing. In this proposed rule, we are applying part 16 procedures modified by the noted exceptions, which is consistent with § 16.5(b).

4. Who Serves as the Presiding Officer at an Informal Hearing? (Proposed § 1.404)

Proposed § 1.404 requires the FDA RFDD, or other official senior to a District Director, to act as the presiding officer of an informal hearing on an appeal of a detention order. As presiding officer, the RFDD would issue the decision on appeal. Because a detention must be approved at the District Director level, we believe it is appropriate that appeals of those decisions should be handled by persons in positions senior to the District Directors.

The presiding officer may be an RFDD from a region other than the one in which the detained article of food is located, or another official senior to a District Director.

5. When Does FDA Have to Issue a Decision on an Appeal? (Proposed § 1.405)

Proposed § 1.405 describes when FDA must issue a decision on an appeal. Proposed § 1.405(a) requires the presiding officer to issue a decision confirming or revoking the detention order within 5 calendar days after the appeal is filed. If FDA fails to provide an opportunity for a hearing, or fails to confirm or terminate the detention order within the 5-day period, the detention order is deemed terminated. While the Bioterrorism Act does not define the meaning of "an opportunity for an informal hearing," we interpret this phrase to mean the FDA gives notice of the opportunity for a hearing (see also proposed § 1.403(a), which states that the detention order provides notice of opportunity for a hearing). Under this interpretation, a failure to provide an opportunity for a hearing means a failure to provide you with notice of your opportunity to request a hearing. This provision is consistent with requirements of section 303 of the Bioterrorism Act.

Proposed § 1.405(b) would allow you to appeal the detention order without a request for an informal hearing. Where you appeal without requesting a hearing, the presiding officer is still required to issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to issue a decision within the 5-day period, the detention order is deemed terminated.

Proposed § 1.405(c) states that if you appeal a detention order and request an informal hearing and your hearing request is denied, the presiding officer is still required to issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to issue a decision within the 5-day period, the detention order is deemed terminated.

Proposed § 1.405(d) states if the presiding officer confirms a detention order, the article of food would continue to be detained until FDA terminates the detention order under proposed § 1.384 or the detention period expires under proposed § 1.379, whichever occurs first.

Proposed § 1.405(e) states that if the presiding officer terminates a detention order, or the detention period expires, FDA would be required to terminate the detention order as specified under proposed § 1.384 (i.e., FDA would be required to issue a detention termination notice releasing the article of food).

Proposed § 1.405(f) states that confirmation of a detention order by the presiding officer is considered a final agency action for purposes of section 702 of title 5, United States Code (5 U.S.C. 702).

6. How Will FDA Handle Classified Information in an Informal Hearing? (Proposed § 1.406)

FDA expects that consistent with responding to bioterrorist threats, there may be instances where the credible evidence or information supporting a detention order consists of Classified National Security Information ("classified information"). Protection of information critical to our nation's security is a priority (Executive Order 12958, April 17, 1995). While mindful of our duty to protect our national security interest, we are also mindful of our obligation to provide a fair, expeditious, and impartial hearing (see § 16.60 regarding hearing procedure). Proposed § 1.406 provides that FDA will not release classified information. However, if the presiding officer may do so, consistent with safeguarding both the information and the source, the presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

Given the events of September 11, 2001, and the need to quickly respond to actual or threatened bioterrorist attacks, we are contemplating the development of general regulations that address handling classified information on an agency-wide basis for all the products regulated by FDA. We believe, though, that we should go forward with the current proposal in this context at this time.

IV. Conforming Amendment to 21 CFR Part 16

We propose to amend § 16.1(b)(1) to include section 304(h) of the act relating to the administrative detention of food for human or animal

consumption to the list of statutory provisions under which regulatory hearings are available.

V. Analysis of Economic Impact

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as a significant regulatory action if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also considers a regulatory action significant if it raises novel legal or policy issues. The Office of Management and Budget has determined that this proposed rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

Need for Regulation

Section 303 of the Bioterrorism Act (Public Law 107–188), gives FDA expanded authority to prevent the distribution of any article of food for which we have credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. Previously, if we received credible evidence or information indicating that an article of food presented a threat of serious adverse health consequences or death to humans or animals, we would typically have taken one of the

following actions: (1) Requested a voluntary recall of the suspected product; (2) developed enough evidence to move directly to seize the food; or (3) referred the matter to the appropriate State authority for most cases involving purely intrastate commerce. Thus, Congress' expansion of our authority to allow administrative detention of food permits us to immediately detain food in commerce, which provides an added measure to ensure the safety of the nation's food supply.

Reason for Regulation

FDA is proposing this regulation to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or plant—particularly if the plant is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of foodborne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to the private efforts to protect against deliberate contamination at the plant level, there are external effects associated with privately produced protection. The economic incentives for firms to engage in food safety activities largely hinges on the ability of consumers to identify and avoid products associated with the responsible party. However, firms can change both their own names and the names of their products, and can also change owners and managers. Therefore, it may be quite costly for

consumers to obtain the information that would allow them to avoid products associated with the responsible party. Moreover, some firms might be infiltrated by those who wish to launch attacks on food safety, or might even have been formed by those having that end in mind. Such firms would not be responsive to normal economic incentives to provide food safety.

The events of September 11, 2001, led Congress to conclude that there should be a regulatory mechanism to temporarily remove from commerce potentially violative food that presents a threat of serious adverse health consequences or death to humans or animals, and store it under an appropriate level of security until we can investigate the potential threat and evaluate whether to initiate judicial enforcement action and, if appropriate, initiate such action. This proposed regulation implements this mechanism.

Regulatory Options

We considered several regulatory options or alternatives as follows in developing this proposal:

Option One: Establish a regulatory framework for administratively detaining food, with expedited procedures for instituting certain enforcement actions involving perishable food (i.e. take the proposed action);

Option Two: Take the proposed action, but change the definition of perishable food, the maximum timeframe for administrative detention of perishable food, or both;

Option Three: Take the proposed action, but define the level of security we require for transportation and storage;

Option Four: Issue regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (i.e. limit the action to the regulations required by section 303 of the Bioterrorism Act).

We request comments on these options, as well as suggestions on other regulatory options that we should consider. We will address comments on this analysis in the analysis of the final rule.

Baseline: The situation before Congress passed the Bioterrorism Act

Usually, we designate the option of taking no regulatory action as the baseline. We then compare the costs and benefits of the various regulatory options to the current regulatory state of affairs. However, for this rule, we chose the situation that existed before Congress enacted the Bioterrorism Act as the baseline. We chose this baseline rather than the current regulatory state of affairs because our authority to administratively detain food under the Bioterrorism Act already exists, regardless of whether we now promulgate regulations setting out the procedures we will follow when we detain food.

Therefore, in order to analyze the impact of Congress giving us the authority to administratively detain food, we needed to specify a baseline that predated our having received that authority. By convention, we do not attribute costs or benefits to the baseline, per se, but instead capture the impacts of the regulation by comparing the costs and benefits of the other options to the baseline. Prior to Congress passing the Bioterrorism Act, we had other enforcement options available to us in those situations in which we can now use administrative detention, that is, in which we receive credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals. We will discuss those enforcement actions as part of the baseline in the following analysis.

In addition, we do not discuss the option of taking no regulatory action as one of the non-baseline options, because that option is not legally feasible. Option Four (establish expedited procedures for instituting certain

enforcement actions involving perishable food only) most closely resembles the option of taking no regulatory action, because in that option we would limit ourselves to only the regulatory action that Congress required us to take in the Bioterrorism Act.

Option One: Establish a regulatory framework for administratively detaining food, with expedited procedures for instituting certain enforcement actions involving perishable food (i.e. take the proposed action)

In the proposed action, we establish a regulatory framework for administratively detaining food.

Costs

The primary costs of the proposed rule arise from differences between administrative detention and other enforcement actions with respect to the following: (1) Cost of transporting and storing food, if necessary; (2) cost of canceling previously scheduled transportation and storage of the affected food when we remove it from commerce, and rescheduling transportation and storage if we later cancel the detention order and release it back into commerce; (3) loss of product value over the detention period, if we later find the food is not violative; and (4) cost of participating in appeals hearings and other enforcement activity.

To analyze the costs of the proposed rule, we first estimate how many times we might use administrative detention. We then estimate the proportion of cases in which we might administratively detain food that we later determine to be not violative. We need to estimate this percentage because we estimate the loss of product value over the detention period for food that we later find to be not violative. (We do not estimate the loss of product value for violative food, because we assume that the violation, not our action,

reduces the value of that food.) We then estimate how costs would change if we substituted an administrative detention action for other enforcement actions. We look at the change in costs relative to the baseline of taking these other actions because we probably would have taken some type of enforcement action if we had received the type of information that would allow us to use administrative detention. In other words, we analyze the cost of administrative detention actions in terms of the costs over and above those that would have been associated with the enforcement actions that we would otherwise have taken. We then multiply the changes in costs by the number of times we might substitute an administrative detention action for the other enforcement actions.

Estimate of number of times we might use administrative detention per year

We do not know how often we will receive credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals that would allow us to administratively detain food. However, if we had received credible evidence or information that an article of food presented a threat of serious adverse health consequences or death to humans or animals before Congress granted us authority to take administrative detention actions, we would probably have taken one of the following three actions: (1) Requested a voluntary recall of the suspected product; (2) moved directly to seize the food; or (3) referred the matter to State authorities. We specify moving directly to seize food because we could also seize food after taking some other enforcement action, including administrative detentions. To avoid having to describe streams of enforcement actions, we have simplified the situation into two phases, a "preliminary phase," in which we take some action to detain the food in order to investigate

it, and a "final phase" in which we take some final action such as seizing the food or referring the matter to State authorities.

We base our estimate on only these three actions because we believe the situations that lead to these types of actions are the most similar to the situations that may lead to administrative detention. Thus, we assume that any administrative detention would replace issuing class I recalls, moving directly to seizure, or referring the matter to State authorities for most cases involving purely intrastate commerce. If we instead assumed that we might substitute administrative detention actions for other types of enforcement actions, including other actions that we subsequently follow with seizure actions, then our estimate of the number of administrative detentions per year could be significantly larger. Examples of other types of enforcement actions include detentions without physical examination (DWPE) and requests to States to embargo food. We assume that the number of administrative detentions might include 0 to 100 percent of the number of class I recalls and instances in which we moved directly to seize food, and 0 to 10 percent of the number of times we referred matters to State authorities. In all cases, we based the low end of the range on the fact that we do not know if we would have used administrative detention, even if we had the authority to do so, and the criteria for using administrative detention had been met. Analyzing all the factors that would lead us to choose one enforcement action over another is beyond the scope of this analysis. We chose 100 percent as the high end of the range for class I recalls because the criteria for class I recalls is quite similar to the criteria for administrative detention. We chose 100 percent as the high end of the range for instances in which we move directly to seize food as a practical expedient because the small number of actions implies that such information

would have had little or no impact on our cost estimates. We chose 10 percent as the high end of the range for State referrals because our experience with those actions suggests that only about 10 percent of recent referrals involved concerns or situations that would have met the criteria for administrative detention. The other referrals do not appear to meet the criteria for administrative detention.

In fiscal year (FY) 2002, we initiated 184 class I recalls involving food that posed a risk of serious adverse health consequences or death to humans or animals. In the same year, we initiated 16 seizures that may have involved food products that posed hazards to human or animal health. In the last 12 months, we estimate that we referred 234 of such matters to State authorities.

These numbers are repeated in table 1 of this document. Based on this information, we estimate that we might administratively detain food 0 to 223 times per year.

TABLE 1.—SUBSTITUTIONS PER YEAR

Action	Estimated Number of Substitutions of Administrative Detention for Other Enforcement Actions per Year
Class I recalls	0 to 184
No preliminary action (move directly to seizure)	0 to 16
No preliminary action (refer matter to State authorities)	0 to 23
Total	0 to 223

Estimate of the proportion of cases in which the food subject to administrative detention turns out to be not violative

Some of the costs that we will discuss later are only relevant if we eventually determine that food that we have administratively detained is not violative. We do not know the proportion of cases in which we might

administratively detain food that we later determine to be not violative. This rate depends on the type of information we receive, and the level of risk aversion we adopt when we apply the criteria allowing us to use administrative detentions, including "credible evidence or information" and "threat of serious adverse health consequences or death to humans or animals." If we only administratively detain food when we are certain or nearly certain that it is violative, then we may eliminate administrative detention as an enforcement option for some food that is violative. However, if we administratively detain food when we are less certain that it is violative, then we will increase the rate at which we administratively detain food that we later determine is not violative.

One way of addressing the proportion of cases in which we might administratively detain food that we later determine to be not violative is to look at data from the detention and release of imported food. However, this data cannot be narrowed to situations where we have detained or prepared to detain food and then later determined that the food was not violative. An import detention is different from administrative detention in that imports can be detained for reasons other than adulteration or misbranding. These other reasons give rise to a large percentage of detentions in which the food is found not to be violative. For instance, an import can be detained because the product is coded in the OASIS (Operational and Administrative System for Import Support system) system as a low acid canned food but the importer did not supply the food canning establishment number. The OASIS system is a national database on imports, and related enforcement activities and findings.

In the first three quarters of 2002, we released 48 percent of the shipments of human and animal food that we detained, excluding the shipments that we

released because the firm reconditioned the food. The percentage of import shipments released includes all releases recorded in the OASIS system. These data include releases from detentions resulting from:

- DWPE notices;
- Routine FDA field sampling assignments;
- Incorrect or incomplete information provided about the product; and
- Imports released with comment, which means the product technically is misbranded or adulterated but we exercise enforcement discretion.

Because of the factors listed previously, and because import detentions may be based on a lower level of information than that required for an administrative detention, we cannot directly impose these numbers on administrative detentions. Rather, 48 percent is an upper limit that will exceed the nonviolative percentage of administratively detained food.

Another way of addressing this issue is to look at the proportion of enforcement actions against nonfood products that involved products that we later determined were not violative. We have had authority to administratively detain medical devices since 1976. During that time, we have not administratively detained any products that we later found to be not violative. This suggests that the rate at which we administratively detain food that is not violative may also be quite low, because in both cases we would be using similar administrative detention procedures. However, the medical device and food contexts may differ with respect to a number of potentially relevant issues, such as the type and amount of products on the market, the types of problems associated with those products, and the type and level of information that we receive on those problems.

Based on this information, we estimate that 0 to 48 percent of the food that we administratively detain will later turn out to be not violative.

Transportation

Under the proposed rule, we might require a firm to transport food that we administratively detain to a storage facility that is both secure and capable of providing the proper conditions for storing that type of food. In other cases, we might allow firms to hold the food in place, but require them to take various other actions to secure the food, such as physically segregating it, locking the area in which they store it, and possibly posting guards to monitor the area in which they store it. We will determine whether or not to require a firm to transport administratively detained food to another storage facility, and to take other actions to secure that food, on a case-by-case basis.

An example of where transporting detained food might be problematic would be the case of large storage grain bins located at private elevators and farms that hold grain. These bins typically hold several hundred tons per bin. It would be costly to transport grain to another holding area. In addition, transporting contaminated grain might spread biological or chemical agents because of the generation and dispersal of dust from the grain as we remove it from the bin and transport it to another location. In this case, it could be preferable to allow the product to be stored in place, possibly with the addition of onsite security.

We do not have sufficiently detailed information on past enforcement actions to estimate the proportion of administrative detentions in which we might require transportation or any other activity. Therefore, we assume that we would require firms to transport food to a secure facility and store them there in 0 to 100 percent of administrative detention actions. To simplify the

analysis, we tentatively assume that the estimated costs of transporting food to a secure facility and storing it there are equal to or greater than the costs of storing the food in place and taking any of the other actions that we might require under our administrative detention authority, except posting additional guards, which we analyze in the discussion of Option Three (take the proposed action, but define the level of security we require for transportation and storage). As we discuss in the section on Option Three, the estimated cost of providing one additional security guard for onsite storage is somewhat higher than the estimated cost of transporting food to a secure facility. Therefore, we have not discussed the cost of providing an additional security guard as part of this option. Nevertheless, providing an additional security guard and storing food in place is consistent with taking the proposed action, and we may take that action in some cases.

The cost of transporting food varies along a number of dimensions, including the following: (1) Type of conveyance used, (2) distance traveled, (3) level of security, (4) type and amount of food involved, and (5) number of trips required. These considerations are interrelated. For example, the appropriate type of conveyance might depend on the level of security, the distance to be traveled, and the amount of food involved. Similarly, the distance to be traveled would depend, in part, on what type of facility meets our security requirements.

Firms may transport food via truck, rail, air, or ship. Based on the distance to be traveled, the level of security we might require, and the type and amount of food involved, we tentatively assume that firms would usually move dministratively detained food by truck.

We also assume that when we require firms to transport food to a "secure storage facility," we will usually interpret that term to mean a bonded or third party public warehouse. We assume that these warehouses would provide proper storage conditions to maintain the safety and wholesomeness of the food. Bonded warehouses, refrigerated warehouses, and most types of third-party public warehouse facilities are readily available around ports of entry into the United States. Most metropolitan areas have an international airport that serves as a port of entry into the United States, and will, therefore, have a variety of warehouses available. Therefore, we assume that the distance that we would require firms to transport administratively detained food would normally be no farther than the distance to the nearest metropolitan area. Firms might undergo additional transportation costs if we later cancel the administrative detention order and release the food back into commerce, because the secure facility might not be as convenient to the subsequent destination as the original location. Therefore, we calculate the transportation costs associated with food that we later release on the basis of round trip travel between its original location and the secure storage facility.

Transportation costs would depend, in part, on the security measures that we direct firms to take. We do not define those measures in this proposed rule. Instead, we will determine the relevant level of security and types of security measures needed on a case-by-case basis. We tentatively assume that a normal or average level of security for transportation of food would be the level associated with bonded or third party carriers. We believe using these types of carriers rather than a firm's own transportation system could provide some additional security because the owner of the bonded or third-party carrier might have a greater financial incentive to monitor and maintain custody of

the food than do the owners of the food. In some cases, we might require higher security. In other cases, we might require lower security, such as that associated with a firm's own transportation system.

The cost of transporting food varies widely with the type and quantity of food. Some food requires specialized trucks, such as bulk liquid or refrigerated carriers. We base our estimate of the average transportation costs on the average rates for transporting the "most usual loads" of various fresh fruits and vegetables as reported in the "Agricultural Marketing Service's Fruit and Vegetable Truck Rate Report" for the week ending November 19, 2002 (Ref. 1). These loads of fresh fruits and vegetables do not require specialized trucks. We think that average transportation costs should be similar because the proportion of food that requires specialized trucks is relatively small. However, we request comment on this assumption, and on the cost of specialized transportation. We assume there would be suitable storage facilities in the nearest major metropolitan area. However, we do not know the average distance from any randomly chosen point in the United States to the nearest metropolitan area. Therefore, we tentatively assume that the distance from any location at which we might detain food to the nearest metropolitan area would be between 30 and 200 miles. Most of the trips in the trucking report were much longer than 200 miles. However, the report listed 10 trips under 300 miles. The trucking report included both a low cost and a high cost estimate. Using these estimates gives an average cost per mile for the 10 trips under 300 miles of between $4.26 and $5.13. The actual cost per mile varied from a high of $23.91 for the high cost estimate for the shortest trip (23 miles) to $1.93 per mile for the low estimate for an intermediate length trip (243 miles). Costs per mile are higher for shorter trips because some costs are probably

fixed and do not increase with mileage. We use the range for the average cost per mile for all trips under 300 miles because we have insufficient information to estimate a distribution of trips by distance. Based on this assumption, we estimate that the average transportation cost per truckload will be between approximately $100 and $1,000.

In order to use these transportation rates, we need to know the average amount of food that we would administratively detain. The amount of food that we administratively detain could be anything from a few packages, to a lot, a shipment, or a production run. The amount of food involved in class I recalls and seizure actions has ranged from 100 pounds or less, in the case of some seizure actions, to millions of pounds, in the case of some class I recalls. Therefore, we estimate that we will administratively detain between 0 and 1 million pounds of food per administrative detention. We request comments on this assumption.

To apply the information on transportation costs, which was based on the most usual load of produce (as defined by the "Agricultural Marketing Service's Fruit and Vegetable Truck Rate Report"), to our assumption about the amount of food that we might administratively detain, which we expressed in pounds, we need to estimate the average weight in pounds of the most usual loads of produce. One way to do this is to look at the average weight of lines of imported produce, and to assume that the size of an average line of produce is comparable to the size of the most usual load of produce. A line in this context is the unit by which we record information on imported food; it does not refer to a product line. We base the assumption relating the size of the line of produce to the most usual load of produce on the fact that most imported produce arrives by truck, so that the typical unit of imported produce

probably corresponds roughly to a usual truckload of that produce. We request comments on this assumption.

In 2001, firms imported approximately 22.6 billion pounds of 48 common types of fresh produce into the United States (Ref. 4). We extrapolated data on the number of lines in the OASIS database for the first three quarters of FY 2002 for all product categories that appear relevant to fresh produce to estimate that the total number of lines will be approximately 1.5 million by the end of FY 2002. If the amount of imports in 2001 were similar to that for FY 2002, then the average line would be about 15,000 pounds. Therefore, we assume that the most usual load of produce would be about the same size as the average line of imported produce, or 15,000 pounds. We have insufficient information to estimate the weight of the average line for any other type of food. Therefore, we assume that the average truckload across all types of food is about 15,000 pounds. Under this assumption, each administrative detention may involve transporting approximately 0 to 67 truckloads of food.

Additional transportation costs might arise if we conditionally released food that we administratively detained, and firms moved the conditionally released food to another location. We have not included these costs because of the voluntary nature of these limited conditional releases. A firm would not request a limited conditional release unless the benefits of doing so outweighed the costs. Therefore, any increase in transportation costs would be at least offset by some form of cost savings. If we were to analyze the impact of the availability of these limited conditional releases, then our estimate of the costs associated with this proposed rule would be somewhat lower. However, the impact would probably be small, because we do not expect many requests for limited conditional release.

We request comments on all assumptions relating to transportation costs, including but not limited to the average amount of food that we might administratively detain, the average amount of food per truck load or per load of other conveyance, the likelihood that firms will use different types of conveyances (i.e. trucks, airplanes, trains, and ships), the costs of using various types of specialized conveyances, and the distances that firms may need to transport food.

As explained earlier in this analysis, we are analyzing the cost of administrative detention actions relative to the baseline of taking the enforcement actions we would have taken prior to having received authority to take administrative detention actions. Therefore, only the costs that go beyond the costs of those other enforcement actions are relevant here. We assume there would be no change in transportation costs if we substituted an administrative detention action for a class I recall, because firms probably already transport food as part of such a recall.

We considered the costs of transportation under class I recalls to be part of the baseline costs, even though such recalls are voluntary, because we have some influence over those decisions. We have influence over those decisions because we could publicize the fact that we requested a firm to recall a product, which might have consequences for that firm's profits. Therefore, those decisions are not purely private market decisions. As such, it is reasonable to classify the costs associated with those recalls as social costs that are comparable to the social costs associated with administrative detention actions for purposes of determining baseline costs. If we did not treat these costs as social costs, then substituting administrative detention for class I recalls would generate additional social costs related to transporting food.

Moving directly to a seizure action or referring a matter to State authorities does not involve any transportation costs prior to the seizure action or referral. Therefore, all transportation costs associated with an administrative detention are relevant in the case of an administrative detention that replaces a case of moving directly to a seizure action or a referral to State authorities. Any transportation costs associated with the actual seizure or State action would not be relevant in this context, because administrative detentions may be followed by seizure actions or State actions, so any transportation associated with the seizure action or State action would take place irrespective of whether it was preceded by an administrative detention or not.

We present transportation costs in table 2 of this document. We calculated these figures by multiplying the number of truckloads that we estimated would be involved in an administrative detention (0 to 67) by the number of times we might use administrative detention in place of class I recall requests, cases of moving directly to seizure, or referring a matter to State authorities. The number of one way trips includes return trips, which we calculated by multiplying the number of trips to secure storage facilities by the estimated percentage of cases in which we might terminate a detention order and allow food back into commerce (0 to 48 percent). In table 2, we estimate the range of additional trips to secure facilities to be 0 to 1,587. The number is based on 0 to 16 seizures (in row 1), a maximum of 67 truckloads per seizure, and a maximum of 48 percent additional trips for those products cleared to enter commerce. We calculate the maximum number of trips as: (16 x 67) + (0.48 x 16 x 67)= 1,587. Again, estimated costs are higher for administrative actions that replace cases of moving directly to seizure actions or referring matters to States than for administrative actions that replace class I recalls because we

are using the costs of those other actions as the baseline, and class I recalls already involve transportation, while cases of moving directly to seizure actions or referring matters to States do not.

TABLE 2.—ANNUAL TRANSPORTATION COSTS

Action	Number of Actions (see table 1)	Additional One Way Trips per Year, in Truckloads	Cost per one Way Trip	Total Transportation Cost (in millions)
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	0 to 1,587	$100 to $1,000	$0 to $2
Administrative Detention that Replaces Class I Recall	0 to 184	0	$100 to $1,000	$0
Administrative Detention that Replaces Referral to States	0 to 23	0 to 2,323	$100 to $1,000	$0 to $2
Total				$0 to $4

Storage

The cost of storing food in secure storage facilities depends on the following factors: (1) Level of security of the facility; (2) type of food; (3) length of time the food is stored; (4) amount of food; and (5) miscellaneous factors, such as geographic location of facility, whether the customer is a regular or repeat customer, volume discounts, etc.

We do not define the security requirements for storage facilities in this rule. Instead, we will determine the relevant level of security on a case-by-case basis. We tentatively assume that the normal or average level of security that we would require is the level associated with bonded or third party public warehouses. Using these warehouses should provide some additional security because the owner of the food relinquishes custody of the food to the warehouse. In some cases, we might require higher security, such as that associated with secure government storage facilities, for example, Customs Examination Stations. In other cases, we might require lower security, such as that associated with a firm's own warehouses. We understand from a discussion with a representative of the International Association of Refrigerated Warehouses that the cost difference between bonded and

nonbonded public warehouses is probably quite small (Ref. 2). Therefore, we use the same storage costs for both bonded and nonbonded warehouses.

Storage costs vary with the type of food being stored. However, we were unable to find data on average storage rates for different types of food under different conditions (Ref. 2). One cold storage facility gave us food storage rates that varied from $0.0002 to $0.0006 per pound per month for a range of food types (Ref. 3). Rates for food that does not need to be refrigerated might be lower than the lower bound of the rates for cold storage. However, we do not have information on these rates, and we assume that these rates will fall in the same range. The same source listed handling rates per shipment of $0.01 to $0.02 per pound. We request comments on these rates. These rates imply storage costs of $0 to $600 per day per administrative detention, and handling rates of $0 to $20,000 per administrative detention, based on a shipment size of 0 to 1 million pounds (67 truckloads per shipment x 15,000 pounds per truckload).

We estimate overall storage costs based on the handling fee per pound, the storage costs per pound per day, the amount of food we might administratively detain, and the change in the maximum number of days that we might require firms to store the food. We assume that there would be no increase in storage costs if we substituted an administrative detention action for a class I recall, because firms probably already store food as part of such a recall. There is no storage associated with taking no preliminary enforcement action prior to a seizure action or a referral of a matter to a State authority. Therefore, any storage associated with an administrative detention would be an additional cost in comparison to moving directly to seizure or referring a matter to a State authority.

Administrative detention involves a maximum storage time of up to 30 days. The actual amount of time that firms would store detained food depends on whether and when they appeal the administrative detention order. Firms would appeal if they expected the costs of doing so would be less than the costs of storing the food until we completed our investigation, or until the detention period expired. We have insufficient information to estimate the percentage of administrative detentions that firms would appeal. Therefore, we use a maximum of 30 days additional storage time for all administrative detentions. We do not know how long firms store food that they voluntarily recall before reconditioning or destroying the food. We tentatively assume that the storage time associated with class I recalls would be similar to the storage time associated with administrative detention.

We provide estimates of annual storage costs, rounded to the nearest million dollars, in table 3.

TABLE 3.—ANNUAL STORAGE COSTS

Action	Number of Actions	Change in Days Storage per Action	Cost per Day (based on average shipment)	Handling Cost per Action	Change in Total Storage Cost (in millions)
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	0 to 30	$0 to $600	$0 to $20,000	$0 to $1
Administrative Detention that Replaces Class I Recall	0 to 184	0	$0 to $600	$0 to $20,000	$0
Administrative Detention that Replaces Referral to State	0 to 23	0 to 30	$0 to $600	$0 to $20,000	$0 to 1
Total					$0 to $2

Loss of product value over detention period, if we later find the product is not violative

Food may lose some or all of its value during an administrative detention because the food may deteriorate, and because firms would have less time to sell food that has a finite shelf life. Reducing the time available to sell food reduces the value of that food because consumers only desire a given quantity

of a particular food in a particular time period. In order to sell additional units of that food during that time period, retailers would need to lower the price of the food to reflect the value consumers place on the additional units. This cost is only relevant if we determine that the food does not present a threat of serious adverse health consequence or death to humans or animals and, therefore, terminate the detention and release the food back into commerce. The loss of product value would not be relevant for detained food found to be violative because such food would have lost its value due to its violative nature, rather than the administrative detention.

We have not estimated costs connected to the marking or labeling food that we administratively detain. As we discussed earlier in this preamble, if we required marking or labeling of food in conjunction with an administrative detention order, and we subsequently cancelled the administrative detention order, then we would remove, or authorize the removal of, the marks or labels. Therefore, we assume there will not be any loss of value from the marking or labeling requirements contained in this proposed rule.

Administrative detention actions might also cause food that we do not administratively detain to lose value if delivery of that food to its final destination were delayed as a result of being packed together with food that we did detain. We have not included the potential loss of value from this source because, based on our experience with other enforcement actions, we expect that we will not cause significant delays in the delivery of food that is packed with food that we administratively detain.

Loss of value over the detention period depends on the following factors: (1) Shelf life of the food under usual storage conditions, (2) rate of value loss over time, and (3) starting value of the food.

The loss of value depends on the shelf life of the food because the longer the shelf life, the less the food will deteriorate during a given time period, and the smaller the proportional reduction in the time remaining to sell the food. For purposes of this analysis, we have designated four shelf life categories:

• *Perishable food.* We define perishable food for purposes of this analysis as food having a shelf life of 7 days or less. This is based on the definition of perishable food discussed earlier in this preamble (i.e. perishable food is 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.) Examples of this type of food include fluid milk that has not been ultra-pasteurized; live fish, lobster, crab, other crustaceans, shellfish; and fresh fruits and vegetables (Ref. 5).

• *Food having a shelf life of between 8 and 30 days.* Food with this shelf life that we regulate include some fresh and processed dairy products, including soft cheeses such as cottage cheese; some bakery items, such as bread, rolls, cakes, pies, and cookies; poultry; and some fruit and vegetable products (Ref. 6). These examples are derived from a list of examples developed by Hurst et al., but do not include products listed as examples in our RPM definition of "perishable commodity."

• *Food having a shelf life of between 30 and 90 days.* These types of food include dairy products, such as butter, margarine, natural hard cheese, processed hard cheese, and ice cream; eggs; some picked food; processed salads; some fruit and vegetable products; cured meats; fatty meats such as luncheon meats, ground beef, lamb and pork; fatty fish such as mackerel;

shellfish; giblets; some frozen bakery food, such as cake batter, pie shells, fruit pies, yeast breads and rolls, frozen bread and roll dough; fried snack food such as potato chips; frozen convenience food such as pre-cooked combination dinners and frozen french fries; dried bakery products such as cookies and crackers; beverages such as ground coffee that is not vacuum packed; canned pickled fish; powdered cream; and fats and oils such as mayonnaise, salad dressing, and vegetable shortening (Ref. 6).

• *Food having a shelf life of over 90 days.*

The only type of enforcement action for which we have readily available data on the type of food involved is imported food that we have refused entry into the United States. Therefore, we used these data for analysis, because we expect the distribution of food by type for domestic food to be similar. The food categories in these data do not correspond precisely to the shelf life categories just discussed. If a food category covered more than one shelf life category, we assumed that an equal amount of the product in that category belonged to each relevant shelf life category. Based on these assumptions and definitions, approximately 20 percent of the imported food that we refused entry into the United States from August 2001 through July 2002 was perishable under the definition in this proposed rule, 20 percent of the food had a shelf life of 8 to 30 days, 30 percent had a shelf life of 31 to 90 days, and 30 percent had a shelf life of 91 days and over.

The rate of value loss over time varies with the type of food involved. To simplify our analysis, we assumed that all perishable food (i.e., food with a shelf life of up to 7 days) would lose a fixed amount of its starting value each day, such that its value would drop to zero by the end of day seven. This corresponds to a value loss of about 14 percent of the starting value per

day. The comparable rates for products with a shelf life of between 8 and 30 days, and between 31 and 90 days, were 3 percent and 1 percent, respectively. We tentatively assume that products with a shelf life of 91 days or more will not lose value during an administrative detention.

In order to apply these rates of value loss, we need the starting value of the food that we would administratively detain. We previously assumed that we would administratively detain 0 to 1 million pounds of food per administrative detention action. The value of this quantity of food would vary considerably with the type of food involved. To estimate an average value, we used the average value of a line of imported food because those data were readily available. After estimating the average value of a line of imported food, we then divide that value by the previously estimated average size of a line of imported food, which was 15,000 pounds, to get an average value per pound. We then multiply that value by 0 to 1 million pounds to arrive at the average value of the amount of food that we might administratively detain. According to U.S. Commerce Department data, the value of imports of food, feeds, and beverages into the United States in 2001 was approximately $47 billion (Ref. 7). To relate the total value to the value of an average line for those types of food, we extrapolated data on the number of lines in the OASIS system for the three quarters of FY 2002 for human and animal food to estimate a total of approximately 4 million lines for human and animal food by the end of FY 2002. This implies an average value per line of about $11,000. We did not have information on the value of other types of imported food, such as dietary supplements or live animals. Therefore, we assumed that the average value per line for all types of food is approximately $11,000. If an average line is 15,000 pounds, then this corresponds to a value per pound of $0.73.

Therefore, the value of 0 to 1 million pounds would be $0 to $730,000. Based on the rates of value loss given earlier, the average loss of value per administrative detention action would be $0 to $102,000 (14 percent loss per day x $730,000) per day for perishable food, and $0 to $22,000 (3 percent loss per day x $730,000) per day for nonperishable food.

We have set the maximum timeframe for all administratively detained food, including perishable food, at 30 days. Therefore, we calculated the loss of value for all food based on 0 to 30 days of additional storage. As we discussed earlier in the preamble, we intend in the case of perishable food to send a seizure recommendation to the DOJ within 4 calendar days after we issue an administrative detention order, unless extenuating circumstances exist. However, we do not know how often extenuating circumstances will exist, or how much time will elapse between our recommendation and the subsequent seizure.

We do not estimate any change in the loss of value if we substitute an administrative detention action for a class I recall request, because we previously assumed that substituting an administrative detention action for a class I recall would not change the amount of time a firm would store the food in question. Therefore, any loss of value resulting from taking action against food that was actually not violative would be the same under either type of action. In contrast, there is no storage associated with moving directly to a seizure action or referring a matter to State authorities. Therefore, any loss of value from storage associated with an administrative detention action would be an additional cost in those cases.

We provide estimates of the value loss for food in table 4 of this document. We estimate the maximum loss of value as the maximum number of actions

in which the product is not violative, multiplied by the maximum loss per action: $730,000, the average total value of a shipment.

TABLE 4.—ANNUAL LOSS OF VALUE

Action	Number of Actions in which Product Not Violative	Change in Days Storage per Action	Change in Total Loss of Value (in millions)
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 8	0 to 30	$0 to $6
Administrative Detention that Replaces Class I Recall	0 to 88	0	$0
Administrative Detention that Replaces Referral to State	0 to 23	0 to 30	$0 to 9
Total			$0 to $15

Costs of marking or labeling

We might label or mark food that we have administratively detained. If we were to label or mark food that we have administratively detained, we could do so in several ways, including, but not limited to, affixing a tag having a self-locking pin that would be inserted in an appropriate seam, border, flap, or other area of the container or product; taping or tying a tag firmly onto the container or item; or affixing the tag to the accompanying documents, or to the carrier. However, if we subsequently cancelled the administrative detention order, then either we, or the firm, would need to remove the label or mark. Class I recalls do not involve marking or labeling. Moving directly to a seizure action or referring a matter to State authorities also does not involve marking or labeling prior to the seizure action.

In an analysis of another proposed rule that we published in 2001, we discussed the costs of marking cartons of imported food with printed labels that we could affix with label guns (Ref. 8). In that analysis, we assumed that an average shipment of imported food would contain about 300 cartons of containers, and that a worker could attach 100 labels per hour. We estimated that the cost of the labor time necessary to attach the labels would be $53 (three hours at $17.64 per hour), and that the cost of labels would be $13 (300 labels at $0.045 per label). A shipment of imported food can involve any

number of lines of imported food. Therefore, we assume that one line could contain between 1 and 300 cartons. We earlier assumed that the average amount of food in a line is 15,000 pounds, so we estimate that a shipment contains 0.02 cartons per pound (300 cartons per shipment/15,000 pounds per shipment). Therefore, an administrative detention action involving between 0 and 1 million pounds would require 0 to 200 hours of labor time (0.02 cartons per pound x 1 million pounds/100 labels per hour), and 0 to 20,000 labels (100 labels per hour x 200 hours). The cost of the labor time necessary to attach the labels to the cartons would be $0 to $3,500 ($17.64 per hour x 200 hours), and the cost of the labels would be $0 to $900 ($0.045 per label x 20,000 labels).

We assume that the costs associated with the type of labeling we would require for administrative detention would be similar to the costs associated with the type of labeling we discussed in the 2001 analysis. We also assume it would take the same amount of labor time to remove the labels, if we canceled the administrative detention order, as it would take us to affix the labels. We request comments on these assumptions. Under the proposed rule, we would attach the labels, and firms, under our supervision, would remove the labels, if we terminated the detention order, or when the detention order expired.

After rounding to the nearest million, we estimate the cost for additional marking or labeling would be $0 to $1 million.

TABLE 5.—MARKING OR LABELING

Action	Number of Actions	Label Cost per Action	Change in Total Loss of Value (Rounded to Nearest Million $)
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	$4,400 to $7,933	$0
Administrative Detention that Replaces Class I Recall	0 to 184	$4,400 to $7,933	$0 to $1
Administrative Detention that Replaces Referral to State	0 to 23	$4,400 to $7,933	$0

TABLE 5.—MARKING OR LABELING—Continued

Action	Number of Actions	Label Cost per Action	Change in Total Loss of Value (Rounded to Nearest Million $)
al			$0 to $1

Costs of Appeals

The appeals process associated with administrative detention actions is another potential source of costs. In order to calculate the costs of administrative detention actions relative to the other baseline enforcement actions, we must first consider the cost of appeals associated with the other actions. There is no formal appeals process associated with class I recalls because these are voluntary. When FDA requests firms to take class I recalls, there is often an informal dialog between those firms and FDA. However, this type of dialog may take place with respect to any enforcement activity, including administrative detentions and seizures. Therefore, we have not included the costs of this informal dialog as part of the baseline costs. Based on these assumptions, our estimate of the appeals costs for administrative detentions that replace class I recalls is simply the total costs associated with appeals of administrative detentions.

There is also no appeals process prior to a seizure action in cases in which we move directly to a seizure action. However, firms can contest seizure actions, once they occur. In addition, firms can appeal federal district court resolutions of contested seizure actions. Most recently, firms have contested approximately 65 percent of our seizure actions involving foods. However, firms rarely appeal federal district court resolutions of contested seizure actions. Previously, we noted that we would not include the costs associated with seizure actions in baseline costs. This is because we might follow an dministrative detention with a seizure action, so any costs associated with seizure actions might take place irrespective of whether those seizure actions

were preceded by administrative detentions. Instead, we viewed administrative detentions as preliminary enforcement actions that had no counterpart in cases in which we moved directly to a seizure action. However, in this instance, we have included our costs associated with contested seizure actions as part of baseline costs. We have included these costs because firms that appeal an administrative detention, and lose that appeal, are probably less likely to contest a subsequent seizure action, than firms that are involved in a seizure action that was not preceded by an administrative detention. Therefore, the appeals process for administrative detentions may, as a practical matter, replace the process of contesting seizure actions in many cases in which we administratively detain food and then seize it. On the other hand, we have not included the costs associated with appealing federal district court resolutions of contested seizure actions as part of baseline costs. These types of appeals are quite rare, and estimating the costs associated with these types of appeals would have little impact on our cost estimates.

Finally, there is no appeals process associated with referring a matter to State authorities. Of course, if State authorities subsequently take enforcement action, then various appeals processes may be available under State laws or regulations for those actions. However, those methods of appeal would be available irrespective of whether the State actions were preceded by administrative detentions. In addition, the variety of State actions and appeals processes suggests that the probability that a firm will appeal a State action is probably not highly related to whether it has already filed and lost an appeal of an administrative detention. Therefore, we assume that administrative detention will not affect the probability that firms will appeal subsequent State actions.

We estimate that our costs for activity related to appeals of administrative detentions would be approximately $50,000 to $70,000 per administrative detention. We based that estimate on our costs for preparing for possible appeals, which would be generated by all administrative detention actions, and our costs for participating in appeals hearings, which would be generated only by those administrative detentions that result in hearings. In order to calculate an average cost per administrative detention action, we assumed that 65 percent of our administrative detentions would result in an appeals hearing. We based that assumption on the proportion of seizure actions that firms contest. Therefore, the incremental change in appeals costs associated with substituting an administrative detention action for a class I recall is approximately $50,000 to $70,000.

Our costs for activity related to firms contesting our seizures are approximately $10,000 to $20,000 per seizure action. We based that estimate on our costs for participating in a contested seizure case, and a 65 percent chance that firms would contest any given seizure action. Therefore, the incremental change in appeals costs associated with substituting an administrative detention action for a case of moving directly to a seizure action is approximately $30,000 to $60,000. We present the resulting cost estimates for the agency in table 6 of this document.

TABLE 6.—APPEALS

Action	Number of Actions	Label Cost per Action	Change in Total Loss of Value (Rounded to Nearest Million $)
Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 16	$30,000 to $60,000	$0 to $1
Administrative Detention that Replaces Class I Recall	0 to 184	$50,000 to $70,000	$0 to $13
Administrative Detention that Replaces Referral to State	0 to 23	$50,000 to $70,000	$0 to $2
Total			$0 to $16

A firm's decision to appeal an administrative detention order is voluntary. A firm would only appeal an administrative detention order if the costs of doing so were less than the costs of not doing so. Therefore, a firm's participation in the appeals process would usually reduce the costs that we previously estimated for storage and value loss by more than the cost of participating in the appeals process. Because we have already estimated storage costs and product value loss as a range that goes to zero, we have not attempted to analyze the cost and benefit implications of firms' decisions to appeal administrative detention actions.

The specific characteristics of the proposed appeals process for administrative detentions would affect the cost of the appeals process for us and for affected firms. Examples of specific characteristics include the time frame under which we would allow firms to file an appeal for perishable and nonperishable food, the information we would require in an appeal, the timeframes in which we would respond to an appeal, and the availability of an appeals hearing, as opposed to some other type of appeals process. We request comments on the impacts of the specific requirements of the proposed appeals procedure.

Other Enforcement Costs

Differences in other enforcement costs associated with administrative detention actions, class I recalls, moving directly to seizure actions, and referring matters to State authorities, are also relevant to this analysis. Both administrative detentions and class I recalls require us to undertake certain types of activity to implement, and we assume that the costs of this activity would be similar for these actions. Although taking no action prior to a seizure action or referring a matter to State authorities requires no activity, the activity

that we undertake to move directly to seize food or to provide information on a matter to State authorities probably overlaps to some degree with the activity that we would undertake to implement an administrative detention action. The cost of the additional activity required to seize food following another enforcement action is significantly less than the cost of the activity required to move directly to seize food, because some of the activity of the preliminary action is also relevant to seizing the food. Therefore, we assume that the cost of the activity that we undertake to directly move to seize food is similar to the cost of the activity we undertake to implement an administrative detention action followed by a seizure action. Similarly, we assume that the cost of the activity that we and States undertake when we refer a matter to State authorities is similar to the cost of the activity that we and States undertake to implement an administrative detention action followed by State action.

Cost summary

We present a summary of the costs in table 7 of this document.

TABLE 7.— ANNUAL COSTS FOR OPTION 1: TRANSPORTATION AND PERISHABLE FOODS (PROPOSED RULE)

Type of Cost	Cost (in millions)
Transportation	$0 to $4
Storage	$0 to $2
Loss of Product Value	$0 to $15
Marking or Labeling	$0 to $1
Appeals	$0 to $16
Total	$0 to $38

Benefits

Administrative detention authority improves our ability to respond to outbreaks from accidental and deliberate contamination from food, and deter deliberate contamination. Based on historical evidence, a strike on the food

supply has a very low probability, but would be a potentially high cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring or the possible reduction in cost of an event, associated with each regulatory option. Further hindering any quantification of benefits is the interactive effect of the other regulations that are being developed to implement title III of the Bioterrorism Act.

Administrative detention differs from existing enforcement alternatives along the following dimensions: (1) Speed of action, (2) need for collaboration with other agencies, (3) maximum level of security, and (4) timeframes. Actions that we can implement faster will reduce risk more than actions that take longer to implement, because we have a higher probability of removing the oduct from commerce before it reaches the consumer. We have a higher probability of successfully taking an action that does not require collaboration because actions that require us to collaborate with other agencies involve more than one set of decision criteria and more than one decision maker. Actions that allow us to require higher security transportation and storage reduce risks because such actions reduce the probability that we will lose control of the product, and that adulterated food will reach consumers. Actions with longer time frames reduce risk because we have more time to complete our investigation and a lower probability of releasing food that is violative back into commerce. The relative advantages of the various enforcement actions are provided in table 8 of this document. The expressions "permanent" and "temporary" in the time frames represent the relative time frames under which we can keep a potentially violative food out of the distribution system.

TABLE 8.—COMPARISON OF ENFORCEMENT ACTIONS

Action	Speed	Collaboration	Highest Potential Security	Timeframes
Administrative Detention	High	No	High	Temporary
;zure	Low	No	High	Permanent
Class I Recall	Low	Yes	Low	Permanent
Referral to State	Low	Yes	Low	Unknown

We have insufficient information to quantify the health benefits of substituting administrative detention for the other enforcement actions. However, to understand the possible costs of an intentional strike on the food supply, table 9 of this document presents information on five outbreaks resulting from accidental and deliberate contamination, involving both domestic and imported foods. These outbreaks do not represent possible forms that a terrorist attack might undertake, but merely illustrate the public health costs of foodborne disasters. It is likely that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens ould be much larger. However, the probability of an attack occurring and the exact reduction in risk resulting from administrative detention is unknown.

TABLE 9.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost
Salmonella enteritidis	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	29,100 in MN; 224,000 Nationwide	$3,187,744,000 to $5,629,792,000
Shigella sonnei	Michigan, 1988	Tofu salad	3,175 cases	Not available	$45,183,000 to $79,795,000
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon, 1984	Salad bars	751 cases; 45 hospitalizations	Not available	$10,687,000 to $18,875,000
Shigella dysentreriae type 2	Texas, 1996	Muffins and doughnuts	12 cases; 4 hospitalizations	All cases identified	$83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalization	Not available	$3,941,000

Salmonella enteritidis in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with *Salmonella enteritidis*. The source of the contamination

appeared to be pasteurized premix that had been contaminated during transport in tanker trailers that carried nonpasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream processed during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 9).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause 1 to 3 days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of 2 to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 10 of this document provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. FDA presents two estimates of values of pain and suffering associated with arthritis, one based on physician estimates (Ref. 10) and

another based on a regression analysis approach (Ref. 11). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

TABLE 10.—THE VALUE OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$660	$0	$599
Moderate	8.1%	3.68	$2,310	$283	$209
Severe	1.2%	9.99	$6,266	$9,250	$188
Arthritis					
Regression Approach					
Short-Term	1.26%	5.41	$3,391	$100	$44
Long-Term	2.40%	2,613.12	$452,554	$7,322	$11,048
Direct Survey Approach					
Short-Term	1.26%	10.81	$6,778	$100 $87	
Long-Term	2.40%	5,223.15	$904,573	$7,322	$21,906
Death	0.04%		$5,000,000		$2,143
Total Expected Loss per Case				Regression Approach Direct Survey Approach	$14,231 $25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with *Shigella sonnei* and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival (Ref. 12). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short-term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of *S. typhimirium* occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram

commune intentionally caused the outbreak by spraying *S. typhimirium* on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 13).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost of known cases for the outbreak of $10,687,000 to $18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All 12 affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 14).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of

gastroenteritis resulting from salmonellosis. This gives a cost of $83,000 for illnesses associated with the event.

TABLE 11.—SUMMARY OF COSTS FOR AN OUTBREAK OF SHIGELLOSIS

Severity	Number of Cases	Cost per Case	Total Cost
Mild	0	$0	$0
Moderate	8	$2,593	$21,000
Severe	4	$15,516	$62,000
Total	12		$83,000

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 15). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 States, two Canadian provinces, and the District of Columbia (Ref. 16).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 16). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20

hospitalizations were reported from the cyclosporiasis outbreak (Ref. 15). No deaths were confirmed.

TABLE 12.—SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of Cases	Cost per Case	Total Cost
Mild	879	$1,650	$1,450,000
Moderate	586	$3,748	$2,196,000
Severe	19	$15,516	$295,000
Total	1,465		$3,941,000

Option Two: Take the proposed action, but change either or both the definition of perishable food and the maximum time frame for administrative detention of perishable food.

Costs

If we established a shorter maximum timeframe for administrative detention of perishable food, then we would reduce the potential storage costs and loss of value associated with administratively detaining that food. If we also broadened the definition of perishable food to include products with a shelf life of over 7 days, then we would further decrease the storage costs and loss of food product value for those additional types of food. One reasonable alternative would be to broaden the definition of perishable food to include any food that might lose all of its value during a 30-day administrative detention period, that is, any food with a shelf life of 30 days or less, and reduce the maximum timeframe for administratively detaining a perishable food to 14 days. We calculated the costs of this option using the same procedures that we used for Option one (take the proposed action). We present these costs in table 13.

TABLE 13.—ANNUAL COSTS FOR OPTION 2: ALTERNATIVE DEFINITION AND MAXIMUM DETENTION PERIOD FOR PERISHABLE FOOD

Type of Cost	Cost (rounded to nearest million $)
Transportation Cost	$0 to $4

TABLE 13.—ANNUAL COSTS FOR OPTION 2: ALTERNATIVE DEFINITION AND MAXIMUM DETENTION PERIOD FOR PERISHABLE FOOD—Continued

Type of Cost	Cost (rounded to nearest million $)
Storage Cost	$0 to $1
Loss of Product Value	$0 to $8
Marking or Labeling	$0 to $1
Appeals	$0 to $16
Total	$0 to $30

If we attempted to maintain the same level of investigation under the shorter maximum timeframes for perishable food by using our enforcement resources more intensively, then enforcement costs might also increase. In that case, we would need to compare the cost of using our investigative resources more intensively for a shorter period of time relative to using those resources less intensively for a longer period of time. More intensive use of resources would probably cost more because it would probably require our employees to work overtime and possibly over weekends and holidays. Therefore, this ould reduce any cost savings introduced by the shorter maximum timeframes for perishables.

Benefits

Changing the definition of perishable food and the maximum timeframes for administrative detentions of perishable food could also affect the health benefits of this rule. Broadening the definition of perishable food and establishing a shorter maximum timeframe for administratively detaining that food would reduce the maximum timeframes for storage of those products that qualified as perishable food relative to the time frame for nonperishable food. The significance of this change depends on how often we need the full 30 days to complete our investigations. If we usually complete our investigations n the time allowed under the hypothetical shorter maximum detention time we could establish for perishable food, then including more products in the

perishable category would have little effect on the risk that we would fail to catch a violative product because of the shorter investigation period. However, if we often need the full 30 days to complete our investigations, then including more products in the perishable category and establishing a shorter maximum detention time for administrative detention of perishable food would increase the risk that we would fail to catch a violative product during the investigation period. We do not have sufficiently detailed information to estimate these changes in health benefits.

We might also be able to maintain the same effect on risk and health benefits under the shorter timeframes by using resources more intensively during the shorter investigation period. For example, if we were to allocate more employees to work on an investigation, or if our employees were to work extra hours, then we might be able to complete the same level of investigation under a shorter timeframe. In that case, this option would have the same health benefits as Option one, but additional costs might be generated by the more intensive use of resources.

Option Three: Take the proposed action, but change the level of security we require for transportation and storage.

Costs

Instead of judging the need for various levels of security on a case-by-case basis, we could require firms to use specified levels of security to transport and store food under specified conditions. In Option one, we assumed, based on information from a trade group, that the costs for using bonded carriers and warehouses were similar to those for using nonbonded carriers and warehouses. However, if we chose a lower security approach and allowed firms to store administratively detained food in place, then we would eliminate the

transportation costs. Eliminating transportation costs would reduce total costs to a range of $0 to $34 million.

If we required firms to undertake security operations they would not otherwise have taken, then we would need to add in the cost of that activity. One example of the type of activity we might require is posting additional security guards. The average hourly wage of a security guard in 2000 was about $9.50 (Ref. 17). We doubled this wage to account for overhead, such as health benefits, to get an annual hourly wage of about $17. Therefore, the average cost of posting one additional security guard would be approximately $450 per day. The number of guards would depend on the number of facilities involved. Firms might already have distributed food that we administratively detain. Based on our experience with other enforcement actions, we believe that between 1 and 20 storage facilities might be involved per administrative detention action. Therefore, we calculate the cost of adding 1 guard by multiplying the cost of 1 additional security guard per day, times a maximum of 30 days storage, times the number of administrative detentions, times the number of facilities involved per administrative detention. Using this approach, we estimate the total costs associated with no transportation and posting one additional guard would be $0 to $45 million.

TABLE 14.—ANNUAL COSTS FOR OPTION 3: NO TRANSPORTATION AND ONE ADDITIONAL GUARD

Type of Cost	Cost (rounded to nearest million $)
One additional guard	$0 to $11
Storage Cost	$0 to $2
Loss of Product Value	$0 to $15
Marking or Labeling	$0 to $1
Appeals	$0 to $16
Total	$0 to $45

We do not have information on the costs of using high security transportation and storage. However, requiring high security transportation and storage would probably substantially increase transportation and storage costs.

Benefits

As discussed in Option one, bonded and third party carriers and warehouses provide some degree of additional security relative to relying on a firm's own transportation system and storage facilities. However, they do not provide the highest level of security because food can be stolen from such facilities, and because the owners of those facilities could, themselves, become involved in deliberately adulterating food. Therefore, requiring a higher level of security for transportation and storage would reduce the probability that an adulterated product might find its way back into commerce during a detention. We have insufficient information to estimate the change in health benefits from more secure transportation and storage.

Option Four: Issue regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (i.e., limit the action to that required by section 303 of the Bioterrorism Act).

The Bioterrorism Act requires us to issue regulations establishing expedited procedures for instituting seizure actions, injunction actions, or both against perishable food. Therefore, taking no regulatory action with regard to those procedures would not be a legally viable option. However, we could promulgate a more limited rule that covered only expedited procedures for enforcement actions involving perishable food, rather than a rule that also included general procedures for administrative detention.

Costs

If we were to issue a more limited rule, we would still be able to administratively detain food because Congress has already granted us that authority under the Bioterrorism Act. We would probably administratively detain food in the same situations in which we would have taken this action under the proposed rule. Therefore, the costs we estimated under Option One would also apply to this option. In addition, there could be some additional enforcement cost associated with relying on the language of the act rather than our own regulations when taking this action. These additional costs would be caused by our need to develop and defend our interpretation of the language of the Bioterrorism Act piecemeal in court, rather than through implementing regulations. These court proceedings would probably take longer and be more complicated than they would be if we were enforcing more specific regulatory language. We have insufficient information to estimate this change in costs. Therefore, we can only determine that the lower bound of the range of potential costs for this option would be somewhat greater than $0 million, and the upper bound would be somewhat higher than $38 million, and the costs associated with this option would be somewhat greater than those associated with Option one under any given scenario.

Benefits

Again, even if we did not include the overall framework for administrative detention in this rule, we would probably use administrative detention in the same situations in which we would use administrative detention under the framework developed in this proposed rule. However, we expect we would have somewhat more difficulty using administrative detention if we relied only on the language of the act rather than also on our more detailed regulations. For example, if we needed to develop and defend our interpretation of the

language of the Bioterrorism Act piecemeal in court, our ability to pursue administrative detentions while such proceedings are ongoing might be limited or even precluded. Therefore, the benefits of this option might be somewhat lower than those for Option one.

Summary of Options

We summarize the costs and benefits of the various options in table 15.

TABLE 15.—SUMMARY OF ANNUAL COSTS AND BENEFITS

Option	Costs (in millions)	Benefits (in millions)
1—transportation and perishable foods as proposed	$0 to $38	> $0
2—perishable foods alternatives	$0 to $30	> $0, but < Option 1
3—no transportation, but one additional guard	$0 to $45	> $0
4—limited to Act	> $0 to > $38	> $0, but < = Option 1

The ranges generated by the underlying uncertainties in our analysis, particularly concerning benefits, preclude us from drawing any firm conclusions about the relative net benefits of the various regulatory options. The potential costs for Option One (the proposed rule) are lower than those for Option Three, and we are unable to differentiate the potential benefits of these two options. The similarity between the estimated ranges of costs and benefits for these two options suggests that we should determine whether to require transportation or storage in place on a case-by-case basis, as we have proposed. The potential costs for Option One are higher than those for Option Two. However, the estimated benefits of Option One are also higher than those of Option Two. We have insufficient information to quantify the difference in benefits. The potential costs for Option One are lower than those for Option Four, and the benefits of Option One are greater or equal to those of Option Four. Therefore, Option One would lead to higher net benefits than Option Four.

B. Initial Regulatory Flexibility Analysis

We have examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this proposed rule would not have a significant economic impact on a substantial number of small entities. Nonetheless, we have provided an initial regulatory flexibility analysis under the Regulatory Flexibility Act, which consists of the analysis below with other relevant sections of this document.

This proposed rule may affect firms involved in the production or handling of human food and animal feed such as the following: (1) Food producers such as farms, ranches, fisheries, dairies, bakeries, breweries, distilleries, and manufacturers of processed food, food additives, dietary supplements, infant formula, and food contact substances; (2) food importers; (3) food wholesalers or brokers; (4) food retailers; (5) food service establishments; and (6) food transporters. The rule might affect producers because we could administratively detain food at one of the producer's facilities prior to distribution of that food to wholesalers or brokers. We could also administratively detain food anywhere in the distribution system, from wholesaler and retailer warehouses, to retail store shelves, to food service establishment kitchens or storerooms. The rule might affect transporters because we might detain food that is en route to another location, and the food might be packed together with food that we would not detain. This might cause delays in the deliveries of the other food.

Potentially affected firms fall into a number of different North American Industry Classification System (NAICS) codes, including the following: 111 Crop Production, 112 Animal Production, 1141 Fisheries, 311 Food Manufacturing, 3121 Beverage Manufacturing, 325412 Pharmaceutical Preparation Manufacturing, 4224 Grocery and Related Products Wholesalers, 4225 Farm Product Raw Material Merchant Wholesalers, 4248 Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers, 445 Food and Beverage Stores, 446191 Food (Health) Supplement Stores, 481112 Scheduled Freight Air Transportation, 481212 Nonscheduled Chartered Freight Air Transportation, 482 Rail Transportation, 483111 Deep Sea Freight Transportation, 483113 Coastal and Great Lakes Freight Transportation, 483211 Inland Water Freight Transportation, 484 Truck Transportation (except 48421 Used Household and Office Food Moving, 4842201 Local Hazardous Materials rucking, 4842203 Dump Trucking, and 4842301 Long Distance Hazardous Materials Trucking), and 722 Food Service and Drinking Places. There is also no NAICS code for manufacturers of food contact material. However, the following NAICS codes cover some of the potentially affected firms: 322215 Non-Folding Sanitary Food Container Manufacturing, 32222 Paper Bag and Coated and Treated Paper Manufacturing, 32611 Plastics Packaging Materials and Unlaminated Film and Sheet Manufacturing, 327213 Glass Container Manufacturing, and 333993 Packaging Machinery Manufacturing. There are no NAICS codes for manufacturers of food additives or for food importers, and we assume these firms are included in the other categories.

The 1997 Economic Census lists 1.6 million establishments in these categories, excluding NAICS codes 111, 112, 1141, and 482, which are not included in the Economic Census. The 2000 County Business Patterns updates

some of the numbers from the 1997 Economic Census. However, the County Business Patterns data includes only establishments with employees. In order to obtain another estimate of the number of firms using the updated data, we combined the number of establishments with employees from the 2000 County Business Patterns with an estimate of the number of establishments without employees based on the proportion of firms with and without employees in the 1997 Economic Census. This procedure also led to an estimate of approximately 1.6 million establishments in these categories, excluding NAICS codes 111, 112, 1141, and 482. An establishment without employees is an establishment that is staffed only by the owners of that establishment.

We also used the Dun and Bradstreet Market Identifiers database to get a count of the number of firms in these categories. This database uses Standard Industry Classification (SIC) codes rather than NAICS codes. SIC codes do not correspond exactly to NAICS codes. We based our estimate on all SIC codes that even partially corresponded to relevant NAICS codes. This database allows one to count firms rather than establishments, and also allows one to identify firms by both primary and secondary activities. According to this database, approximately 1.8 million firms could be affected by this rule. However, we would not be able to affect more firms in 1 year than the estimated number of administrative detentions that we might take in 1 year. In the analysis of impacts above, we estimated that we might administratively detain food between 0 and 200 times per year. Therefore, we estimate that this rule may affect between 0 and approximately 200 firms per year.

The Small Business Administration (SBA) publishes definitions of small businesses by six-digit NAICS code (Ref. 18). Some of the NAICS codes listed previously above are less than six digits. In those cases, we used the range

of small business definitions for all six-digit subcategories in the relevant NAICS code. The current SBA definitions in terms of either maximum annual average receipts or number of employees are as follows: 111 ($0.75 million), 112 ($0.75 to $10.5 million), 1141 ($3.5 million), 311 (500 to 1,000), 3121 (500 to 750), 322215 (750), 32222 (500), 325412 (750), 32611 (500), 327213 (750), 333993 (100), 4224 (100), 4225 (100), 42251 (100), 4228 (100), 445 ($6 to $23 million), 446191 ($6 million), 481112 (1,500), 481212 (1,500), 482 (500), 483111 (500), 483113 (500), 483211 (500), 484 except 48421, 4842201, 4842203, and 4842301 ($21.5 million), 722 ($6 million to $17.5 million). We applied the relevant range of sizes to the SIC codes that at least partially corresponded to the relevant NAICS codes and found that approximately 84 to 90 percent of the firms that this rule might affect are small businesses under SBA size definitions. Therefore, we estimate that this rule may affect between and 180 small businesses each year.

The potential cost per administrative detention for small entities based on taking the proposed action and the information and assumptions in the preceding impact analysis would be $20,000 to $330,000, depending on the type of product involved and the type of enforcement action that we would replace with an administrative detention, and whether or not the firm appealed the administrative detention order. However, we based this range on a number of assumptions that are probably more reasonable when applied to average or expected costs across a large number of actions than to a single action. Thus, the actual range of potential costs for a single detention action would be much larger. In addition, the cost per firm would depend on the number of times that we detain that firm's products in a given time period. The most we can say about costs on a per firm basis is that the average expected cost per firm

across all potentially affected firms would presumably be quite low, but the cost for a particular firm in a particular year could be significant, depending on a number of variables including the type and amount of product involved. FDA requests comment on the impact of this proposed rule on small entities.

The fact that most of the potentially affected firms are small businesses suggests that the options that would be relevant to small businesses are the same as the options relevant for all firms discussed in the impact analysis above. Options two and three would both reduce the impact on small firms. However, these options would also reduce benefits, and we do not have sufficient information to estimate the change in net benefits.

Administrative detention involves preventing the movement of food upon credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This standard applicable without regard to the size of any business involved. Most of the businesses impacted by this proposed rule are small businesses. To provide an exemption for small businesses under this proposed rule would defeat the purposes of the statute. Accordingly, we are not providing exemptions from the requirements of this regulation to small businesses.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The urrent inflation-adjusted statutory threshold is $112.3 million per year. We have estimated that the total cost of the proposed rule would be no more than

$38 million per year. Therefore, we have determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, the Office of Management are Budget (OMB) has determined that this proposed rule, when final, will not be a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

We tentatively conclude that these proposed information collection provisions are exempt from OMB review under 44 U.S.C. 318(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2)

applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. We seek comment on our tentative conclusion that these information collections are exempt from OMB review.

VII. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

IX. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this document. Two copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." The provisions in this proposed rule that describe the procedures for how FDA will detain an article of food, how FDA will expedite certain enforcement actions with respect to perishable food, and the process for appealing a detention order will enhance FDA's ability to prevent distribution of food that presents a threat of serious adverse health consequences or death to humans or animals. The legislative history of the

Bioterrorism Act, with respect to the regulation required by section 303 of that act, notes that the "Secretary should promptly complete such rule making" (cf. Conf. Rept. No. 107–481, at 131 (2002)). This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies.

FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after the 60-day comment period closes. Due to the need to promptly complete this rulemaking, FDA does not intend to grant any requests for extensions of the comment period.

X. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register.**

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3. Price list from California Refrigerated Services, Inc., received October 3, 2002.

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5. "Regulatory Procedures Manual," August 1997. Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs, U.S. Food and Drug Administration, U.S. Department of Health and Human Services. chap. 11, p. 497, August, 1997.

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11. Scharff, R. and Jessup, A., Valuing Chronic Disease for Heterogeneous Populations: The Case of Arthritis, 2002, Mimeo.

12. Lee L. A., Ostroff S. M., McGee H. B., Johnson D. R., Downes F. P., Cameron D. N., Bean N. H., and P.M. Griffin, "An Outbreak of Shigellosis at an Outdoor Music Festival," *American Journal of Epidemiology*, 133:6:608–615.

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14. Kolavic S. A., Kimura A., Simons S. L., Slusker L., Barth S., and C. E. Haley, "An Outbreak of *Shigella Dysenteriae* Type 2 Among Laboratory Workers Due to Intentional Food Contamination," *The Journal of the American Medical Association*, 278:5:396–403.

15. Colley D. G., Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter), *Emerging Infectious Diseases*, 2:4:354–356.

16. Herwaldt B. L., Ackers M. L., and Cyclospora Working Group, "An Outbreak in 1996 of Cyclosporiasis Associated With Imported Raspberries," *New England Journal of Medicine*, May 29, 1997, pp. 1548–1556.

17. 2000 National Occupational Employment and Wage Estimates, Protective Service Occupations, U.S. Department of Labor, Bureau of Labor Statistics, available on Internet at http://stats.bls.gov/oes/2000/oes_33Pr.htm, accessed October 22, 2002.

18. Small Business Size Standards Matched to North American Industry Classification System (NAICS), Small Business Administration, available on Internet at http://www.sba.gov/size/sizetable.html, accessed November 20, 2002.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, and Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1 and 16 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart K is added to part 1 to read as follows:

Subpart K–Administrative Detention of Food for Human or Animal Consumption

General Provisions

Sec.

1.377 What definitions apply to this subpart?

1.378 What criteria does FDA use to order a detention?

1.379 How long may FDA detain an article of food?

1.380 Where and under what conditions must the detained article of food be held?

1.381 May a detained article of food be delivered to another entity or transferred to another location?

1.382 What labeling or marking requirements apply to a detained article of food?

1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

1.384 When does a detention order terminate?

How does FDA order a detention?

1.391 Who approves a detention order?

1.392 Who receives a copy of the detention order?

1.393 What information must FDA include in the detention order?

What is the appeal process for a detention order?

1.401 Who is entitled to appeal?

1.402 What are the requirements for submitting an appeal?

1.403 What requirements apply to an informal hearing?

1.404 Who serves as the presiding officer at an informal hearing?

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

1.406 How will FDA handle classified information in an informal hearing?

Subpart K – Administrative Detention of Food for Human or Animal Consumption

GL per Barbara SubAC 5/5/03

General Provisions

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

In addition, for the purposes of this subpart:

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

Authorized FDA representative means an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food 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, bakery goods, snack foods, candy, and canned foods.

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.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

§ 1.378 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.

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10 calendar day detention period at the time the detention order is issued or at any time within the 20 calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with § 1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a limited conditional release under § 1.381(c) before you move the detained article of food to a secure facility.

(d) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.381 May a detained article of food be delivered to another entity or transferred to another location?

(a) An article of food subject to a detention order under this subpart may not be delivered to another entity under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article

of food is subject to a detention order under section 304(h) of the act, it may not be delivered to any of its importers, owners, or consignees.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or 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 of food under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request for a limited conditional release of a detained article of food for any of the following purposes:

(1) To destroy the article of food,

(2) To move the detained article of food to a secure facility under the terms of a detention order,

(3) To maintain or preserve the integrity or quality of the article of food, or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for the limited conditional release of the detained article in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting a limited conditional release for the

purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the "Federal Rules of Civil Procedure."

(e) If FDA approves a request for limited conditional release, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained article, you must immediately notify in writing the authorized FDA representative who approved the limited conditional release of the article of food that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax or e-mail or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative who approves the limited conditional release of the detained article of food under this section.

(g) The transfer of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.382 What labeling or marking requirements apply to a detained article of food?

The officer or qualified employee of FDA issuing a detention order under § 1.393 may label or mark the detained article of food with official FDA tags or labels that include the following information:

(a) A statement that the article of food is detained by FDA in accordance with section 304(h) of the act (21 U.S.C. 334(h));

(b) 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;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§ 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to the Department of Justice within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the Department of Justice of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not

limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§ 1.384 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 and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

How does FDA order a detention?

§ 1.391 Who approves a detention order?

An authorized FDA representative, i.e., the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director, must approve a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

§ 1.392 Who receives a copy of the detention order?

(a) FDA must 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 is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) 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, we also 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.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals.

(b) The detention order must include the following information:

(1) The detention order number;

(2) The date and hour of the detention order;

(3) Identification of the detained article of food;

(4) The period of the detention;

(5) A statement that the article of food identified in the order is detained for the period shown;

(6) A brief, general statement of the reasons for the detention;

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless subject to a limited conditional release under § 1.381;

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, e-mail address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located; and

(13) A statement indicating the manner in which approval of the detention order was obtained, i.e., orally or in writing.

What is the appeal process for a detention order?

§ 1.401 Who is entitled to appeal?

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the "Federal Rules of Civil Procedure."

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, e-mail address, or fax number identified in the detention order according to the following applicable timeframes:

(1) *Perishable food*: If the detained article is a perishable food, as defined in § 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

(2) *Nonperishable food*: If the detained article is not a perishable food, as defined in § 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for

hearing, your appeal must be filed within 10 calendar days of receipt of the detention order.

(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the "Federal Rules of Civil Procedure."

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, as defined in section 201(x) of the act, and FDA grants your request, the hearing will take place according to the following applicable timeframes:

(1) *Perishable food*: If the detained article is a perishable food, as defined in § 1.377, the hearing will be held within 2 calendar days after the date the appeal is filed.

(2) *Nonperishable food*: If the detained article is not a perishable food, as defined in § 1.377, the hearing will be held within 3 calendar days after the date the appeal is filed.

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(b) A request for a hearing under this section must be addressed to the FDA District Director in whose district the article food involved is located.

(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart.

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart.

(e) Section 1.406, rather than §16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information.

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, e.g., regional food and drug directors or other officials senior to a district director, who preside at hearings under this subpart.

(g) The presiding officer may require that a hearing conducted under this section be completed within 1 day, as appropriate.

(h) Provisions of part 16 of this chapter that provide for the presiding officer to issue a report and recommended decision only do not apply. The presiding officer will issue the final agency decision.

§ 1.404 Who serves as the presiding officer at an informal hearing?

The presiding officer of an informal hearing on an appeal of a detention order, who also must decide the appeal, must be an FDA regional food and drug director or another FDA official senior to an FDA district director.

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

(a) The presiding officer must issue a decision confirming or revoking the detention within 5 calendar days after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-day period, the detention order is deemed terminated.

(b) If you appeal the detention order but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under § 1.384.

(f) Confirmation of a detention order by the presiding officer is considered final agency action for purposes of 5 U.S.C. 702.

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive order as requiring protection from unauthorized disclosure in the interest of national security ("classified information"), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

4. Section 16.1 is amended in paragraph (b)(1) by adding a new statutory provision in numerical order as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 304(h) of the act relating to the adminstrative detention of food for human or animal consumption (see part 1, subpart k, of this chapter).

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Dated: April 30, 2003.

Mark B. McClellan,
Commissioner of Food and Drugs.

Dated: MAY - 5 2003

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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