

(Response) As stated previously, FDA will decide on a case-by-case basis who will be responsible for transporting food that is detained administratively. In some cases it may be necessary for us to designate a third party to transport the food, if we believed that control of the food could be lost if the recipient of the detention order transported it. In cases where we believed that this risk is not present, we may direct the recipient of the detention order to transport the food. FDA does not believe that it is necessary to state in its approval of a request for modification of a detention order that the mode of transportation must not introduce an adulterant or otherwise deleteriously impact the quality of the detained food. However, if the food does become further adulterated during transport, possible ultimate release of the food could be affected.

(Comment 66) One comment indicates that FDA's current practice is to place routine imports of certain items on the "Refused Entry/Administrative Detention" status as part of the standard protocol for items such as raisins and avocado paste. The comment states that such a product is then held for additional testing in the United States before release when the product is shown to present no threat to U.S. health. The comment encourages FDA to exhibit discretion and allow for limited conditional release of such items and allow the product to be held in a facility capable of maintaining and preserving

the integrity and quality of the article of food because they are low risk.

(Response) FDA believes that this comment is confusing FDA's refusal authority under section 801(a) of the FD&C Act and our "administrative detention" authority under section 303 of the Bioterrorism Act. Any current import alerts, such as those for raisins and avocado paste, are unaffected by this final rule.

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

(Comment 67) One comment recommends that, in addition to the information on the FDA tags or labels described in § 1.382(d) of this rule, they should also include the expiration date of the detention order and the name of the authorized FDA representative who approved the detention order. This comment also states that if the detention period is extended for any additional time up to the 10-calendar day limit, the detention order and the affixed tags or labels should be amended accordingly.

(Response) FDA disagrees with the comment to revise § 1.382(d) to add the expiration date of the detention order and the name of the authorized FDA representative who approved the detention order to FDA's tags or labels. The name of the person

who issued the detention order is required to be on the tag or label. In addition, FDA is revising the final rule to include § 1.393(b)(14), which requires that the detention order include the name and title of the authorized FDA representative who approved the detention order.

The period of detention is required on the tag or label; thus, the expiration date of the detention can be determined from this information. FDA agrees that, in the event that a detention is extended from 20 to 30 calendar days, another detention order must be issued and new tags affixed to the articles.

(Comment 68) A few comments state that applying a label or mark to the detained product should be avoided at all cost because, if the product is detained erroneously, the label or mark may make the food unmarketable. A few other comments ask whether FDA will remove the labels or marks upon termination of a detention order. One comment strongly recommends that detained articles be marked only on the packing cases, because any visible detention mark would make the food unmarketable.

(Response) As FDA stated in the proposed rule, 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 detention order is terminated, FDA will remove, or authorize the removal of, the required labels or tags, as described in § 1.384. Accordingly, we would not expect the labeling and marking provision to impair the marketability of an article of food for which the detention order is terminated.

F. Comments on What Expedited Procedures Apply When FDA Initiates a Seizure Action Against a Detained Perishable Food?

(Proposed § 1.383)

(Comment 69) FDA requested comments on this or other procedures that would address concerns about expedited enforcement actions with respect to perishable food. One comment states that the provision for expedited procedures to initiate a seizure action against a detained perishable food is unfair because the claimant would be robbed of any right to appeal a detention order in certain circumstances. The comment states that if the detention order is issued on a Wednesday, the claimant would be required to file its appeal by Friday. However, according to this comment, the FDA also is obligated to "file" its seizure action with the DOJ on that same day (Friday) because the actual 4th calendar day after detention is Sunday, when the Court is not in session. The comment argues that the

claimant would not have a chance to appeal since the right to appeal is terminated when a seizure action is initiated.

(Response) FDA disagrees with this comment. The Bioterrorism Act requires FDA to provide by regulation, expedited procedures for instituting certain judicial enforcement actions involving perishable foods that are detained under section 303 of the Bioterrorism Act. The purpose of this statutory requirement is to ensure that FDA decides on an expedited basis whether to pursue Federal court seizure of detained perishable food, and that the owners of such perishable food have timely information about how the government plans to proceed with respect to their detained food.

The final rule is consistent with the Bioterrorism Act's directive. The comment appears to misunderstand the mechanics of the regulation's procedures. FDA's process of sending a seizure recommendation to DOJ is not contemporaneous with the filing of that action in federal court. FDA anticipates that, if we send a seizure recommendation in these circumstances, the seizure will be filed, the court will issue a warrant, and the U.S. Marshal will seize the food, soon after the recommendation is sent to the DOJ. FDA lacks authority to mandate the timing of these actions. As a result, the filing and execution of the seizure may not occur on the same calendar day that the recommendation is sent to DOJ.

Moreover, the Bioterrorism Act provides that an appeal of an administrative detention is terminated once an enforcement action involving the detained food is instituted in Federal court, that is, when the court has issued a warrant, and the U.S. Marshal has seized the food. The regulation is consistent with this statutory provision. Until the seizure action is filed in Federal court, the appeal process will continue. Owners of detained food can increase their chances of having their views heard in the administrative forum of the appeal process by submitting an appeal immediately after the food is detained. Once a seizure action has been filed in Federal court, and the food has been seized, however, any challenge to the administrative detention would be moot, as the food would be under seizure under Federal district court rules. The owner of the food, or another party with sufficient interest in the food, can then contest the seizure action in Federal court. There, it can challenge the government's position that the food is adulterated or misbranded and is subject to seizure, condemnation, and forfeiture under section 304(a) of the FD&C Act. A claimant in a seizure action has the same opportunity to be heard in Federal court as the government. Although the forum may change from an administrative hearing before an FDA presiding officer to a judicial proceeding before a Federal court judge, the claimant nonetheless has the right to challenge

FDA's determination that the food should be removed from commerce.

G. Comments on When Does a Detention Order Terminate?

(Proposed § 1.384)

(Comment 70) One comment asks how a detention order can expire if confirmation of a detention order is considered final agency action.

(Response) Confirmation of a detention order by the presiding officer at a hearing on an appeal of a detention order is considered final agency action for purposes of the judicial review provisions of the Administrative Procedure Act (5 U.S.C. 702). Even if the order is confirmed, it expires on the 21st calendar day (or 31st calendar day if the detention has been extended) following the issuance of the detention order.

(Comment 71) One comment suggests that FDA amend § 1.379(c) to state that, in accordance with § 1.384, information regarding the termination of a detention shall be provided to the company in writing within calendar day of the decision by FDA that the order shall be terminated.

(Response) FDA expects that we would normally be able to issue the detention termination notice to the person who received the detention order (e.g., the owner, operator or agent in charge of the place where the food is located and the owner of the food, if known) within 1 calendar day of the decision to

terminate a detention, unless extenuating circumstances exist. However, we are not revising the rule to incorporate such a deadline because in some instances it may not be possible to inform the company in writing within 1 calendar day due to unforeseen circumstances beyond the agency's control.

H. Comments on How Does FDA Order a Detention?

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

(Comment 72) One comment recommends the establishment of a national detention approval board to ensure a uniform application of the regulation and to avoid costly errors and delays. A few comments state that the detention order must be approved at the Regional Food and Drug Director level or higher because the judgment of credible threats is case-by-case and the District Director level provides too much discretion.

(Response) FDA disagrees with these comments. Congress included language in the Bioterrorism Act that specifies who is authorized to approve a detention order, i.e., the Secretary or an official designated by the Secretary (who may not be so designated unless the official is the director of the district in which the article involved is located, or is an official senior to such director). FDA believes that the Bioterrorism Act does not contemplate any sort of a national detention approval board. To the contrary, the statute makes clear that Congress

expected that FDA District Directors, or officers senior to such directors, could and would exercise this authority.

(Comment 73) One comment states that the approval of a detention order should always be written to avoid misunderstandings.

(Response) Written approval of a detention order is required under § 1.391. This § 1.391 states that prior written approval must be obtained, or if prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. Thus, written approval always will be obtained.

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

(Comment 74) Many comments state that it is imperative that FDA provide a copy of the detention order to the owner of the article of food that has been detained to ensure that such owner has all of the necessary information to address any potential corrective action or to determine if an appeal should be filed. These comments suggest that the recordkeeping and facility registration provisions of the Bioterrorism Act should permit identification of the owner of the food.

(Response) As provided in § 1.392, FDA will provide the detention order to the owner or agent in charge of the place where the detained article of food is located and the owner of

the food, if the owner's identity can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food.

As the comment suggests, section 305 of the Bioterrorism Act requires facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003 (68 FR 58893); however, this registration information does not always identify the owner of a particular article of food. The registration documents contain information such as the name of the facility that manufactured/processed the food (which may or may not be the current owner of the food), the type of establishment and what product(s) the facility manufactures/processes. Therefore, the fact that FDA has a registration from a manufacturer, processor, packer, or holder of an article of food does not necessarily facilitate contacting the owner of an article of food that has been detained. Nor is information identifying the owner of the food necessarily readily available from the records that are

required to be maintained under section 306 of the Bioterrorism Act.

(Comment 75) One comment asks whether the agent in charge of the place where the article of food is located is the same U.S. agent who is responsible for registration and prior notice under the Bioterrorism Act.

(Response) Use of the term "agent in charge" in this final rule simply means the person who is in charge of the place where an article of food is located at the time of a detention. The registration interim final rule (68 FR 58893), issued under section 305 of the Bioterrorism Act, requires that all foreign facilities required to register have a U.S. agent. The U.S. agent must be a person residing or maintaining a place of business in the United States, whom the owner, operator, or agent in charge of a foreign facility designates as its U.S. agent for purposes of registration. Thus, depending on where and when an article of food is detained, the U.S. agent may or may not be the same person as the agent in charge of the place where an article of food is located at the time of a detention. The prior notice interim final rule (68 FR 58974) does not require a U.S. agent..

(Comment 76) Several comments state that the exporting country of an article of food that has been detained must receive information concerning the detention so that it may take

appropriate action. These comments suggest that FDA should contact the embassy of the country or the competent authority of the country. A few comments state that various parties should be informed of the administrative detention of imported articles of food (e.g., the exporter, agent or importer, and the customhouse broker). A few other comments state that FDA should be able to notify the recipients of products subject to the detention order at multiple locations by accessing records maintained under the recordkeeping section of the Bioterrorism Act.

(Response) FDA disagrees with these comments in part. FDA will issue the detention order to the owner or agent in charge of the facility where the food is located and, as stated previously, the owner of the food, if their identity is readily available. However, FDA does not currently plan to routinely publicize the issuance of detention orders. The parties who receive the detention order may choose to inform any additional interested parties regarding the detention. In the event of a public health emergency, FDA may issue a Talk Paper or Press Release with information regarding an article of food that presents a threat of serious adverse health consequences or death to humans or animals. In such an emergency, FDA also may inform other departments, agencies or governments to ensure public health protection, as deemed appropriate based on the circumstances of each case.

Although it may be possible to identify other interested parties by accessing records maintained under the recordkeeping provisions, we do not believe that it is appropriate for FDA to be obligated to notify all of the various parties requested by the comments. Interested parties may request information regarding administrative detentions under an FOIA request. Such information may be released after FDA has removed any information that is protected from disclosure to the public.

(Comment 77) One comment suggests that FDA should publish information concerning administrative detentions in the Import Refusal Report. A few other comments state that information concerning administrative detentions should be considered confidential and only disclosed to the owner of the products and the exporting country when there is a proven threat of serious adverse health consequences or death to humans or animals. These comments suggest that such disclosure should be through a rapid alert system. Some comments suggest that we devise and test a method of communicating essential information to key industry officials in the United States in the event of a food security event.

(Response) As we stated previously, FDA will issue the detention order to the owner, operator, or agent in charge of the facility where the detained article of food is located, and as stated previously, the owner of the food if its identity is

readily available. At this time, we have no plans to routinely publicize the issuance of detention orders, e.g., in Import Refusal Reports or the European Union's Rapid Alert System. This is consistent with the practice FDA uses for medical device detentions, which are not routinely publicized in the manner suggested by these comments.

However, FDA agrees that there may be information related to administrative detention of food that is confidential or classified. A number of statutes, regulations, and policies address protection of these kinds of information from unauthorized disclosure.

We believe the request for FDA to devise and test a method of communicating essential information to key industry officials in the United States in the event of a food security event is intended to include activities beyond administrative detention. Consequently, this discussion is outside the scope of this rulemaking.

(Comment 78) One comment states that procedural safeguards should be put in place to protect both manufacturers and their customers during what is essentially a seizure-type action. This comment recommends that FDA revise the regulation to ensure that, similar to FDA's seizure authority under the FD&C Act and relevant court rules, notice of detention be

accompanied by personal service upon the responsible party at individual locations.

(Response) FDA believes that the regulation in its present form adequately protects the interests of potential claimants. We note that administrative detention is not the equivalent of a seizure action, but is instead an administrative action that may precede a seizure action in Federal Court. If we were to institute a seizure after an administrative detention, the government would provide notice of that action in accordance with the Federal Rules of Civil Procedure and applicable local rules, which vary as to their requirements for personal service.

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

(Comment 79) A couple of comments state that the detention order should include a copy of the written approval granted by the authorized FDA representative. These comments state that the approval should include the information upon which the administrative detention was based, what actions will be taken with the product, and the expected time period for which the product will be held. A few other comments state that the detention order should include information such as grower codes, lot codes and other identifiers. A few comments believe it would be valuable for the appeal procedures and applicable deadlines to be explained in the detention order. One comment suggests

that the detention order should include provisions regarding the appropriate storage and transportation conditions, such as refrigerated foods kept under 40 degrees Fahrenheit (F) and frozen foods kept under -4 degree F to meet the regulatory requirements and common industry practices and satisfy their customer expectations.

(Response) FDA agrees in part with these comments. Section 1.393(b)(6) requires that the detention order include a brief, general statement of the reason for the detention. Section 1.393(b)(4) requires that the detention order include the period of the detention. Section 1.393(b)(3) requires that the detention order include information about the identification of the detained article of food. Identifying codes, such as lot numbers, may be included in the description of the detained article of food provided on the detention order. However, most food products are not required to bear a manufacturer's code; thus, this information may not be available. FDA notes that section 303 of the Bioterrorism Act provides that FDA may detain food for up to 30 calendar days to enable FDA to institute a seizure or an injunction action. Section 1.393(b)(10) requires that the detention order include the text of section 304(h) of the FD&C Act (section 303 of the Bioterrorism Act), as well as

§§ 1.401 and 1.402, which describe the administrative detention authority, who may submit an appeal, and the requirements for submitting an appeal, respectively.

Section 1.393(b)(7) requires that the detention order include a description of the appropriate storage conditions, and § 1.393(b)(8) requires a description of any applicable conditions of transportation. As we stated earlier, FDA will determine the conditions under which detained food must be held on a case-by-case basis, based upon the totality of information available to us about the article of food. The record evidencing written approval and the detention order would be released to a requester under an FOIA request after FDA removes any information that is protected from disclosure to the public.

(Comment 80) Another comment states that the detention order should include the type of analysis, procedures for analysis, and the criteria used to determine if the product is adulterated. This comment further states that it is not clear who will do the sampling, who will pay for this process, and whether there will be a guarantee that the food has not been contaminated.

(Response) FDA disagrees with this comment because the nature of bioterrorist attacks or other food emergencies makes it difficult to predict whether sampling and analysis will be necessary, or the types of analyses that will be needed. If an

analysis is done, FDA may disclose the type of analysis or the analytical procedure during an informal hearing. FDA routinely uses approved and validated methods. For information related to FDA's laboratory, laboratory procedures, new techniques and useful analytical findings in support of FDA regulatory activities. (See http://www.fda.gov/ora/science_ref/default.htm.) In most situations, FDA will do the sampling and offer to pay for the sample. FDA will do the sample analyses. However, the agency cannot guarantee that a particular article of food has not been contaminated, even if there are negative analytical findings of samples of the article. Given the nature of bioterrorist acts, the varied possible scenarios for contamination of food, and the various possible contaminants that may be used, we do not believe that it is possible for anyone to absolutely guarantee that a particular article of food has not been contaminated.

I. Comments on What Is the Appeal Process for a Detention Order?

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

(Comment 81) One comment asks whether someone who does not have a proprietary interest in the detained object, but has a commercial interest (e.g., the importer, U.S. agent (as defined in the registration interim final rule), or shipper), can appeal

a detention order. Another comment asks whether someone designated by the owner, such as a lawyer or food technologist, can appeal a detention order. One comment indicates that the rule should state whether the person who appeals the detention has to have certain characteristics and reside in the United States.

(Response) We do not know what is meant by "certain characteristics," but a person entitled to appeal a detention order need not be a resident of the United States. With respect to whether a proprietary interest is required, section 304(h)(4) of the FD&C Act states in part that "any person who would be entitled to be a claimant for such article if the article were seized under section (a) may appeal the order." Thus, if a person were entitled to be a claimant in a seizure action, that person would also be entitled to be a claimant in an appeal from a detention order. To be a claimant in a seizure action, a person must have an interest in the seized goods sufficient to confer standing under both Article III of the U.S. Constitution, and Supplemental Rule C(6) of the "Federal Rules of Civil Procedure." ^(available at <http://www.uscourts.gov/rules>) The local rules of the Federal Court district in which a seizure or administrative detention occurs set forth the procedures by which a party establishes entitlement to be a claimant. A person who asserts an interest in, or right against, property that is the subject of an action must file a

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verified statement identifying the interest or right. The meaning of "verified statement" under Supplemental Rule C(6) 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. A determination of whether a party has a sufficient interest in the food is made on a case-by-case basis. As such, it is outside the scope of this rulemaking.

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

(Comment 82) FDA sought comments 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). One comment states that for appeals, and any other sections of the regulations that incorporate specific timeframes, the timeframes should be ruled by "international timetables."

(Response) FDA's understanding is that the comment is asking FDA to take international time zones into consideration when counting calendar days to meet the various timeframe deadlines described in this final rule. FDA disagrees with this comment. It is not feasible for FDA to make exceptions on how we count calendar days based on the time zone where the owner of the goods is located. The total elapsed time from the time the

detention order is issued throughout the detention process will be the same regardless of the time zone in which the detention order was issued. Under the final rule, the "start" and "end" times of a detention order, and all deadlines within that period, will be measured by the time zone in which the detention order was issued.

(Comment 83) One comment says that FDA stated that the request for appeal by the industry could be verbal, and FDA will respond by mail or letter, but it is not clear how quickly FDA is going to answer the request. Another comment asks whether the 5 days from the date of appeal that FDA has to issue a decision on an appeal are natural or working days.

(Response) FDA believes that this comment misunderstood the requirements in § 1.402(a). Section 1.402(a) of this rule requires all appeals to be submitted in writing. The written appeal can be delivered to the FDA District Director in person, by mail, e-mail, or fax. As stated previously, the Bioterrorism Act requires FDA to issue a decision on an appeal within 5 calendar days after the date of appeal. Therefore, FDA will issue a decision within the 5-calendar day statutory deadline. However, as FDA states earlier in this rule, FDA is committed to acting as expeditiously as possible when we detain an article of food, especially in the case of an article of perishable food. Section 1.405 requires FDA to issue a decision on appeal within

5 calendar days from the date of appeal. Section 1.377 of the rule defines "calendar day" to mean every day shown on the calendar, which includes holidays and weekends.

(Comment 84) One comment states that Congress's directive that FDA issue procedures to expedite detention of perishable food appears at section 304(h)(2) of the FD&C Act as added by section 303(a) of the Bioterrorism Act, which is a provision relating to the "period of detention." The comment asserts that FDA's proposal to implement this directive, however, relates only to appeals of detention orders, a subject addressed at section 304(h)(4) of the FD&C Act. In the comment's opinion, Congress's decision to place its mandate for the expediting of administrative detention procedures for perishable foods in the section entitled "period of detention," rather than in the section entitled "appeal of detention order," indicates its intent that FDA take direct action to accelerate the pace with which erroneously detained perishable food may be released, not merely the pace at which an informal hearing may be convened. The comment states that Congress required issuance of the expedited procedures to safeguard a claimant's rights with respect to perishable food, and FDA's proposal to restrict the rights of prospective claimants to appeal detention of such food is inconsistent with that objective. Another comment is

concerned that the appeals procedure may cause undue delay in the detention process.

(Response) FDA disagrees with these comments. Section 303(a)(2) of the Bioterrorism Act requires the Secretary to provide procedures for instituting certain judicial enforcement actions under the FD&C Act on an expedited basis with respect to perishable foods. FDA provides for expedited procedures for initiating seizure actions in § 1.383 by requiring FDA to submit a seizure recommendation for a detained perishable food to DOJ within 4 calendar days after FDA issues the detention order, unless extenuating circumstances exist. Although a claimant may opt not to appeal the detention order, FDA is required to offer the opportunity to appeal under section 304(h)(4) of the FD&C Act.

The appeal and hearing procedures assist the process of appealing a detention order. Section 304(h)(4) of the FD&C Act requires FDA to confirm or terminate any detention order within 5 calendar days after an appeal is filed. However, if a claimant files an appeal sooner rather than later in the time period for filing appeals, a decision to terminate a detention order could occur before the 5-calendar day statutory deadline is reached.

(Comment. 85) One comment suggests that FDA should provide for an "automatic appeal" on the second day after an administrative detention order is issued, with a decision on the

appeal to be made within 24 hours of the hearing. Another comment requests that the appeal process for chilled, live shellfish that have a commercial shelf life of 48 hours following harvest, be measured in hours, with all attempts to release suitable consignments within 24 hours.

(Response) FDA disagrees with these comments and maintains the same timeframe for perishable food as we proposed. A more rapid procedure is not practicable. Furthermore, even a more rapid procedure would result in reductions in the shelf life of highly perishable food products, such as fresh seafood, possibly requiring such products to be reconditioned and sold as something other than "fresh seafood." We do plan to work with claimants to preserve the article of food when possible; a request for modification of a detention order, for instance, may be used to move a detained article of food from refrigerated storage to a freezer. As we stated earlier, we are committed to acting as expeditiously as possible when we detain an article of food.

(Comment 86) A few comments ask that FDA treat all foods in the same manner as perishable foods for appeal purposes. Another comment indicates that a "reasonable period" of 20 calendar days, which could be extended to 30 calendar days, means in practical terms that all perishable foods/drinks, including those "commercially" perishable, are no longer

suitable for sale. The comment states that this means that, if a "fast-track" appeal for perishable food does not allow a quicker release of detained food when it is found to be safe, the value of such an appeal is questionable.

(Response) FDA disagrees with these comments and is maintaining the same timeframes for appeal as we proposed. The Bioterrorism Act allows FDA to institute a detention for a reasonable period, not to exceed 20 calendar days, unless a greater period, not to exceed 30 calendar days, is necessary to enable the Secretary to institute a seizure or injunction action. As stated earlier, the Bioterrorism Act also requires FDA to provide an opportunity to file an appeal of the detention order and to confirm or terminate the detention order within 5 calendar days after an appeal is filed. If a claimant files for an appeal sooner rather than later in the time period for filing appeals, a decision to terminate a detention could occur before the 5-day statutory deadline for rendering a decision on appeal. The Bioterrorism Act also requires FDA to confirm or terminate a detention order within 5 calendar days after an appeal is filed, whether the food is a perishable commodity or not. Thus, the claimant of a nonperishable food, including one that is seasonal in nature could file an appeal within the first 2 calendar days after receipt of the detention order rather than later in the 10 calendar days allowed under the procedures for a nonperishable

food, and obtain a decision as soon as than would occur under the "fast-track" appeal process for perishables.

(Comment 87) One comment states that FDA should establish that, in cases where the detention order is given to someone who is not authorized to appeal it, the time table for submitting the appeal should not begin until a person who has the right to appeal has been notified.

(Response) FDA disagrees with this comment. As described in § 1.392(a) of the final rule, FDA will provide a copy of the detention order to the owner or agent in charge of the place where the detained articles of food located. Under § 1.392(a) of this rule, FDA also will provide a copy of the detention order to the owner of the food if their identities can be readily determined. Under § 1.392(b) of this rule, 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 also will 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. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any

information he or she may have regarding the identity of the owner of the article of food. There may be times when FDA cannot determine who would be entitled to be a claimant of the article. The purpose of administrative detention is to hold in place, and protect against any movement that could lead to further distribution of, the food that poses the threat of serious adverse health consequences or death to humans or animals. Consequently, the action is against the articles, not the owner of the articles. We believe that it is likely that any responsible firm who has had product detained on their premises will notify the rightful owner. In addition, it is an owner's responsibility to know the whereabouts of its food product, and to be familiar with the chain of custody related to that food.

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

(Comment 88) Several comments argue that FDA should not have discretion to deny a request for an informal hearing; the comments argue that our interpretation is inconsistent with the Bioterrorism Act's plain meaning and legislative history, and violates due process under the Fifth Amendment. A few comments indicate that FDA must determine and specify the criteria used to concede or deny a hearing.

(Response) FDA disagrees with these comments because the Bioterrorism Act requires only that FDA "provid[e] opportunity

for an informal hearing"; the statutory language does not require FDA to conduct an informal hearing for every claimant who appeals a detention order. Our interpretation of this section of the Bioterrorism Act is consistent with our long-standing interpretation of similar statutory language in section 304(g) of the FD&C Act (21 U.S.C. 334(g)), which governs medical device detentions. FDA has authority to deny a hearing when the appeal raises no genuine and substantial issue of fact. (See Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 620-621 (1973).)

The final rule also is consistent with our regulation at § 16.26(a), which states that we do not have to grant all requests for hearings:

A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom the authority to make the final decision on the matter has been delegated under part 5 determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be

given to the parties explaining the reason for denial.

(Comment 89) FDA sought comments on the timeframes for holding the informal hearing. One comment states that the hearing should be held within 2 calendar days from appeal. Another comment asks that FDA shorten the period for holding a hearing in appeals for perishable food to 3 calendar days. One other comment states that, because the timing of the hearing has no direct impact on the rendering of the agency's confirmation or termination of the detention order, FDA's proposal would have no inherent effect on expediting the release of erroneously detained perishable food. Another comment believes that the FDA has wisely decided upon an expedited hearing process for perishable foods that are detained administratively, but states that the proposed process is not fast enough. The comment notes that, as stated in the proposed regulation, an appeal and request for a hearing must be filed within 2 calendar days of receipt of a detention order. If FDA grants the request, the hearing will be within 2 calendar days after the date the appeal is filed. FDA's decision on the appeal must be issued within 5 calendar days of the date of the appeal filing. The comment states that this proposed procedure will still take up to 7 calendar days, and for highly perishable fresh seafood products, this would leave only 2 to 3 calendar days of acceptable shelf

life remaining. Practically, these remaining days would be used in distribution so that a shipment of perishable food (e.g., fresh seafood), in most cases, would be a total loss. One comment asks that FDA extend the time limit so that exporting countries will have enough time to prepare documents. Another comment states that, because the presiding officer may be an RFDD from another region or another official senior to the district director, the transit time from one region to the other must be factored into the established hearing deadlines.

(Response) FDA acknowledges that the timeframes for holding a hearing are relatively short. Because the Bioterrorism Act requires FDA to issue a decision on an appeal within 5 days after the appeal is filed, FDA had to establish quick timeframes for holding the hearing to ensure that we adhere to the statutory requirement. Short timeframes also should help to minimize the impact on an article of food that is detained, but is subsequently released from detention. FDA did not receive any comments that suggested alternate procedures that would both allow for a hearing and for compliance with the statutory requirement for the agency to issue a decision on an appeal within 5 days after the appeal is filed. Therefore, FDA is maintaining the timeframes we proposed.

If FDA grants a hearing, the timeframes will adhere to § 1.402(d) of the rule, which requires FDA to hold a hearing for

food that has been detained within 2 calendar days after the date the appeal is filed. A claimant can control the time by which the hearing has to take place and the time by which FDA has to issue a decision if the claimant appeals the detention order sooner rather than later, i.e., this final rule specifies the maximum timeframes claimants have to file an appeal.

Claimants certainly can file earlier.

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

(Comment 90) Many comments recommend that the individual presiding over an appeal hearing must be senior to the individual who approved the detention order. Another comment suggests that the informal hearing on an appeal of a detention order also should allow third-party participants or attendees, not just participation by an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

(Response) FDA disagrees with the comment that the individual presiding over an appeal hearing must be senior to the individual who approved the detention order. FDA's regulation on presiding officers, § 16.42, ensures that the officer presiding over an appeal hearing is free from bias or prejudice.

Under §§ 16.42(c)(2) and 1.404, an FDA Regional Food and Drug Director, or another FDA official senior to an FDA District

Director, may preside over an appeal hearing as long as that person has not participated in the investigation or action that is the subject of the hearing, or is subordinate to a person, other than the Commissioner of Food and Drugs (the Commissioner), who has participated in such investigation or action.

With respect to the suggestion that the hearing should allow participation or attendance by third parties, § 16.60 states that "a regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information * * *." FDA also notes that, if the hearing involves the discussion of classified information, we only would allow participation by parties, both within and outside FDA, by persons with the appropriate security clearance.

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

(Comment 91) Several comments recommend that FDA's decision on appeal should be sooner than within 5 calendar days after the appeal is filed, e.g., within 2 calendar days or 3 calendar days after the appeal is filed. Many comments recommend that FDA's decision on appeal should be made within 2 calendar days after

the hearing for detained perishable and nonperishable foods. Another comment asks whether FDA can realistically accommodate administrative detention appeals in a timely manner. These comments state that, when identifying the detention and appellate timeframes, the agency must consider the logistical requirements (placing shipping orders, transportation and other distribution requirements) in evaluating the potential shelf life and value of the food product.

(Response) Under section 303 of the Bioterrorism Act, FDA must confirm or terminate a detention order within 5 calendar days after an appeal is filed. Because each detention and appeal will be assessed based on the facts of the particular situation, FDA can not know in advance what work will have to be accomplished or what information will have to be considered to make our decision to confirm or terminate a detention order following an appeal. Therefore, it is not appropriate to limit the authority and flexibility that Congress provided in the Bioterrorism Act by reducing the number of calendar days the agency has to confirm or terminate a detention order following an appeal. FDA notes that these are maximum timeframes for rendering a decision. As stated previously, FDA intends to act as expeditiously as possible. Thus, FDA may render decisions on appeal sooner than 5 calendar days if we are able to do so.

(Comment 92) One comment acknowledges that confirmation of a detention order by the presiding officer is to be considered a final agency action for purposes of the Administrative Procedure Act (5 U.S.C. 702) and asks if it is possible to further appeal a decision on the detention.

(Response) After the presiding officer confirms the detention order, no provisions for further review or appeal within the agency or HHS apply. A claimant's further recourse would be to initiate proceedings in Federal court.

In the proposed rule, § 1.402(d), which governs the requirements for submitting an appeal, referenced the definition of an informal hearing in section 201(x) of the FD&C Act. Section 201(x)(5) of the FD&C Act requires the presiding officer to prepare a written report of the hearing, and states that the participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report. FDA is revising §§ 1.403 and 1.405 to provide this opportunity for the hearing participant to review and request changes to the conclusions of the presiding officer, as reflected in his or her proposed decision. FDA is revising § 1.403(h) to clarify that § 16.60(e) and (f) does not apply to an informal hearing on an administrative detention. Revised §§ 1.403(h) and 1.405(a) provide that the presiding officer must issue a written report of the hearing, including a proposed decision with a statement

of reasons. This section also provides for a 4-hour opportunity during which the hearing participant may review and comment on the written report. Under § 1.403(h), the presiding officer will then issue the final agency decision.

FDA is also revising § 1.403, which governs the requirements that apply to an informal hearing, by adding new paragraph (j) to make clear that § 16.119 does not apply to an informal hearing on an administrative detention. Section 16.119 states that, after any final administrative action that is the subject of a hearing under part 16, any party may petition the Commissioner for reconsideration or a stay of the decision or action.

FDA is revising § 1.403 to clarify that § 16.80(a)(4) does not apply to an informal hearing on administrative detention. Revised § 1.403(i) states that the presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

FDA is also revising § 1.403 to clarify that § 16.95(b) does not apply to an informal hearing on an administrative detention. New § 1.403(k) states that the administrative record of an informal hearing on an administrative detention as specified in §§ 16.80(a)(1), (a)(2), (a)(3), (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. In addition, § 1.403(k) states

that, for purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

(Comment 93) One comment argued that the proposed expedited procedures for perishable foods do not accomplish what Congress intended in the Bioterrorism Act, i.e., implementing regulations mandated by the Bioterrorism Act are supposed to achieve accelerated termination of detention orders and release of the detained perishable food when the agency finds there to be a lack of credible evidence or information that the detained article presents a threat of serious adverse consequences or death to humans or animals. The comment further explains that our proposed procedure would do nothing to expedite release of such food. The comment further states that, in some cases, the proposed procedure would allow FDA 3 calendar days after an informal hearing to render its decision with respect to perishable food, but only 2 calendar days with respect to nonperishable food (the example in the comment uses an appeal date of 2 calendar days after receipt of the detention order for both a perishable and nonperishable food).

(Response) FDA disagrees with this comment because it appears to confuse the expedited procedures mandated by the Bioterrorism Act for initiating certain enforcement actions against detained perishable food with the process for appealing

a detention order. The Bioterrorism Act requires the Secretary to provide procedures for instituting certain judicial enforcement actions under the FD&C Act on an expedited basis with respect to perishable foods. Section 1.383 provides for expedited procedures for initiating seizure actions by requiring FDA to submit a seizure recommendation against a detained perishable food to DOJ within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.

The appeal and hearing procedures assist the process of appealing a detention order. The Bioterrorism Act requires FDA to confirm or terminate any detention order within 5 days after an appeal is filed. However, if a claimant files for an appeal sooner rather than later in the time period for filing appeals, a decision on a detention order could occur before we are statutorily required to render that decision.

FDA notes that the comment is correct in that there is one situation where FDA would have more time to consider whether to confirm or terminate a detention order for perishable food than for nonperishable food and that would be if the appeals for both a perishable food and a nonperishable food were filed on the same calendar day and the hearings were held on the second and third calendar days following the appeals, respectively. The only way to eliminate this situation while still allowing FDA up

to 5 calendar days to render a decision on appeal is to revise the timeframe within which FDA would hold a hearing, if granted, to 2 calendar days after the date the appeal is filed for both perishable and nonperishable food. FDA is, therefore, revising § 1.402(d)(1) and (d)(2) to state that if a hearing is granted, it will be held within 2 calendar days after the date the appeal is filed for both perishable and nonperishable food. As we stated previously, FDA intends to proceed as expeditiously as possible to resolve all issues involved with administrative detentions.

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

(Comment 94) Many comments are concerned that this provision may lead to withholding information that a company would find necessary to prepare its defense against a detention order, including sampling and testing of the product to determine whether the article of food presents a threat of serious adverse health consequences or death to humans or animals. These comments also are concerned that this provision would restrict a company's ability to appeal or prepare for a hearing on the detention order. The comments ask that FDA provide, whenever possible, the specific reason why the agency believes the article of food presents a threat of serious adverse health consequences or death to humans or animals, i.e., the product may be contaminated with agent X.

(Response) FDA is finalizing this provision as proposed. Under existing law, there is no accommodation or exception for disclosing classified information to individuals without the proper security clearance. However, we will provide as much information as we can without compromising the classified nature of the information. FDA notes that private companies can choose to obtain private facility security clearances through the Defense Industrial Security Clearance Office (DISCO) within the Defense Security Service (DSS), which is an agency within the Department of Defense.

FDA indicated in the proposed rule that the agency may develop general regulations for handling classified information on an agency-wide basis. After further review, however, we have decided that such regulations are unnecessary. The handling of classified information is a standardized process across the Federal Government and is governed by Executive Order 12958. Executive Order 12958 was last amended in March of 2003 (68 FR 15313, March 28, 2003).

IV. Conforming Amendment to Part 10

We are amending § 10.45(d) because under the administrative detention procedures, it is the final decision of the presiding officer, and not the Commissioner, that constitutes final agency action.

V. Conforming Amendment to Part 16

We are amending § 16.1(b)(1) to include section 304(h) of the FD&C 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.

VI. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

We have examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs us 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 regulatory action 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 or more, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also classifies a regulatory action as significant if it raises novel legal or policy issues. We have determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

*Costs and Benefits of Administrative Detention Final Rule:**Summary*

Administrative detention of food is a new enforcement tool, and we are not able to directly estimate how often it will be used. For an indirect estimate, we assumed that events that trigger certain existing enforcement actions represent a pool of events some of which might in the future trigger administrative detention. To estimate the size of this pool, we used the sum (for fiscal year 2002) of Class 1 recalls (184), instances in which we moved directly to seizure (16), and 10 percent of the instances referred to State authorities (23, or 0.01×230 actions referred to States). This sum--223 actions--represents the upper bound number of times we anticipate using administrative detention. The lower bound is zero; we may not use administrative detention at all.

The benefits of administrative detention will be the value of the illnesses or death prevented because the agency administratively detained food suspected of being adulterated. These benefits will be generated if the following two conditions hold: (1) The food is in fact adulterated, and (2) administrative detention prevents more illnesses or deaths than would have been prevented had we relied on our existing enforcement tools. The more often these conditions hold, and the larger the amount of adulterated food administratively detained,

the larger will be the benefits of this final rule. There may also be benefits in terms of deterrence, to the extent that administrative detention increases the likelihood that adulterated products will not be shipped in the future.

One of the main costs of administrative detention, the loss of product value over the detention period, is associated with the administrative detention of food that is not in fact adulterated.

We do not know what fraction of detained products will prove to not be adulterated. For an upper bound we used the fraction of imported foods that we detain and then release: 48 percent. This percentage is an overestimate as applied to administrative detention, because less evidence is needed to detain an import under our current program than will be required to detain a food administratively. The lower bound percentage is zero, because we might never detain a food administratively that is not adulterated.

We estimate the range of costs for this final rule using a range of 0 to 223 administrative detentions and a range of 0 to 48 percent of those detentions involving products that turn out not to be adulterated. The total costs of this final rule will be the sum of the following components:

- Additional transportation to secure storage facility,

- Additional storage,
- Delay of conveyances that contain detained products,
- Loss of product value for foods with limited shelf lives,
- Marking or labeling of detained products, and
- Costs of appeals of administrative detentions.

The following summary table 1 shows the estimated range of costs:

Summary Table 1.--Annual Costs for Administrative Final
Rule

Types of Cost	Costs (in Millions)
Transportation	\$0 to \$4
Delay of Conveyances	\$0 to \$4
Storage	\$0 to \$2
Loss of Product Value	\$0 to \$22
Marking or Labeling	\$0 to \$2
Appeals	\$0 to \$16
Total	\$0 to \$50

Regulatory Options

We considered the following regulatory options in the analysis of the proposed rule: (1) Take the proposed action (establish a regulatory framework for detaining food

administratively, with expedited procedures for instituting certain enforcement actions involving perishable food); (2) take the proposed action but change the definition of perishable food, the maximum timeframe for administrative detention of perishable food, or both; (3) take the proposed action but define the level of security we require for transportation and storage; (4) 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 received comments pertaining to the first two options. We also received some comments on the maximum timeframe for administrative detention of nonperishable food. We have included these under Option Two and have renamed that option as follows: Take the proposed action but change the definition of perishable food, the maximum timeframe for administrative detention, or both. In addition, we received comments suggesting that we revise the proposed rule in various ways that we did not address in any of the other regulatory options. We will discuss the economic implications of these comments under a new regulatory Option Five: Take the proposed action but revise the proposed action in some other way. In many cases, a comment discussed a cost and suggested a way to minimize that cost. In those cases, we discuss the portion of the comment that dealt with the cost of

the proposed rule under Option One (take the proposed action), and we discuss the portion of the comment that suggested revising the rule under one of the other options.

1. Option One: Take the Proposed Action (Establish a Regulatory Framework for Detaining Food Administratively, With Expedited Procedures for Instituting Certain Enforcement Actions Involving Perishable Food)

General

(Comment 95) One comment argues that our analysis of the proposed rule did not meet guidelines established by the Office of Management and Budget (OMB) for the five elements of a regulatory impact analysis. According to this comment, we did not adequately consider the need for, and consequences of, the rule on society in general; we did not show that the potential benefit of the rule outweighs the costs; we did not select our regulatory objectives with the goal of maximizing net benefits for society; we did not select the regulatory alternative having the lowest net cost for society; and we did not consider the affected food industries, potential future regulatory actions, and the weak state of the national economy.

(Response) We disagree that we did not meet the guidelines established by OMB for a regulatory impact analysis. We were unable to estimate annual benefits because this rule addresses low probability but potentially high risk events. These events

do not occur regularly, and we have insufficient information to predict their occurrence. Our inability to estimate annual benefits meant that we were also unable to evaluate regulatory options that generated tradeoffs between costs and benefits to the extent that we would normally do so. However, the guidelines for regulatory impact analyses acknowledge that we will not always have sufficient information to quantify all relevant effects.

Benefits

(Comment 96) One comment suggests that the proposed rule would not generate any benefits because we can already request Class I recalls in situations in which we could use administrative detention. Another comment argues that the proposed rule would do little to improve food safety.

(Response) We discussed the benefits of the proposed rule given our enforcement alternatives prior to enactment of the Bioterrorism Act, including Class I recalls, in the analysis of the proposed rule. These comments did not provide information that would allow us to revise that discussion.

(Comment 97) One comment argues that we failed to consider the potential benefits of the proposed rule that go beyond avoiding adverse health consequences. This comment notes that an intentional food contamination event could have significant national and international implications because it could lead

authorities to impose restrictions on the distribution and sale of similar products or lead some consumers to avoid buying the product. As an example of the latter effect, this comment notes that the discovery of a single cow in Alberta, Canada that tested positive for bovine spongiform encephalopathy (BSE) caused significant changes in cattle prices and retail sales of beef products.

(Response) Preventing adverse health consequences from adulterated food may reduce disruptions in consumer demand for that type of food. The effect of changes in consumer demand is primarily distributional because such changes harm some industries and help others. Of course, these distributional effects may be significant for the firms involved. In addition, these effects could generate net social costs by causing temporary unemployment, the loss of value of specialized inputs, and the loss of inventory, that are not balanced by increases in employment and the value of specialized inputs, and the use of otherwise unusable inventory, in competing industries that benefit from the shift in demand. Preventing adverse health consequences from food may also reduce the probability that authorities would place restrictions on the distribution and sale of food. The effect on industry of these restrictions would be similar to the effect of a shift in consumer demand, but these restrictions might also generate social costs in the

form of lost consumer utility and enforcement costs because they would not necessarily reflect underlying changes in consumer demand. We recognize that preventing such effects would be a benefit of this rule. However, we have insufficient information to quantify these effects.

Costs

In the analysis of the proposed rule, we requested comments on a number of issues. These issues included the type of transportation, the cost of any specialized transportation, the amount of food that we might detain in an average administrative detention, the size of an average truckload of food that we might detain, the distances that we might need to transport food, storage and handling rates, labeling and marking costs, and the impact of the specific requirements of the proposed appeals procedures. We did not receive comments on any of these issues except for the appeals procedures. However, we received comments on a number of other issues relating to the costs of this rule.

(Comment 98) One comment argues that the administrative burden generated by the proposed rule would dilute effective food safety measures by industry and divert our resources away from more effective food safety measures. This comment suggests that the net effect of the proposed rule would be to reduce food safety rather than increase it. Another comment argues that the

proposed rule might increase food safety risks because it would slow the movement of food through the distribution system, thereby creating additional opportunities for adulteration. The comment envisioned numerous unguarded storerooms or garage sheds containing detained food, which the comment suggests would significantly increase the statistical probability that that food would be attacked.

(Response) This rule will not generate any administrative burden for a particular firm unless that firm were actually involved in an administrative detention. In the analysis of the proposed rule, we estimated 0 to 223 administrative detentions per year, and we estimated the universe of potentially affected firms to be 1.6 to 1.8 million firms. Therefore, the expected annual administrative burden for all potentially affected firms would be quite small and would not significantly displace food safety expenditures by industry. Similarly, this rule will only generate enforcement costs in those cases in which we choose to use it, and we would only use it if it were the most effective enforcement alternative available in a particular situation. Therefore, we disagree that this rule will generate a significant reallocation of our enforcement resources away from more effective food safety measures. This rule would slow distribution times for any food that we detain administratively and subsequently release. However, we can require firms to move

food to secure storage or take other actions to ensure that food that we detain administratively is secure. Therefore, food that we detain administratively would not make an easy target for intentional adulteration during the detention period.

(Comment 99) Some comments note that the proposed rule could affect a wide variety of firms. These comments discuss live food animals; restaurants; color pigments used in indirect food contact applications; outer food packaging; raw materials and formulated products that are used as components in the manufacture of food-contact articles, such as conveyor belts, oven gaskets, coatings for film, paper, and metal substrates, adhesives, antifoam agents, antioxidants, polymeric resins, polymer emulsions, colorants for polymers, rubber articles, release coatings, and the like; ceramic and lead crystal tableware; and animal feed and pet food.

(Response) We discussed the wide variety of firms that might be affected in the analysis of the proposed rule. However, we based the cost estimate on conventional fresh or processed food for human consumption. The cost of an administrative detention for each of the product categories and types of firms mentioned by these comments would vary along a number of dimensions, including the production and distribution system, the typical mode of transport, the typical lot or shipment size, handling and storage costs, and rate of product

value loss, if any. The comments did not provide estimates of how the costs for these firms would differ from the costs we estimated for the analysis of the proposed rule, and it would be costly and time consuming for us to analyze the costs for every type of firm and product that this rule might affect. In addition, as we discuss later in this analysis, if it were technically difficult or impossible to adulterate these types of food, then we would rarely or never receive information that would require us to detain it administratively. Based on these considerations, we have not revised the analysis to include a discussion of each of these types of products and firms.

(Comment 100) Some comments were concerned that any labeling or marking that we put on food that we detain administratively would remain on the food if we later determined that the food was not adulterated and terminated the detention order. One comment argues that we should place any marking or labeling on packing cases and not on the product itself. The comment notes that consumers would be skeptical of purchasing a product that we had marked in conjunction with an administrative detention.

(Response) Labeling or marking would not lead to a loss of product value because, if we terminated an administrative detention order, we would remove any labeling or marking, or authorize someone else to remove it.

(Comment 101) One comment suggests that we add the expiration date of administrative detention orders to the information that we put on the tags or labels that we affix to food that we detain administratively. The comment also suggests that we amend the tags or labels if we later amend the expiration date.

(Response) We would indicate the initial 20- or 30-calendar day expiration date of an administrative detention order on any tags or labels that we affix to food that we detain administratively. If the initial period for the detention were 20 calendar days and we extended the period an additional 10 calendar days, then we would amend the tags or labels to reflect the new expiration date of the detention period. We did not include the cost of amending tags or labels in the analysis of the proposed rule. We assume that the cost of amending a tag or label is the same as the cost of affixing the tag or label. We do not know how frequently we may need to use the additional 10 calendar days of detention, so we also assume that we may need to amend every tag or label. Under these assumptions and using the same procedures that we used to estimate these costs in the analysis of the proposed rule, we estimate this cost to be \$0 to \$2 million per year, rather than \$0 to \$1 million per year that we reported in the analysis of the proposed rule.

(Comment 102) One comment argues that we might detain entire containers or truckloads, but subsequently determine that only one or a very few cases of food are actually adulterated. This comment suggests that we might release a majority of the food that we detain administratively. Another comment suggests that we might intentionally detain more food than we believed was actually adulterated. For example, we might believe that a particular lot was adulterated, but we might detain the container that holds that lot along with other lots. One comment notes that a single shipping container might hold many small shipments of different products of different origins. The comment suggested we might detain the entire container in such a situation.

(Response) In the analysis of the proposed rule, we estimated that we might release 0 to 48 percent of the food that we detain administratively. Although this is not consistent with the comment's suggestion that we might release a majority of the food that we detain administratively, it is consistent with the notion that we might release a considerable portion of it. As we discussed in the analysis of the proposed rule, we based the upper end estimate of 48 percent on the number of import detentions that we subsequently released during the first three quarters of 2002. As we discussed in that analysis, it is highly unlikely that we would release a higher proportion of the

food that we detain administratively than the proportion of food that we place on import detention and subsequently release because the legal standard for administrative detention is higher than the legal standard for import detention. The comment did not provide sufficient information for us to change this assessment. If we determine that a container of food products contains both food that meets the criteria for administrative detention and food or other items that do not meet the criteria, the food or other items that can be readily segregated and not detained can be segregated and moved.

(Comment 103) Some comments argue that some food that has a shelf life of more than 7 days might suffer a significant loss of value if we detained it administratively under the conditions applying to nonperishable foods. One comment argues that this is true of snacks and snack ingredients. Another comment discusses pasteurized chilled juices and juice beverages that are transported and stored under refrigeration. This comment argues that most consumer outlets (retail and institutional) would not accept this type of food unless it had a remaining shelf life greater than it would have if we detained it administratively for 20 calendar days prior to delivery. This comment argues that the rate at which this food would lose value during an administrative detention is greater than the 1 to 3

percent per day that we assumed in the analysis of the proposed rule.

Some comments note that bakery products such as tortillas or snack cakes, might have a shelf life of 10 to 35 days, but retailers and distributors are more likely to reject delivery of these products, if the expiration date is less distant than other comparable products that are available at the time of purchase because consumers prefer products with more distant expiration dates. According to these comments, even a relatively brief administrative detention could render such products unmarketable. These comments also note that potato chips and cookies might have a shelf life of 60 to 120 days, but would be subject to a loss of value by the same mechanism. Some comments made a similar point about "nouveau" wines, which firms release for consumption on a specific date. These comments argue that this product would lose a significant amount of its value if it were not available for sale at the optimum date. These comments also note that the annual sales of this product typically take place within a brief period of 2 to 3 weeks.

One comment notes that farms often have limited on-farm storage and inflexible deadlines for delivering products to markets or for further processing. The comment notes that the loss of value of food that we detain administratively on farms could be very rapid. One comment discusses "fresh products"

that have a shelf life of more than 7 days. This comment argues that one would not be able to market these products if we detained them for 7 days because they would not have enough shelf life left.

(Response) In the analysis of the proposed rule, we assumed that all administrative detentions could last up to 30 calendar days. We also assumed that food with a shelf life of 8 to 30 days would lose 3 percent of its starting value per day, which would essentially reduce the value of that product to zero by day 30. We have revised the daily rate of value loss to the more precise 3.3 percent. It is possible that food with a shelf life of more than 30 days might also lose its entire market value during a 30-calendar day detention period. However, in many cases, one could presumably sell such food at a discount to reflect the shortened shelf life or the suboptimal selling time. To reflect the possibility that this food might lose all of its value during a 30-calendar day detention, we have revised the rate of product loss for all shelf life categories that we used in the analysis of the proposed rule to 3.3 percent per day. Under this assumption and using the same procedures that we used to estimate these costs in the analysis of the proposed rule, we estimate this cost to be \$0 to \$22 million per year, rather than \$0 to \$15 million per year that we reported in the analysis of the proposed rule.

(Comment 104) One comment notes that our proposed definition of perishable food refers to the shelf life of the food from the time it was produced rather than from the time we detain it administratively.

(Response) One implication of this comment is that food with a shelf life of more than 30 days might become unmarketable during the detention period if we detained it when it had only part of its shelf life remaining. We discussed this phenomenon in the context of a previous comment. However, another implication of this comment is that we may have overestimated the loss of value for food that we detain near the end of its normal shelf life. Under the linear method that we used to estimate loss of product value over time in the analysis of the proposed rule, such food would already have lost a considerable portion of its starting value for reasons unrelated to the detention. However, we do not need to revise our analysis to account for this effect because our estimated range of the potential annual loss of product value goes to \$0 at the low end.

(Comment 105) One comment discusses the shelf life of air freighted fish and fish products. This comment notes that chilled finfish has a normal commercial shelf life of about 7 days from the time of capture. They argue that attempting to extend the shelf life of this fish by freezing it would destroy

its commercial value. Some comments note that chilled, live shellfish and crustaceans have a commercial shelf life of about 48 hours from the time they are packed for export. This comment notes that one may extend the shelf life for some species by introducing them back into temperature controlled, oxygenated, salt water. However, these comments doubted that we intended to operate appropriate tanking facilities at airports to handle detained live seafood in this way. Consequently, these comments argue that the current timeframes for administrative detention would almost certainly eliminate the value of these products if we detained and subsequently released them. These comments argue that any detention period longer than 24 hours would result in a loss of the value of the product.

Another comment argues that a detention period of 7 calendar days was excessive in the case of fresh salmon because the quality of fresh salmon would begin to deteriorate within 4 days. One comment notes that, for perishable foods, the maximum time between receipt of the detention order and an appeal is 2 calendar days, and that we have 5 calendar days from receipt of the appeal to confirm or set aside the detention order. This comment argues that these time periods are impracticable and would lead to the loss of the product. Some comments note that the appeals process may take up to 7 calendar days, assuming owners request an appeal within 2 calendar days of receipt of

the administrative detention notice and we would reach a decision on the appeal 5 calendar days after the date of the filing of the appeal. This comment suggests that this would leave only 2 or 3 days of acceptable shelf life for highly perishable fresh seafood products, which would be insufficient time to distribute it to retail outlets. Thus, this comment suggests that the proposed procedure would lead to a total loss of value for this type of product.

(Response) These comments are consistent with the analysis of the proposed rule, in which we estimated that perishable food might lose up to all of its value during the detention period. We discuss suggestions to revise the rule under Options Two and Five.

(Comment 106) One comment argues that we might direct someone to move food that we detain administratively from refrigerated storage to a freezer. The comment notes that this might reduce the value of the food because the owner could no longer sell it as "fresh."

(Response) We would not direct someone to move food from refrigerated storage to a freezer. If we detained the food in place, then the food would remain under existing storage conditions unless the owner requested us to change those conditions. Similarly, if we directed a firm to transport food to a secure storage facility, then we would allow that firm to

maintain existing storage conditions during transport and storage, unless the owner requested otherwise.

(Comment 107) Some comments were concerned about the economic consequences of detaining large oceangoing vessels. They noted that detaining such vessels administratively for up to 30 calendar days would generate large costs. One comment notes that detaining such vessels might cause the deliveries of other cargoes to be delayed, which could cause some manufacturing plants to shut down because they lacked necessary inputs. Some comments thought we might detain or reroute trucks and their drivers for up to 30 calendar days. One of these comments notes that we did not account for the costs associated with the idling of trucks and their drivers during administrative detentions. One comment discusses trucks that transport bulk food, including liquid commodities such as vegetable oil. This comment notes that if we detained such a vehicle, then the trailer would be unusable for the period of the detention.

(Response) In situations involving conveyances, a request can be made for modification of a detention order to offload the cargo to a secure storage facility. However, in some cases, it may not be feasible to offload the cargo. In that case, the conveyance itself might be delayed. The comment did not provide information on the costs of delaying a ship. However, a recent

newspaper story suggested that delaying one ship for 1 day may cost as much as \$80,000 (Ref. 1). This implies that detaining one ship for 30 calendar days could cost up to \$2.4 million. It is possible, but unlikely, that a single administrative detention could involve more than one ship. We might also detain other types of conveyances.

The comment that discussed the costs of delaying tanker trailers did not provide information on those costs. However, one firm that posted a cost proposal on the Internet listed a standard rate as of July 1, 2002, of \$250 per day for a semitrailer with code tanker and \$200 per day for a semitrailer with liquid transporter (Ref. 2). These rates probably overstate the cost of the loss of a tanker trailer because in some cases in which we detain food on a tanker trailer, the semitrailer itself could probably be used with another tanker trailer. However, this might not always be possible. This implies that the loss of the use of one tanker trailer could cost up to \$8,000 over a 30-calendar day detention period. In addition, in some cases, the drivers of tanker trailers may be idled during the detention period. The average wage of a truck driver in July 2002 was \$14.40 per hour (Ref. 3). If we assume 100 percent overhead, then idling a truck driver for 30 calendar days would cost an additional \$7,000. Therefore, the total potential cost of detaining one tanker truck and driver for 30

calendar days could be up to \$15,000. A single administrative detention might involve more than one tanker trailer or other types of equipment. In the analysis of the proposed rule, we assumed that any given detention could involve up to 67 truckloads of food. Detaining 67 tanker trailers for up to 30 calendar days could generate estimated costs of up to \$1 million.

We do not have information on the cost of delaying other types of conveyances such as trains, airplanes, or other types of trucks. However, those costs are probably similar to the cost of delaying ships and tanker trucks. Delaying conveyances could also generate costs by disrupting the delivery or production schedules of other firms. We do not have information on these costs. We could attempt to construct a model to estimate these costs. However, that would be costly and time consuming and would reflect a great deal of variability in the potential costs. Therefore, we determined that it would probably not be worthwhile to construct such a model for this rule. Although the costs of detaining conveyances are potentially quite high, the probability that we would need to detain conveyances is quite low. None of the 223 enforcement actions that we discussed in the analysis of the proposed rule in the context of estimating the maximum number of times we might use administrative detention per year involved a situation

in which we would have detained conveyances. In addition, none of the 24 seizure actions that we took in fiscal year 2002 or in fiscal year 2003 involved a situation in which we would have detained conveyances. Therefore, our best estimate of the number of times per year that we might need to detain conveyances is zero.

Detaining food located on conveyances may also generate other costs that we did not discuss in the analysis of the proposed rule. In those cases in which we required a firm to transport the detained food to a secure storage facility, we would generate costs associated with the loss of the use of the conveyance and the idling of the crew or drivers during the offloading process and the costs for other firms generated by that delay. If we assume that offloading takes 0 to 6 hours, then the cost of delaying a ship would be \$0 to \$20,000 based on a cost of up to \$80,000 for delaying a ship 24 hours. We do not have information on the costs for other firms generated by the delay of a ship, and the estimated cost of \$80,000 per day might already reflect those costs. Again, it is unlikely that we would delay more than one ship as part of a single administrative detention.

The estimated cost of delaying a fleet of tanker trucks by 0 to 6 hours would be \$0 to \$8,000 based on the cost information we provided earlier. We assume that the cost of delaying other

types of conveyances, such as trains, airplanes, and other types of trucks, would be less than the cost of delaying a ship, despite the higher probability that we might delay more than one of these other types of conveyances. We do not know how many of the 223 enforcement actions on which we based our estimate of the maximum number of administrative detentions in the proposed rule involved food located on conveyances. Therefore, we assume that between 0 and 223 of the estimated administrative detentions that we might take per year could involve food located on conveyances. In that case, the estimated cost from delaying conveyances would be \$0 to \$4 million per year.

(Comment 108) One comment notes that most tanker trucks containing food are sealed at all openings and that we would need to break those seals to investigate such food. The comment notes that receivers would not accept loads with broken seals. The comment suggests that some receivers might not accept such a load even if we resealed the load using an FDA seal.

(Response) If we were to break the seal on a truck or other conveyance and subsequently release all or some of the cargo on that conveyance, then we would reseal the conveyance with an FDA seal. Therefore, transporters would not need to deliver loads with broken seals. In the analysis of the proposed rule, we did not account for the possibility that a receiver might not accept a load even if we resealed it with an FDA seal. The comment did

not provide information on the prevalence of this practice. However, we would expect market forces to minimize this effect because investigating and resealing a load should have little effect on the underlying value of that load. Therefore, we have not revised the analysis to account for this possibility.

(Comment 109) One comment notes that firms challenge our food seizure actions 65 percent of the time and suggests that firms would probably challenge administrative detentions at least as often, and perhaps more often, because of the ambiguity of the legal criteria involved.

(Response) In the analysis of the proposed rule, we assumed that 65 percent of administrative detentions would result in appeal hearings based on the rate at which firms have contested recent seizure actions. It is possible that firms might be more likely to request appeal hearings for administrative detentions than they are to contest seizure actions. However, we have no information establishing this would be the case. In the proposed rule, we noted that the credible evidence or information standard has been applied in various other judicial and administrative contexts. In addition, we are currently developing a separate rulemaking that defines "serious adverse health consequences," as this term is used in several provisions in Title III, Subtitle A, of the Bioterrorism Act, not just in its section 303. Therefore, the ambiguity surrounding the

criteria for administrative detention may be less than suggested by this comment.

In addition, we would only grant a request for a hearing after an appeal is filed, if the information a firm submitted raised a genuine and substantial issue of fact. In contrast, we have no comparable pre-screening process to determine whether firms can contest seizure actions. This suggests that the rate at which firms contest seizure actions may be greater than the rate at which we would hold appeal hearings for administrative detentions. We have no way of knowing whether the rate for contesting seizure actions will be greater than the rate at which we would hold appeal hearings for administrative detentions. Therefore, we have assumed for purposes of this analysis that we will grant all requests for appeal hearings. Based on these considerations, we have not revised our assumption concerning the estimated number of appeal hearings.

(Comment 110) One comment notes that it appeared as though we attempted to expedite the appeals process for perishable food by conducting appeal hearings within 2 calendar days from when a firm filed a request for such a hearing rather than within 3 calendar days, as for nonperishable food. This comment notes that this provision would not necessarily reduce the timeframes for perishable food, because the date on which we hold an appeal hearing does not necessarily dictate when we will reach a

decision on that appeal. Some comments note that we said that we would make a decision on an appeal involving nonperishable goods within 2 calendar days of the hearing, but that we committed to no comparable deadline for perishable food.

One comment notes that the expedited hearing process for perishable food is not fast enough to prevent the effective total loss of market value of fresh produce, fluid milk, and live fish and seafood. They note that a claimant must file an appeal within 2 calendar days of receiving the detention order. Then, if we grant a hearing, we would hold the hearing within 2 calendar days of when the appeal was filed. We would then reach a decision based on the hearing within 5 calendar days. This comment notes that this process implies a total time for the appeal hearing process for perishable food of 4 to 10 calendar days after a firm receives the administrative detention order.

(Response) The timeframe under which we must reach a decision on an appeal hearing is 5 calendar days after the appeal is filed for both perishable and nonperishable food. In the analysis of the proposed rule, we estimated that perishable food might lose up to all of its value during the detention period even under the expedited appeal hearing process.

(Comment 111) One comment argues that the ambiguity surrounding the legal criteria for using administrative

detentions would encourage some firms to attempt to use administrative detention to discredit competitors.

(Response) If this effect were to occur, then it would decrease the net benefits of this rule by generating administrative detentions that have costs but no corresponding benefits. This effect would probably be minimal because of the legal and financial consequences of supplying us with false information to discredit competitors.

(Comments 112) Some comments argue that firms would not be able to provide counterevidence during an appeal because we would not provide them with complete information on the reasons we detained a food administratively. These comments argue that this would make the appeal process ineffective, which could lead to administrative detentions that appear arbitrary.

(Response) As we explain earlier, if we detain an article of food based on classified information, we will provide as much information as we can without divulging classified information to those without the proper security clearance. Finally, we disagree that the appeals process would necessarily be rendered ineffective because of our inability to share classified information with those that do not have the proper security clearance. Based on these considerations, we have not revised the rule.

Distributional Issues

(Comment 113) One comment thinks that we were unclear about who would pay for the storage of food that is detained administratively. The comment wonders how we intend to ensure that the owner or carrier would be able to afford the storage costs, if they were responsible for those costs. Another comment asks who would be responsible for feeding, watering, and providing adequate housing and medical care to live animals that we detain. One comment asks who would be responsible for the costs associated with administrative detention in the case of a food that was produced in one country and then repackaged in another country before being imported into the United States.

(Response) The party or parties responsible for paying the storage costs of food that we detain administratively is a matter between the private parties involved with the food. FDA is not liable for those costs. An owner, operator, or agent in charge of the place where the food is located can always request modification of a detention order to destroy the food if they do not want to store it. This does not change the analysis of the proposed rule because firms would not choose to destroy food unless the cost of doing so were less than the combined cost of storing the food and any loss of product value during the storage period. We set the low end of our range of potential costs to zero to account for the fact that we might not detain any food during a given year. Therefore, the estimated range

includes the costs that would arise if some owners found it less costly to destroy food than to pay for storage.

(Comment 114) One comment argues that the proposed rule would give a competitive advantage to domestic food over imported food because we only subject domestic food to administrative detention, but we subject imported food to both administrative detention and normal import detention. One comment notes that in the analysis of the proposed rule, we based the upper end of the estimated range of the potential number of administrative detentions per year that involve food that we later determine is not adulterated on the number of import detentions that we released per year. The comment notes that we stated that we expected that this rate would probably be less than the rate at which we release import detentions, because the criteria for administrative detention are more restrictive than the criteria for normal import detentions. The comment argues that this showed that we treated imported food unfairly relative to domestic food.

(Response) This rule covers both domestic and imported food, and we will apply it in the same way to both types of food.

(Comment 115) One comment notes that the costs associated with administrative detentions would impose a substantial hardship on farmers because they have little or no ability to

pass on any costs. The comment also notes that administrative detentions could create marketing disruptions that could cause a farm to lose its reputation as a reliable supplier for many years. One comment argues that a motor carrier and driver would bear some of the costs of administrative detention because the motor carrier would lose the use of the equipment during the period of the detention, and the driver might be detained or rerouted, thereby losing compensation for miles driven.

(Response) This rule may adversely affect some farmers and motor carriers. We have insufficient information to quantify the expected or average effect on these specific types of firms, nor did comments submit such information.

(Comment 116) Some comments suggest that if we told the public that we detained a particular product, then we would damage the reputation of the company that manufactured the product, even if we subsequently found that the product was not adulterated and reported that information to the public.

(Response) We do not currently plan to routinely inform the public of administrative detentions, although we might if there were public health reasons for doing so. Therefore, it is possible that we might inform the public of an administrative detention that we later terminated based on a successful appeal or that we later determined involved food that did not pose a threat of serious adverse health consequences or death to humans

or animals. In that case, our announcement of the administrative detention could generate changes in consumer perceptions that might adversely affect some firms. We classify this type of impact as a distributive issue rather than a social cost, per se, because reductions in the demand for a given product will be offset by increases in the demand for other products, so that the net impact to society is uncertain. We have insufficient information to quantify this effect, nor did comments provide this information.

Table 2.--Annual Costs for Option One:

Final Rule

Types of Cost	Costs (in Millions)
Transportation	\$0 to \$4
Delay of Conveyances	\$0 to \$4
Storage	\$0 to \$2
Loss of Product Value	\$0 to \$22
Marking or Labeling	\$0 to \$2
Appeals	\$0 to \$16
Total	\$0 to \$50

2. Option Two: Take the Proposed Action but Change the Definition of Perishable Food, the Maximum Timeframe for Administrative Detention, or Both

(Comment 117) A number of comments address the option of changing the definition of perishable food or the maximum timeframe for administrative detentions. Many of these comments suggest changes that would reduce costs but might also reduce benefits. However, these comments did not provide sufficient information to allow us to quantify the changes in costs or benefits. Therefore, we are unable to revise our estimates of the costs and benefits of this option.

Some comments recommend that we define perishable food as food with a shelf life of 90 days or less. Other comments recommend that we define perishable food as food with a shelf life of 120 days or less. One comment suggests that we define perishable foods according to the definition in the Perishable Commodities Act, which includes fresh fruits and vegetables of every kind and character where the original character has not been changed. One comment suggests that we base our definition of a perishable food on the definition of perishable food in the NIST Handbook 130 Regulations for Uniform Open Dating. The comment also suggests that we adopt the definition of semiperishable foods from that regulation and that we treat semiperishable food the same as perishable food. The comment

notes that the relevant definition of perishable food is any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days of the date of packaging, and the definition of semiperishable food is any food having a significant risk for spoilage, loss of value, or loss of palatability after a minimum of 60 days and a maximum of 6 months after the date of packaging.

One comment suggests that we revise the rule to define perishable food as "food that may have been heat-treated or otherwise preserved so as to prevent the quality of the food from being adversely affected for a period of 90 days or less under normal shipping and storage conditions." This comment notes that this definition would include raw agricultural commodities, refrigerated pasteurized products (milk and milk products, juice and juice concentrates), and packaged produce, all of which have a short shelf life and need to move expeditiously through marketing channels to the consumer. However, the comment notes that, even under this revised definition, detaining perishable food which has less than 14 days of shelf life remaining would essentially prevent the product from reaching the market, even with an expedited appeal process and a decision in favor of the owner of the food. One comment argues that we should not consider the issue of whether a food had been subjected to heat treatment or thermal

processing to be relevant to the definition of perishable food. Some comments argue that we should take into account not only physical or biological properties, but also how a product is marketed. Some comments argue that we should treat all food as perishable food for purposes of an appeal.

(Response) Changing the definition of perishable food as suggested by these comments would allow more products to qualify for the expedited procedures for appeals and for initiating certain judicial enforcement actions that we established for perishable food. The expedited procedures for initiating certain judicial enforcement actions may reduce the overall duration of an administrative detention in some cases. However, we have insufficient information to determine the impact of these procedures on the duration of administrative detentions. If these procedures reduced the duration of detentions, then it would also reduce storage and loss of product value in cases in which detentions involved food that we later determined does not present a threat of serious adverse health consequences or death to humans or animals. However, it might also increase our enforcement costs or reduce benefits. It would increase our enforcement costs if we could compensate for the shortened timeframe by assigning additional personnel to the enforcement action. It would decrease benefits in those cases in which we could not fully compensate for the shortened timeframe by

assigning additional personnel. Treating more or all food as perishable for appeal purposes would reduce the maximum timeframe in which firms must file appeals for that food from 10 calendar days to 2 calendar days after receipt of the detention order. The reduced timeframe would probably reduce the number of appeals, because any firm that could file an appeal within 2 calendar days is not precluded from doing so with a maximum specified timeframe for filing an appeal of 10 calendar days. Some firms, however, that would be able to file an appeal within 10 calendar days might have difficulty doing so with a maximum specified timeframe for filing an appeal of 2 calendar days. Reducing appeals would decrease our enforcement costs for administering hearings. However, it might also reduce benefits because appeals may allow us to terminate detention orders that we would not have terminated in the absence of appeals. Terminating detention orders would eliminate the storage and loss of product value for detained articles of food. However, reducing the timeframe in which we hold appeal hearings would also increase our enforcement costs and possibly reduce benefits. Again, it would increase our enforcement costs if we could compensate for the shortened timeframe by assigning additional personnel to the appeal hearing. It would decrease benefits in those cases in which we could compensate fully for the shortened timeframe by assigning additional personnel.

(Comment 118) A number of comments raised various issues relating to the timeframes involved in administrative detentions. Some comments argue that we should provide information on the criteria that we intend to use to determine the "reasonable period" of time that we detain food administratively because of the impact of that decision on the costs of administrative detention. One comment questions whether this reasonable period of time would depend on the availability of FDA resources. Another comment argues that we should give top priority to any sampling and testing associated with administrative detentions to ensure that we minimize the amount of time that we require. One comment suggests that we initiate any sampling and diagnostic testing within 24 hours of issuing an administrative detention order.

(Response) Defining the criteria that we would use to establish the reasonable amount of time that we would detain food administratively would increase the cost for us to develop this rule because we would need to evaluate every consideration that might affect that time. Also, if we wrote these criteria into the rule, and we failed to anticipate all considerations that might affect this timeframe, then we might need to release food that we detained administratively before we determined that such food should be released. The benefit of defining these

criteria is that it would allow the public to provide input on the factors that we believe lead to these time requirements.

(Comment 119) Some comments suggest that we reduce the maximum time of administrative detentions from 30 to 15 days. One comment suggests a maximum of 10 days. One comment suggests a maximum of 7 days. One comment argues that we should revise the rule to limit the period of detention for perishable commodities, including fresh cut salads, fresh fruits, and vegetables to 7 days. One comment suggests that we revise the rule to limit the administrative detention period to 7 days for foods with a shelf life of between 8 and 30 days. Some comments suggest that we develop a system to determine within 24 hours if detention continues to be necessary for perishable food such as fruit, vegetables, and fresh fishery products. These comments suggest that we should only detain fresh noncitrus fruit a few hours, and that we should not detain peppers and citrus fruits for more than 24 hours.

(Response) Reducing the maximum time that we could detain food administratively would reduce storage costs and the loss of value of any food that we later determine is not adulterated. However, this change would also reduce benefits by increasing the risk that an administrative detention order would terminate before we were able to fully assess the health risks associated with the detained food.

(Comment 120) One comment argues that we should inform the owner within 1 calendar day if we terminate an administrative detention order. The comment argues that this would minimize the possible loss of market value by allowing the owner to distribute the food as soon as possible.

(Response) We would only directly inform the owner of the termination of a detention order if we had been able to readily identify the owner and had sent the owner a copy of the detention order. In such a case, we would normally be able to inform the owner of the termination of the detention order within 1 calendar day of when we terminated the detention order. In some other cases, owners could make arrangements with the owner, operator or agent in charge of the place where the food is located to notify them if we notified the owner, operator or agent in charge of the place where the food is located that we terminated a detention order. The timeframe in that case would also be 1 calendar day because we expect that we would normally be able to inform the owner, operator or agent in charge of the place where the food is located within 1 calendar day. Allocating additional employees to this task could generate opportunity costs by reducing the employees that we can assign to other tasks having public health consequences. We have insufficient information to quantify these opportunity costs. The benefit of committing to informing the owner within 1

calendar day, if we inform the owner, would be up to a 1-calendar day reduction in storage costs and loss of product value.

(Comment 121) Some comments state that we set a deadline for making decisions on appeals involving nonperishable food, but we did not set a comparable deadline for appeals involving perishable food. These comments suggest that we revise the rule to specify that the same deadline that applies to nonperishable foods also applies to perishable foods. One comment suggests that we reach decisions on appeals involving perishable foods within four days of the date of the appeal. One comment suggests that we commit to reaching decisions on appeals involving perishable food within 24 hours of the appeal hearing. One comment suggests that we set up an expedited appeal procedure for perishable food.

(Response) Our deadline for making decisions on appeals is the same for both perishable and nonperishable food, i.e., no more than 5 calendar days after an appeal is filed. Reducing the timeframe in which we must render a decision on appeals involving perishable food from 5 to 4 calendar days or to 1 calendar day would either increase our enforcement costs or decrease benefits as per the mechanism we described earlier. It would increase our enforcement costs if we could compensate for the shortened timeframe by assigning additional personnel to the

appeal. In other cases, reducing the time we have to reach decisions might decrease benefits by increasing the risk that we would inappropriately terminate detention orders. However, reducing the time we have to reach decisions on appeals involving perishable foods would also reduce storage costs and loss of product value in those cases in which we terminated those detentions because of those appeals.

(Comment 122) One comment suggests that we extend the timeframe for appealing detentions beyond the proposed 4 calendar days for nonperishable foods and 2 calendar days for perishable food. The comment argues that, in the case of imports, the parties in the exporting countries would not have sufficient time to prepare the necessary documents under the proposed deadlines.

(Response) Although firms must indicate their intention to appeal administrative detentions of nonperishable food within 4 calendar days of when we deliver the detention notice to the owner, operator, or agent in charge of the place where the food is located, they have 10 calendar days to prepare and file their appeals. Therefore, in the case of nonperishable food, both the proposed rule and this final rule are consistent with the comment. Extending the timeframe for appealing nonperishable food would increase our enforcement costs because we would need to keep employees assigned to those cases throughout the

potential appeal period to prepare for a possible appeal. It would also increase the number of appeals, which would increase our enforcement costs for reviewing those appeals and administering any appeal hearings that we might grant. However, increasing the number of appeals might also increase benefits by allowing us to terminate some detentions that we might not have otherwise terminated or that we might have terminated after a longer detention period.

We were unable to determine that any of the suggested revisions would generate higher net benefits than the actions that we discussed in the analysis of the proposed rule, which were to broaden the definition of perishable food to include any food with a shelf life of 30 days or less and reduce the maximum timeframe for detaining a perishable food administratively to 14 calendar days. However, we have updated the cost estimates for that action to reflect the revisions we previously discussed under Option One.

Table 3.--Annual Costs for Option for Option
Two: Alternative Definition and Maximum Detention
Period for Perishable Food

Types of Cost	Costs (in Millions)
Transportation	\$0 to \$4
Delay of Conveyances	\$0 to \$4

Storage	\$0 to \$1
Loss of Product Value	\$0 to \$15
Marking or Labeling	\$0 to \$2
Appeals	\$0 to \$16
Total	\$0 to \$42

3. Option Three: Take the Proposed Action, but Define the Level of Security We Require for Transportation and Storage

We did not receive any comments on this option. However, we have updated the cost estimates for that action to reflect the revisions we previously discussed under Option One.

Table 4.--Annual Costs for Option Three: No Transportation and One Additional Guard

Types of Cost	Costs (in Millions)
One Additional Guard	\$0 to \$11
Delay of Conveyances	\$0 to \$4
Storage	\$0 to \$2
Loss of Product Value	\$0 to \$22
Marking or Labeling	\$0 to \$2
Appeals	\$0 to \$16
Total	\$0 to \$56

4. 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 did not receive any comments on this option.

5. Option Five: Take the Proposed Action But Revise the Proposed Action in Some Other Way

(Comment 123) In the analysis of the proposed rule, we requested comments on other regulatory options that we should consider. A number of comments suggested revisions that did not correspond to any of the other regulatory options. Many of these suggestions involved revisions that would reduce costs but might also reduce benefits. Other suggestions involved revisions that would reduce some costs, such as costs faced by industry, but would increase other costs, such as our enforcement costs.

(Response) The comments did not provide sufficient information to allow us to quantify the changes in costs or benefits. Therefore, we have insufficient information to determine that any of the recommended changes would increase the net benefits of this rule. Nevertheless, we list the more significant suggested revisions in the following paragraphs and indicate the tradeoffs that would be involved in those revisions.

a. General. (Comment 124) One comment argues that rather than adding to industry's burden for food security, we should

provide government funding to help industry institute measures to improve food security.

(Response) This comment raises an issue that is beyond the scope of this rulemaking. In the discussion of Option One, we argued that the expected annual burden for all potentially affected firms would be quite small and would not significantly displace food safety expenditures by industry. Declining to issue this rule would generate minimal cost savings because the authority to detain food is self-implementing and is in effect now. This regulation specifies procedures and defines terms to ensure we meet the statutory timeframes for detaining food, and rendering a decision on appeal.

(Comment 125) Some comments suggested that we provide foreign language translations of the Bioterrorism Act and any explanatory information that we prepare on this regulation. The comments suggest that we disseminate the translated material on our Web site and by other means. Some comments request that we establish foreign language consultation services at U.S. embassies.

(Response) As stated earlier in this rule, we have posted on FDA's Web site transcripts of the May 7, 2003, public meeting that we held to discuss both the administrative detention and recordkeeping proposed rules. We also posted transcripts of the broadcast in English, French, and Spanish, which are the three

official WTO languages. We plan to make similar outreach efforts directed to both domestic and international stakeholders after publication of this final rule. Providing other translations and foreign language consultants would increase our enforcement costs, but reduce the costs of foreign firms that wished to appeal administrative detentions. Reducing the cost of appeals for firms would probably increase the number of appeals. As we discussed earlier, increasing the number of appeals would increase our enforcement costs but would also allow us to terminate administrative detentions that we would otherwise not have terminated or terminated after a longer detention period. Terminating administrative detentions would reduce storage costs and loss of product value.

b. Coverage. (Comment 126) One comment suggests that we exempt regulated indirect food contact color pigments that firms may use in the manufacture of food packaging. This comment argues that exempting these products would have a minimal effect on benefits. According to this comment, our regulations require that indirect food contact color pigments be proven safe and incapable of migrating into food in more than de minimis quantities. This comment also argues that color pigments must be almost completely insoluble in the medium in which they are used, particularly for food packaging, which means that the amount of contaminant that would be necessary to pose a threat

to food by migration from polymers and coatings would almost certainly compromise the basic stable coloration function of the pigment. This comment also states that if someone did manage to adulterate these products, then it would probably affect the chemistry of these substances in such a way that the pigment would no longer function correctly in the packaging, polymer or coating systems. The comment also notes that they know of no biological contaminants that could occur in food that could survive in the harsh environment of bulk commercial color pigments or the severe environment that occurs in the manufacturing of plastics, inks and coatings. Finally, the comment notes that they know of no cases of foodborne illness that have been attributed to contaminants that migrated from a color pigment used in food packaging.

Some comments suggest that we exempt outer food packaging. These comments argue that the risk to humans and animals from the adulteration of outer food packaging is relatively small compared to the risk from the adulteration of food contact packaging.

One comment suggests that we exempt raw materials and formulated products that are used as components in the manufacture of food-contact articles, such as conveyor belts, oven gaskets, coatings for film, paper, and metal substrates, adhesives, antifoam agents, antioxidants, polymeric resins,

polymer emulsions, colorants for polymers, rubber articles, release coatings, and the like.

One comment suggests that we exempt ceramic and lead crystal tableware. This comment argues that such products would be unlikely to feature in terrorist incidents and that deploying our resources to deal with these products would reduce our ability to deal with other products.

One comment suggests that we exempt animal feed and pet food and limit the scope of the proposed regulations to food that is intended for direct human consumption without further processing.

One comment suggests that we exempt food in purely intrastate commerce.

(Response) The scope of the detention authority extends to those articles that meet the definition of food in section 201(f) of the FD&C Act. Exempting the products in this comment that meet this definition would have little effect on estimated costs because, if it were technically difficult or impossible to adulterate these types of food, then we would rarely or never receive information that would require us to detain it administratively. There are no costs associated with this rule for products that do not appear to present a threat of serious adverse health consequences to humans or animals. However, exempting these products could significantly reduce benefits

because we would be unable to use administrative detention in the unlikely case that someone did manage to adulterate these products in a way that generated a risk of serious adverse health consequences. This type of event, although rare, could generate significant health costs. Therefore, the net effect of this revision would be to reduce the net benefits of this rule.

(Comment 127) Some comments suggest that we limit our use of administrative detention to situations involving real or suspected intentional acts of terrorism. Some comments argue specifically that we should continue to request Class I recalls in situations involving unintentional adulteration. One comment argues that we should not use administrative detention to deal with imported food containing undeclared allergens.

(Response) Limiting the use of administrative detention to situations involving real or suspected terrorism would significantly reduce both the potential costs and benefits of this rule. Only one of the 223 enforcement actions upon which we based our estimate in the proposed rule of the potential maximum number of times we might use administrative detention in 1 year may have involved intentional contamination, and it is possible that none of them did. We did not estimate the number of outbreaks per year that this rule might prevent due to our ability to remove food that presents a threat of serious adverse health consequences or death to humans or animals from commerce

by placing it under administrative detention while we pursue a seizure action. However, the number of intentional outbreaks would be much smaller than the number of intentional outbreaks plus the number of unintentional outbreaks because most outbreaks have been unintentional.

(Comment 128) Some comments suggest that we cooperate with TTB of the U.S. Department of the Treasury when detaining alcoholic beverages administratively because the TTB is normally responsible for regulating these products and has expertise on that sector of the economy. The comment suggests that we revise the rule to specify that TTB officials are responsible for ordering any administrative detentions of alcoholic beverages.

(Response) As stated previously, FDA recognizes that working in conjunction with TTB is an important tool we have in the event of a threat to the nation's food supply. However, TTB does not have exclusive jurisdiction over alcoholic beverages. FDA exercises jurisdiction over alcoholic beverages as "food" for the purposes of the adulteration provisions and other provisions of the FD&C Act. FDA has concluded that alcoholic beverages are covered under the administrative detention regulation because alcohol is food, as that term is defined in section 201(f) of the FD&C Act. The term "food" as used in section 303 of the Bioterrorism Act has the meaning given in section 201(f) of the FD&C Act.

c. Definition of criteria. (Comment 129) Some comments state that we should define "credible evidence or information" and "threat of serious adverse health consequences or death to humans or animals." These comments argue that these steps would be necessary to protect against arbitrary or unsupported detentions that might function as trade barriers. Some comments suggest we use internationally valid standards, such as Codex standards, when defining these terms. One comment suggests that we provide additional guidance on "credible evidence or information" by naming all the sources of information that we consider reliable and describing requirements with respect to accuracy of the information. One comment suggests that we adopt a more precise definition of the criteria involved because it would minimize the cost of wrongly ordered detentions. One comment argues that we should not define the criteria for administrative detention, but should instead decide whether a particular case meets the definition on a case-by-case basis, as we proposed. This comment argues that we should not limit our discretion to use administrative detention by identifying the types of evidence that we would need to support a detention order because terrorist events might arise under conditions that we could not anticipate.

One comment offers suggestions about how to define "threat of serious adverse health consequences or death to humans or

animals." Some comments suggest that we define "credible evidence" to require evidence, such as laboratory analyses, to confirm the presence of an adulterant or affidavits sworn to under penalty of perjury. One comment argues that we should define "serious adverse health consequences or death to humans or animals" so that it necessarily involves risks for a large part of the population and also for the average consumer, not just a sensitive subpopulation.

(Response) We are developing a separate rule in which we will define the phrase, "serious adverse health consequences or death to humans or animals." This phrase is also used in other provisions in Title III, Subtitle A, of the Bioterrorism Act, not just in its section 303. Therefore, it would not be efficient to define this phrase in this rule.

More precisely defining "credible evidence or information" would increase the cost for us to develop this rule because we would need to consider and evaluate a number of possible scenarios in order to define that term. In addition, if we wrote a definition of this term into this rule, then we might need to revise the rule as we encountered new situations. Also, if we wrote a definition into the rule, and we failed to anticipate all relevant situations, then we might be unable to use administrative detentions in some situations in which there might be benefits from doing so. The benefit of more precisely

defining this term is that it would reduce the possibility that some people might perceive administrative detentions as arbitrary. In the discussion of Option One, we pointed out that the credible evidence or information standard has been applied in various other judicial and administrative contexts.

d. Administrative detention orders and the dissemination of other information relating to administrative detentions.

(Comment 130) A number of comments addressed the issue of who would receive copies of administrative detention orders. One comment notes that § 1.392 of the proposed rule provides that we would provide a copy of the detention order to the owner, operator or agent in charge of the place where the food is located, and that we would provide a copy to the owners of the food if we could readily determine their identity. The comment notes that because we are requiring operators to register with us, we should be able to readily identify the sending company, the buying company and all intermediaries of the food detained. The comment argues that at least one of these parties would typically be the owner and suggested that we inform all of them of detention orders. The comment suggests that this would be the only way to give the owner a realistic chance to file an appeal.

One comment notes that the owner of the place or the vehicle where we detain food administratively might not have a

vested interest in the detained product. This comment suggests that we also notify the importer or the owner of the food. One comment suggests that if we detain an exporter's product, then we should notify that exporter. One comment suggests that we notify the importer and exporter of record and the Customhouse broker. One comment requests that we notify the agent or importer. One comment requests that we notify people of administrative detentions by both a formal written communication and a telephone call.

(Response) We will issue an administrative detention order to the owner, operator, or agent in charge of the place where the food is located. We will also provide a copy of the detention order to the owner of the food, if the owner of the food is different from the owner, operator, or agent in charge of the place where the food is located, and if we can readily determine the owner's identity. Finally, we will provide a copy of the detention order to the shipper of record and to the owner and operator of the vehicle or other carrier, if the food is located on a common carrier, and if we can readily determine the identities of the owners and operators. We intend personally to deliver the detention order to the owner, operator, or agent in charge of the place where the food is located because it permits our investigator to observe the article of food and therefore better describe it in the detention order. We will notify other

parties using whatever method of communication is quickest, given the information that we can readily determine about how we can contact them. The registrations that we will be requiring in another rulemaking will not provide us with a list of parties that would probably include the owners of food that we detain administratively. Committing to notifying additional parties beyond those specified in the proposed rule, notifying owners even when we cannot readily determine their identities, or notifying owners by telephone and written communications even when we cannot readily determine their phone numbers or addresses, would increase our enforcement costs.

The benefit of such a revision is that it would increase the probability that we would notify a party that has an incentive to appeal an administrative detention in time for them to meet our deadlines for filing an appeal. This would increase the number of appeals. As we previously discussed, this may generate social benefits because appeals may allow us to terminate some detentions. Terminating detentions would limit the storage and loss of product value associated with those detentions.

(Comment 131) One comment suggests that we revise the rule to require that we accompany a notice of detention by personal service upon the responsible party at individual locations.

(Response) We will notify in person the owner, operator, or agent in charge of the place where the food is. If more than one location is involved, then we would notify in person the owner, operator, or agent in charge of each location. Committing to notifying other parties in person would substantially increase our enforcements costs and might decrease benefits because notifying other parties in person might not be the quickest way of notifying them. The comment did not provide a mechanism by which notifying other parties in person would generate benefits. Therefore, this change would probably not increase the net benefits of this rule.

(Comment 132) A number of comments ask questions about who would receive information on administrative detentions other than copies of detention orders. Some comments suggest that we provide essential information, such as the cause of administrative detentions, to key industry officials in the event of a food security event. One comment suggests that we provide information on administrative detentions to the government of the home country of the owner, operator, or agent in charge of the place where the food is located. Some comments suggest that we inform foreign governments if we detain products from their countries so they can take measures to recall or otherwise deal with the products. One comment suggests that we provide information on administrative

detentions to foreign governments only if the product from that country constituted a serious threat. Some countries suggest methods by which we could provide information. One comment suggests that we notify foreign governments using a rapid alert system, if a product from that country constituted a serious threat. Some comments suggest that we devise and test a method of communicating essential information to key industry officials in the United States in the event of a food security event.

(Response) We will directly notify foreign governments and industry officials of administrative detentions on a case-by-case basis when we think there would be benefits to doing so. Committing to notifying these parties of every administrative detention would increase our enforcement costs. However, it might also generate benefits because we might otherwise fail to notify these parties of administrative detention in some situations in which such notification would generate benefits. The probability that we would fail to notify these parties in situations in which such notification would generate benefits is probably small.

(Comment 133) Some comments raise the issue of the information that we would provide to owners or others, either as part of the administrative detention order or otherwise. Some comments request information that would help them identify the detained food. Some comments suggest that we provide owners

with grower codes so that they or others could trace the secondary supplier. One comment suggests that we provide a description of the food, the quantity, and the lot or code numbers or other identifiers.

(Response) We will provide information relevant to identifying food that we detain administratively in the detention order. This information will typically include a description of the food, the quantity of food, and any identifying codes, such as grower codes and lot numbers, that we can readily determine. Committing to always providing particular codes would increase our enforcement costs. In some cases, such as a detention involving a number of pallets containing products from multiple lots, it might be difficult for us to identify all of the relevant lot codes. Committing to always providing particular identifying codes would generate benefits because it would help owners, and possibly other parties such as foreign governments, to take steps to investigate the potential problem and possibly reduce the risk of additional serious adverse health consequences. In addition, some parties may find particular identifying codes useful during the appeal process.

(Comment 134) One comment suggests that we provide foreign governments with the produce name and lot number, the producer, and the exporter of the detained food.

(Response) In those cases in which we directly inform foreign governments of administrative detentions, we would provide them with a copy of the detention order and any other information we deem appropriate, which may include the name of the product, the lot number, the producer, and the exporter. Committing to always providing foreign governments with this information would increase our enforcement costs and possibly increase other food safety risks. The benefit of committing to always providing this information is that foreign governments might be able to take more effective steps to address potential food safety risks than they would otherwise. We have insufficient information to quantify the net impact of this revision.

(Comment 135) Other comments discuss the information that we would provide as the bases for administrative detentions. One comment suggests that we include in the detention order the information upon which we based an administrative detention. Some comments suggest that we provide owners with complete information on the reasons for detentions so that owners can provide counterevidence during an appeal. One comment suggests that we should at least include a description of the "credible evidence or information" that resulted in the detention order, because without such information, the owner of the detained article would be denied information critical to its own

investigation, which would hamper or deny its ability to make a meaningful appeal. The comment notes that we could provide information on why we believe the article of food subject to the order "presents a threat of serious adverse health consequences or death to humans or animals" even if the "credible evidence" that we used is classified information. One comment suggests that we provide foreign governments with the reasons for administrative detentions.

(Response) We will provide a statement of the reasons for a detention in the detention order, but we will not divulge classified information to those without the proper security clearance. Similarly, in those cases in which we directly notify foreign governments or other parties of administrative detentions, we will provide a statement of the reasons for those detentions as is consistent with national security considerations and applicable disclosure laws. Providing classified information to those without the proper security clearance could generate costs by increasing the risk of future food safety incidents. It would also be illegal.

(Comment 136) One comment suggests that we include in the detention order a description of the actions we intend to take with the product and the amount of time we intend to hold the product.