

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 10, and 16

[Docket No. 2002N-0275]

RIN 0910-AC38

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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

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DATES: This rule is effective [insert date 30 days after date of publication in the Federal Register].

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SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background and Legal Authority
- II. Highlights of the Final Rule
- III. Comments on the Final Regulation
  - A. General Comments
  - B. Comments on Foreign Trade Issues
  - C. Comments on What Definitions Apply to This Subpart?  
(Proposed § 1.377)
    - 1. Definition of "The Act"
    - 2. Definition of "Authorized FDA Representative"
    - 3. Definition of "Calendar Day"
    - 4. Definition of "Food"
  - D. Comments on What Criteria Does FDA Use to Order a Detention? (Proposed § 1.378)

- E. Comments on How Long May FDA Detain an Article of Food? (Proposed § 1.379)
1. Comments on Where and Under What Conditions Must the Detained Article of Food be Held? (Proposed § 1.380)
  2. Comments on May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location? (Proposed § 1.381)
  3. Comments on What Labeling or Marking Requirements Apply to a Detained Article of Food? (Proposed § 1.382)
- F. Comments on What Expedited Procedures Apply When FDA Initiates a Seizure Action Against a Detained Perishable Food? (Proposed § 1.383)
- G. Comments on When Does a Detention Order Terminate? (Proposed § 1.384)
- H. Comments on How Does FDA Order a Detention?
1. Comments on Who Approves a Detention Order? (Proposed § 1.391)
  2. Comments on Who Receives a Copy of the Detention Order? (Proposed § 1.392)
  3. Comments on What Information Must FDA Include in the Detention Order? (Proposed § 1.393)

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

1. Comments on Who is Entitled to Appeal?  
(Proposed § 1.401)
2. Comments on What Are the Requirements for Submitting an Appeal? (Proposed § 1.402)
3. Comments on What Requirements Apply to an Informal Hearing? (Proposed § 1.403)
4. Comments on Who Serves as the Presiding Officer at an Informal Hearing? (Proposed § 1.404)
5. Comments on When Does FDA Have to Issue a Decision on an Appeal? (Proposed § 1.405)
6. Comments on How Will FDA Handle Classified Information in an Informal Hearing? (Proposed § 1.406)

IV. Conforming Amendment to Part 10

V. Conforming Amendment to Part 16

VI. Analysis of Economic Impact

- A. Final Regulatory Impact Analysis
- B. Final Regulatory Flexibility Analysis
- C. Unfunded Mandates
- D. Small Business Regulatory (SBREFA) Major Rule

VII. Paperwork Reduction Act of 1995

## VIII. Analysis of Environmental Impact

## IX. Federalism

## X. References

### I. Background and Legal Authority

On May 9, 2003 (68 FR 25242), FDA issued a proposed rule providing procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The events of September 11, 2001, had highlighted the need to enhance the security of the United States' food supply. Congress responded by enacting the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002. Section 303 of the Bioterrorism Act amends section 304 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 334) by adding paragraph (h) to provide that an officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. This provision also requires the Secretary of Health and Human Services (the Secretary) to provide by regulation procedures for instituting seizure or

injunction actions against perishable food subject to a detention order on an expedited basis. Section 303 of the Bioterrorism Act also amends the FD&C Act by adding a new prohibited act as paragraph (bb) to section 301 of the FD&C Act (21 U.S.C. 331).

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

- Criteria used to trigger an administrative detention: Amends section 304 of the FD&C Act to authorize an officer or qualified employee of FDA to order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act, if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.
- Approval required: The Secretary, or an official designated by the Secretary, must approve the detention order. An "official designated by the Secretary" means the District Director of the district where the detained article of food is located, or an FDA official senior to such director.
- Period of detention: The detention period will be for a reasonable period, not to exceed 20 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.

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

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

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

- Prohibited act: Amends section 301 of the FD&C Act making it a prohibited act to transfer a detained

article of food in violation of a detention order, or to remove or alter any mark or label required by the detention order to identify the article of food as detained.

- Section 303 of the Bioterrorism Act also includes a provision authorizing temporary holds at ports of entry that will not be addressed in this final regulation. The temporary hold provision authorizes FDA to ask the Secretary of the Treasury to institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and FDA is unable immediately to inspect, examine, or investigate such article. FDA has received comments on the temporary hold provision in the public docket (Docket No. 2002N-0275). FDA plans to consider these comments as we develop our approach on how best to implement this provision of the Bioterrorism Act.

Under the Homeland Security Act of 2002 (Public Law 107-296), the responsibilities and functions of the Secretary of the Treasury for all relevant Customs authorities have been transferred to the Secretary of Homeland Security, who has in turn delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP). Thus, wherever section 303 of the

Bioterrorism Act refers to the Secretary of Treasury, we will refer to the Secretary of Homeland Security.

In addition to amending title 21 of the Code of Federal Regulations (21 CFR) by establishing a new subpart to part 1 (21 CFR part 1) consisting of subpart K entitled, "Administrative Detention of Food for Human or Animal Consumption," this final rule also makes conforming amendments to part 16 (21 CFR part 16) entitled "Regulatory Hearing Before the Food and Drug Administration" and part 10 (21 CFR part 10) entitled "Administrative Practices and Procedures."

Although the statutory requirements in section 303 of the Bioterrorism Act are self-executing and are currently in effect, FDA is issuing this regulation to further refine aspects of the administrative detention requirements. Section 303 of the Bioterrorism Act requires FDA only to issue regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order; however, FDA also is describing in this regulation the procedures for how we will detain both perishable and nonperishable articles of food and the process for appealing a detention order. FDA established requirements for the process for appealing a detention order in this final rule to ensure that we meet section 303's timing requirements and to define

certain terms used in the Bioterrorism Act (e.g., perishable food).

This final rule is not related to, and does not implement, section 801(a) of the FD&C Act (21 U.S.C. 381), even though it uses the term "detention." This final rule implements section 303 of the Bioterrorism Act, which amends the seizure provision at section 304 of the FD&C Act by adding paragraph (h) to that section. This amendment grants FDA the authority to detain (i.e., prevent the further movement of) any article of food that is found during an inspection, examination, or investigation if FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

Some of the comments that we received continue to reflect some confusion of our authority to detain food administratively under section 304(h) of the FD&C Act (as added by the Bioterrorism Act) with our authority to refuse admission of imported food under section 801(a) of that act, despite our explanation of this issue in the proposed rule. (See 68 FR 25242.) The following discussion provides additional explanation of FDA's authority under each of these provisions so as to make clear that our authority to detain food administratively under section 304(h) of the FD&C Act is separate and distinct from our authority to refuse admission of imported food under section

801(a) of the FD&C Act.

Section 801 of the FD&C Act sets out standards and procedures for FDA review of imports under its jurisdiction. Generally, when an FDA-regulated product is imported, customs brokers submit entry information to CBP on behalf of the importers of record. CBP then provides entry information to FDA to enable admissibility decisions to be made. If FDA determines that refusal under section 801(a) FD&C Act appears appropriate, FDA, as set out in its regulations, gives written notice to the owner or consignee. (See § 1.90(a).) In guidance dating back many years, FDA refers to this written notice as the notice of detention and hearing.

FDA's evaluation of imported foods under section 801(a) of the FD&C Act largely focuses on whether the article of food appears to have been safely produced, packed, and held; contains no contaminants or illegal additives or residues; and is properly labeled. Section 801(a) of the FD&C Act provides that an article of food is subject to refusal of admission if it "appears, from physical examination or otherwise": (1) To have been manufactured, processed, or packed under insanitary conditions; (2) to be forbidden or restricted in sale in the country in which it was produced or from which it was exported; or (3) to be adulterated or misbranded. The food adulteration and misbranding provisions (sections 402 and 403 of the FD&C Act

(21 U.S.C. 342 and 21 U.S.C. 343)) set out most of the FD&C Act's requirements for foods.

In section 304(h) of the FD&C Act, Congress gave FDA the authority to detain food administratively where we have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals so that we can bring such food under FDA control. Historically, FDA has had the authority to seize misbranded or adulterated food in domestic commerce; however, adulterated food could enter commerce and put consumers at risk during the time that it takes to file a seizure action. In some instances, FDA has been able to partner with State authorities to have such food embargoed by the State where the food is located so that it is under their control while the seizure action is being prepared and filed, until the court issues the warrant, and until the U.S. marshal can seize the food. However, this process is not always possible.

We do not, at this time, foresee frequently using administrative detention under section 304(h) of the FD&C Act to control the movement of imported food subject to section 801 of the FD&C Act. When FDA determines it is appropriate to bring imported food under FDA control using the authority under section 304(h) of the FD&C Act, the standard for administrative detention will be the same as it is for other products, i.e., we

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must have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

This final rule implements the administrative detention requirements in section 303 of the Bioterrorism Act. This final rule, published today, as well as the interim final rules that FDA and CBP published on October 10, 2003, to implement section 307, prior notice of imported food shipments (68 FR 58974), and section 305, registration of food facilities (68 FR 58893), of the Bioterrorism Act, along with the final rule implementing section 306 of the Bioterrorism Act (maintenance and inspection of records for food), <sup>which will be</sup> published in ~~this issue of~~ the Federal Register, <sup>in the near future</sup> will help FDA act quickly when responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Administrative detention will provide FDA with an added measure to help ensure the safety of the nation's food supply. In establishing and implementing this final rule, FDA believes it has complied fully with the United States' international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA).

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In addition to section 303 of the Bioterrorism Act, which amends the FD&C Act as described previously in this document, FDA is relying on section 701(a) of the FD&C Act (21 U.S.C.

371(a)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the FD&C Act.

## II. Highlights of the Final Rule

The key features of this final rule are as follows:

- An officer or qualified employee of FDA may order the detention of food for up to 30 calendar days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.
- FDA's District Director in the district in which the article of food is located, or an FDA official senior to such director, must approve a detention order.
- FDA may require that the detained article of food be labeled or marked as detained with official FDA tags or labels. FDA's tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative.
- A violation of a detention order or the removal or alteration of the tag or label is a prohibited act.

- FDA will state in the detention order the location and any applicable conditions under which the food is to be held.
- If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. An article of food moved to a secure facility remains under detention before, during, and after such movement.
- FDA may approve a request for modification of a detention order to permit movement of a detained article of food for purposes of destruction, movement to a secure facility, preservation of the detained article of food, or any other purpose that FDA believes is appropriate. In any of these circumstances, an article of food may be transferred but remains under detention before, during, and after the transfer.
- Any transfer of a detained article of food in violation of a detention order is a prohibited act.
- Any person who would be entitled to be a claimant for the article of food, if seized, may appeal a detention order and, as part of that appeals process, may request an informal hearing. If a hearing is granted, an FDA Regional Food and Drug Director (RFDD) or another official senior to

an FDA District Director will serve as the presiding officer of the hearing.

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

- Perishable food:

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

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

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

- Nonperishable food:

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

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

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

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

- The expedited procedures for initiating certain enforcement actions with respect to perishable foods require FDA to submit a seizure recommendation to the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.
- Confirmation of a detention order by FDA's presiding officer is considered final agency action.

In response to comments that were received, FDA has made two changes to the proposed rule. First, the required information in the detention order did not include the name of the authorized FDA representative who approved the detention order. This is required information in this final rule (§ 1.393(b)(14)). Second, the proposed rule stated that, if a hearing is requested in the appeal, and FDA grants the request, the hearing will be held within 2 calendar days after the date the appeal has been filed for perishable food, and within 3 calendar days after the date the appeal has been filed for nonperishable food (§ 1.402(d)). This section III.I.2 of this final rule is revised to state that the hearing will be held within 2 calendar days after the date the appeal is filed for both perishable and nonperishable foods. In addition, FDA has

also made clarifying revisions to the procedures that 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. The hearing participant may review this report and suggest changes within 4 hours of the issuance of the report. The presiding officer will then issue the final agency decision. In addition, FDA has added § 1.403(i) and (k) to clarify the components of the administrative record and the record of the administrative proceeding. We have also included clarifying comments in the preamble to this final rule.

We have made two other changes to the proposed rule in order to avoid confusion with CBP terminology and requirements. First, the proposed rule used the term "limited conditional release" to refer to the process whereby FDA grants a request to modify a detention order to permit movement of a detained article of food. The term "limited conditional release" has a different meaning as used by CBP. In order to avoid confusion, we have therefore changed applicable sections of the codified in this final rule to eliminate the use of this term, and instead use the term "request for modification of a detention order."

Second, § 1.381(a) in the proposed rule prohibited delivery of a detained article of food "to another entity under the execution of a bond." This section could have been misinterpreted to prohibit delivery of an article to a storage facility just because it is under a customs bond (as opposed to a penal bond), thereby potentially slowing the flow of trade. In the final rule, § 1.381(a) has been revised to make clear that the existence of an appropriate customs bond required by Customs law and regulation does not prohibit movement of a detained article at FDA's direction.

As noted in the proposed rule, FDA intends to define "serious adverse health consequences" in a separate rulemaking.

### III. Comments on the Final Regulation

FDA received approximately 100 submissions in response to the proposed rule, and each of them raised one or more comments. To make it easier to identify comments and FDA's responses to the comments, the word "Comment" will appear in parentheses before the description of the comment, and the word "Response" will appear in parentheses before FDA's response. FDA also has numbered the sets of comments to make it easier to identify a particular issue. The number assigned to each set of comments is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted to FDA's docket.

A. General Comments

(Comment 1) Many comments state that administrative detention should be limited to use only when there is intentional adulteration (bioterrorism) against the food supply. One comment indicates that administrative detentions should be imposed only when there are no other means to prevent the product from moving in commerce, e.g., when a responsible company will not recall or hold the product. 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) The Bioterrorism Act gives FDA the authority and flexibility to detain administratively articles of food for which FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act does not limit FDA's administrative detention authority to only those situations involving intentional adulteration. Unintentional adulteration can pose the same threats of serious adverse health consequences or death. Therefore, the agency has not changed the final rule as requested by comment 1 in section III A. of this document.

In response to the comment that FDA should only employ an administrative detention when voluntary cooperation is not available, FDA believes that a detention may not be necessary if a firm takes prompt and complete voluntary action, e.g., in a Class I recall situation. However, FDA may nonetheless choose to detain administratively an article of food that has been recalled. Circumstances under which FDA may choose to do so include, but are not limited to, when there is concern that the food may reenter commerce. Thus, FDA will not limit its authority to detain an article of food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 2) FDA sought comments on whether its conclusion that it has authority to detain food in intrastate commerce administratively is correct, and if so, whether the agency should use that authority. A few comments agree with FDA's conclusion that it has authority to impose an administrative detention on articles of food that are only in intrastate commerce. One comment is concerned about the broader jurisdictional implications of FDA not meeting the interstate commerce criterion. Another comment argues that FDA's conclusion that it has authority to detain food administratively that does not enter interstate commerce is inconsistent with limitations imposed by the commerce clause of the U.S. Constitution. In

response to FDA's assertion that Congress, in the Bioterrorism Act, gave the agency authority to detain food administratively in intrastate commerce, this comment states that the commerce clause generally restricts Congress' power to regulate purely intrastate commerce, and that Congress cannot delegate power to FDA that it does not possess. The comment argues that FDA should have assumed that Congress did not intend to violate the Constitution, and that FDA should amend the administrative detention provisions accordingly.

Another comment argues that the agency's use of administrative detention authority on articles of food that are engaged only in intrastate commerce challenges long established federal and state jurisdictional boundaries. This comment further states that, under these new regulations, FDA is moving into areas delegated to state control under the enabling statute and the 10th Amendment to the U.S. Constitution, and that by proposing this regulatory scheme, the agency can avoid and circumvent the very safeguards established to provide against rampant unauthorized expansion of federal authority.

(Response) In the preamble to the proposed rule, FDA tentatively concluded that all food would be subject to administrative detention under section 303 of the Bioterrorism Act if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or

death to humans or animals, whether or not the food enters interstate commerce. FDA is mindful that our interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (See Solid Waste Agency of Northern Cook County v. U.S., 531 U.S. 159 (2001).) The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the commerce clause of the Constitution (Art. I, section 8). Based on these considerations, FDA does not change its conclusion that it has the authority to detain food administratively that does not enter interstate commerce.

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

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

health consequences or death to humans or animals.

This language does not include a limitation similar to that in section 304(g) of the FD&C Act providing for administrative detentions of devices during inspections conducted under section 704 of that act (21 U.S.C. 374), a provision that has an interstate commerce component. In addition, the prohibited act related to administrative detention of food, section 301(bb) of the FD&C Act, unlike some other prohibited acts in section 301, does not include an interstate commerce component. Accordingly, FDA concludes that the Bioterrorism Act does not limit administrative detention only to those foods that enter interstate commerce.

Congress's constitutional power to legislate under the commerce clause is very broad. However, such power is not without limits, see, e.g., United States v. Lopez, 514 U.S. 549, 567 (1995); U.S. v. Morrison, 529 U.S. 598, 618 (2000), and these limits have been construed in light of relevant and enduring precedents. In particular, in Lopez, supra, the Supreme Court acknowledged the continuing vitality of Wickard v. Filburn, 317 U.S. 111 (1942), noting that, "although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not enough to remove him from the scope of federal regulation where, as here, his contribution, taken

together with that of many others similarly situated, is far from trivial.'" 514 U.S. at 556. This principle applies to the administrative detention provision of the Bioterrorism Act. Administrative detention prevents the movement of food where there is credible evidence or information that the food presents a threat of serious adverse health consequences or death. Even if that food is so-called "intrastate" food, the collective impact of that food on interstate commerce is such that FDA believes Congress acted within its power under the commerce clause when it enacted legislation subjecting that food to administrative detention.

FDA's conclusion is also consistent with section 709 of the FD&C Act, which states that, in any action to enforce the FD&C Act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress' goal in enacting the Bioterrorism Act because the potential harm from bioterrorist attacks or other food emergencies can be great, whether or not the food moves from one state to another. The usefulness of the administrative detention authority also can be significant in food emergencies where interstate shipment has not occurred. As a practical matter, FDA believes that this decision should have little if any impact on whether a given food is subject to administrative detention because virtually

all food manufactured, processed, packed, transported, distributed, received, held, or imported, moves, or is considered to move, in interstate commerce. Accordingly, FDA is retaining its conclusion that it has the authority to detain any food administratively when the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals, regardless of whether that food enters interstate commerce.

(Comment 3) A few comments state that FDA should make clear that the detention of cargo always should be managed so as to minimize delay or interference with the orderly movement of an oceangoing vessel or other conveyance. They note that this clarification will be consistent with the intent of the Bioterrorism Act and FDA's relationship with CBP. These comments state that the Bioterrorism Act grants FDA limited detention authority, which should not be interpreted as expanding the agency's authority to inspect and detain imported food on a vessel at a port of entry when this authority belongs, in the first instance, to CBP. These comments note FDA's acknowledgment in our proposal that it intends, primarily, to continue to regulate imported food in conjunction with CBP and under section 801(a) of the FD&C Act. They also note that the provision in section 303(c) of the Bioterrorism Act, which allows an officer of qualified employee of FDA to " \* \* \* request the Secretary of

Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate" further confirms that the authority to detain cargo on board a vessel remains primarily with the CBP service and not FDA.

(Response) As stated in the background section I. of this rule, because of the authorities available to FDA and CBP to control the movement of imported food under section 801(a) of the FD&C Act and various provisions of title 19 of the U.S. Code, FDA does not foresee frequently using administrative detention under section 303 of the Bioterrorism Act to control the movement of imported food subject to those authorities. However, it is within FDA's authority to detain food under section 303 of the Bioterrorism Act that has been offered for import into the United States upon credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals. Consequently, FDA may detain imported food cargo on a conveyance under section 303 of the Bioterrorism Act. If FDA detains imported articles of food on a conveyance, we will consult with CBP to minimize the disruption of the conveyance movement in trade.

(Comment 4) One comment indicates that most tank truckloads

of food are sealed at all openings and that these seals will be broken by FDA inspectors who investigate a suspected problem load. They state that, in the bulk food trucking industry, "a broken seal equals a rejected load." The comment requests that FDA develop a process whereby an FDA representative who breaks a seal to gain access to a load that is found not to present a problem would then reseal the load with an FDA seal and so indicate it on an official FDA document. While not required to, a receiver may be more inclined to accept the load.

(Response) FDA agrees in part with this comment, but is not sure what is meant by an official document upon resealing. Under current practice, which will be continued after the effective date of this rule, whenever FDA reseals a conveyance (e.g., a truckload of goods) after an FDA investigator has broken the seal to examine the goods, the FDA investigator reseals the conveyance with an official FDA metal seal. An FDA document does not accompany the metal seal because the FDA seal is the official indication that FDA has opened and resealed the conveyance. Our internal practice is to record the number of the seal in the investigator's official notes.

(Comment 5) A couple of comments suggest that FDA should avoid implementing a "one size fits all" rule for transportation providers to accommodate the operational differences within the transportation industry. These comments suggest that, instead,

FDA should examine the operational capabilities and realities of the differing transport modes to formulate mode-specific rules, as is currently being done by CBP for the Trade Act of 2002 (Trade Act). These comments further suggest that the agency work closely with CBP to ensure that any rules for importation and exportation of food do not conflict with CBP requirements. The comments suggest that FDA work with CBP to take advantage of the cross-border supply chain security program already in place, to avoid burdensome duplication of effort.

(Response) FDA does not agree that it is necessary to adopt different administrative detention requirements for different modes of transport. The Trade Act deals with advance notice of items arriving in the United States, not with detention of potentially unsafe food to ensure it does not move into distribution pending the filing of a court action. Congress specifically directed CBP to consider different advance notice timeframes for items arriving on different modes of transport (e.g., truck, air, vessel, rail). This Congressional directive did not extend to actions taken by FDA to implement section 303 of the Bioterrorism Act. In the implementation of section 303, different transport modes are irrelevant because food subject to administrative detention will either be detained in place or detained by offloading it from the transport mode and transferring it to another facility. This is true regardless of

whether the mode of transport is truck, air, vessel, or rail. FDA will continue to work with CBP to coordinate actions at the border.

(Comment 6) One comment states that bulk transportation of food products in tank trailers and dry bulk trailers is significantly different from packaged or prepared food transportation. This comment urges FDA to recognize these differences either in the language of the regulation, or by a separate section strictly dealing with bulk transportation.

(Response) Section 1.393(b)(8) states that FDA must include in the detention order any applicable conditions of transportation of the detained article of food. FDA will take into consideration the mode of transportation being used for the detained product, and the form in which the article of food is being transported, e.g., packaged or dry bulk, when setting forth these conditions.

(Comment 7) With respect to detained shipments of imported food, one comment believes that FDA should work with CBP to immediately control these foods, and to program CBP's Automatic Commercial System (ACS) and Automated Broker Interface (ABI) to not issue a CBP release for any such shipment.

(Response) When imported food at the border is found to warrant administrative detention under section 304(h) of the

FD&C Act, FDA will continue to work with CBP as the agency currently does with respect to section 801(a) of the FD&C Act. FDA will issue a detention order under §§ 1.392 and 1.393, which will specify the terms of the detention. Under § 1.393(b)(9), the order will include a statement that "the article of food is not be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381." Accordingly, FDA does not believe it is necessary to communicate detentions through ACS or ABI.

(Comment 8) One comment is concerned about where imported food will be detained. The comment describes FDA's current procedures of only detaining imported food at the port where the consumption entry is filed with CBP, which may not be the port of arrival. Currently, imported food is detained at the port where the consumption entry is filed after FDA receives the declaration and the Operational and Administrative System Import Support declaration is made. The comment wants this procedure to continue unchanged.

(Response) In this comment, the person is describing FDA's current procedures for refusing admission under section 801(a) of the FD&C Act. In the event that imported food is detained administratively under section 303 of the Bioterrorism Act, the product would be detained as soon as FDA had credible evidence

or information that the food product posed a threat of serious adverse health consequences or death. This could presumably occur while the product was still at the port of entry where the goods arrived in the United States. Thus, it is conceivable that FDA could administratively detain a food product at the port of entry where arrival took place, the port of destination, or any location in between. This is consistent with the purpose of administrative detention, which 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. Under § 1.393(b)(7), the detention order will specify the address and location where the article of food is to be detained and the appropriate storage conditions.

(Comment 9) One comment suggests that their written comments can at best only highlight some of the issues and implications raised by FDA's proposal. The comment further states that the best way to address these subjects is through a working group that brings together members of the trading community with officials from FDA and CBP. If a meeting is not possible, the comment requests to schedule a meeting at FDA's earliest convenience to further discuss the matter.

(Response) FDA conducted extensive outreach on the proposed administrative detention rule, including attending international

and domestic meetings to ensure that affected parties were aware of the Bioterrorism Act administrative detention requirements and understood the proposed requirements so that they could provide meaningful comments. On May 7, 2003, FDA held a public meeting (via satellite downlink) to discuss both the administrative detention and recordkeeping proposed rules. (See 68 FR 16998, April 8, 2003 or

<http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm>.)

The live broadcast was available to participants in North America, Central America, and South America, and the Caribbean. The meeting was later rebroadcast to Europe, Southern Africa, Asia, and the Pacific. FDA also has posted transcripts of the broadcast in English, French, and Spanish (the three official WTO languages) on the agency's Web site.

(Comment 10) One comment is concerned that pet products will be administratively detained due to unwarranted association with countries or geographic areas that may face animal health or food safety emergencies. Another comment questions whether FDA's administrative detention authority applies to transit shipments in the United States, i.e., goods in transit through the United States that are not declared for U.S. consumption. Another comment asks what relationship or obligation has been established between the Bioterrorism Act and hazard analysis and

critical control points (HACCP) and good manufacturing practices (GMPs).

(Response) FDA can detain an article of food administratively only if FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. That is the standard that must be met for administrative detention of all food, including pet food. FDA also has authority to detain administratively any food in the United States that meets the standard for administrative detention, including transit shipments of food. Finally, it is not clear what is meant by the terms "relationship" and "obligation" with respect to the Bioterrorism Act and HACCP and GMPs. FDA has authority to detain food administratively when that food meets the standard for administrative detention, regardless of how the food comes to meet that standard, e.g., by failure to follow GMPs, as the result of an act of bioterrorism, etc. FDA's decision to employ administrative detention or other applicable authorities under the FD&C Act will be made on a case-by-case basis depending on the facts of each particular case.

(Comment 11) One comment asks if FDA is suggesting that carriers, warehouses and others in the supply chain process must

adhere to specific security standards, and if so, suggests that such standards be clearly identified.

(Response) This final rule does not establish general requirements or guidance relating to specific security standards or practices for carriers, warehouses and others in the supply chain. However, FDA recently published several guidance documents concerning preventative food safety measures that individual firms may wish to consider as they develop their own security measures. FDA's guidance documents can be found on the agency's Web site. (See <http://www.cfsan.fda.gov/~dms/fsterr.html>.) If FDA does issue a detention order, the order would contain the address and location where the article of food is to be detained, and the appropriate storage conditions.

(Comment 12) One comment indicates that if an officer detains a product in temporary hold for 24 hours, then the total time invested in the appeal and hearing process will exceed the timeframe for perishable foods. This comment asks FDA to specify 7 days for the detention process from the formal detention until the final resolution or termination based on the definition for perishable food, which is that the quality of the product is adversely affected after 7 days of storage. The comment states that a product that has been under a temporary hold and detained for 7 days will exceed the useful time of a perishable food.

Another comment states that FDA must take into account the 24-hour period of the temporary hold in the detention time of 30 days. Another comment states that they do not challenge the right of FDA to inspect food products at the border, but that, in their view, the 24 hour temporary hold is an unreasonable time to force a truck and driver to wait for FDA to conduct an inspection and issue a decision. This comment indicates that the proposed recordkeeping rule will require companies to turn over records to FDA within 4 hours during normal business hours, and 8 hours on evenings and weekends, and suggests that, if FDA is willing to impose such short timeframes on industry, then it should also be required to adhere to them in the conduct of its own operations.

Another comment suggests that the guidance on temporary holds should be made available as soon as possible because there is no explanation about why FDA must ask specifically the "Secretary of Treasury" to institute the temporary hold. This comment states that it is not clear if the alternative exists for the "Secretary of Treasury" to designate or to enable someone with proper skills to replace him when he is not available. A few comments state that the proposed provision for the temporary holding of imports for 24 hours is open to abuse. They indicate that not only is there no comparable provision for domestic products, but there is a real risk that the provision

could amount to a "holding bay" for import inspections while FDA resources are used to deal with domestic alerts elsewhere.

(Response) As indicated in the background section I. of this rule, the temporary hold provisions authorized in section 303 of the Bioterrorism Act are outside the scope of this rulemaking. FDA plans to consider these comments as we develop our approach on how best to implement this provision of the Bioterrorism Act.

FDA notes, however, that the period of detention for administrative detention under section 303 of the Bioterrorism Act does not begin until the detention order is issued.

(Comment 13) Several comments ask that the implementation date of these regulations be pushed back because the new authorities are extensive and the timeframe for implementation is unusually quick for such a sweeping change. Furthermore, the comments state that the proposed timeframes are not sufficient for producers in exporting countries to adapt their products to the requirements of the Bioterrorism Act, and will result in unnecessary costs and delays.

(Response) Even if FDA delayed implementation of the regulations, the authority for administrative detention is self-executing and currently in effect. In addition, FDA believes that it is in the public's interest to implement these

regulations as soon as possible to facilitate the resolution of administrative detentions.

(Comment 14) One comment indicates that the new regulations are burdensome and overlap with current requirements under parts 7, 110, 123, and 1240 (21 CFR parts 7, 110, 123, and 1240). This comment states that if these provisions were properly implemented, they would be more than adequate to address concerns FDA may have with rapid location of affected product and ingredient traceability that are the major concerns with this new provision. Another comment states that FDA's Investigations Operations Manual (IOM), subchapter 750, describes the procedure that FDA must follow currently for detention activities and that the new regulations do not appear substantially different. Another comment questions the need for this rulemaking because it appears that FDA considers the threshold for detention to be equivalent to the standard for initiating a Class I recall.

(Response) FDA disagrees with these comments. The regulations in parts 7, 110, 123, and 1240, and subchapter 750 of the IOM, do not address administrative detentions of food under section 303 of the Bioterrorism Act. Further, the regulations cited in the comment are not based on the substantive standard for administrative detention under section 303 of the Bioterrorism Act, which is that the detained article

of food presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 15) Numerous comments ask that FDA provide compensation for losses incurred as a result of a detention. Some comments refer to detentions where the product is eventually released, but is no longer marketable. Other comments want compensation for detentions in which damages are incurred as a result of any detention, i.e., including detentions where the product is confirmed to present a threat of serious adverse health consequences or death to humans or animals. Another comment states that the regulation does not adequately address the legal and financial responsibility for the disposal of food as a result of the threat it presents. This comment suggests that an entity with a vested interest in the product, e.g., the owner, would bear the responsibility, and that failure on the part of the food product owner to pay storage, handling and related costs should be considered a violation of the FD&C Act. 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) Neither the FD&C Act nor the Bioterrorism Act provides for damages or other costs associated with administrative detention. In addition, the failure to pay storage, handling, and related costs is not a violation of the

FD&C Act. With respect to the comment that FDA should provide government funding to help industry institute measures to improve food security, that issue is beyond the scope of this rulemaking and would require statutory authorization and appropriations.

(Comment 16) A few comments suggest that the rule should require that FDA determine the party actually responsible for the threat against the food and define their responsibility. One comment indicates that FDA must consider that the party responsible for the threat could be a third party, i.e., a party not included in the importation or distribution of the product. Another comment asks who will be held responsible in the case where a product is packaged in bulk in one country and repackaged in another country for export to the United States. One comment asks how FDA will differentiate between an actual threat and a hoax and if it will matter. Another comment asks what penalty exists for the supplier of suspect shipments. Another comment requests that FDA provide the owner of the food with information about the threat even if the credible evidence is classified information.

(Response) The Bioterrorism Act allows FDA to detain articles of food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. It does not

require FDA to determine who is responsible for the threat in order to detain the product. Whether the person responsible for that threat or the person responsible for supplying the suspect article of food may be held liable or subject to criminal prosecution under other statutory provisions is beyond the scope of this rulemaking.

The purpose of any FDA investigation is to determine and document facts concerning a particular issue so that the agency can make informed and sound decisions. FDA cannot rule out the possibility that a hoax could give rise to an administrative detention and, in evaluating the evidence or information to determine whether it is credible, FDA will be mindful of the fact that hoaxes do occur.

In response to the comment that FDA provide the owner of the food with information about the threat even if the credible evidence is classified information, 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.

(Comment 17) Many comments state that industry is motivated to cooperate with FDA to protect consumers and maintain national security interests in the event of a real threat. They indicate that it is imperative that FDA and industry work together as a team to quickly address such

occurrences. These comments state that FDA must devise a clear communications strategy and that the agency should test such plans to make sure that they will work seamlessly.

(Response). These comments are outside the scope of this rulemaking. We agree that it is imperative that FDA and industry work together to protect the U.S. food supply. The agency recognizes the cooperation and effort that the industry has already shown in the area of food safety and security. One such example of industry and FDA partnering to protect the U.S. food supply was in the development of a Food Security Guidance that food producers can use if they choose to improve the protection of their products against tampering or terrorist actions. (See <http://www.cfsan.fda.gov/~dms/fsterr.html>.) FDA also agrees that it is imperative to have clear communication strategies in place and to test such plans to ensure that they will be effective in the event of a bioterrorism or other food-related emergency. We have been developing plans in this area and continue to examine other possible ways to better manage food emergencies and consult with industry on this.

(Comment 18). One comment states that development of reasonable preventative measures and appropriate responses, including rational governmental activities that are effective within every facet of the food system, are critical to protecting public safety. This comment asserts that, to be

effective, these measures must be driven by the public and the food industry, not by regulation.

(Response) This comment is outside of the scope of this rulemaking. As stated in FDA's response to the previous comments, the agency recognizes the outside cooperation and effort that have already been shown in the area of food safety and security. However, FDA also believes that it is important for the agency to implement the statutory provisions on food safety and to fulfill its statutory mandates concerning food safety. FDA will provide ongoing opportunities for consumers, industry, state and local governments, and other constituents to keep informed of, and involved in, the agency's activities related to the development of preventative measures and responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Before issuing the proposed rules concerning sections 303, 305, 306, and 307 of the Bioterrorism Act, the agency provided an opportunity for constituents to identify concerns and suggest ways to address them. It is imperative that FDA and its constituents work together to protect the U.S. food supply.

(Comment 19) Some comments assert that the regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade. One comment states that this negative impact will likely result in negative ramifications for U.S.

food exports because the future may well find retaliatory trade restrictions placed upon U.S. exports as a direct result of the regulatory requirements generated from the Bioterrorism Act.

(Response) In drafting the final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act. FDA carefully considered comments received regarding the burden imposed by this rule, including its impact on international trade.

(Comment 20) Several comments ask that FDA provide clear guidance and training to industry personnel at all levels and agency field personnel about the procedures for implementing the regulation. A few comments suggest that an easy to follow guide for the appeal process would be desirable. A few comments request that FDA establish consultation services at U.S. embassies staffed with speakers of various different foreign languages, such as Japanese and Spanish, and that the Bioterrorism Act and all documents associated with the detention be accompanied by official translations to facilitate comprehension and proper use. The comments suggest that we disseminate the translated material on our Web site and by other means.

(Response) FDA conducted extensive outreach on the proposed administrative detention rule, including attending international and domestic meetings, to ensure that affected parties were

aware of the Bioterrorism Act administrative detention requirements.

FDA plans similar future outreach efforts. More specifics regarding our outreach activities will be included on FDA's Web site at <http://www.fda.gov>.

FDA also plans training for its field personnel on the administrative detention procedures.

FDA does not have the resources to establish consultation services at U.S. embassies staffed with speakers of foreign languages, or to provide official translations of all documents associated with a detention and the Bioterrorism Act.

(Comment 21) One comment asks whether the United States has developed biosecurity and sophisticated devices to test and control dangerous biological agents and toxins, including those that present a threat to plants or animals. This comment also asks if the United States has developed new methods to detect contaminated foods, to work with state food safety regulators, and to protect crops and livestock.

(Response) The issues described in these comments are outside the scope of this final rule. However, we are sensitive to these concerns and wish to assure the comments that the agency is doing a number of things to increase our ability to detect the presence of agents that may present a threat to foods

for human and animal consumption. We do not believe it is appropriate to discuss these activities in this final rule; however, more information can be obtained on FDA's Web site. (See "'Hot Topics" on the Web site at: <http://www.fda.gov>.)

(Comment 22) Two comments state that every effort should be made to ensure that information regarding the detention of a product is accurate and publicized only when necessary in an effort to protect public health. The comments state that such publicity should be transmitted in a clear, unemotional, and factual manner without unduly or inaccurately raising public concern. The comments also indicate that the agency should be aware that if the public is told a product has been detained and it is later found to be nonviolative, the reputation of the company likely will be damaged due to the public perception that the product was somehow unsafe because it had been detained. The comment is concerned that information that a detained product has been released seldom reaches the public. One of these comments states that to minimize these losses, the detention order should become a part of the public record only if FDA determines that the product presents a threat of serious adverse health consequences or death to humans or animals.

(Response) FDA has no plans to routinely publicize the issuance of detention orders. However, in the event of a public health emergency, FDA may issue a Talk Paper or Press Release

with information regarding a detained article of food that presents a threat of serious adverse health consequences or death to humans or animals. In such an emergency, FDA may also inform other departments, agencies or governments. In addition, administrative detentions can be precursors to enforcement action in Federal court, particularly seizures, which are public filings in the courts. Information regarding a detention could be included in the complaint for forfeiture. Information regarding administrative detentions also may be released under a Freedom of Information Act (FOIA) request after FDA has removed any information that is protected from disclosure to the public.

(Comment 23) Several comments request clarity concerning which rule will be applied to imports and under what circumstances. These comments indicate that FDA's regulatory framework for imports is more stringent than that applied to domestic products. One of these comments suggests that an administrative detention mechanism that allows FDA to take action against domestic foods that appear to be adulterated or misbranded is needed. Another of these comments indicates that historically, detention orders have not been delivered directly to the owners or importer of record in a timely fashion. This comment further indicates that, because detention orders have historically covered future shipments of the product and

included nonrelated growers, FDA should consider removing the time limit to file appeals regarding detention orders.

Another comment argues that the proposed rule would give a competitive advantage to domestic food over imported food because domestic food would be subject only to administrative detention, while imported food would be subject to both administrative detention and "normal" import detention.

(Response) The issues concerning how FDA has implemented section 801 of the FD&C Act are outside the scope of this regulation. FDA reiterates that this final rule does not implement section 801 of the FD&C Act, despite its use of the term "detention." This final rule implements section 303 of the Bioterrorism Act, which amends section 304 of the FD&C Act, by adding paragraph (h) to that section.

Section 304(h) of the FD&C Act applies the same standard to domestic and imported food. The criteria for administrative detention under section 304(h) of the FD&C Act are credible evidence or information that an article of food presents a threat of severe adverse health consequences or death to humans or animals. The procedures for administrative detention under section 304(h) of the FD&C Act are described in this rule and will be applied in the same way to both imported and domestic food that is detained administratively under section 304(h).

FDA disagrees that domestic food has a competitive advantage over imported food. FDA investigators and inspectors are authorized under the FD&C Act to inspect domestic food manufacturers, packers, and distributors to determine their compliance with the FD&C Act and its implementing regulations. As part of its vigorous domestic enforcement program, FDA inspects domestic food facilities and collects domestic food product samples for examination by FDA scientists or for label checks. When warranted, judicial enforcement actions are brought against violative articles of food and their manufacturers and distributors.

B. Comments on Foreign Trade Issues

(Comment 24) Some comments question the consistency of the regulation with U.S. obligations under the NAFTA and various WTO agreements.

(Response) FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation. FDA believes that these regulations are consistent with these international trade obligations. In addition, and as discussed elsewhere in this preamble, FDA does not foresee frequently using administrative detention under section 304(h) of the FD&C Act to control the movement of imported food subject to section 801 of the FD&C Act.

(Comment 25) Some comments assert that the regulation is burdensome, costly, discriminatory, and will have a negative impact on foreign trade.

(Response) In drafting the final rule, FDA structured the rule to be consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. FDA carefully considered comments received regarding the burden imposed by this rule, including its impact on international trade.

C. Comments on What Definitions Apply to This Subpart?

(Proposed § 1.377)

1. Definition of "The Act"

(Comment 26) FDA did not receive comments on the definition of "the act."

(Response) We did not change the definition in the final rule.

2. Definition of "Authorized FDA Representative"

(Comment 27) Several comments state that based on the serious nature of administrative detentions, decisions to detain products administratively should be made by an official at the regional FDA director level or higher because of the cost implications and serious business impact such an action would cause. In addition, some comments state that approval at the FDA District Director level allows too much discretion, and that a

higher level of approval is necessary to ensure some level of uniformity.

(Response) Permitting approval of an administrative detention at the FDA District Director level is consistent with section 303 of the Bioterrorism Act, which allows such approval at the FDA district level, or above. As required by § 1.391, all detention orders must be approved by an authorized FDA representative. FDA defines authorized FDA representative for the purpose of this final regulation as an FDA District Director in whose district the detained article of food is located or an FDA official senior to such director. For example, an RFDD is an FDA official senior to an FDA District Director.

(Comment 28) A couple of comments state that defining "qualified employee" at even the District Director level is problematic because of what the comments characterize as FDA's erroneous decisions in the past regarding "tainted foods" (e.g., fish, fruits, vegetables). They note that these industries have fallen victim to otherwise "qualified" federal and state employees who have wrongly accused many commodities of potential contamination.

(Response) Although a comment alleged that FDA has made wrong decisions in the past, they did not identify any particular wrong decision.

FDA is not limiting "officer or qualified employee" to the District Director level or higher. The officers or qualified employees of FDA who may order a detention include, but are not limited to, FDA field investigators; FDA employees who have security clearance to receive national security information; and health, food, or drug officers or employees of any State, Territory, or political subdivision thereof, duly commissioned by FDA as officers of the Department under section 702(a) of the FD&C Act (21 U.S.C. 372). Only an authorized FDA representative, however, can approve a detention order. FDA is defining an "authorized FDA representative" as an FDA District Director in whose district the detained article of food is located, or an FDA official senior to an FDA District Director. This language is drawn from section 303 of the Bioterrorism Act. Clearly, Congress envisioned that only FDA officials with a given level of seniority would have authority to approve a detention order.

(Comment 29) One comment questions how the owner/carrier will know that FDA's personnel are authorized to detain their product.

(Response) Section 1.391 states that an authorized FDA representative, i.e., the FDA's District Director in whose district the article of food is involved is located or an FDA official senior to such director, must approve the detention order. If prior written approval is not feasible, prior oral

approval must be obtained and confirmed in writing as soon as possible. Consequently, all FDA personnel issuing a detention must be authorized in advance to issue the detention order. Under § 1.393(b)(13), the detention order must indicate the manner in which approval of the detention order was obtained, i.e., verbally or in writing.

We have revised the final rule to include § 1.393(b)(14), which requires that the name and title of the authorized FDA representative who approved the detention order be included in the detention order.

Section 1.392(a) of the final rule requires FDA to issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily. Under § 1.392(b), if FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, we also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily. Thus, the owner and carrier will know from the detention order how the approval was

obtained and the name and title of the authorized FDA representative who approved the detention order.

(Comment 30) One comment notes that FDA must employ strict internal procedural requirements for FDA officers and employees and our agents that are involved in determination of potential adulteration or intentional contamination.

(Response) FDA officers, employees, and agents authorized to carry out an administrative detention will be fully trained.

### 3. Definition of "Calendar Day"

(Comment 31) FDA did not receive comments on the definition of "calendar day."

(Response) We did not change the definition in the final rule.

### 4. Definition of "Food"

(Comment 32) A few comments state that alcoholic beverages should not be covered under this provision because they are regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB), as well as by individual states. One of these comments suggests that FDA should revise the rule to specify that TTB officials are responsible for ordering any administrative detentions of alcoholic beverages. Another comment states that FDA should secure a legislative amendment to the Bioterrorism Act that exempts wines and spirits and other alcoholic beverages under the jurisdiction of TTB from its application, in the same way as

meat, poultry, and egg products under the jurisdiction of the U.S. Department of Agriculture (USDA) are excluded from its scope. This comment indicates that the inconsistency does not appear to be founded on any objective criteria such as risk analysis.

(Response) This rule complies with section 315 of the Bioterrorism Act, "Rule of Construction," which states that nothing in Title III of the Bioterrorism Act, or an amendment made by Title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services (HHS) under applicable statutes and regulations. Accordingly, this final rule does not apply to food regulated exclusively by USDA under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

Unlike USDA, there are no provisions in section 303 of the Bioterrorism Act that specifically address the jurisdiction of TTB. Under existing law, TTB does not have exclusive jurisdiction over alcoholic beverages. TTB establishes tariffs and licensure requirements, and has primary jurisdiction over the labeling of alcoholic beverages. However, FDA exercises jurisdiction over alcoholic beverages as "food" for the purposes of the adulteration and other provisions of the FD&C Act.

FDA recognizes that working in conjunction with TTB and individual states is an important tool we have in the event of a threat to the nation's food supply. However, 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 (21 U.S.C. 321(f)). As stated in the proposed rule, and discussed in detail in the following paragraphs, 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.

FDA reiterates that, under this final rule, any administrative detention ordered by an officer or qualified employee must be approved by an authorizing official.

Comments suggesting that FDA should request a legislative amendment to the Bioterrorism Act are outside the scope of this rulemaking.

(Comment 33) A few comments state that indirect food additives, such as color pigments for packaging, packaging polymers, and coatings should be exempt from coverage under section 303 of the Bioterrorism Act because, by definition as a food additive, the manufacturer must demonstrate under FDA's food additive regulations that they are safe and stable. 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. Another comment suggests that tableware, including ceramic and lead crystal, also should be exempt from coverage under this provision of the Bioterrorism Act because Congress did not intend such a broad scope. This comment states that contaminated food products present an immediate risk to public health, whereas adulterated food contact articles present a risk only once they have contact with food, and only if the poisonous or deleterious substance actually migrates into the food. The comment further states that the lack of immediacy means that there is a significant potential for intervening actions; for example, washing purchased tableware items before using them for the first time to reduce or eliminate any risks posed by a bioterrorist act aimed at food contact articles.

Two comments state the belief that live food animals, pet food, and animal feed, including fertilizers that end up in animal feed, should not be covered by this rule because Congress did not intend such a broad scope. Another comment states that any material that might end up in food, but that has nonfood uses, should be exempt from coverage under section 303 of the Bioterrorism Act unless the manufacturer knows the material will

be consumed in the United States as food. One comment states that food that will be used in trade shows should be exempt from coverage under this provision because the trade shows have their own self-regulation and because FDA could visit the trade shows and easily inspect the products. Another comment states that technical samples of food, e.g. less than 100 grams (g) of a product, should be exempt from coverage under this rule.

(Response) FDA disagrees with these comments and is finalizing the definition of "food" as proposed. FDA is not excluding food contact materials, live animals, alcoholic beverages, or other articles of food from coverage under this regulation.

These comments raise the question of what Congress intended "food" to mean for purposes of administrative detention. In construing the administrative detention provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented ("Chevron step one") Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have focused directly on the question presented and have articulated clearly its intention. Young v. Community Nutrition Institute, 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. Chevron, 467 U.S. at 842-843. If, however,

the Bioterrorism Act is silent or ambiguous as to the meaning of "food," FDA may define "food" in a reasonable fashion ("Chevron step two"). Chevron, 467 U.S. at 842-843; FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000).

The agency has determined that, in enacting section 303, Congress did not speak directly and precisely to the meaning of "food." As noted, the FD&C Act has a definition of "food" in section 201(f) of the FD&C Act. It is a reasonable assumption that, when the term "food" is used in the FD&C Act, section 201(f) applies. However, although there may be "a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted], \* \* \*the presumption is not rigid.\* \* \*" Atlantic Cleaners & Dyers, Inc. v. U.S., 286 U.S. 427, 433 (1932). Accord: U.S. v. Cleveland Indians Baseball Co., 532 U.S. 200, 213 (2000). Thus, the same word may be given different meanings, even in the same statute, if different interpretations are what Congress intended. (Atlantic Cleaners & Dryers, Inc., supra.)

Even before the Bioterrorism Act amendments, the term "food" was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical "(other than food)" in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit noted that Congress meant to exclude only "articles used

by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value" and not all substances defined as food by section 201(f) of the FD&C Act. Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983). Similarly, section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) defines a food contact substance as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (emphasis added)." This definition makes sense only if "food" in that section is interpreted to exclude materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.<sup>1</sup>

Thus, in this larger statutory context, FDA has evaluated section 303 of the Bioterrorism Act to determine whether the meaning of the word "food" is ambiguous. In conducting this Chevron step one analysis, all of the traditional tools of statutory interpretation are available to determine whether

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<sup>1</sup> FDA's long-standing interpretation of the act's definition of color additive, section 201(t) of the FD&C Act (21 U.S.C. 201(t)), is an additional example of where "food" is used more narrowly than as defined in section 201(f). A color additive is defined in section 201(t) of the FD&C Act as a substance that "when applied to a food \* \* \* is capable \* \* \* of imparting color thereto \* \* \*". The agency's food additive regulations distinguish between color additives and "colorants," the latter being used to impart color to a food-contact material. (21 CFR 178.3297(a); see also 21 CFR 70.3(f).) Thus, "food" as it appears in the statutory definition of color additive, necessarily excludes food contact materials.

Congress's intent is ambiguous. Pharmaceutical Research & Manufacturers of America v. Thompson, 251 F. 3d 219, 224 (D.C. Cir. 2001). Beginning with the language of the statute, in section 303 of the Bioterrorism Act, "food" is used to describe which subset of FDA-regulated articles are subject to administrative detention: An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this section, of any article of food that is found during an inspection, examination, or investigation under the Bioterrorism Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals (emphasis added).

The Bioterrorism Act is silent as to the meaning of "food." Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other possibilities noted previously, or another meaning. Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole. Martini v. Federal Nat'l Mortgage Association, 178 F. 3d 1336, 1345 (D.C. Cir. 1999), citing K Mart Corp. v. Cartier, Inc., 486 U.S. 281

(1988). Indeed, the analysis should not be confined to the specific provision in isolation, because the meaning or ambiguity of a term may be evident only when considered in a larger context. FDA v. Brown & Williamson Tobacco Corp., supra at 132 (2000).

FDA has considered other sections of the Bioterrorism Act and has concluded that the meaning of "food" in the Bioterrorism Act is ambiguous. FDA previously considered the meaning of "food" in section 305 of the Bioterrorism Act, governing registration of food facilities, and concluded that it is ambiguous (68 FR 58894). Section 305 of the Bioterrorism Act amends the FD&C Act by adding section 415 to that act. In section 415(a)(1) of the FD&C Act, the word "food" is modified by the phrase "for consumption in the United States." It's not clear whether this modifying phrase limits the definition of "food" to food that is ingested--a narrower definition of "food" than that in section 201(f) of the FD&C Act. In addition, the definition of "facility" in section 415(b)(1) of the FD&C Act exempts "farms; restaurants; other retail establishments." It's not clear whether the phrase "other retail establishments" includes retailers of food contact materials; the legislative history indicates that it does not, thereby giving rise to additional ambiguity about which definition of "food" applies to section 415 of the FD&C Act.

MAY 26 2004

FDA also considered the meaning of "food" in section 307 of the Bioterrorism Act, governing prior notice of imported food shipments, and concluded that it is ambiguous (68 FR 58974). Section 307 of the Bioterrorism Act amends the FD&C Act by adding section 801(m) to that act. Section 801(m) of the FD&C Act refers to an "article of food." However, the legislative history of section 307 of the Bioterrorism Act indicates that packaging materials are not subject to section 307, and can be read to imply that Congress was not relying on the definition of food in section 201(f) of the FD&C Act, thereby giving rise to ambiguity about which definition of "food" applies to section 307 of the Bioterrorism Act.

Finally, FDA considered the meaning of "food" in developing a final rule to implement section 306 of the Bioterrorism Act, governing maintenance and inspection of records for foods, which ~~is also being published in this issue of the Federal Register~~ <sup>will be</sup> <sup>in the near future.</sup> ~~of the Federal Register~~. Section 306 of the Bioterrorism Act amends the FD&C Act by adding section 414 to that act. Section 414(a) of the FD&C Act, which covers inspection of records, refers to "an article of food," and "food." But section 414(b) of the FD&C Act, which covers establishment and maintenance of records, refers to "food, including its packaging." Elsewhere in the record provisions, section 414 of the FD&C Act refers to "food safety," "a food to the extent it is within the exclusive jurisdiction of

KMS  
CFSA

[USDA]," and "recipes for food." There is, thus, ambiguity about which definition of "food" applies to section 306 of the Bioterrorism Act.

The ambiguity surrounding Congress's use of "food" in sections 303, 305, 306, and 307 of the Bioterrorism Act, coupled with the lack of a definition of the term in that act, support a conclusion that the meaning of "food" in the Bioterrorism Act is ambiguous.

Having concluded that the meaning of "food" in the Bioterrorism Act and in section 303 of that act is ambiguous, FDA has considered how to define the term to achieve a "permissible construction" of the administrative detention provision. Chevron, USA, Inc. v. NRDC, Inc., *supra* at 843. In conducting this Chevron step two analysis, the agency has considered the same information evaluated at step one of the analysis. Bell Atlantic Telephone Co. v. FCC, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); Chevron U.S.A., Inc. v. FERC, 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the administrative detention provision, to use the definition of "food" in section 201(f) of the FD&C Act.<sup>2</sup>

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<sup>2</sup> Alternatively, it may be argued that the meaning of "food" in section 303 of the Bioterrorism Act is not ambiguous, and that the Chevron analysis stops at step one. Under either approach, the definition of "food" in section 201(f) of the FD&C Act applies to section 303 of the Bioterrorism Act.

Use of the definition of food in section 201(f) of the FD&C Act is consistent with the language of section 303 of the Bioterrorism Act. Section 303 of the Bioterrorism Act repeatedly uses the term "food" without adjectives. There is only one instance in which section 303 uses an adjective with the term "food," and that is in section 304(h)(2) of the FD&C Act, which directs the Secretary to provide for procedures for instituting certain judicial enforcement actions on an expedited basis with respect to "perishable foods." Use of the adjective "perishable" in this context does not limit the reach of section 303 of the Bioterrorism Act to a subset of "food" as defined in section 201(f) of the FD&C Act. Rather, the adjective "perishable" serves to distinguish perishable from nonperishable food for purposes of deciding what type of food is subject to the procedures mandated by section 304(h)(2) of the FD&C Act. Nonperishable food, though not necessarily subject to the procedures mandated by section 304(h)(2) of the FD&C Act, is nonetheless subject to administrative detention.

Use of the definition of "food" in section 201(f) of the FD&C Act is also consistent with the fact the judicial enforcement actions that may be instituted under administrative detention have been consistently interpreted to use that same definition. Section 304(a)(1) of the FD&C Act authorizes seizure of any "article of food" that is adulterated or

misbranded under specified conditions. In applying section 304(a)(1) of the FD&C Act, FDA and the federal courts use the definition of "food" in section 201(f) of the FD&C Act. See, e.g., Natick Paperboard Corp. v. Weinberger, 525 F.2d 1103 (1st Cir. 1975); U.S. v. An Article of Food, 752 F.2d 11 (1st Cir. 1985). Section 302 of the FD&C Act authorizes injunction to restrain violation of certain provisions of section 301 of that act, which repeatedly uses the term "food." In applying section 302 of the FD&C Act (21 U.S.C. 332), FDA and the federal courts use the definition of "food" in section 201(f) of the FD&C Act. See, e.g., U.S. v. Blue Ribbon Smoked Fish, Inc., 179 F.Supp.2d 30 (E.D.N.Y. 2001).

FDA is therefore retaining its interpretation of "food" in section 303 of the Bioterrorism Act to mean "food" as defined in section 201(f) of the FD&C Act. Food subject to section 303 of the Bioterrorism Act thus includes, but is not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients; infant formula, beverages, including alcoholic beverages and bottled water, live food animals (such

as hogs and elk), bakery goods, snack foods, candy, and canned foods.<sup>3</sup>

The standard for administrative detention—credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals is a high threshold. Where this threshold is met for any article of food, it is appropriate for FDA to use the full authority provided by the Bioterrorism Act and thereby protect public health to the fullest extent possible.

#### 5. Definition of "Perishable Food"

(Comment 34) FDA sought comments and supporting data on how to best define "perishable food" for purposes of this rule. Several comments state that the definition for "perishable food" should be revised to mean foods with a shelf life of 90 days from the date of packaging, including products that are thermally processed or treated to extend the shelf life to 90 days from the date of packaging. Another comment states that FDA should use the definitions in the National Institute of Standards and Technology (NIST) handbook, which are: Perishable, 60-day shelf life from date of packaging; semiperishable, 60 days to 6 months shelf life from the date of packaging; and long

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<sup>3</sup> The agency notes that the scope of the definition of "food" in the regulations implementing section 303 of the Bioterrorism Act (administrative detention) is broader than the scope of the definition of "food" in the regulations implementing sections 305 (registration) and 307 (prior notice) (68 FR 58894, October 10, 2003, and 68 FR 58974, respectively).

shelf life, greater than 6 months shelf life from the date of packaging. Yet another comment suggests that we use the definition for perishable foods as it is described in the Perishable Commodities Act. One comment states that live animals should be considered perishable food items because they must be fed, watered, and possibly medicated to stay alive. That comment asks who will be responsible for feeding, watering, and medicating the animals if they are detained. A few comments state that the definitions should consider loss of marketability, and not just loss of physical and biological properties. These comments indicate that many products have optimum release dates, such as seasonal items (Valentine's candy), special release items (wines), and strict stock rotational items (snack foods, baked goods, and tortillas) that would quickly lose their marketability. Many comments suggest that the definition for "perishable food" should be revised to include foods that have 120 days of shelf life because products with older "sell by" dates lose their marketability. One comment asks whether products in bulk form that are intended for further processing and have a short shelf life are covered under the definition of "perishable food."

(Response) FDA disagrees with these comments and is finalizing the proposed definition for "perishable food" without any revisions. The context in which the term "perishable food"

appears in section 303 of the Bioterrorism Act indicates that, at least with respect to administrative detention, Congress was concerned with articles of food that would spoil relatively quickly. It is unlikely that Congress would have mandated expedited procedures for instituting certain enforcement actions against foods that have a shelf life of up to 90 days, given that the statute only allows FDA to detain foods for a maximum of 30 days while it seeks to initiate certain judicial enforcement actions.

The definition of "perishable food" in this final rule has been modeled after the current Regulatory Procedures Manual (RPM) definition of "perishable commodity." We decided to use the RPM definition of "perishable commodity" as the basis for the definition of "perishable food" because the RPM definition is commonly used and understood by both industry and FDA. Furthermore, we believe this definition is appropriate in light of the 5-calendar day (maximum) deadline for FDA to issue a decision on an appeal of a detention order. Under the deadline for appeals involving the detention of a perishable food, FDA would issue a decision on an appeal before the expiration of the 7-calendar day period. FDA believes that this timeframe offers the best protection to appellants and products. FDA notes that a claimant for any nonperishable detained product may file for

an appeal within the first 2 calendar days after receipt of a detention order, similar to the procedures set forth in § 1.402(a)(1) for perishable foods.

FDA will determine the conditions for holding detained food, including live animals, on a case-by-case basis based upon the totality of information available to us about the article of food. If necessary, FDA may consult with the owner of the food, if readily known, about appropriate storage conditions. The business arrangements for storing detained food, including live animals, are a private matter between the recipient of the detention order and the facility where the food will be stored. The recipient of the detention order is responsible for making these arrangements.

#### 6. Definition of "We"

(Comment 35) FDA did not receive comments on the definition of "we."

(Response) We did not change the definition in the final rule.

#### 7. Definition of "Working Day"

(Comment 36) FDA did not receive comments on the definition of "working day."

(Response) We did not change the definition in the final rule.

#### 8. Definition of "You"

(Comment 37) FDA did not receive comments on the definition of "you."

(Response) We did not change the definition in the final rule.

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

(Comment 38) One comment agrees that FDA should not define the term "credible evidence or information" and should evaluate such decisions on a case-by-case basis, given that a bioterrorism event may arise in an unanticipated scenario. This comment agrees that FDA should not bind its discretion by identifying the types of evidence that it ultimately may need to rely upon to support a detention order.

The majority of comments request that FDA define by regulation or guidance clear evidentiary standards and procedures for the determination of "credible evidence or information." These comments state that the term should be defined to ensure that the Bioterrorism Act is not interpreted more broadly than Congress intended and to ensure that affected persons have some protection against arbitrary or unsupported detentions. A few comments state that as long as the factors on which a detention decision is based are not known, there is no possibility to assess and evaluate the legitimacy of the decision. These comments request that FDA publish guidance on

how the credible evidence or information standard will be documented (e.g., name all sources of information that may be considered "reliable," describe the requirements with respect to accuracy of the information, etc.). Another comment suggests that guidance should indicate the authorities that FDA might rely upon to determine whether information it receives is credible, such as health authorities (i.e., Centers for Disease Control and Prevention), law enforcement authorities (i.e., Federal Bureau of Investigation), or other appropriate authorities (i.e., Department of Homeland Security). A few comments state that "credible evidence/information" should be similar to a "probable cause" standard and more than mere speculation or an anonymous telephone tip.

One comment states that, because administrative detention authority also is triggered in the context of FDA inspection and sampling authorities, the agency should ensure that the evidentiary standards and procedures adopted satisfy applicable Fourth Amendment and other constitutional requirements. In particular, the comment urges the agency to examine the "credible evidence" standard with reference to Fourth Amendment and related evidentiary standards developed in case law, and not to rely on a superficial reading of the Bioterrorism Act or a plain language interpretation drawn from Webster's Dictionary. The comment states that the "public health triggers" defining

FDA authority under the Bioterrorism Act are critically important jurisdictional provisions, which authorize extraordinary intrusions and control over private commercial property, including products subject to administrative detention.

(Response) FDA has considered these comments, and we have decided to maintain our decision not to define the term "credible evidence or information." The decision to not define credible evidence or information reflects how the credible evidence or information standard has been applied in various other judicial and administrative contexts, and the need to maintain flexibility, given the range of circumstances in which articles of food might be detained under the administrative detention authority. The "credible evidence or information" standard requires fact-specific inquiries for which maximum interpretive discretion should be maintained. FDA intends to apply the credible evidence standard consistent with the terms of that standard and with applicable Fourth Amendment principles and case law.

(Comment 39) One comment states that administrative detention is triggered by two undefined criteria: The first is "credible evidence or information," and the second is "serious adverse health consequences or death to humans or animals." Many comments express concern that if these standards are not

defined, detention decisions would be subjective, discriminatory and void of objective, scientific grounds. The comments argue that the question of the role of the application of the "precautionary principle" likewise arises.

(Response) The comment expressing concern about the application of the "precautionary principle" did not explain what they meant by their use of the term in the context of this rule. The standard for administrative detention as set out in the Bioterrorism Act is whether credible evidence or information exists indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals. This is the standard that we must apply. FDA intends to define "serious adverse health consequences" in a separate rulemaking. We will not define "credible evidence or information" for reasons set forth in our prior response to a similar comment.

(Comment 40) A few comments state that FDA should have clear evidence, such as laboratory analysis, to confirm the presence of an adulterant, and/or affidavits sworn under penalty of perjury. Several comments ask that FDA use internationally recognized methods for laboratory analyses, as well as internationally recognized standards such as Codex Alimentarius, an international food code, and provide countersamples to the owner of the article of food. One comment requests that FDA

require that sampling and diagnostic testing (to confirm or deny suspicions of food tampering) be initiated within 24 hours of the date the detention order is issued.

(Response) FDA disagrees with these comments. Given the range of circumstances in which articles of food may be detained under the administrative detention authority, the agency needs to maintain flexibility to respond appropriately on a case-by-case basis. The "credible evidence or information" standard requires fact-specific inquiries for which maximum interpretive discretion should be maintained. FDA intends to apply the credible evidence standard consistent with the terms of that standard and with applicable constitutional principles and case law.

With respect to providing what some comments refer to as countersamples, section 702(b) of the FD&C Act describes FDA's responsibility to provide a part of an official sample of food to certain individuals, when a sample is collected for analysis under the FD&C Act. Section 702(b) of the FD&C Act requires the Secretary to, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of

this section as he finds necessary for the proper administration of the provisions of this act. Exceptions from this section are set forth in 21 CFR 2.10.

(Comment 41) One comment suggests that credible evidence or information be directly related to a serious health consequence. Another comment is concerned whether the evidence for suspicion will be corroborated before an order for detention is made, or whether such an order would be made on a totally discretionary/subjective basis.

(Response) The Bioterrorism Act authorizes FDA to order an administrative detention only when an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. Consequently, serious adverse health consequences or death is an element of the standard FDA will apply in ordering that an article of food be detained. In evaluating whether credible evidence or information exists for purposes of administrative detention, FDA may consider a number of factors including, but not limited to, the reliability and reasonableness of the evidence or information, and the totality of the facts and circumstances.

(Comment 42) A few comments recommend issuing guidance with a list of criteria that define "serious adverse health

consequences" because an illustrative list from FDA will ensure that excess (or unnecessary) detentions do not occur.

A few comments state that indications should be given to limit the scope of implementation of the law. These comments specifically request that interpretation of serious adverse health consequences should be based on the risk to a large part of the population, as opposed to merely a few individuals. These comments state that in situations where the risk associated with a food product only affects a very limited group of people, detention would not be the appropriate action to take. Furthermore, they state that the health consequences must be severe to the average person to justify a detention.

(Response) FDA agrees with the comments that the agency should define the term, "serious adverse health consequences" and intends to define the term in a separate rulemaking. The agency is developing a separate rule because the term is used in several provisions in Title III of the Bioterrorism Act, not just in section 303. FDA believes that defining "serious adverse health consequences" will promote uniformity and consistency across the agency in the understanding of this term and in the actions taken, as well as inform the public of what FDA considers a "serious adverse health consequence."

(Comment 43) One comment states that nonFDA employees from other agencies or states commissioned or deputized by FDA should

not be considered officers or qualified employees of FDA for purposes of administrative detention.

(Response) Section 303 of the Bioterrorism Act provides that an officer or qualified employee of FDA may order a detention of a food found during an inspection, examination, or investigation under the FD&C Act. FDA agrees that, under existing law, employees of other Federal agencies cannot be considered officers or qualified employees of FDA for purposes of ordering an administrative detention. The same cannot be said of State employees commissioned by FDA as officers of the Department. Section 702(a) of the FD&C Act authorizes the Secretary to conduct examinations and investigations for purposes of the FD&C Act, through officers and employees of the Department, or through health, food, or drug officers or employees of any State, Territory, or political subdivision thereof, duly commissioned as officers of the Department. Because they are "officers" of the Department, FDA believes that such State and local officers or employees have authority to order an administrative detention under section 303 of the Bioterrorism Act. FDA reiterates that under this final rule, any administrative detention ordered by an officer or qualified employee must be approved by an authorizing official.

(Comment 44) One comment states that "qualified employee" must be limited to those in FDA who, in their day-to-day job

responsibilities, conduct food inspections, examinations and investigations.

(Response) Consistent with section 303 of the Bioterrorism Act, § 1.378 provides that an officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the FD&C Act if the officer or qualified employee has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals. Consequently, any FDA employees, or State or local officers or employees commissioned by FDA as officers of the Department, may order a detention as part of their function of inspecting, examining or investigating an article of food. FDA does not believe the limitation proposed by the comment is necessary. Section 1.391 requires any detention to be approved by the FDA District Director in whose district the article of food is located or an FDA official senior to such director.

E. Comments on How Long May FDA Detain an Article of Food?

(Proposed § 1.379)

(Comment 45) Many comments state that FDA should be required to limit the detention period to that period that is absolutely minimally necessary to undertake an investigation into the possible threat that underlies the detention order.

These comments further state that the extension of time up to 30 calendar days must not be by a "block" of 10 calendar days, but rather a possible extension of up to 10 extra calendar days. One comment states that they agree that an article may be detained for an additional 10 calendar days; however, they want the reason for the extension to be limited to certain conditions, such as waiting for test results. This comment also states that the company should be immediately informed of any additional time requirement, the reason for the additional time, and the actual time period that will be required (up to 10 calendar days).

One comment proposes that the only reason a detention should be extended from 20 to 30 calendar days is to take legal action in a civil suit. A few comments state that the extension of the detention period should not be considered justified or "necessary" if the reason for the extension is because the testing of the affected product had not been conducted expeditiously, or that it could have been completed within the 20-calendar day period had it been accorded appropriate priority. One comment asks how FDA is going to notify the owner of the article of food if the detention period is extended beyond the initial 20 calendar days. Another comment states that there is no indication of the criteria used to determine the "reasonableness" of the detention period.

(Response) As FDA stated earlier, we intend to proceed as expeditiously as possible to resolve all issues involved with administrative detentions. However, FDA disagrees with the comments that want to preclude FDA from extending a detention in a "block" of 10 calendar days. It is not the best use of the agency's resources to grant extensions of the detention period in small increments, e.g. 1 day at a time. Moreover, the fact that a detention is extended for a "block" of 10 calendar days does not mean that an article will always be detained 10 additional calendar days; just as FDA may terminate a detention order on any day during the period initially specified in the detention order, FDA may terminate the detention on any one of the 10 calendar days covered by the extension. FDA has authority to extend a detention for 10 calendar days as necessary to enable the agency to institute a seizure or injunction action. Because the development of a seizure or injunction action is fact-specific, FDA will not always be able to specify, at the time of the extension, the precise steps that remain. Indeed, Congress made clear that a maximum detention period of 20 or 30 calendar days is reasonable when Congress included these detention timeframes in the Bioterrorism Act. Any extension of the length of a detention period to 30 calendar days requires the agency to prepare a new detention order and, if applicable,

to place new tags or labels on the detained article of food to indicate the change in the detention dates.

In addition, FDA notes that under § 1.379(a), FDA can order detention of the article of food for 30 calendar days in the original detention order, if we know from the outset that 30 calendar days rather than 20 calendar days will be needed to institute a seizure or injunction against the detained article of food.

(Comment 46) Several comments suggest that the maximum length of time for a detention should be shortened, e.g., to 15 calendar days, 10 calendar days, or 7 calendar days, and for perishable food, to 24 hours, because of the impact a detention can have on the normal flow of trade. A few comments suggest that fresh fruit should be kept in detention for only a few hours. A few other comments state that the maximum period of detention should be in accordance with the type of product to minimize costs for the exporters.

(Response) FDA disagrees with these comments because it is not appropriate to limit the authority and flexibility that Congress intended FDA to have under section 303 of the Bioterrorism Act, which authorizes FDA to detain an article of food that presents a threat of serious adverse health consequences or death to humans or animals for 20 calendar days, unless a greater period, not to exceed by 30 calendar days, is

necessary to institute a seizure or injunction action. However, FDA intends to act as expeditiously as possible on all detentions. Detentions of perishable foods are subject to the shortened timeframes for filing an appeal and convening a hearing in § 1.402(a)(1) and (d), respectively, to process these detentions as quickly as possible. These shortened timeframes require both FDA and affected parties to move expeditiously.

(Comment 47) A few comments state that the availability of FDA resources and staff shortages should not be a justification for FDA's failure to act quickly on administrative detentions. Another comment states that any sampling and testing conducted with respect to a detention order should be given top priority at the appropriate FDA laboratory (or FDA contract laboratory) to expedite the process, such that the need for an additional 10 calendar days can be eliminated or shortened to less than 10 calendar days.

(Response) As we stated previously, FDA intends to proceed as expeditiously as possible to resolve all issues involved with administrative detentions. FDA agrees that any investigation and sampling of articles of food associated with an administrative detention should be given high priority.

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

FDA received many comments on this section III.E.1 of the rule. To clarify the resolution of the issues raised in the comments, we grouped the comments into topic areas that reflect the paragraphs in § 1.380.

As noted previously, the term "limited conditional release," which was used in proposed rule, has been replaced by the term "modification of a detention order" in this final rule. Therefore, our responses to the comments that discuss a "limited conditional release" refer instead to a "modification of a detention order."

- Hold the detained article of food in the location and under the conditions specified by FDA in the detention order (proposed §1.380(a)).

(Comment 48) One comment asks how FDA will determine the conditions under which detained food will be kept and how we will notify the owner. A few comments recommend that FDA should develop procedures for administrative detention of perishable foods that include a process for asking from the owners of such foods information as to the best storage methods to ensure the salvage of such foods. Another comment indicates that the rule should include a provision to allow, at the request of the owner, operator, or agent in charge, the freezing of detained "fresh" product that is (or will likely be) detained for 4 or more calendar days. One comment indicates that the Bioterrorism

Act provides FDA with the authority to direct articles of food to be moved to a secure facility and, if necessary, to be moved from refrigerated storage to a freezer (§ 1.381), but that such an action is usually not neutral for the quality and integrity of the food, given that frozen food may then no longer be marketed as "fresh" food. The comments state that this action will change the intrinsic nature of the food.

(Response) FDA will determine the conditions for holding detained food on a case-by-case basis based on the totality of information available to us about the article of food. For example, if the food item is simply labeled "Keep Refrigerated," with no additional information in the shipping documents, we are likely to specify that the food be stored under refrigerated conditions that comply with appropriate temperature recommendations (e.g., recommended refrigeration temperatures for food in retail establishments listed in FDA's Model Food Code or common commercial practices). On the other hand, if the shipping documents specify that a specific refrigeration temperature must be maintained, we are likely to order that the food be stored at the temperature specified by the shipper. As stated in § 1.393(b)(7), the detention order will describe the appropriate storage conditions, e.g., storage temperature. If necessary, FDA may consult with the owner of the food, if readily known, about appropriate storage conditions.

FDA advises that the removal of a detained article of "fresh" food from refrigerated storage to a freezer is an appropriate basis upon which the person who received the detention order, or that person's representative, may seek modification of the detention order of the detained food. However, FDA is unlikely to order a fresh food to be moved from refrigerated storage to a freezer, unless the owner, or that person's representative, advises us that such a move is appropriate. Section 1.381(c)(3) allows for a request to modify a detention order for this purpose, inasmuch as it provides that the request may be "to maintain or preserve the integrity or quality of the article of food \* \* \*". Consequently, FDA does not believe a revision in the rule is needed.

(Comment 49) A few comments state that FDA should, upon request of the owner, provide the records of the storage conditions maintained during detention. Several comments state that if the storage conditions indicated in the detention order are not complied with during detention, causing loss of quality, there must be an opportunity to submit a claim to FDA for reimbursement. These comments suggest that FDA should include an appeal structure in the rules and create a fund for this purpose.

(Response) As we stated previously, the business arrangements for storing detained food are a private matter

between the recipient of the detention order and the facility where the food will be stored. The recipient of the detention order is responsible for these arrangements, including matters concerning records to document that the specified storage conditions were maintained throughout the detention period. Neither the FD&C Act nor the Bioterrorism Act includes a provision for FDA compensating affected parties for any losses.

(Comment 50) Several comments address concerns about food being subject to administrative detention aboard a conveyance, i.e., ships, trucks and railcars. These comments urge FDA to revise the regulation to require that when FDA issues an administrative detention order and the food is on a ship, truck, or railcar, FDA also must issue an order to the transporter to deliver the food to either the consignee or to a secure location, as determined by FDA officials. The comments further state that the order should specify that the person with the legal title to the food (i.e., the shipper, the consignee, or a food broker), should bear the cost to store the detained food. Some comments state that the detention order should include provisions for the immediate removal to secure storage of a food that is detained administratively aboard a conveyance. One comment suggests that we define and make available for public comment the conditions that we believe would warrant transporting administratively detained food to secure storage.

facilities. Others state that the bases upon which a claimant may seek a limited conditional release should explicitly include the removal of a product from a conveyance to secure storage.

Another comment states that detaining food in place on a ship will affect the ship's schedule, causing deliveries of other cargoes to be delayed, which could cause plant shutdowns for lack of product. This comment also states that discharging a suspect cargo ashore into storage tanks would allow the cargo to be tested while under government supervision, which would provide the most cost effective solution while providing for security concerns.

(Response) FDA understands that detention of food aboard a conveyance may impact other activities of commerce that are dependent upon the ongoing operation of the conveyance. FDA will consult with CBP concerning the movement of food detained administratively aboard a conveyance to limit the impact the flow of trade. However, we disagree with the suggestion that we should revise the regulation to obligate FDA to issue an order to the transporter to deliver the food to a specified destination at the expense of the person with the legal title to the food. We believe that the determination of whether we should order the food to be moved from the conveyance to another location should be made based on considerations about the nature of the contaminant, security, preservation of the food, and

accessibility to the food during the period of administrative detention. Based on our historical use of administrative detention with medical devices, we believe that we would detain food on a conveyance only under rare circumstances. It is more likely that we will allow the detained food to be removed from the conveyance to a storage facility.

FDA also disagrees with the suggestion that we specify in the detention order that a third party (e.g., the shipper, consignee, or food broker) bear the cost of the transport of the food to secure storage. The business arrangements for storing detained food are a private matter between the recipient of the detention order and the facility where the food will be stored. The recipient of the detention order is responsible for making these arrangements.

With regard to the transporter's concerns that the detention of food aboard a conveyance has the potential to impact other activities of commerce that are dependent upon the ongoing operation of the ship, truck, or railcar, FDA advises that a transporter may seek modification of a detention order in order to remove a detained food from a conveyance to a storage facility. In § 1.381(c)(4), allows the transporter to request modification of a detention order for this purpose, inasmuch as it provides that the request may be "for any other purpose that the authorized FDA representative believes is appropriate\* \* \*."

Accordingly, FDA does not believe a revision to §1.381(c)(4) is warranted. However, FDA also advises that, although the regulations allow a transporter to request modification of a detention order to move the food from a conveyance to a storage facility, we will evaluate any such request on a case-by-case basis, considering all of the factors relevant to the specific case, such as whether the storage facility identified in the request can provide the necessary level of security for the food.

(Comment 51) One comment states that the proposed rule does not adequately address the case in which pet food products are detained administratively with shipments that may contain suspect food. The comment further states that the resulting delay could result in great loss to firms who plan to exhibit the detained products at a trade show.

(Response) If articles of detained food are part of a shipment containing food that is not subject to the detention order, the articles of food that are not subject to the detention order and can be readily segregated, can be so segregated and moved.

(Comment 52) One comment states that the detention process itself could increase the risk of intentional contamination of food because food, which normally moves quickly from farm to table, would be more vulnerable to attack when held for periods

of time in storage or on a truck. The comment expresses concern about attacks on food under detention occurring in unguarded storerooms and garage sheds. Several comments ask that the detention be done where the merchandise is dispositioned to avoid the increase of the storage costs and the risk of robbery or damage of the merchandise. Another comment asks whether an article of food that is subject to a detention order must always be moved to a secure location.

(Response) The purpose of administrative detention is to help ensure that food for which the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals does not move in commerce, and to help ensure that such food is not distributed before the agency can initiate judicial enforcement actions against the food as appropriate. If FDA is concerned that a detained food is vulnerable to attack while under storage, we would order the storage to take place in an appropriately secured facility.

Section 1.380(b) states that if FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. FDA will consider, on a case-by-case basis, whether the article of food must be moved to a secure facility based on the situation and whether a given facility can provide the appropriate level of security.

(Comment 53) One comment addresses the potential impact of administrative detention on farmers. The comment states that, for many farmers, and all dairy farms, limited on-farm storage of perishable products will lead to a complete loss of value if products are stopped from shipment to markets or for further processing. The comment urges FDA to be careful when prohibiting shipment of food products from farms due to the unrecoverable costs of unmarketable product to the affected farm or farms. The comment further states that, for certain products, a critical market opportunity and the reputation of that farm as a reliable supplier could be lost for many years by a disruption in their ability to market their products.

(Response) FDA notes that the standard to detain any article of food is very high--credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. If FDA orders a food to be detained administratively on a farm, and storage at the farm is limited, the farmer may, under § 1.381(d), request modification of the detention order to move the food to an offsite facility. In evaluating the request, we will consider, on a case-by-case basis, whether the facility identified in the request can provide an appropriate level of security.

In addition, we reiterate that we intend to proceed as expeditiously as possible to resolve all issues associated with particular administrative detentions.

- Removal to a secure facility, if FDA determines that such movement is appropriate (proposed § 1.380(b)).

(Comment 54) One comment states that it would be beneficial for FDA to identify any specific security requirements for storing detained product. This comment also states that nothing in the proposed regulation should be interpreted as elevating a warehouse's duty of care beyond that identified in the Uniform Commercial Code (UCC), as to do so will jeopardize the warehouse's insurance coverage.

(Response) Under the final rule, the detention order will identify specific storage security requirements for the detained food at issue. Issues regarding a warehouse's duty of care are beyond the scope of this rulemaking.

(Comment 55) One comment states that, if FDA orders the movement of a detained article of imported food to a secure location before a consumption entry is filed at the port of entry, the shipment would have to be moved in-bond, creating additional work and expense to the carrier and consumer. This comment suggests that FDA should publish, for public comment, the conditions that would warrant detained food articles to be transported before finalizing this rule. The comment states that

it is critical that affected persons understand what the conditions are to ensure compliance with such conditions.

(Response) There are many situations that may arise that would warrant the movement of detained food to secure locations. At the present time, it is extremely difficult for FDA to anticipate and describe all scenarios and all conditions that would warrant detained food to be transported to a secure facility. When it is necessary for such transportation to occur, FDA will specify the appropriate conditions on a case-by-case basis in the detention order.

(Comment 56) One comment believes that FDA stated that detained articles of food should be moved by bonded carriers to make sure that the merchandise will be delivered to the facility that will be selected by FDA after the merchandise is released by CBP. In this situation, the comment asks that FDA put a high security seal (provided by the U.S. broker ahead of time) on the trailer and release the food to the U.S. broker or the trucking company facility. The comment states that this would be less expensive to the importers due to the fact that bonded carriers are expensive; demurrage charges are based on how many days it will take an FDA inspector to release or refuse the merchandise. Affected parties also will incur additional costs from the

company that will be receiving the trailers, swamper and forklift services.

(Response) We do not define the security requirements for carriers or storage facilities in this rule. Instead, we will determine the relevant level of security of the facility on a case-by-case basis.

In some cases, we might require higher security, such as that associated with secure government storage facilities. In other cases, we might require lower security.

We note that we do not define the term "secure facility" either in this final rule or the final rule on prior notice. As we stated in the proposed rule on administrative detention, we will determine the relevant level of security for storage facilities on a case-by-case basis. Although we do not define the term "secure facility," we note that the range of facilities available for storage of food that is detained administratively is broader than the range of facilities available for storage of food offered for import that is refused admission for a prior notice violation. This is because food offered for import that is refused admission for a prior notice violation is "general order merchandise" under Title 19 of the United States Code. (See § 1.283(a)(2).) That merchandise must be stored in a bonded warehouse authorized to accept general order merchandise

if one is available and capable of such storage. By comparison, food that is detained administratively has not been deemed to be subject to title 19 of the United States Code's limitations on general order merchandise. Accordingly, if the food product is imported and still subject to CBP control, FDA and CBP may determine that a facility other than a general order warehouse constitutes a "secure facility" for purposes of administrative detention.

(Comment 57) One comment states that detained articles of food should only be ordered moved to a secure facility in exceptional circumstances.

(Response) FDA will not know in advance all of the circumstances that may warrant removal to a secure facility. Each administrative detention action will be assessed based on the facts of the particular situation, including whether the storage facility can provide the necessary level of security for the food.

(Comment 58) Several comments raise issues concerning the costs for secure and nonsecure storage of detained food. One comment asks how recipients of the detention order would be informed about the costs charged by secure facilities for holding food. Other comments ask FDA whether there would be a standard fee for the storage costs, and whether FDA would ensure that the responsible party is able to afford the storage costs.

(Response) If removal to a secure facility is appropriate, FDA will state a specific location for storage of the food in the detention order, as provided in § 1.380(a), or in response to a request for modification of the detention order under § 1.381(c). The recipient of the detention order may contact the storage facility to determine the costs for storing the detained product. It is also possible that FDA could order a detained article of food to be stored in government storage, which may be less expensive.

(Comment 59) A few comments address the importance of adequate facilities being available for holding detained food. One comment states that FDA must guarantee that there will be enough facilities to "ensure the conservation of the merchandise that is detained."

(Response) Inasmuch as FDA will not operate the facilities that will be used to store detained foods, we are unable to guarantee that any particular facility will be available for use in storing detained foods at any particular time. However, we note that detained food will not necessarily be required to be removed to a secure facility. If detained food is required to be removed to such a facility, then, as we stated in the proposed rule, secure facilities are readily available throughout the United States.

(Comment 60) One comment states that it is necessary to know who is in charge of transporting food that is under administrative detention and where FDA has ordered such transportation.

(Response) FDA will decide on a case-by-case basis who will be responsible for transporting detained food. In some cases it may be necessary for us to designate a third party to transport the food, for example, if we believe that control of the food could be lost if the recipient of the detention order transported it. In cases where we believe that this risk is not present, we may direct the recipient of the detention order to transport the food.

- If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order before you move the detained article of food. (proposed § 1.380) (c)

See comments under § 1.381, "May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location?"

- You must ensure that any required tags or labels accompany the detained article during and after movement (proposed § 1.380) (d)

See comments under § 1.382, "What Labeling or Marking Requirements Apply to a Detained Article of Food?"

- The movement of an article of food in violation of a detention order is a prohibited act under section 301 of the FD&C Act (proposed § 1.380(e))

(Comment 61) FDA did not receive comments on this issue.

(Response) We did not make any changes to this section.

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

(Comment 62) A few comments state that FDA should be required to allow detained food to be delivered to the importer, owner or consignee, subject to conditional recall, except where FDA believes there is an immediate threat of harm. One of these comments states that FDA could retain a bond to allow detained articles to be released for delivery to the importer, owner, or consignee until the detention has been terminated.

(Response) FDA disagrees with these comments because we do not have the authority to allow the delivery of foods that have been detained administratively to the owner's or importer's premises under bond. Section 303 of the Bioterrorism Act specifically states that this section may not be construed as authorizing the delivery of an article of food that is subject to a detention order under the execution of a bond while the article of food is subject to a detention order, and section 801(b) of the FD&C Act does not authorize the delivery of the

article under the execution of a bond while the article is subject to the order.

(Comment 63) A couple of comments ask if FDA will ensure fast procedures with respect to requests for the authorized movement of the detained article of food.

(Response) FDA intends to proceed as expeditiously as possible to resolve all issues involved with particular administrative detentions.

(Comment 64) One comment asks if the period of detention is suspended for the amount of time that it takes to complete the request and move the article of food under a limited conditional release.

(Response) The length of time to process a request for modification of a detention order and to move an article of food does not affect or extend the period of detention stated in the detention order (a maximum of 20 or 30 calendar days, as appropriate).

(Comment 65) One comment states that, if the distributor does not have direct control of the mode of transport, FDA's limited conditional release should stipulate that the mode of transport must not introduce any condition or substance that would adulterate or otherwise deleteriously impact the quality of the detained food.