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

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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 Sec. 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 Sec. 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,

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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 Sec. 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 Sec. 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 Sec. 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,

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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.\1\

\1\ 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.

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 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

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``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.

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 will be published in this issue of the Federal Register in the near future. ''. . . which will be published in the Federal Register in the near future. 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 [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.\2\

\2\ 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.\3\

\3\ 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).

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.

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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 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 Sec. 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 Sec. 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 non-FDA 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

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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, Sec. 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 Sec. 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 Sec. 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 Sec. 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

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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 Sec. 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 Sec. 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.''

<bullet> Hold the detained article of food in the location and under the conditions specified by FDA in the detention order (proposed Sec. 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 (Sec. 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 Sec. 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 on 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,

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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 Sec. 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 Sec. 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 Sec. 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.

<bullet> Removal to a secure facility, if FDA determines that such movement is appropriate (proposed Sec. 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 Sec. 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 Sec. 1.380(a), or in response to a request for modification of the detention order under Sec. 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.

<bullet> 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 Sec. 1.380)(c))

See comments under Sec. 1.381, ``May a Detained Article of Food be Delivered to Another Entity or Transferred to Another Location?''

<bullet> You must ensure that any required tags or labels accompany the detained article during and after movement. (proposed Sec. 1.380)(d))

See comments under Sec. 1.382, ``What Labeling or Marking Requirements Apply to a Detained Article of Food?''

<bullet> 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 Sec. 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 Sec. 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.

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

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

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

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

(Comment 67) One comment recommends that, in addition to the information on the FDA tags or labels described in Sec. 1.382(d) of this rule, they should also include the expiration date of the detention order and the name of the authorized FDA representative who approved the detention order. This comment also states that if the

detention period is extended for any additional time up to the 10-calendar day limit, the detention order and the affixed tags or labels should be amended accordingly.

(Response) FDA disagrees with the comment to revise Sec. 1.382(d) to add the expiration date of the detention order and the name of the authorized FDA representative who approved the detention order to FDA's tags or labels. The name of the person who issued the detention order is required to be on the tag or label. In addition, FDA is revising the final rule to include Sec. 1.393(b)(14), which requires that the detention order include the name and title of the authorized FDA representative who approved the detention order.

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

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

(Response) As FDA stated in the proposed rule, any label or mark of detention will be attached as appropriate given the circumstances. In some instances, the mark or label may be attached to the food container, while in other instances, the mark may be fastened to a packing container. Where the agency cannot mark or label a container or packing container, a mark or label may be attached to accompanying documents. FDA may use other means of marking or labeling as appropriate or necessary. Once the detention order is terminated, FDA will remove, or authorize the removal of, the required labels or tags, as described in Sec. 1.384. Accordingly, we would not expect the labeling and marking provision to impair the marketability of an article of food for which the detention order is terminated.

F. Comments on What Expedited Procedures Apply When FDA Initiates a Seizure Action Against a Detained Perishable Food? (Proposed Sec. 1.383)

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

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

The final rule is consistent with the Bioterrorism Act's directive. The comment appears to misunderstand the mechanics of the regulation's procedures. FDA's process of sending a

seizure recommendation to DOJ is not contemporaneous with the filing of that action in federal court. FDA anticipates that, if we send a seizure recommendation in these circumstances, the seizure will be filed, the court will issue a warrant, and the U.S. Marshal will seize the food, soon after the recommendation is sent to the DOJ. FDA lacks authority to mandate the timing of these actions. As a result, the filing and execution of the seizure may not occur on the same calendar day that the recommendation is sent to DOJ.

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

G. Comments on When Does a Detention Order Terminate? (Proposed Sec. 1.384)

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

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

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

(Response) FDA expects that we would normally be able to issue the detention termination notice to the person who received the detention order (e.g., the owner, operator or agent in charge of the place where the food is located and the owner of the food, if known) within 1 calendar day of the decision to terminate a detention, unless extenuating circumstances exist. However, we are not revising the rule to incorporate such a deadline because in some instances it may not be possible to inform the company in writing within 1 calendar day due to unforeseen circumstances beyond the agency's control.

H. Comments on How Does FDA Order a Detention?

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

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

(Response) FDA disagrees with these comments. Congress included language in the Bioterrorism Act that specifies who is authorized to approve a detention order, i.e., the Secretary or an official designated by the Secretary (who may not be so designated unless the official is the director of the district in which the article involved

is located, or is an official senior to such director). FDA believes that the Bioterrorism Act does not contemplate any sort of a national detention approval board. To the contrary, the statute makes clear that Congress expected that FDA District Directors, or officers senior to such directors, could and would exercise this authority.

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

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

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

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

(Response) As provided in Sec. 1.392, FDA will provide the detention order to the owner or agent in charge of the place where the detained article of food is located and the owner of the food, if the owner's identity can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food.

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

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maintained under section 306 of the Bioterrorism Act.

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

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

(Comment 76) Several comments state that the exporting country of an article of food that has been detained must receive information concerning the detention so that it may take appropriate action. These comments suggest that FDA should contact the embassy of the country or the competent authority of the country. A few comments state that various parties should be informed of the administrative detention of imported articles of food (e.g., the exporter, agent or importer, and the customhouse broker). A few other comments state that FDA should be able to notify the recipients of products subject to the detention order at multiple locations by accessing records maintained under the recordkeeping section of the Bioterrorism Act.

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

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

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

(Response) As we stated previously, FDA will issue the detention order to the owner, operator, or agent in charge of the facility where the detained article of food is located, and as stated previously, the owner of the food if its identity is readily available. At this time, we have no plans to routinely publicize the issuance of detention orders, e.g., in Import Refusal Reports or the European Union's Rapid Alert System. This is consistent with the practice FDA uses for medical device detentions, which are not routinely publicized in the manner suggested by these comments.

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

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

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

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

3. Comments on What Information Must FDA Include in the Detention

Order? (Proposed Sec. 1.393)

(Comment 79) A couple of comments state that the detention order should include a copy of the written approval granted by the authorized FDA representative. These comments state that the approval should include the information upon which the administrative detention was based, what actions will be taken with the product, and the expected time period for which the product will be held. A few other comments state that the detention order should include information such as grower codes, lot codes and other identifiers. A few comments believe it would be valuable for the appeal procedures and applicable deadlines to be explained in the detention order. One comment suggests that the detention order should include provisions regarding the appropriate storage and transportation conditions, such as refrigerated foods kept under 40 degrees Fahrenheit (F) and frozen foods kept under -4 degree F to meet the regulatory requirements and common industry practices and satisfy their customer expectations.

(Response) FDA agrees in part with these comments. Section 1.393(b)(6) requires that the detention order include a brief, general statement of the reason for the detention. Section 1.393(b)(4) requires that the detention order include the period of the detention. Section 1.393(b)(3) requires that the detention

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order include information about the identification of the detained article of food. Identifying codes, such as lot numbers, may be included in the description of the detained article of food provided on the detention order. However, most food products are not required to bear a manufacturer's code; thus, this information may not be available. FDA notes that section 303 of the Bioterrorism Act provides that FDA may detain food for up to 30 calendar days to enable FDA to institute a seizure or an injunction action. Section 1.393(b)(10) requires that the detention order include the text of section 304(h) of the FD&C Act (section 303 of the Bioterrorism Act), as well as Sec. Sec. 1.401 and 1.402, which describe the administrative detention authority, who may submit an appeal, and the requirements for submitting an appeal, respectively.

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

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

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

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

1. Comments on Who is Entitled To Appeal? (Proposed Sec. 1.401)

(Comment 81) One comment asks whether someone who does not have a proprietary interest in the detained object, but has a commercial interest (e.g., the importer, U.S. agent (as defined in the registration interim final rule), or shipper), can appeal a detention order. Another comment asks whether someone designated by the owner, such as a lawyer or food technologist, can appeal a detention order. One comment indicates that the rule should state whether the person who appeals the detention has to have certain characteristics and reside in the United States.

(Response) We do not know what is meant by ``certain characteristics,'' but a person entitled to appeal a detention order need not be a resident of the United States. With respect to whether a proprietary interest is required, section 304(h)(4) of the FD&C Act states in part that ``any person who would be entitled to be a claimant for such article if the article were seized under section (a) may appeal the order.'' Thus, if a person were entitled to be a claimant in a seizure action, that person would also be entitled to be a claimant in an appeal from a detention order. To be a claimant in a seizure action, a person must have an interest in the seized goods sufficient to confer standing under both Article III of the U.S. Constitution, and Supplemental Rule C(6) of the ``Federal Rules of Civil Procedure'' (available at http://www.uscourts.gov/rules). The local rules of the Federal Court district in which a seizure or administrative detention occurs set forth the procedures by which a party establishes entitlement to be a claimant. A person who asserts an interest in, or right against, property that is the subject of an action must file a verified statement identifying the interest or right. The meaning of ``verified statement'' under Supplemental Rule C(6) is governed by the local Federal District Court rules in which the detention takes place, and usually means that the statement must be accompanied by an oath or affirmation attesting to the statement's veracity. A determination of whether a party has a sufficient interest in the food is made on a case-by-case basis. As such, it is outside the scope of this rulemaking.

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

(Comment 82) FDA sought comments on whether there are other ways we should be counting days for filing appeals, while adhering to the statutory deadline of 5 days for FDA to issue a decision on appeal (for both perishable and nonperishable food). One comment states that for appeals, and any other sections of the regulations that incorporate specific timeframes, the timeframes should be ruled by ``international timetables.''

(Response) FDA's understanding is that the comment is asking FDA to take international time zones into consideration when counting calendar days to meet the various timeframe deadlines described in this final rule. FDA disagrees with this comment. It is not feasible for FDA to make exceptions on how we count calendar days based on the time zone where the owner of the goods is located. The total elapsed time from the time the detention order is issued throughout the detention process will be the same regardless of the time zone in which the detention order was issued. Under the final rule, the ``start'' and ``end'' times of a detention order, and all deadlines within that period, will be measured by the time zone in which the detention order was issued.

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

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

as expeditiously as possible when we detain an article of food, especially in the case of an article of perishable food. Section 1.405 requires FDA to issue a decision on appeal within 5 calendar days from the date of appeal. Section 1.377 of the rule defines ``calendar day'' to mean every day shown on the calendar, which includes holidays and weekends.

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

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

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

(Comment 85) One comment suggests that FDA should provide for an ``automatic appeal'' on the second day after an administrative detention order is issued, with a decision on the appeal to be made within 24 hours of the hearing. Another comment requests that the appeal process for chilled, live shellfish that have a commercial shelf life of 48 hours following harvest, be measured in hours, with all attempts to release suitable consignments within 24 hours.

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

(Comment 86) A few comments ask that FDA treat all foods in the same manner as perishable foods for appeal purposes. Another comment indicates that a ``reasonable period'' of 20 calendar days, which could be extended to 30 calendar days, means in practical terms that all perishable foods/drinks, including those ``commercially'' perishable, are no longer suitable for sale. The comment states that this means that, if a ``fast-track'' appeal for perishable food does not allow a quicker release of detained food when it is found to be safe, the value of such an appeal is questionable.

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

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

(Response) FDA disagrees with this comment. As described in Sec. 1.392(a) of the final rule, FDA will provide a copy of the detention order to the owner or agent in charge of the place where the detained articles of food are located. Under Sec. 1.392(a) of this rule, FDA also will provide a copy of the detention order to the owner of the food if their identities can be readily determined. Under Sec. 1.392(b) of this rule, if FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also will provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food. There may be times when FDA cannot determine who would be entitled to be a claimant of the article. The purpose of administrative detention is to hold in place, and protect against any movement that could lead to further distribution of, the

food that poses the threat of serious adverse health consequences or death to humans or animals. Consequently, the action is against the articles, not the owner of the articles. We believe that it is likely that any responsible firm who has had product detained on their premises will notify the rightful owner. In addition, it is an owner's responsibility to know the whereabouts of its food product, and to be familiar with the chain of custody related to that food.

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

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

(Response) FDA disagrees with these comments because the Bioterrorism Act requires only that FDA ``provid[e] opportunity for an informal hearing''; the statutory language does not require FDA to conduct an informal hearing for every claimant who appeals a detention order. Our interpretation of this section of the Bioterrorism Act is

consistent with our long-standing interpretation of similar statutory language in section 304(g) of the FD&C Act (21 U.S.C. 334(g)), which governs medical device detentions. FDA has authority to deny a hearing when the appeal raises no genuine and substantial issue of fact. (See Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 620-621 (1973).)

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

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

(Comment 89) FDA sought comments on the timeframes for holding the informal hearing. One comment states that the hearing should be held within 2 calendar days from appeal. Another comment asks that FDA shorten the period for holding a hearing in appeals for perishable food to 3 calendar days. One other comment states that, because the timing of the hearing has no direct impact on the rendering of the agency's confirmation or termination of the detention order, FDA's proposal would have no inherent effect on expediting the release of erroneously detained perishable food. Another comment believes that the FDA has wisely decided upon an expedited hearing process for perishable foods that are detained administratively, but states that the proposed process is not fast enough. The comment notes that, as stated in the proposed regulation, an appeal and request for a hearing must be filed within 2 calendar days of receipt of a detention order. If FDA grants the request, the hearing will be within 2 calendar days after the date the appeal is filed. FDA's decision on the appeal must be issued within 5 calendar days of the date of the appeal filing. The comment states that this proposed procedure will still take up to 7 calendar days, and for highly perishable fresh seafood products, this would leave only 2 to 3 calendar days of acceptable shelf life remaining. Practically, these remaining days would be used in distribution so that a shipment of perishable food (e.g., fresh seafood), in most cases, would be a total loss. One comment asks that FDA extend the time limit so that exporting countries will have enough time to prepare documents. Another comment states that, because the presiding officer may be an RFDD from another region or another official senior to the district director, the transit time from one region to the other must be factored into the established hearing deadlines.

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

If FDA grants a hearing, the timeframes will adhere to Sec. 1.402(d) of the rule, which requires FDA to hold a hearing for food that has been detained within 2 calendar days after the date the appeal is filed. A claimant can control the time by which the hearing has to take place and the time by which FDA has to issue a decision if the claimant appeals the detention order sooner rather than later, i.e., this final rule specifies the maximum timeframes claimants have to file an appeal. Claimants certainly can file earlier.

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

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

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

Under Sec. Sec. 16.42(c)(2) and 1.404, an FDA Regional Food and Drug Director, or another FDA official senior to an FDA District Director, may preside over an appeal hearing as long as that person has not participated in the investigation or action that is the subject of the hearing, or is subordinate to a person, other than the Commissioner of Food and Drugs (the Commissioner), who has participated in such investigation or action.

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

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

(Comment 91) Several comments recommend that FDA's decision on appeal should be sooner than within 5 calendar days after the appeal is filed, e.g., within 2 calendar days or 3 calendar days after the appeal is filed. Many comments recommend that FDA's decision on appeal should be made within 2 calendar days after the hearing for detained perishable and nonperishable foods. Another comment asks whether FDA can realistically accommodate administrative detention appeals in a timely manner. These comments state that, when identifying the detention and appellate timeframes, the agency must consider the logistical requirements (placing shipping orders, transportation and other distribution requirements) in evaluating the potential shelf life and value of the food product.

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

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

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

In the proposed rule, Sec. 1.402(d), which governs the requirements for submitting an appeal, referenced the definition of an informal hearing in section 201(x) of the FD&C Act. Section 201(x)(5) of the FD&C Act requires the presiding officer to prepare a written report of the hearing, and states that the participants in the hearing shall be given the opportunity to review and correct or supplement the

presiding officer's report. FDA is revising Sec. Sec. 1.403 and 1.405 to provide this opportunity for the hearing participant to review and request changes to the conclusions of the presiding officer, as reflected in his or her proposed decision. FDA is revising Sec. 1.403(h) to clarify that Sec. 16.60(e) and (f) does not apply to an informal hearing on an administrative detention. Revised Sec. Sec. 1.403(h) and 1.405(a) provide that the presiding officer must issue a written report of the hearing, including a proposed decision with a statement of reasons. This section also provides for a 4-hour opportunity during which the hearing participant may review and comment on the written report. Under Sec. 1.403(h), the presiding officer will then issue the final agency decision.

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

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

FDA is also revising Sec. 1.403 to clarify that Sec. 16.95(b) does not apply to an informal hearing on an administrative detention. New Sec. 1.403(k) states that the administrative record of an informal hearing on an administrative detention as specified in Sec. Sec. 16.80(a)(1), (a)(2), (a)(3), (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. In addition, Sec. 1.403(k) states that, for purposes of judicial review under Sec. 10.45, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

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

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

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

FDA notes that the comment is correct in that there is one situation where FDA would have more time to consider whether to confirm or terminate a detention order for perishable food than for nonperishable food and that would be if the appeals for both a perishable food and a nonperishable food were filed on the same calendar day and the hearings were held on the second and third calendar days following the appeals, respectively. The only way to eliminate this situation while still allowing FDA up to 5 calendar days to

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

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

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

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

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

IV. Conforming Amendment to Part 10

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

V. Conforming Amendment to Part 16

We are amending Sec. 16.1(b)(1) to include section 304(h) of the FD&C Act relating to the administrative detention of food for human or animal consumption to the list of statutory provisions under which regulatory hearings are available.

VI. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

We have examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a regulatory action as a significant regulatory action if it meets any one of a number of

specified conditions, including: Having an annual effect on the economy of $100 million or more, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also classifies a regulatory action as significant if it raises novel legal or policy issues. We have determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

Costs and Benefits of Administrative Detention Final Rules: Summary

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

The benefits of administrative detention will be the value of the illnesses or death prevented because the agency administratively detained food suspected of being adulterated. These benefits will be generated if the following two conditions hold: (1) The food is in fact adulterated, and (2) administrative detention prevents more illnesses or deaths than would have been prevented had we relied on our existing enforcement tools. The more often these conditions hold, and the larger the amount of adulterated food administratively detained, the larger will be the benefits of this final rule. There may also be benefits in terms of deterrence, to the extent that administrative detention increases the likelihood that adulterated products will not be shipped in the future.

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

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

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

<bullet> Additional transportation to secure storage facility,
<bullet> Additional storage,
<bullet> Delay of conveyances that contain detained products,
<bullet> Loss of product value for foods with limited shelf lives,
<bullet> Marking or labeling of detained products, and
<bullet> Costs of appeals of administrative detentions.

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

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

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

Regulatory Options

We considered the following regulatory options in the analysis of the proposed rule: (1) Take the proposed action (establish a regulatory framework for detaining food administratively, with expedited procedures for instituting certain enforcement actions involving perishable food); (2) take the proposed action but change the definition of perishable food, the maximum timeframe for administrative detention of perishable food, or both; (3) take the proposed action but define the level of security we require for transportation and storage; (4) issue regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (i.e., limit the action to the regulations required by section 303 of the Bioterrorism Act). We received comments pertaining to the first two options. We also received some comments on the maximum timeframe for administrative detention of nonperishable food. We have included these under Option Two and have renamed that option as follows: Take the proposed action but change the definition of perishable food, the maximum timeframe for administrative detention, or both. In addition, we received comments suggesting that we revise the proposed rule in various ways that we did not address in any of the other regulatory options. We will discuss the economic implications of these comments under a new regulatory Option Five: Take the proposed action but revise the proposed action in some other way. In many cases, a comment discussed a cost and suggested a way to minimize that cost. In those cases, we discuss the portion of the comment that dealt with the cost of the proposed rule under Option One (take the proposed action), and we discuss the portion of the comment that suggested revising the rule under one of the other options.

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

General

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

(Response) We disagree that we did not meet the guidelines established by OMB for a regulatory impact analysis. We were unable to estimate annual benefits because this rule addresses low probability but potentially high risk events. These events do not occur regularly, and we have insufficient information to predict their occurrence. Our inability to estimate annual benefits meant that we were also unable to evaluate regulatory options that generated tradeoffs between costs and benefits to the extent that we would normally do so. However, the guidelines for regulatory impact analyses acknowledge that we will not always have sufficient information to quantify all relevant effects.

Benefits

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

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

(Comment 97) One comment argues that we failed to consider the potential benefits of the proposed rule that go beyond avoiding adverse

health consequences. This comment notes that an intentional food contamination event could have significant national and international implications because it could lead authorities to impose restrictions on the distribution and sale of similar products or lead some consumers to avoid buying the product. As an example of the latter effect, this comment notes that the discovery of a single cow in Alberta, Canada that tested positive for bovine spongiform encephalopathy (BSE) caused significant changes in cattle prices and retail sales of beef products.

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

Costs

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

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other issues relating to the costs of this rule.

(Comment 98) One comment argues that the administrative burden generated by the proposed rule would dilute effective food safety measures by industry and divert our resources away from more effective food safety measures. This comment suggests that the net effect of the proposed rule would be to reduce food safety rather than increase it. Another comment argues that the proposed rule might increase food safety risks because it would slow the movement of food through the distribution system, thereby creating additional opportunities for adulteration. The comment envisioned numerous unguarded storerooms or garage sheds containing detained food, which the comment suggests would significantly increase the statistical probability that that food would be attacked.

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

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

(Response) We discussed the wide variety of firms that might be affected in the analysis of the proposed rule. However, we based the cost estimate on conventional fresh or processed food for human consumption. The cost of an administrative detention for each of the product categories and types of firms mentioned by these comments would vary along a number of dimensions, including the production and distribution system, the typical mode of transport, the typical lot or shipment size, handling and storage costs, and rate of product value loss, if any. The comments did not provide estimates of how the costs for these firms would differ from the costs we estimated for the analysis of the proposed rule, and it would be costly and time consuming for us to analyze the costs for every type of firm and product that this rule might affect. In addition, as we discuss later in this analysis, if it were technically difficult or impossible to adulterate these types of food, then we would rarely or never receive information that would require us to detain it administratively. Based on these considerations, we have not revised the analysis to include a discussion of each of these types of products and firms.

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

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

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

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

(Comment 102) One comment argues that we might detain entire containers or truckloads, but subsequently determine that only one or a very few cases of food are actually adulterated. This comment suggests that we might release a majority of the food that we detain administratively. Another comment suggests that we might intentionally detain more food than we believed was actually adulterated. For example, we might believe that a particular lot was adulterated, but we might detain the container that holds that lot along with other lots.

One comment notes that a single shipping container might hold many small shipments of different products of different origins. The comment suggested we might detain the entire container in such a situation.

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

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

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

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

One comment notes that farms often have limited on-farm storage and inflexible deadlines for delivering products to markets or for further processing. The comment notes that the loss of value of food that we detain administratively on farms could be very rapid. One comment discusses ``fresh products'' that have a shelf life of more than 7 days. This comment argues that one would not be able to market these products if we detained them for 7 days because they would not have enough shelf life left.

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

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

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

(Comment 105) One comment discusses the shelf life of air freighted fish and fish products. This comment notes that chilled finfish has a normal commercial shelf life of about 7 days from the time of capture. They argue that attempting to extend the shelf life of this fish by freezing it would destroy its commercial value. Some comments note that chilled, live shellfish and crustaceans have a commercial shelf life of about 48 hours from the time they are packed for export. This comment notes that one may extend the shelf life for some species by introducing them back into temperature controlled, oxygenated, salt water. However, these comments doubted that we intended to operate appropriate tanking facilities at airports to handle detained live seafood in this way. Consequently, these comments argue that the current timeframes for administrative detention would almost certainly eliminate the value of these products if we detained and subsequently released them. These comments argue that any detention period longer than 24 hours would result in a loss of the value of the product.

Another comment argues that a detention period of 7 calendar days was excessive in the case of fresh salmon because the quality of fresh salmon would begin to deteriorate within 4 days. One comment notes that, for perishable foods, the maximum time between receipt of the detention order and an appeal is 2 calendar days, and that we have 5 calendar days from receipt of the appeal to confirm or set aside the detention order. This comment argues that these time periods are impracticable and would lead to the loss of the product. Some comments note that the appeals process may take up to 7 calendar days, assuming owners request an appeal within 2 calendar days of receipt of the administrative detention notice and we would reach a decision on the appeal 5 calendar days after the date of the filing of the appeal. This comment suggests that this would leave only 2 or 3 days of acceptable shelf life for highly perishable fresh seafood products, which would be insufficient time to distribute it to retail outlets. Thus, this comment suggests that the proposed procedure would lead to a total loss of value for this type of product.

(Response) These comments are consistent with the analysis of the proposed rule, in which we estimated that perishable food might lose up to all of its value during the detention period.

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We discuss suggestions to revise the rule under Options Two and Five.

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

(Response) We would not direct someone to move food from refrigerated storage to a freezer. If we detained the food in place, then the food would remain under existing storage conditions unless the

owner requested us to change those conditions. Similarly, if we directed a firm to transport food to a secure storage facility, then we would allow that firm to maintain existing storage conditions during transport and storage, unless the owner requested otherwise.

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

(Response) In situations involving conveyances, a request can be made for modification of a detention order to offload the cargo to a secure storage facility. However, in some cases, it may not be feasible to offload the cargo. In that case, the conveyance itself might be delayed. The comment did not provide information on the costs of delaying a ship. However, a recent newspaper story suggested that delaying one ship for 1 day may cost as much as $80,000 (Ref. 1). This implies that detaining one ship for 30 calendar days could cost up to $2.4 million. It is possible, but unlikely, that a single administrative detention could involve more than one ship. We might also detain other types of conveyances.

The comment that discussed the costs of delaying tanker trailers did not provide information on those costs. However, one firm that posted a cost proposal on the Internet listed a standard rate as of July 1, 2002, of $250 per day for a semitrailer with code tanker and $200 per day for a semitrailer with liquid transporter (Ref. 2). These rates probably overstate the cost of the loss of a tanker trailer because in some cases in which we detain food on a tanker trailer, the semitrailer itself could probably be used with another tanker trailer. However, this might not always be possible. This implies that the loss of the use of one tanker trailer could cost up to $8,000 over a 30-calendar day detention period. In addition, in some cases, the drivers of tanker trailers may be idled during the detention period. The average wage of a truck driver in July 2002 was $14.40 per hour (Ref. 3). If we assume 100 percent overhead, then idling a truck driver for 30 calendar days would cost an additional $7,000. Therefore, the total potential cost of detaining one tanker truck and driver for 30 calendar days could be up to $15,000. A single administrative detention might involve more than one tanker trailer or other types of equipment. In the analysis of the proposed rule, we assumed that any given detention could involve up to 67 truckloads of food. Detaining 67 tanker trailers for up to 30 calendar days could generate estimated costs of up to $1 million.

We do not have information on the cost of delaying other types of conveyances such as trains, airplanes, or other types of trucks. However, those costs are probably similar to the cost of delaying ships and tanker trucks. Delaying conveyances could also generate costs by disrupting the delivery or production schedules of other firms. We do not have information on these costs. We could attempt to construct a model to estimate these costs. However, that would be costly and time consuming and would reflect a great deal of variability in the potential costs. Therefore, we determined that it would probably not be worthwhile to construct such a model for this rule. Although the costs of detaining conveyances are potentially quite high, the probability that we would need to detain conveyances is quite low. None of the 223 enforcement actions that we discussed in the analysis of the proposed rule in the context of estimating the maximum number of times we might use administrative detention per year involved a situation in which we would have detained conveyances. In addition, none of the 24 seizure actions that we took in fiscal year 2002 or in fiscal year 2003 involved a situation in which we would have detained conveyances. Therefore, our best estimate of the number of times per year that we might need to detain conveyances is zero.

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

The estimated cost of delaying a fleet of tanker trucks by 0 to 6 hours would be $0 to $8,000 based on the cost information we provided earlier. We assume that the cost of delaying other types of conveyances, such as trains, airplanes, and other types of trucks, would be less than the cost of delaying a ship, despite the higher probability that we might delay more than one of these other types of conveyances. We do not know how many of the 223 enforcement actions on which we based our estimate of the maximum number of administrative detentions in the proposed rule involved food located on conveyances. Therefore, we assume that between 0 and 223 of the estimated administrative detentions that we might take per year could involve food located on conveyances. In that case, the estimated cost from delaying conveyances would be $0 to $4 million per year.

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

(Response) If we were to break the seal on a truck or other conveyance and subsequently release all or some of the cargo on that conveyance, then we would reseal the conveyance with an FDA seal. Therefore, transporters would not need to deliver loads with broken

seals. In the analysis of the proposed rule, we did not account for the possibility that a receiver might not accept a load even if we resealed it with an FDA seal. The comment did not provide information on the prevalence of this practice. However, we would expect market forces to minimize this effect because investigating and resealing a load should have little effect on the underlying value of that load. Therefore, we have not revised the analysis to account for this possibility.

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

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

In addition, we would only grant a request for a hearing after an appeal is filed, if the information a firm submitted raised a genuine and substantial issue of fact. In contrast, we have no comparable pre-screening process to determine whether firms can contest seizure actions. This suggests that the rate at which firms contest seizure actions may be greater than the rate at which we would hold appeal hearings for administrative detentions. We have no way of knowing whether the rate for contesting seizure actions will be greater than

the rate at which we would hold appeal hearings for administrative detentions. Therefore, we have assumed for purposes of this analysis that we will grant all requests for appeal hearings. Based on these considerations, we have not revised our assumption concerning the estimated number of appeal hearings.

(Comment 110) One comment notes that it appeared as though we attempted to expedite the appeals process for perishable food by conducting appeal hearings within 2 calendar days from when a firm filed a request for such a hearing rather than within 3 calendar days, as for nonperishable food. This comment notes that this provision would not necessarily reduce the timeframes for perishable food, because the date on which we hold an appeal hearing does not necessarily dictate when we will reach a decision on that appeal. Some comments note that we said that we would make a decision on an appeal involving nonperishable goods within 2 calendar days of the hearing, but that we committed to no comparable deadline for perishable food.

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

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

(Comment 111) One comment argues that the ambiguity surrounding the legal criteria for using administrative detentions would encourage some firms to attempt to use administrative detention to discredit competitors.

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

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

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

Distributional Issues

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

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

(Comment 114) One comment argues that the proposed rule would give a

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

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

(Comment 115) One comment notes that the costs associated with administrative detentions would impose a substantial hardship on farmers because they have little or no ability to pass on any costs. The comment also notes that administrative detentions could create marketing disruptions that could cause a farm to lose its reputation as a reliable supplier for many years. One comment argues that a motor carrier and driver would bear some of the costs of administrative detention because the motor carrier would lose the use of the equipment during the period of the detention, and the driver might be detained or rerouted, thereby losing compensation for miles driven.

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

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

(Response) We do not currently plan to routinely inform the public of administrative detentions, although we might if there were public health reasons for doing so. Therefore, it is possible that we might inform the public of an administrative detention that we later terminated based on a successful appeal or that we later determined involved food that did not pose a threat of serious adverse health consequences or death to humans or animals. In that case, our announcement of the administrative detention could generate changes in consumer perceptions that might adversely affect some firms. We classify this type of impact as a distributive issue rather than a social cost, per se, because reductions in the demand for a given product will be offset by increases in the demand for other products, so that the net impact to society is uncertain. We have insufficient information to quantify this effect, nor did comments provide this information.

Table 2.--Annual Costs for Option One: Final Rule

Types of cost	Costs (in millions)
Transportation	$0 to $4
Delay of Conveyances	$0 to $4
Storage	$0 to $2