Loss of Product Value	$0 to $22
Marking or Labeling	$0 to $2
Appeals	$0 to $16
Total	$0 to $50

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

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

Some comments recommend that we define perishable food as food with a shelf life of 90 days or less. Other comments recommend that we define perishable food as food with a shelf life of 120 days or less. One comment suggests that we define perishable foods according to the definition in the Perishable Commodities Act, which includes fresh fruits and vegetables of every kind and character where the original character has not been changed. One comment suggests that we base our definition of a perishable food on the definition of perishable food in the NIST Handbook 130 Regulations for Uniform Open Dating. The comment also suggests that we adopt the definition of semiperishable foods from that regulation and that we treat semiperishable food the same as perishable food. The comment notes that the relevant definition of perishable food is any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days of the date of packaging, and the definition of semiperishable food is any food having a significant risk for spoilage, loss of value, or loss of palatability after a minimum of 60 days and a maximum of 6 months after the date of packaging.

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

(Response) Changing the definition of perishable food as suggested by these comments would allow more products to qualify for the expedited procedures for appeals and for initiating certain judicial enforcement actions that we established for perishable food. The expedited procedures for initiating certain judicial enforcement actions may reduce the overall duration of an administrative detention in some cases. However, we have insufficient information to determine the impact of these procedures on the duration of administrative detentions. If these procedures reduced the duration of detentions, then it would also reduce storage and loss of product value in cases in which detentions involved food

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

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

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

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

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

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

(Response) We would only directly inform the owner of the termination of a detention order if we had been able to readily

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

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

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

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

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

(Response) Although firms must indicate their intention to appeal administrative detentions of nonperishable food within 4 calendar days of when we deliver the detention notice to the owner, operator, or agent in charge of the place where the food is located, they have 10 calendar days to prepare and file their appeals. Therefore, in the case of nonperishable food, both the proposed rule and this final rule are consistent with the comment. Extending the timeframe for appealing nonperishable food would increase our enforcement costs because we would need to keep employees assigned to those cases throughout the potential appeal period to prepare for a possible appeal. It would also increase the number of appeals, which would increase our enforcement costs for reviewing those appeals and administering any appeal hearings that we might grant. However, increasing the number of appeals might also increase benefits by allowing us to terminate some detentions that we might not have otherwise terminated or that we might have terminated after a longer detention period.

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

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

Types of cost	Costs (in millions)
Transportation	$0 to $4
Delay of Conveyances	$0 to $4
Storage	$0 to $1
Loss of Product Value	$0 to $15
Marking or Labeling	$0 to $2
Appeals	$0 to $16
Total	$0 to $42

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

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

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

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

4. Option Four: Issue Regulations Only to Establish Expedited Procedures for Instituting Certain Enforcement Actions Involving Perishable Food (i.e. Limit the Action to the Regulations Required by Section 303 of the Bioterrorism Act)

We did not receive any comments on this option.

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

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

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

a. General. (Comment 124) One comment argues that rather than adding to industry's burden for food security, we should provide government funding to help industry institute measures to improve food security.

(Response) This comment raises an issue that is beyond the scope of this rulemaking. In the discussion of Option One, we argued that the expected annual burden for all potentially affected firms would be quite small and would not significantly displace food safety expenditures by industry. Declining to issue this rule would generate

minimal cost savings because the authority to detain food is self-implementing and is in effect now. This regulation specifies procedures and defines terms to ensure we meet the statutory timeframes for detaining food, and rendering a decision on appeal.

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

(Response) As stated earlier in this rule, we have posted on FDA's Web site transcripts of the May 7, 2003, public meeting that we held to discuss both the administrative detention and recordkeeping proposed rules. We also posted transcripts of the broadcast in English, French, and Spanish, which are the three official WTO languages. We plan to make similar outreach efforts directed to both domestic and international stakeholders after publication of this final rule. Providing other translations and foreign language consultants would increase our enforcement costs, but reduce the costs of foreign firms that wished to appeal administrative detentions. Reducing the cost of appeals for firms would probably increase the number of appeals. As we discussed earlier, increasing the number of appeals would increase our

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enforcement costs but would also allow us to terminate administrative detentions that we would otherwise not have terminated or terminated after a longer detention period. Terminating administrative detentions would reduce storage costs and loss of product value.

b. Coverage. (Comment 126) One comment suggests that we exempt regulated indirect food contact color pigments that firms may use in the manufacture of food packaging. This comment argues that exempting these products would have a minimal effect on benefits. According to this comment, our regulations require that indirect food contact color pigments be proven safe and incapable of migrating into food in more than de minimis quantities. This comment also argues that color pigments must be almost completely insoluble in the medium in which they are used, particularly for food packaging, which means that the amount of contaminant that would be necessary to pose a threat to food by migration from polymers and coatings would almost certainly compromise the basic stable coloration function of the pigment. This comment also states that if someone did manage to adulterate these products, then it would probably affect the chemistry of these substances in such a way that the pigment would no longer function correctly in the packaging, polymer or coating systems. The comment also notes that they know of no biological contaminants that could occur in food that could survive in the harsh environment of bulk commercial color pigments or the severe environment that occurs in the manufacturing of plastics, inks and coatings. Finally, the comment notes that they know of no cases of foodborne illness that have been attributed to contaminants that migrated from a color pigment used in food packaging.

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

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

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

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

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

(Response) The scope of the detention authority extends to those articles that meet the definition of food in section 201(f) of the FD&C Act. Exempting the products in this comment that meet this definition would have little effect on estimated costs because, if it were technically difficult or impossible to adulterate these types of food, then we would rarely or never receive information that would require us to detain it administratively. There are no costs associated with this rule for products that do not appear to present a threat of serious adverse health consequences to humans or animals. However, exempting these products could significantly reduce benefits because we would be unable to use administrative detention in the unlikely case that someone did manage to adulterate these products in a way that generated a risk of serious adverse health consequences. This type of event, although rare, could generate significant health costs. Therefore, the net effect of this revision would be to reduce the net benefits of this rule.

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

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

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

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

c. Definition of criteria. (Comment 129) Some comments state that we should define ``credible evidence or information'' and ``threat of serious adverse health consequences or death to humans or animals.'' These comments argue that these steps would be necessary to protect against arbitrary or unsupported detentions that might function as trade barriers. Some comments suggest we use internationally valid standards, such as Codex standards, when defining these terms. One comment suggests that we provide additional guidance on ``credible evidence or information'' by naming all the sources of information that we consider reliable and describing requirements with respect to accuracy of the information. One comment suggests that we adopt a more precise definition of the criteria involved because it would minimize the cost of wrongly ordered detentions. One comment argues that we should not define the criteria for

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administrative detention, but should instead decide whether a particular case meets the definition on a case-by-case basis, as we proposed. This comment argues that we should not limit our discretion to use administrative detention by identifying the types of evidence that we would need to support a detention order because terrorist events might arise under conditions that we could not anticipate.

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

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

More precisely defining ``credible evidence or information'' would increase the cost for us to develop this rule because we would need to consider and evaluate a number of possible scenarios in order to define that term. In addition, if we wrote a definition of this term into this rule, then we might need to revise the rule as we encountered new situations. Also, if we wrote a definition into the rule, and we failed to anticipate all relevant situations, then we might be unable to use administrative detentions in some situations in which there might be benefits from doing so. The benefit of more precisely defining this term is that it would reduce the possibility that some people might perceive administrative detentions as arbitrary. In the discussion of Option One, we pointed out that the credible evidence or information standard has been applied in various other judicial and administrative contexts.

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

One comment notes that the owner of the place or the vehicle where we detain food administratively might not have a vested interest in the detained product. This comment suggests that we also notify the importer or the owner of the food. One comment suggests that if we detain an exporter's product, then we should notify that exporter. One comment suggests that we notify the importer and exporter of record and the Customhouse broker. One comment requests that we notify the agent or importer. One comment requests that we notify people of administrative detentions by both a formal written communication and a telephone call.

(Response) We will issue an administrative detention order to the owner, operator, or agent in charge of the place where the food is located. We will also provide a copy of the detention order to the owner of the food, if the owner of the food is different from the owner, operator, or agent in charge of the place where the food is located, and if we can readily determine the owner's identity. Finally, we will provide a copy of the detention order to the shipper of record and to the owner and operator of the vehicle or other carrier, if the food is located on a common carrier, and if we can readily determine the identities of the owners and operators. We intend personally to deliver the detention order to the owner, operator, or agent in charge of the place where the food is located because it permits our investigator to observe the article of food and therefore better describe it in the detention order. We will notify other parties using whatever method of communication is quickest, given the information that we can readily determine about how we can contact them. The registrations that we will be requiring in another rulemaking will not provide us with a list of parties that would probably include the owners of food that we detain administratively. Committing to notifying additional parties beyond those specified in the proposed rule, notifying owners even when we cannot readily determine their identities, or notifying owners by telephone and written communications even when we cannot readily determine their phone numbers or addresses, would increase our enforcement costs.

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

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

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

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

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

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

(Comment 133) Some comments raise the issue of the information that we would provide to owners or others, either as part of the administrative detention order or otherwise. Some comments request information that would help them identify the detained food. Some comments suggest that we provide owners with grower codes so that they or others could trace the secondary supplier. One comment suggests that we provide a description of the food, the quantity, and the lot or code

numbers or other identifiers.

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

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

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

(Comment 135) Other comments discuss the information that we would provide as the bases for administrative detentions. One comment suggests that we include in the detention order the information upon which we based an administrative detention. Some comments suggest that we provide owners with complete information on the reasons for detentions so that owners can provide counterevidence during an appeal. One comment suggests that we should at least include a description of the ``credible evidence or information'' that resulted in the detention order, because without such information, the owner of the detained article would be denied information critical to its own investigation, which would hamper or deny its ability to make a meaningful appeal. The comment notes that we could provide information on why we believe the article of food subject to the order ``presents a threat of serious adverse health consequences or death to humans or animals'' even if the ``credible evidence'' that we used is classified information. One comment suggests that we provide foreign governments with the reasons for administrative detentions.

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

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

(Response) Detention orders will be dated and will include the period of detention. Therefore, anyone can determine the expiration date of that detention order. We could attempt to predict at the time we issued detention orders whether we might terminate those detention orders or move to seizure actions before the expiration date, or whether we might need to extend the detentions for an additional 10 calendar days. We could then revise detention orders as our assessment changed over time. However, that would substantially increase our enforcement costs. The benefit of this action is that the recipient of the detention order might be in a better position to plan any appeals or subsequent disposition of the food.

(Comment 137) One comment suggests that we provide information on the analyses and methods that we use to analyze food that we detain administratively.

(Response) As we discussed earlier in this preamble, information on the analyses and methods that we use to analyze food is available on FDA's Web site at http://www.fda.gov.

(Comment 138) Some comments suggest that we provide the owner a sample of the detained food to allow them to conduct their own tests.

(Response) With respect to providing counter-samples, 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 the FD&C Act. Therefore, when our own collection of a sample requires us to

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provide a part of that sample to the owners, we will do so. However, when we are not required to provide a part of that sample to the owners, we will not do so. If we do not take a sample, then we will also not provide owners with a sample. Always providing owners with a sample when we collect a sample would increase our enforcement costs but might reduce costs in some situations by allowing us to terminate some detention orders. Providing owners with samples in situations in which we do not take samples for our own purposes would increase our enforcement costs and would have a minimal impact on other costs. In particular, if we did not rely on testing to establish our case for an administrative detention, then providing owners with samples would probably likely have little impact on the appeal.

(Comment 139) One comment suggests that we allow owners of detained food to have access to the written approval granted by the authorized FDA representative to ensure that the owners have all of the necessary information to address any potential concerns.

(Response) The owner of detained food can obtain a copy of the written approval granted by the authorized FDA representative under FOIA, after we have removed any information that is protected from disclosure to the public. However, owners might not be able to get such a copy quickly enough to use during their appeal. Providing owners of food that we detain administratively faster access to written approvals granted by authorized FDA representatives would increase our enforcement costs and would probably generate no or minimal benefits. Allowing owners access to written approvals would allow them to confirm that administrative detention orders were properly approved. However, owners do not need access to those documents to raise this issue in an appeal. Therefore, making this change would probably not increase net benefits.

(Comment 140) Some comments were concerned about the information that we would provide to the public concerning administrative detentions. Some comments suggest that we should only make information on administrative detentions public if it were necessary to protect public health. These comments suggest that we ensure that any information that we release to the public on administrative detentions is accurate and that we transmit such information in a clear, unemotional, and factual manner without unduly or inaccurately raising public concern.

(Response) We do not currently plan to publicize administrative detentions unless it is necessary to protect the public health. However, members of the public can request information on administrative detentions under the Freedom of Information Act. If we found it necessary to inform the public for public health reasons, then we would ensure that the information that we provided to the public is accurate and that we transmitted it in an appropriate manner that would not unduly or inaccurately raise public concern.

(Comment 141) One comment suggests that we revise the rule to require that Regional FDA Directors or more senior level officials approve administrative detentions because of the serious cost

implications involved.

(Response) This revision would increase our enforcement costs by reducing the number of eligible authorizing officials and by increasing the payroll and opportunity costs associated with approving detentions. The potential benefit would be a reduction in the number of administrative detentions that we later terminate because of a successful appeal or because we later determined that they involved food that did not pose a serious adverse health consequences or death to humans or animals threat. We have no information establishing that this benefit would occur.

(Comment 142) One comment notes that we proposed that government employees commissioned or deputized by FDA may order a detention. This comment argues that we should revise the rule to allow only FDA employees to order and administer detentions because that would aid in the credibility of the process.

(Response) Revising the rule to allow only FDA employees to order and administer administrative detentions would increase our enforcement costs. If this revision aided the credibility of the process, then it might reduce the possibility of legal complaints and might also reduce the number of unjustified appeals, both of which would decrease costs. However, the comment did not provide information establishing that this effect would occur.

e. Compensation. (Comment 143) Many comments argue that we should compensate firms for costs associated with administrative detentions that we later terminate because of a successful appeal or because we later determined that it involved food that did not pose a threat of serious adverse health consequences or death to humans or animals. One comment suggested that we should at least compensate firms for some percentage of the costs, because it would provide us with an incentive to avoid excessive use of administrative detentions. One comment suggests that we compensate farmers for the costs of administrative detentions.

(Response) Neither the FD&C Act nor the Bioterrorism Act provide FDA with authority to compensate firms for costs associated with administrative detention. Even if FDA had such authority, if we compensated firms for costs associated with administrative detentions, then we would shift the burden of those costs from the affected firms to taxpayers in general. This is primarily a distributional issue that goes beyond the scope of this analysis.

f. Labeling and marking. (Comment 144) One comment suggests that we add the name of the authorized FDA representative to the information that we put on the tags or labels that we affix to food that is detained administratively.

(Response) Including the name of the authorized FDA representative on the tags or labels that we affix to detained food would increase our enforcement costs slightly, but would not affect other costs or benefits. We will provide information on how to appeal or obtain more information on administrative detentions in the detention order. It is possible that someone might have access to the tag or label but not the detention order, so there could be some benefit to adding a contact name to the tag or label. However, this situation is probably unlikely. Most people who may be interested in appealing an administrative detention will probably be able to obtain a copy of the detention order. Therefore, this change would probably not increase net benefits.

g. Transportation. (Comment 145) One comment suggests that we define and make available for public comment the conditions that we believe would warrant transporting food that is detained administratively to secure storage facilities.

(Response) Defining the conditions that would warrant transporting food to secure storage facilities would increase the cost for us to develop this rule because we would need to consider and evaluate every scenario that might require transportation. In addition, if we wrote these conditions into the rule, then we might need to revise the rule as we gain experience with administrative detentions. Also, if we wrote these conditions into the rule, and we failed to anticipate all situations in which transportation was appropriate, then we might need to resort to relatively inefficient and expensive alternatives.

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The benefit of defining the conditions warranting transporting food to secure storage facilities is that it would prevent inconsistent decisions about transporting food to secure storage and would allow the public to provide input on when transportation would be most worthwhile.

(Comment 146) One comment requests that we change the rule to include some provisions regarding appropriate transportation conditions, such as keeping refrigerated foods under 40 degrees F and frozen foods under -4 degrees F. One comment notes that we did not define the mode of transport in the case of limited conditional release and argues that we should require that the mode of transport not introduce any condition or substance that would adulterate or otherwise deleteriously impact the quality of the detained food.

(Response) We will normally maintain existing storage conditions during transportation to secure storage facilities. If the owner wishes, he or she can request that we maintain different storage conditions or request modification of a detention order. In the case of a request to modify the detention order, the party requesting modification of the detention order would determine the conditions during transportation.

(Comment 147) One comment requests that we revise the rule to require that the owner, purchaser, importer, or consignee, pay the transportation costs of food that is detained administratively. This comment notes that this would be consistent with the rule on prior notice (part 1, subpart I). The comment argues that a trucking company should not have to pay transportation costs because they have no control over the quality or safety of what a shipper loads into the trailer.

(Response) Resolving the issue of who should pay for transportation is a distributional issue that is beyond the scope of this analysis.

h. Storage facilities. (Comment 148) Some comments state that we should guarantee that we will have enough secure storage facilities with appropriate storage conditions for products that we detain administratively.

(Response) Guaranteeing that we have appropriate secure storage facilities for all food that we might detain administratively could generate significant costs because of the uncertainty over the number and location of detentions and whether there is a need to transport detained food to secure storage. It would generate minimal benefits because, in many cases, it may be cheaper and more or equally effective to secure detained food in place. Therefore, this change would probably increase the net costs of this rule.

(Comment 149) One comment notes that our decision to move food to secure storage, and our selection of appropriate storage facilities, could have a significant impact on the storage costs that the owners of detained food would face. The comment suggests that we ensure that such storage facilities impose the minimum cost necessary to achieve the objectives of the detention, with respect to both security and food storage conditions such as refrigeration.

(Response) Ensuring that storage facilities impose the minimum cost necessary to achieve the objectives of administrative detentions would increase our enforcement costs by requiring us to spend time shopping for storage facilities. This would also increase the time we need to implement administrative detentions, which might reduce benefits. The benefit of ensuring that we use the lowest cost storage facility is that it would give us an incentive to reduce storage costs to the lowest level possible. This benefit would probably be small. When we use commercial storage facilities, the price difference between the facility that we choose and the lowest cost appropriate storage facility would probably be relatively modest due to price competition in the commercial storage market. The same considerations apply to any conveyances that we use to move food that we detain administratively to secure storage facilities.

(Comment 150) One comment suggests that we require the person holding legal title to the food to bear the cost of storing food that is detained administratively. This person might be a shipper, the consignee, or a food broker. One comment requests that we revise the rule to require that the owner, purchaser, importer, or consignee pay any storage costs. This comment notes that this would be consistent with the rule on prior notice (part 1, subpart I). The comment argues that a trucking company should not pay storage costs because they have no control over the quality or safety of the food a shipper loads into the trailer.

(Response) The issue of who should pay for storing food that is

detained administratively is a distributional issue that is beyond the scope of this analysis.

(Comment 151) One comment suggests that we provide records of storage conditions during detention to owners of detained food, upon request.

(Response) Providing records of storage conditions to owners upon request would increase our enforcement costs slightly. This revision would probably have a minimal impact on benefits or distributional effects because we will allow owners to verify storage conditions, except where security concerns prevent it.

(Comment 152) Some comments argue that owners should be able to inform us about the optimal storage conditions for food that we detain administratively and that they should be able to submit a claim against us if we do not follow their recommendations. One comment requests that we revise the rule to include some provisions regarding appropriate storage, such as keeping refrigerated foods under 40 degrees F and frozen foods under -4 degrees F. One comment requests that we commit to holding refrigerated and frozen food at the same refrigerated and frozen temperatures and conditions that are found in U.S. commercial cold storage facilities. This comment also suggests that we allow owners, operators, or agents to request that we freeze detained fresh products that are or are likely to be, detained for 4 or more days. One comment recommends that we develop procedures regarding administrative detention for perishable foods, including a specific process that would ensure the preservation of such foods until we resolve the administrative detention.

(Response) We will normally maintain existing storage conditions during administrative detentions. If the owner wishes, he or she can request that we hold the food under different conditions or request modification of the detention order. We would accede to one or the other of these requests except where security concerns prevent it. We know of no process that would ensure the preservation of perishable foods during the detention period.

i. Off loading from conveyance/partial loads. (Comment 153) One comment suggests that we reduce the potential economic effects of detaining large oceangoing vessels by taking one of the following actions: (1) Not detaining products on vessels at ports without first allowing the product to be offloaded to secure storage; (2) specifically providing for the removal of products from vessels to secure storage in the detention order; or (3) specifying that moving detained product from the vessel qualifies as a basis for a conditional release, thus permitting the movement of detained product to secure storage. One comment notes that ships carrying bulk vegetable oils hold the oil in individual parcel tanks. This comment notes that a ship might transport many parcel tanks of various types of vegetable oil to many buyers in different locations. The comment notes

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that a single ship could carry more than 50 separate parcel tanks. This comment argues that if we receive intelligence on the potential contamination of a particular parcel tank, then we should remove that parcel tank to secure shore storage and allow the ship to proceed with deliveries of the remaining parcel tanks. One comment argues that removal of a product from a conveyance to secure storage should be one of the bases on which a claimant may seek a limited conditional release. Another comment suggests that we revise the rule to indicate that, if we detain food on a truck, then we will issue an order to the trucking company to deliver the food to either the consignee or to a secure location.

(Response) Owners and operators of conveyances may request modification of a detention order to move food from a conveyance to other storage. We generally would accede to such requests unless they generated health risks or raised security concerns. If we determine that only a portion of a cargo of food products meets the criteria for administrative detention, the food or other items that can be readily segregated and not detained can be segregated and moved. In the analysis of the proposed rule, we noted that our experience with other enforcements actions is that we would not cause significant delays in the delivery of food that is packed with food that we detain administratively. These comments did not provide information that would require us to revise that assessment.

(Comment 154) One comment requests that we develop a process by which we would reseal a tank truck load that we determined did not present a problem with an FDA seal and indicate the resealing on an official FDA document. The comment notes that receivers might still reject the load, but that they would be less likely to reject it under these conditions.

(Response) We will reseal a tank truck load that did not present a problem with an FDA seal, but we will not provide an official FDA document to that effect. Providing an official FDA document would increase our enforcement costs slightly. It is possible that such a document might reduce costs by encouraging receivers to accept resealed loads. However, in the discussion of this issue under Option One, we concluded that market forces would probably minimize unnecessary rejections of resealed loads. The comment did not provide information that would allow us to quantify this practice or to estimate the effect of an official FDA document on reducing it.

j. Timeframes. (Comment 155) One comment argues that if we needed to use any of the additional 10 calendar days beyond the initial 20-calendar day period, then we should inform the owner of the food of this additional time requirement, the reasons we need the additional time, and the actual time period that we will require, up to the maximum of 10 calendar days.

(Response) The initial detention order will include an expiration date based on the initial 20-calendar day period. 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 rather than 20 calendar days will be needed to institute a seizure or injunction against the detained article of food.

If we needed to use the additional 10 calendar days, then we would issue a new detention order with a new period of detention based on that time period. Basing the period of detention of the new detention order on our estimate of the portion of the maximum period of 10 calendar days that we think we might require would increase our enforcement costs because it would require us to develop a model to estimate the time required, and we might need to prepare additional detention orders if we underestimated the time that we needed. The benefit of this change is that it would allow owners to make plans based on our current assessment of the time that we require. This benefit would probably be minimal because we will inform owners as quickly as possible if we terminate a detention order before the detention period has expired. Providing owners with the reasons we need additional time would also increase our enforcement costs. The benefit of providing this information to owners is unclear. Any benefit would probably be minimal because we intend to proceed as quickly as possible with activities pertaining to food that we detain administratively. Therefore, these changes would probably not increase net benefits.

k. Appeal hearings. (Comment 156) One comment suggests that we start the timeframe for appeal when we notify someone who is authorized to file an appeal. One comment requests that we revise the rule to give the shipper the right to appeal. One comment wonders whether everyone with a commercial interest in the food, such as an importer, could file an appeal. One comment suggests that we revise the rule to allow the owner to designate someone else to appeal a detention order, such as a lawyer or a food engineer, in case the owner felt that he or she did not have the proper skills to do so.

(Response) Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the FD&C Act, may appeal an administrative detention. 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, or files a statement of interest under the revised Supplemental Rule C(6) of the ``Federal Rules of Civil Procedure,'' and a determination of whether a party has a sufficient interest in the goods is made on a case-by-case basis.

As required in Sec. 1.392, we will provide a copy of the detention order to the owner, operator or agent in charge of the place where the food is located and to 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. Though FDA will make reasonable efforts to identify the owner of the food and to notify that person of the administrative detention while there is still time to file an appeal, it may not always be possible for us to identify the owner of the food.

Other parties with a commercial interest in the food, including importers and shippers, would generally be able to file an appeal. Owners or other parties who wished to appeal an administrative detention may choose to have other parties, such as lawyers and food engineers, represent them for purposes of the appeal, once the appeal is filed in the owner's name.

Changing the rule to ensure that at least one party that is able to file an appeal has time to file an appeal after they learn of the detention, or that everyone with a financial interest in the food has time to appeal a detention, or that owners or other parties who wished to appeal a detention have an opportunity to arrange for other parties to represent them, would increase our enforcement costs. It would also probably increase the number of appeals, which would further increase our enforcement costs but also increase benefits by the mechanism we described earlier. These changes might also address some distributional concerns.

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The revised Sec. Sec. 1.403(h) and 1.405(a) require the presiding officer to issue a report, including a proposed decision confirming or revoking the detention order, by noon on the fifth calendar day, while giving the participant 4 hours to submit changes and corrections before a final decision is issued. These changes will increase the probability that we will correctly terminate a detention order when the food does not present a risk, but will also increase our enforcement costs by some amount.

(Comment 157) Some comments argue that we should guarantee the right to a hearing. One comment suggests that we establish a national detention approval board to ensure uniform application of the regulation. The comment argues that establishing such a board would allow us to avoid costly errors and delays.

(Response) As we indicated earlier, we would only grant a request for a hearing after an appeal is filed, if a firm submitted material that raised a genuine and substantial issue of fact. Guaranteeing the right to an appeal hearing would increase our enforcement costs. It might also increase benefits, because in some cases, our initial assessment of whether a firm submitted material that raised a genuine and substantial issue of fact might be incorrect. In that case, we might fail to terminate a detention that we would otherwise have terminated. This effect would probably be minimal because, as stated earlier, we will probably grant a hearing in most cases in which a hearing is requested.

Establishing a national detention approval board would increase our enforcement costs. It might reduce the costs of this rule by allowing us to avoid costly errors and delays. However, the comment did not provide evidence that this effect would occur.

(Comment 158) Some comments request that we provide additional guidance on how to file an appeal, addressing such issues as whether we require all appeals to include certain basic information. One comment suggests that we run workshops for local trainers and prepare slide and video presentations, online training manuals, and explanatory leaflets on how to appeal administrative detentions. One comment suggests that we describe appeal procedures and deadlines in the detention order. The comment suggests that we include the following information in the detention order: The claimant has a right to appeal the order; the appeal must be submitted in writing to the appropriate (and identified) FDA District Director, the number of days the claimant has to file the appeal and request a hearing, and the date by which such an appeal and request must be made.

(Response) We will provide information on how to appeal administrative detentions in the detention orders. As stated previously, we also plan extensive outreach materials, including explanatory materials, such as slide presentations, a satellite downlink meeting, and fact sheets, to explain the requirements of the final rule, similar to what we did for the proposed rule. Providing other information and guidance would increase our enforcement costs. It would probably have a minimal impact on other costs and distributional effects because anyone wishing to file an appeal could learn what to do from these materials.

(Comment 159) Some comments suggest that we revise the rule to require that the official presiding at an informal hearing be senior to the official who approved the detention order. They argue that presiding officials may be less likely to terminate detention orders if FDA employees senior to those presiding officials authorized those orders.

(Response) Revising the rule as this comment suggests might increase the likelihood that we would terminate some administrative detention orders during the appeal process for the reasons this comment suggests. However, we have insufficient information to establish that this effect would take place. This revision would increase our enforcement costs by reducing the pool of employees that would be eligible to either authorize administrative detentions or to preside at appeals hearings.

(Comment 160) One comment suggests that appeals hearings should include participation or attendance by third parties.

(Response) Including a third party in appeals hearings would increase the costs associated with those hearings. The comment did not explain the mechanism by which the presence of a third party would reduce costs or increase benefits. We note, however, that hearings generally are open to anyone who wishes to attend as a nonparticipant, unless classified or confidential information (e.g., information exempt from disclosure under applicable laws) is being discussed.

1. Summary. Table 5 of this document summarizes the range of costs and benefits for the five options that we have considered. We have indicated that we cannot determine the effects of many of the suggested revisions that we discussed under Option Five. However, we have insufficient information to establish that any of those revisions would increase net benefits.

Table 5.--Summary of Annual Costs and Benefits

Option	Costs (in millions)	Bene
One--Transportation and Perishable Foods as Proposed.	$0 to $50.....	>$0.
Two--Perishable Foods Alternatives.....	$0 to $42.....	>$0, But < Option On
Three--No Transportation, But One Additional Guard.	$0 to $56.....	>$0.
Four--Limited to the Bioterrorism Act..	>$0 to >$50.....	>$0, But <= Option O
Five--Revise in Other Ways.....	N/A.....	N/A.

B. Final Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule would not have a significant economic impact on a substantial number of small entities.

(Comment 161) In the analysis of the proposed rule, we requested comments on the impact of the proposed rule on small entities. The only comment we received on this issue noted that most firms making indirect food contact color pigments that firms may use in the manufacture of food packaging are small businesses.

(Response) This comment is consistent with the analysis in the proposed rule. Therefore, we have not

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revised the analysis that we presented in the proposed rule.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires cost-benefit and other analyses before any rulemaking if

the rule would include a ``* * * Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112.3 million per year. We have estimated that the total cost of the proposed rule would be no more than $50 million per year. Therefore, we have determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule

SBREFA (Pub. L. 104-121) defines a major rule for the purpose of congressional review as having caused, or being likely to cause, one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is not a major rule for the purpose of congressional review.

VII. Paperwork Reduction Act of 1995

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

We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the decision to detain an article of food.

VIII. Analysis of Environmental Impact

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

IX. Federalism

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

X. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.

1. Holcomb, Harry, Area officials have adapted a tracking system to watch over U.S. ships in an age of terrorism, accessed on the Internet at http://www.philly.com/mld/inquirer/5369951.htm, accessed on September 16, 2003.

2. AAA Environmental Industry, Inc., Cost Proposal, Schedule of Standard Rates Effective July 1, 2002, available on the Internet at http://vendornet.state.wi.us/vendornet/wais/bulldocs/1431_4.doc, accessed on September 16, 2003.

3. National Compensation Survey: Occupational Wages in the United States, July 2002. U.S. Department of Labor, Bureau of Labor Statistics, June 2003. Available on the Internet at http://stats.bls.gov/ncs/ocs/sp/ncbl0539.pdf, accessed on September 16, 2003.

List of Subjects

21 CFR Part 1

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

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 16

Administrative practice and procedure.

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 10, and 16 are amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

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

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

General Provisions

Sec.

How Does FDA Order a Detention?

What is the Appeal Process for a Detention Order?

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

General Provisions

Sec. 1.377 What definitions apply to this subpart?

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

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

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

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions.

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

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

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

Sec. 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

Sec. 1.379 How long may FDA detain an article of food?

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

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

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

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

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

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

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order under Sec. 1.381(c) before you move the detained article of food to a secure facility.

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

(e) The movement of an article of food in violation of a detention order issued under Sec. 1.393 is a prohibited act under section 301 of the act (21 U.S.C. 331).

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

(a) An article of food subject to a detention order under this subpart may not be delivered under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h) of the act (21 U.S.C. 334(h)), it may not be delivered to any of its importers, owners, or consignees. This section does not preclude movement at FDA's direction of imported food to a secure facility under an appropriate Customs' bond when that bond is required by Customs' law and regulation.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article of food under Sec. 1.384 or the detention period expires under Sec. 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request to modify a detention order to permit movement of a detained article of food for any of the following purposes:

(1) To destroy the article of food,

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

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

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

(d) You must submit your request for modification of the detention order in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting modification of a detention order for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with

Supplemental Rule C to the ``Federal Rules of Civil Procedure.''

[[Page 31703]]

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

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

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

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

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

(a) A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;

(b) A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;

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

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

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

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

Sec. 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

How Does FDA Order a Detention?

Sec. 1.391 Who approves a detention order?

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

Sec. 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA 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.

Sec. 1.393 What information must FDA include in the detention order?

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

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

(1) The detention order number;

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

(3) Identification of the detained article of food;

(4) The period of the detention;

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

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

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

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

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under Sec. 1.381(c);

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

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

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

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

(14) The name and the title of the authorized FDA representative who approved the detention order.

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What Is the Appeal Process for a Detention Order?

Sec. 1.401 Who is entitled to appeal?

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

Sec. 1.402 What are the requirements for submitting an appeal?

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

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

(2) Nonperishable food: If the detained article is not a perishable food, as defined in Sec. 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order.

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

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act (21 U.S.C. 276) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.

Sec. 1.403 What requirements apply to an informal hearing?

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

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

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

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

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

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

(f) Section 1.404, rather than Sec. 16.42(a) of this chapter, describes the FDA employees, e.g., Regional Food and Drug Directors or other officials senior to a District Director, who preside at hearings under this subpart;

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

(h) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.

(i) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. 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.

(j) No party shall have the right, under Sec. 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.

(k) If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that Sec. 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in Sec. Sec. 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under Sec. 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

Sec. 1.404 Who serves as the presiding officer for an appeal, and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

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

(a) The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth calendar day after the appeal is filed; after your 4 hour opportunity for submitting comments under Sec. 1.403(h), the presiding officer must issue a final decision within the 5-calendar day period after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-calendar day period, the detention order is deemed terminated.

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

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision

on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

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

1.379, whichever occurs first.

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

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

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

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

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES

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3. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

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4. Section 10.45 is amended by revising paragraph (d) introductory text to read as follows:

Sec. 10.45 Court review of final administrative action; exhaustion of administrative remedies.

* * * * *

(d) Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under Sec. 10.25(a), on a petition for reconsideration submitted under Sec. 10.33, on a petition for stay of action submitted under Sec. 10.35, on an advisory opinion issued under Sec. 10.85, on a matter involving administrative action which is the subject of an opportunity for a hearing under Sec. 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with Sec. 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act (21 U.S.C. 355(j)(2)(C)) and Sec. 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

* * * * *

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

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

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

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6. Section 16.1 is amended in paragraph (b)(1) by adding an entry in alphanumerical order as follows:

Sec. 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

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

* * * * *

Dated: May 13, 2004.
Lester M. Crawford,
Acting Commissioner of Food and Drugs.

Dated: May 25, 2004.
Tommy G. Thompson,
Secretary of Health and Human Services.
[FR Doc. 04-12366 Filed 5-27-04; 10:57 am]

BILLING CODE 4160-01-P

Protecting the Food Supply

May 2004

FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA'S New Food Bioterrorism Regulation Final Rule: Administrative Detention

Section 303(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) adds section 304(h) to the Federal Food, Drug, and Cosmetic Act to authorize FDA to detain an article of food for which there is credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals. This authority is self-executing and provides an added measure to ensure the safety of the nation's food supply. The Bioterrorism Act also requires FDA to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. FDA has now issued a final rule that includes these expedited procedures for perishable foods as well as procedures describing how FDA will detain an article of food and the process for appealing a detention order.

What food is subject to the regulation? The definition of food used in the final rule references the definition of food in section 201(f) of the Federal Food, Drug, and Cosmetic Act. It includes food and beverages for human and animal consumption. Food regulated exclusively by USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act is not covered by the administrative detention regulation. All other food is subject to this regulation whether or not it enters interstate commerce.

What constitutes "perishable food?" FDA defines perishable food as food that is not heat-treated, not frozen, and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions.

What criteria does FDA use to order a detention? An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the Federal Food, Drug, and Cosmetic Act if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.

Who approves a detention order? The final rule requires a detention order to be approved by the District Director of the district where the detained article of food is located, or an official senior to such director.

What information must FDA include in the detention order? The final rule requires the detention order to include the detention order number; the hour and date of the order; identification of the detained article of food; the detention period; a statement that the article of food identified in the order is detained for the period shown; a brief, general statement of the reasons for the detention; the name of the authorized FDA representative who approved the detention order; and the address and location where the article of food is to be detained and the appropriate storage and transportation conditions.

How long may FDA detain an article of food? The detention period cannot exceed 30 days.

Where and under what conditions must the detained article of food be held? The final rule requires the detained article of food to be held in the location and under the conditions specified by FDA in the detention order. The detention order must require the removal of the detained article of food to a secure facility, as appropriate.

May a detained article of food be delivered to another entity or transferred to another location? The final rule states that an article of food subject to a detention order may not be delivered to another entity, such as its importers, owners, or consignees. Detained food may not be transferred from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article or the detention period expires, whichever occurs first. A "request for modification of a detention order" for a detained article of food may be approved for destroying the article of food, moving the detained article of food to a secure facility, maintaining or preserving the integrity or quality of the article of food, or for any other appropriate purpose. It is important to note that the existence of an appropriate customs bond required by Customs law and regulation does not prohibit movement of a detained article of food at FDA's direction.

What labeling or marking requirements apply to a detained article of food? A detention order may require that the detained article of food be labeled or marked as detained. The FDA tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative. This marking is different from the marking that FDA may require under section 308 of the Bioterrorism Act for food refused admission into the United States.

What expedited procedures apply when FDA initiates a seizure action against a detained perishable food? If FDA initiates a seizure against a perishable food subject to a detention order, the final rule requires FDA to send the seizure recommendation to the Department of Justice (DoJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist.

Who receives a copy of the detention order? FDA will issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different form the owner, operator, or agent in charge of the place where the article of food is located, then FDA will provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily. If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

Who is entitled to appeal? Any person who would be entitled to claim the detained article of food if it were seized may appeal the detention order to the Secretary.

What are the requirements for submitting an appeal? For perishable food, an appeal must be filed within 2 calendar days of receipt of the detention order. For non-perishable food, a notice of intent to file an appeal and to request a hearing must be filed within 4 calendar days of receipt of the detention order, with the requirement that the actual appeal be filed within 10 calendar days of the receipt of the detention order.

Will a hearing be held if an appeal is made? The final rule states that, if a hearing is requested in the appeal, and FDA grants the request, then the hearing will be held within 2 calendar days after the date the appeal has been filed for both perishable and nonperishable foods.

When does FDA have to issue a decision on an appeal? Within 5 calendar days after such an appeal is filed, and after providing opportunity for an informal hearing, FDA must confirm or terminate the detention order.

When does a detention order terminate? If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order, or that person's representative. If FDA fails to issue a detention termination notice and the detention period expires, the detention order is deemed to be terminated.

What is the difference between an import detention and administrative detention?" Our authority to detain food administratively under section 304(h) of the Federal Food, Drug, and Cosmetic Act is separate and distinct from our authority to refuse admission of imported food under section 801(a) of that act, even though refusal under section 801(a) is preceded by an action referred to as "detention and hearing."

In section 304(h), Congress gave FDA the authority to detain food administratively where we have credible evidence or information that the article of food presents a threat of serious adverse health consequences or death to humans or animals so that we can bring such food under FDA control.

FDA's evaluation of imported foods under section 801(a) largely focuses on whether the article of food appears to have been safely produced, packed, and held; contains no contaminants or illegal additives or residues; and is properly labeled. If FDA determines that refusal under section 801(a) appears appropriate, FDA, as set out in its regulations, gives written notice to the owner or consignee (see 21 CFR 1.94(a)). In guidance dating back many years, FDA refers to this written notice as the notice of detention and hearing.

We do not, at this time, foresee frequently using administrative detention under section 304(h) to control the movement of imported food subject to section 801. When FDA determines it is appropriate to bring imported food under FDA control using the authority under section 304(h), the standard for administrative detention of imported food will be the same as it is for other food, i.e., we must have credible evidence or information that the article of

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

When do the administrative detention requirements take effect? The administrative detention authority in section 303 of the Bioterrorism Act took effect immediately upon enactment of the Act. The procedures FDA will follow for administratively detaining food that is specified in the final rule take effect 30 days after it publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
CFSAN(食品安全応用栄養センター)

2003 年 10 月

本文書は、FDAが 2003 年の 10 月に発行したFact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule - Registration of Food Facilities の翻訳です。FDAによる翻訳版文書発行の目的は、幅広い国際社会の読者の役に立つ情報を提供することにあります。内容については、できるだけ正確に翻訳するように努めていますが、翻訳の過程で、類似の表現への置き換えや、不明瞭な表現、不正確な情報が生じる場合があります。FDAの正式文書は英語版となりますのでご了承ください。

FDA による新しい食物バイオテロリズム規制のファクトシート:
暫定最終規則 - 食品施設の登録

公衆衛生安全保障バイオテロリズム法（バイオテロ法）は、保健福祉省長官が米国の食品供給に対するテロリストからの脅威または攻撃から国民を守るための手段をとることを義務付けています。バイオテロリズム法の規定を施行するために、FDAは2003年10月10日に暫定最終規則「食品施設の登録」を発行しました。これにより、米国で人または動物に供する食品を生産/処理、包装、または保管する国内外の施設はFDAに登録することが義務付けられます。この暫定最終規則では、該当するすべての施設は2003年12月12日までに登録する必要があります。潜在的または実際のバイオテロリズムが起きたり、食物が原因の疫病が発生した場合、FDAは設備の登録情報を基に事件の場所と原因を究明し、汚染された設備を速やかに通知することができます。施設の登録は、インターネットを使ってオンラインで行うことも、登録用紙または関連情報を保存したCD-ROMをFDAに提出することによっても行えます。オンライン登録は、2003年10月16日に使用できるようになります。オンライン登録についてのご質問は、米国内からは1-800-216-7331 または 301-575-0156、国外（日本）からは 010-1-301-575-0156にお電話いただくか、010-1-301-210-0247にFaxしてください。また、furls@fda.gov に電子メールすることもできます。オンライン登録のヘルプデスクは、2003年10月16日から米国東部時間の午前7時から午後11時まで質問を受け付けます。

この新しい規則は、米国で供する食品を生産/処理、包装、または保管する施設(規則により規定)にのみ適用されます。「食品」の例は次のとおりです。

栄養補助食品および栄養成分
乳幼児用ミルク
飲料(アルコール飲料およびボトル入りの水を含む)
果物および野菜
魚およびシーフード
乳製品および殻つき卵
食品または食品成分として使用する農業原材料製品(Raw agricultural commodities)

缶詰または冷凍食品
パン菓子、スナック　フード、キャンディ(チューインガムを含む)
生きている食用動物
動物飼料およびペットフード

食品接触物質および農薬は、暫定最終規則で定義する「食品」に該当しません。よって、食品接触物質および農薬を生産/処理、包装、または保管する施設は FDA に登録する必要はありません。

誰が登録するのですか?米国で人または動物に供する食品を生産/処理、包装、または保管する国内外の施設を管轄する所有者、オペレータ、エージェント、またはその権限を委任された者は、2003 年 12 月 12 日までにその施設を FDA に登録する必要があります。国内施設は、その施設からの食品が州境を超える取引きに入るかどうかにかかわらず登録が必要です。国外の施設は、輸入者または仲介ブローカーなどの U.S.エージェントを任命する必要があります。U.S.エージェントは、米国内で居住するか継続的にビジネスを行い、登録に際して米国に滞在している必要があります。

登録する必要がないのはどのような施設ですか?

- 個人住居。食品を生産/処理、包装、または保管する場合でも不要です。
- 飲料水収集/分配設備および建物(公共水道システムなど)
- 運送業として通常食物を保管する車両
- 農場。つまり、穀物の栽培/収穫、動物(シーフードを含む)の飼育、またはその両方のために使用する土地にある施設。洗浄、外葉の切り取り、農産物の冷蔵も収穫作業とみなす。「農場」には、同一所有のもとで栽培、飼育、または消費される食品を包装または保管する設備、および同一所有のもとで消費される食品を生産/処理する施設も含まれる。
- レストラン。食品を調理し、消費者にその場で消費することを目的に直接販売する施設。動物に食物を提供するペットシェルター、犬小屋、家畜施設を含む。商業航空などの州間運輸に食物を提供する施設や、調理して直接消費者に提供しないセントラルキッチンなどは、この規則でいうレストランに該当しない。
- 小売食物施設。スーパー、デリ、屋台などの消費者への食品販売を主な業とする(消費者への年間売上がその他の購買者への売上よりも大きい)施設。食品を生産/処理、包装、または保管し、そこで生産/処理する食品を含め、施設から消費者に直接販売することを主な業とする施設は小売食品施設であり、登録する必要はない。
- 非営利食品施設。IRS(内国歳入庁)の§ 501(c)(3)の条件を満たし、食品を消費者に直接提供するか、米国セントラルフードバンク、スープキッチン、および非営利食品配達サービスを通じて人または動物が消費するための食品または食事を提供する非営利団体がこの例である。
- 漁船。漁業に使用する船舶。このような船舶で魚を保存するために頭や内臓を除去したり、冷凍しても、規則適用を免除される。

- 施設中のどの部分も米国農務省によってのみ規制されている施設。すなわち獣肉製品、鶏肉製品、または卵製品のみを扱う施設。

米国で消費される食品を生産/処理、包装、または保管する国外施設はすべて登録する必要がありますか?いいえ。食品を米国に輸出する前にさらに生産/処理、包装を行うために別の国外施設に送る場合は、後者の国外施設に登録の義務があります。ただし、後者の国外施設で行う作業がラベルを貼るなどの些末な作業の場合は、両方の施設が登録する必要があります。また、食品の最後の国外生産/処理者の後で包装または保管する国外施設も登録する必要があります。

登録する頻度は?登録する必要があるのは、食品施設ごとに 1 回です。ただし、登録情報に変更があった場合は、更新する必要があります。

登録番号は何を意味しますか?施設の所有者が、FDA に登録することによりこの規則を遵守していることを意味します。番号を得たことにより、FDA がその施設または製品を承認したり、推奨したりすることを意味するものではありません。

登録料は必要ですか?登録およびその更新には費用はかかりません。

登録方法は?登録またはその更新にはフォーム 3537 を使用する必要があります。インターネットを使用して、www.fda.gov/furls から登録することもできます。このサイトは、2003 年 10 月 16 日から毎日 24 時間使用できます。このWebサイトには、図書館、コピーセンター、学校、インターネットカフェなど、インターネットに接続が可能などんな場所からでもアクセスできます。ヘルプが必要な場合、www.fda.gov/furls からアクセスできるオンラインヘルプの他に、オンライン登録ヘルプデスクがあります。

- 米国内からは 1-800-216-7331 または 301-575-0156 に電話する。
- 国外 (日本) からは 010-1-301-575-0156 に電話する。
- 国外 (日本) からは質問を 010-1-301-210-0247 に Fax する。
- 質問の電子メールを furls@fda.gov に送る。

これらの電話番号では、2003 年 10 月 16 日から米国東部時間の午前 7 時から午後 11 時まで質問を受け付けます。

インターネットへのアクセスが容易にできない場合は、301-575-0156 に電話するか、
次の住所にリクエストを郵送することにより、FDA からフォームを入手できます。

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville MD 20857
USA

フォームを見やすく完全に記入したら、上の住所に郵送するか、(301) 210-0247 に Fax します。また、以下に説明するように、複数施設の登録を CD-ROM を使って FDA に提出できます。

複数の食品施設を 1 度にまとめて行う方法はありますか?FDA は、CD-ROM フォーマット ISO 9660 (CD-R または CD-RW)データフォーマットで提出された登録を受け付けます。これらのファイルは、PDF 形式のフォーム 3537 および登録フォームの宣誓ステートメントに署名したファイルとともに提出する必要があります。個々の提出 CD-ROM には、フォーム 3537 の当該ブロックに、同一の希望郵送先を使用する必要があります。この方法で提出可能な登録の数に上限はありません。ただし、個々の CD-ROM での登録ごとに固有のファイル名(32 文字以下)を付ける必要があります。ファイル名の最初の部分で親会社を識別できるようにすることもできます。情報がこれらの仕様に準じていない場合は、FDA は登録を受け付けず、CD-ROM を返却します。

FDA は、CD-ROM、郵送、ファックスによる登録を受け付けた順に処理します。

FDA が電子登録を奨励するのはなぜですか?FDA がこの登録方法を奨励するのは、それが施設と FDA の双方にとって最も安価で効率の良い方法だからです。電子登録では、必要な情報がすべて記入されていないと、システムは登録を受け付けません。受け付けられた時点で、登録者には登録確認と登録番号が送られます。登録用紙による登録は費用もかかり、FDA に必要な施設情報を伝えるにも、施設に登録番号を伝えるにも効率がよくありません。さらに、登録用紙による登録ではミスや記入漏れが発生しやすく、処理の完了までにさらに時間がかかります。

必要な情報は何ですか?各登録には、施設の名前、住所、電話番号および親会社(該当時のみ)、所有者、オペレータ、委任されたエージェントの名前、住所、電話番号、施設が使用するすべての商号、FDA 規則 21 CFR 170.3 で規定された該当する食品分類、提出された情報が真実かつ正確であり、登録を提出する者が所有者、オペレータ、委任されたエージェント以外の場合は、登録を提出する権限があることを宣誓するステートメントを含める必要があります。国外施設は、さらに U.S.エージェントの名前、住所、電話番号を提出する必要があります。国外施設は、緊急時連絡先とする担当者を任命しない場合は、U.S.エージェントの緊急連絡先電話番号も提出する必要があります。国内施設も緊急連絡先電話番号を提出する必要があります。

それ以外に要求される情報はありますか?FDA は必須にはしていませんが、登録フォームで任意情報を求めています。任意情報により、実際のまたは潜在的なテロリストからの脅威やその他の食品関連緊急事態の標的となる可能性のある施設とより効果的に連絡をとることができます。たとえば、特定の健康補助食品、乳幼児用ミルク、動物飼料は 21 CFR 170.3 の食品分類リストに含まれませんが、これらの種類の食品が食品関連緊急事態の焦点となることもあります。このため FDA は、必須にはしませんが、フォーム 36537 で任意とされている情報も提供することを奨励しています。

登録情報は一般に公開されますか?いいえ。登録された施設リスト、この規則に基づいて提出された登録文書、リストや文書から派生する登録された特定人物の氏名や場所を特定するようないかなる情報も、情報公開法(FOIA)に基づいて公開されることはありません。

提出した登録情報が変更になった場合はどうしますか?施設の登録情報の必須要素(例えば、オペレータ、委任エージェント、U.S.エージェント)が変更になった場合、所有者、オペレータ、委任エージェント、またはこれらのいずれの者から承認された者は、変更の発生から 60 日以内にインターネットwww.fda.gov/furls または用紙による更新プロセスによりこれを届け出る必要があります。

施設が倒産した場合はどうしますか?施設が倒産した場合は、インターネットwww.fda.gov/furls または用紙によるプロセスにより、フォーム 3537aを使用して登録を取り消す必要があります。

新しい所有者が既に登録済みの施設を取得した場合はどうしますか?以前の所有者は変更から 60 日以内にフォーム 3537a を使用して施設の登録を取り消す必要があります。新しい所有者は、フォーム 3537 を使用して、その施設を再登録する必要があります。取り消しと再登録のいずれも、インターネットまたは用紙によるプロセスを通じて行えます。

施設を登録しないとどうなりますか?国内施設、国外施設の登録、必要事項の更新、規則に準じた登録取り消しを怠ることは、連邦食品薬品化粧品法の禁止事項です。連邦政府は、民事訴訟を起こして、連邦裁判所が禁止事項を行った者に禁止措置を依頼したり、連邦裁判所に刑事訴訟を起こして、禁止事項を行った者を訴追することができます。国外施設が登録の義務がありながら登録しなかった場合、その国外施設から米国に輸入された食品は、FDA または税関および国境保護庁(CBP)による指示がない限り、輸入港で差し止められます。FDA は 801(m)(1)項の輸入食品の拒否、または 801(l)項の輸入食品の差し止めに関する FDA の方針の強制ガイダンスを発行する予定があります。このガイダンス文書は一般に公開され、FDA はその存在を連邦広報で通知します。

この暫定最終規則に追加コメントは受け付けられますか?FDAは、この暫定最終規則に関連する特定の問題に 75 日のコメント期間を設けています。さらに、この暫定最終規則にコメントを寄せる人々がFDAの支援および教育努力の恩恵を受け、この暫定最終規則のシステム、時間枠、データ要素の経験を積むために、局は 2004 年 3 月からさらに 30 日間コメント期間を再度設ける予定です。この暫定最終規則の更新情報とコメントの方法には、http://www.fda.gov/oc/bioterrorism/bioact.html からアクセスできます。

FDAは、コメント期間中、この暫定最終規則のどのように強制しますか?FDAは、当初の規則施行の時期とそれを過ぎた後でも、公衆衛生の保護を確保するとともに、登録暫定最終規則の強制施行に関する裁量行使を積極的に行っていく考えです。登録暫定最終規則は2003年12月12日に施行され、これ以降、対象となる施設はこの要件に準拠する義務があります。FDAは、影響を受ける者の中には、

規則の要件とFDAが12月12日以前に行う広範な支援および教育活動の後でも、規則要件の理解と準拠方法を理解するのに補助が必要な関係者がいるだろうということを認識しています。これらの理由からFDAは、施行日から最初の数ヶ月間、関係者が要件と準拠方法を理解することを強力に支援する方針を採用する予定です。FDAは間もなく、FDAが強制裁量を行使する基準を示した準拠方針ガイドが入手可能になった旨の通知を出します。ただし、このガイダンスは、FDAが食品安全に関する問題の検査を行ったり、連邦食品薬品化粧品法に基づいて行うその他のアクションを含む、必要なアクションをとる能力に影響を与えるものではありません。この方針は、また税関および国境保護局が19 U.S.C. 1595a(b)に基づいて罰則を科したり、その他の権限に基づいて取り締まりを行う能力に影響を与えるものでもありません。

詳細について:この暫定最終規則の特定要件に関する詳細については、暫定最終規則を参照してください。暫定最終規則は、http://www.cfsan.fda.gov/~furls/ffregfr.html で閲覧できます。

Federal Register

Friday,
October 10, 2003

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 20

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Interim Rule

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Interim Rule

Risk Assessment for Food Terrorism and Other Food Safety Concerns; Availability; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

[Docket No. 02N–0276]

RIN 0910–AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final regulation that requires domestic and foreign 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. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires domestic and foreign facilities to register with FDA by December 12, 2003, even in the absence of a final regulation. Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual terrorist attack on the U.S. food supply by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify quickly the facilities that might be affected by the outbreak.

DATES: This interim final rule is effective December 12, 2003. Submit written or electronic comments by December 24, 2003.

FOR FURTHER INFORMATION CONTACT: Leslye M. Fraser, Center for Food Safety and Applied Nutrition (HFS–4), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2378.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

SUPPLEMENTARY INFORMATION:

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I. Background and Legal Authority

On February 3, 2003 (68 FR 5378), FDA and the Department of the Treasury jointly issued a proposed rule requiring certain food facilities to register with FDA. The events of September 11, 2001, had highlighted the need to enhance the security of the infrastructure of the United States, including the food supply. Congress had responded by enacting the Bioterrorism Act (Pub. L. 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 305, which requires the Secretary of Health and Human Services (the Secretary) to develop a regulation to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA by December 12, 2003. The provision creates section 415 and amends sections 301 and 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331 and 381). The Bioterrorism Act also requires FDA to issue regulations mandating prior notice of imported food shipments (section 307), directs FDA to issue regulations regarding the maintenance of certain records (section 306), and grants FDA the authority to administratively detain food (section 303). FDA and the Department of the Treasury have jointly published proposed rules implementing section 307 (68 FR 5428, February 3, 2003), and FDA has published proposed rules implementing section 303 (68 FR 25242, May 9, 2003), and section 306 (68 FR 25188, May 9, 2003). The prior notice interim final rule appears elsewhere in this issue of the **Federal Register**.

The major components of section 305 of the Bioterrorism Act are as follows:

- The owner, operator, or agent in charge of a facility is responsible for the submission of a registration to FDA;
- Each facility must be separately registered and the registration must include the name and address of the facility, and all trade names under which the registrant conducts business from that facility. The registration for foreign facilities also must include the name of the U.S. agent for the facility;
- FDA also may require each registration to include the general food category (as identified under § 170.3 (21 CFR 170.3)) of the food manufactured, processed, packed, or held at the facility, if FDA determines through guidance that this submission is necessary. FDA issued guidance on July 17, 2003 (68 FR 42415), available at *http://www.fda.gov/oc/bioterrorism/bioact.html,* that concluded that information about food product categories is necessary for a quick, accurate, and focused response to an actual or potential bioterrorist incident or other food-related emergency;
- Foreign facilities that manufacture/process, pack, or hold food that is exported for consumption in the United States are required to register unless the food undergoes further processing or packaging at another facility outside the United States;
- Establishments excluded from the registration requirement are farms, restaurants and other retail food establishments, nonprofit food establishments, and fishing vessels (except those engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k));
- FDA shall notify the registrant when it has received the registration

and assign a unique registration number to each registered facility;

• FDA may encourage electronic registration;

• Registered facilities must notify FDA in a timely manner of changes to their registration information;

• FDA is required to compile and maintain an up-to-date list of registered facilities; and

• FDA's list of facilities and registration documents are not subject to public disclosure under 5 U.S.C. 552 (the Freedom of Information Act). Information derived from this list or these documents is also not subject to such disclosure to the extent that it discloses the identity or location of a specific registered facility.

In addition to section 305 of the Bioterrorism Act, FDA is relying on section 701(a) and (b) of the FD&C Act (21 U.S.C. 371(a) and (b)) in issuing this interim final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the FD&C Act authorizes FDA and the Department of Treasury jointly to prescribe regulations for the efficient enforcement of section 801 of the FD&C Act (21 U.S.C. 381).

This interim final rule implements the food facility registration requirements in section 305 of the Bioterrorism Act. Elsewhere in this issue of the **Federal Register**, FDA is issuing an interim final rule implementing section 307 (prior notice of imported food). The two interim final rules published in this issue of the **Federal Register**, as well as the regulations FDA will issue to implement section 306 (recordkeeping/records access) and section 303 (administrative detention) of the Bioterrorism Act, will help FDA act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies. Registration will provide FDA with information about facilities that manufacture/process, pack, or hold food for consumption in the United States. In the event of an outbreak of foodborne illness, such information will help FDA and other authorities determine the source and cause of the event. In addition, the registration information will enable FDA to notify more quickly the facilities that might be affected by the outbreak. In developing this interim final rule, FDA has complied with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA).

II. Highlights of the Interim Final Rule and Summary of the Significant Changes Made to the Proposed Rule

A. The Highlights of This Interim Final Rule Are Described Briefly Below and Are Discussed in More Detail Later in the Preamble

The highlights of this interim final rule are as follows:

• The owner, operator, or agent in charge of a facility engaged in manufacturing/processing, packing, or holding food for consumption in the United States by humans or animals is responsible for registering the facility with FDA;

• The owner, operator, or agent in charge of a facility that is required to register may authorize an individual to submit the facility's registration to FDA;

• Facilities covered under this rule must be registered by December 12, 2003;

• A foreign facility is exempt from registering if food from the facility undergoes further processing or packaging by another facility outside the United States. The facility is not exempt from registration if the processing or packaging activities of the subsequent facility are limited to affixing a label to a package or other de minimis activity. The facility that conducts the de minimis activity also must register;

• The following domestic and foreign facilities are also exempt from registration: Farms; restaurants and other retail food establishments; nonprofit food facilities that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States; fishing vessels not engaged in processing as defined in § 123.3(k); and facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (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.*);

• Registrants must use Form 3537 to register. This form is available either on the Internet (see address below) or via mail or phone request. FDA will begin processing paper registrations on October 16, 2003. Registrants must use Form 3537a to cancel their registration;

• FDA strongly encourages electronic registration, which will be quicker and more convenient for both facilities and FDA than registration by mail or CD–ROM;

• To register electronically, beginning on October 16, 2003, a registrant may visit *http://www.fda.gov/furls*, which is available for registration 24 hours a day, 7 days a week. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes, as well as through a foreign facility's U.S. agent or other authorized individual if the facility makes such arrangements;

• Regardless of the mode of submission (electronic, paper, or CD–ROM), each registration must include the name and contact information for the facility and its parent company (if applicable); all trade names the facility uses; applicable food product categories as identified in § 170.3 of this chapter; a statement certifying that the information submitted is true and accurate and that the person submitting the registration is authorized by the facility to register on its behalf; and if a foreign facility, the name of and contact information for the facility's U.S. agent. A domestic facility must provide emergency contact information;

• No registration fee is required;

• Updates to registration information or cancellation of registration must be submitted within 60 calendar days of any change to any of the required information previously submitted;

• Failure of a domestic or foreign facility to register, update, or cancel its registration in accordance with this regulation is a prohibited act under section 301(dd) of the FD&C Act;

• The disposition of food imported or offered for import from an unregistered foreign facility will be governed by the procedures set out in subpart I of this part 1 (21 CFR part 1) (Prior Notice of Imported Food); and

• Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

B. Significant Changes Made to the Proposed Rule

The significant changes FDA made to the proposed rule are as follows:

• The interim final rule provides that private residences of individuals and nonbottled water drinking water collection and distribution establishments and structures are not facilities and, therefore, are not required to register;

• The interim final rule clarifies that transport vehicles are not facilities if they hold food only in the usual course of business as carriers;

• The definition of farm now states that washing, trimming of outer leaves, and cooling produce are part of harvesting;

• The definition of farm now includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership;

• The definition of food for purposes of the Bioterrorism Act excludes food contact substances as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) and pesticides as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136(u);

• Packaging (when used as a verb) has been defined and means "placing food into the container that directly contacts the food and that the consumer receives;"

• The definition of "retail food establishment" has been revised to

an establishment that sells food products directly to consumers as its primary function. A retail establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food that it manufactures/processes, packs, or holds directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to the consumers exceeds the annual monetary value of sales of food products to all other buyers. The term 'consumers' does not include businesses. A 'retail food establishment' includes grocery stores, convenience stores, and vending machine locations.

• FDA has added a definition for "trade name" as "the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product;"

• FDA has determined that it will contact the foreign facility's U.S. agent when an emergency occurs, unless the registration specifies another emergency contact under § 1.233(b);

• FDA is clarifying that having a single U.S. agent for FDA registration purposes does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of registration;

• FDA is allowing registrants to submit their registrations by fax or CD–ROM, which FDA will enter into its registration system, along with the mailed submissions, as soon as practicable, in the order received;

• FDA has changed the timeframe in which registrants must update their registrations from 30 days to within 60 days of any change in the required information;

• FDA has deleted the requirement to update optional information previously submitted, but encourages facilities to do so voluntarily; and

• FDA has clarified that if a facility has a new owner, the former owner must submit a cancellation within 60 calendar days of the change and the new owner must re-register the facility.

• FDA now provides that the failure of an owner, operator, or agent in charge of a facility governed by this interim final rule to register such facility, update required elements of its registration, or cancel its registration, is a prohibited act under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)).

III. Comments on the Proposed Rule

FDA received approximately 350 submissions in response to the proposed rule, which raised almost 200 major issues. To make it easier to identify comments and FDA's responses to the comments, the word "Comment" will appear in parentheses before the description of the comment, and the word "Response" will appear in parentheses before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

(Comment 1) Most commenters state that they generally support protection of the U.S. food supply under the Bioterrorism Act. Although some commenters assert that the proposed rule should be amended to reflect more accurately industry practices, other commenters believe the regulation should be strengthened to ensure that FDA has all the information required to identify foods that may pose a health or security threat. Other commenters question how the interim final rule would enhance FDA's ability to improve food safety and whether the benefits outweigh the costs.

Some commenters argue that the proposed regulation should either be reproposed or not implemented at all. These commenters claim that the proposed rule is seriously flawed, unduly burdensome, and will unnecessarily interfere with trade. Some of these commenters also argue that FDA already has complete information to allow for identification of, and quick communication with, affected facilities before a shipment is introduced into U.S. commerce.

(Response) In response to the comments regarding reproposing or not implementing the rule, these options are not available to FDA under the Bioterrorism Act, because that act requires FDA to "promulgate proposed and final regulations for the requirement of registration" by December 12, 2003. The Bioterrorism Act further states that the registration requirement takes effect on December 12, 2003, even if FDA does not have a final regulation in effect by the deadline. FDA believes that both the proposed rule and this interim final rule properly implement section 305 of the Bioterrorism Act, and thus, there is no need to repropose the regulation. Further, based on the many comments supporting the proposed regulation as well as those comments suggesting limited changes to the rule as proposed, FDA disagrees that the proposed regulation is so flawed that reproposal is required.

FDA is aware that the registration regulation may alter industry practices to some extent. In enacting the Bioterrorism Act, Congress determined that registration with FDA was necessary to respond to bioterrorism and other food-related emergencies. Registration will give FDA information it does not currently have about facilities that manufacture/process, pack, or hold food for consumption in the United States, and current contact information for all of these facilities. FDA will be able to use this information to target its contacts to both domestic and foreign facilities in the event of a bioterrorist threat or other food-related emergency. Information about food product categories will permit FDA to screen food imports more carefully because the agency will be able to match a registrant's food product category with the product code and common or usual or market name submitted as part of a prior notice (21 CFR part 1, subpart I). Registration will also give FDA information that we can use to focus and better utilize the agency's limited inspection resources.

Registering with FDA creates an information trail, which would, even if the information in the registration were falsified, provide evidence that could link the registration to the registrant. By creating this paper trail, persons in the food supply chain who might intentionally contaminate food may be deterred by the creation of additional evidence that might be used against them. Persons who might intentionally contaminate the food supply but refuse to register would be subject to criminal and civil sanctions and would risk having their product, if imported, held at the port.