Information Verification February 2, 2004
- FDA Notice Regarding Firms Offering Registration Services June 30, 2003

- **Prior Notice of Imported Food Shipments**
  - *Guidance for Industry:* Prior Notice of Imported Food Contingency Plan for System Outages August 12, 2004
    (Federal Register Notice of Availability August 16, 2004)
  - *Press Release:* FDA and CBP Define Their Transitional Compliance Policy on Food Imports Under the Bioterrorism Act December 11, 2003
    - *Compliance Policy Guide:* Guidance for FDA and CBP Staff November 2005
      (Federal Register Notice of Availability November 14, 2005)
    - *Summary Information:* Prior Notice Summary Information April 2005
  - *Press Release:* FDA and CBP Bolster Safeguards on Imported Food December 3, 2003
  - *Joint FDA-CBP Plan* for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes August 2004
  - *Fact Sheet:* FDA's New Food Bioterrorism Regulation: Interim Final Rule - Prior Notice of Imported Food Shipments October 2003
    (also available in French, Malay, Polish, Portuguese, Spanish, Arabic (PDF*), Chinese (PDF*), Hindi (PDF*), and Japanese (PDF*))
  - *Flyer - Notice to Truckers:* New FDA Regulations Will Affect Imported Food Shipments November 2003
    (also available in Spanish)
  - *Flyer - Notice to Importers and Filers:* New FDA Regulations Will Affect Imported Food Shipments November 2003
  - *Booklet (SECG):* What You Need to Know About Prior Notice of Imported Food Shipments November 2003 (also available in French and Spanish)
    (Federal Register Notice of Availability December 12, 2003)
  - *Interim Final Rule:* Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 October 10, 2003
    - *Corrections* to Interim Final Rule February 2, 2004 (also available in PDF*)
    - Reopening of Comment Period April 14, 2004
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  - *Slide Presentation:* Overview of Prior Notice Interim Final Rule Implementing the Bioterrorism Act October 15, 2003
    (also available in Arabic, French, Malay, and Spanish)
  - *Guidance for Industry:* Prior Notice of Imported Food: Questions and Answers *(Edition 2)* May 3, 2004
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  - *Guidance for Industry:* Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators August 26, 2004
    - HTS Codes September 2, 2005
    - HTS Codes Revision History September 2, 2005
  - *Guidance for Industry:* Entry Types and Entry Identifiers - Prior Notice of Imported Food April 7, 2005
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  - *Gift Packs:* Importing Gift Packs and Prior Notice November 2004
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  - **How to Submit Prior Notice**
    - *Submit* Prior Notice through PNSI, Overview & Background
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- *Slide Presentation:* New FDA Rules Implementing the Bioterrorism Act of 2002 - Overview of Registration and Prior Notice Interim Final Rules April 2004
  (also available in Korean)

- *Videos:* FDA's Implementation of the Bioterrorism Act: An update with Leslye Fraser March 2004 (27:22 min) (Requires Real Player or Windows Media Player)
  (also in captioned English, Chinese, French, Japanese, Korean, Spanish, and Thai)

- October 28, 2003 Satellite Broadcast on Registration and Prior Notice
  (Discussion of interim final rules)
  - Regulations Implementing Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Notice of Public Meeting via SATELLITE downlink October 28, 2003 (also available in PDF) October 1, 2003
  - *Videos* of Satellite Broadcast (1:43 hrs.) (Requires Real Player or Windows Media Player)
    (also in captioned English, French, and Spanish)
  - *Transcript:* Text of Closed Captioning of Satellite Broadcast (also available in French and Spanish)

- *Bioterrorism Outreach Meetings For Asia (April 2004):* "What You Need to Know to Ensure Compliance With the New FDA Bioterrorism Act Registration and Prior Notice Final Rules" April 2004

- *Domestic Outreach Meetings (March & April 2004):* FDA Updates - "What You Need to Know to Ensure Compliance With the New FDA Bioterrorism Act Registration and Prior Notice Final Rules" February 2004

- Risk Assessment for Food Terrorism and Other Food Safety Concerns October 7, 2003

See also Background Information on Protecting the Food Supply

*PDF Readers are available for free from the Adobe Acrobat web site.

Federal Register

Thursday,
December 9, 2004

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Establishment and Maintenance of Records for Foods; Notice of Public Meeting; Availability of Draft Guidance for Records Access Authority; Final Rules and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. 2002N-0277]

RIN 0910-AC39

Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and immediate subsequent recipients of food. The final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and is necessary to help address credible threats of serious adverse health consequences or death to humans or animals. The requirement to establish and maintain records is one of several tools that will help improve FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food. 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 information will improve FDA's ability to quickly notify the consumers and/or facilities that might be affected by the outbreak.

DATES: *Effective Date*: This final rule is effective February 7, 2005.

Compliance Dates: The compliance date is December 9, 2005; except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is June 9, 2005; and except that for very small businesses that employ 10 or fewer full-time equivalent employees, the compliance date is December 11, 2006.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1400.

SUPPLEMENTARY INFORMATION:

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I. Background and Legal Authority

The events of September 11, 2001, have highlighted the need to enhance the security of the infrastructure of the United States, including the food supply. Congress responded by enacting the Bioterrorism Act (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of Food and Drug Supply), subtitle A—Protection of Food Supply, section 306, which amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 414, Maintenance and Inspection of Records (21 U.S.C. 350c). (In the regulation itself, which is codified in title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act is referred to as "the act." Thus, when the regulation is quoted in this preamble, the term "the act" will be used to refer to the Federal Food, Drug, and Cosmetic Act. However, in this preamble, we refer to the Federal Food, Drug, and Cosmetic Act as "the FD&C Act" to distinguish it from the Bioterrorism Act.) Section 414(b) of the FD&C Act provides, in part, that the Secretary of Health and Human Services (the Secretary), may by regulation establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that are required to be kept by these regulations are those needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. Section 306(d) of the Bioterrorism Act provides that the Secretary "shall" issue regulations establishing recordkeeping requirements under section 414(b) of the FD&C Act no later than 18 months after enactment of the Bioterrorism Act, that is, by December 12, 2003.

In addition, the Bioterrorism Act adds a new section 414(a) to the FD&C Act

that provides records inspection authority to FDA. Section 414(a) of the FD&C Act provides that, if the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons who manufacture, process, pack, distribute, receive, hold, or import food must provide access to records related to the food that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

Section 306 of the Bioterrorism Act also amends section 704(a) of the FD&C Act (21 U.S.C. 374(a)) to authorize FDA inspections of all records and other information described in section 414 of the FD&C Act, when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

In addition, section 306(c) of the Bioterrorism Act amends section 301 of the FD&C Act (21 U.S.C. 331) to make it a prohibited act to refuse to permit access to, or copying of, any record as required by section 414 or 704(a) of the FD&C Act; or to fail to establish or maintain any record as required by section 414(b) of the FD&C Act; or to refuse to permit access to, or verification or copying of, any such required record; or for any person to use to his own advantage, or to reveal, other than to the Secretary or officers or employees of the Department of Health and Human Services, or to the courts when relevant in any judicial proceeding under the FD&C Act, any information acquired under authority of section 414 of the FD&C Act.

To implement these provisions, on May 9, 2003 (68 FR 25188), FDA issued a proposed rule to require the establishment and maintenance of records to identify the immediate previous sources and immediate subsequent recipients of food. In addition to section 306 of the Bioterrorism Act, which amends the FD&C Act as described previously, FDA is relying on section 701(a) of the FD&C Act (21 U.S.C. 371(a)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the FD&C Act.

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

A. Highlights of this Final Rule

The highlights of this final rule are described briefly in the following paragraphs, and are discussed in more detail later in the preamble of this document:

- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in part 1 (21 CFR part 1) subpart J of this final rule (i.e., recordkeeping and access requirements);
- The following persons or facilities are excluded from all of the regulations in subpart J of this final rule: Farms; restaurants; those performing covered activities when the food is subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*); and foreign persons, except foreign persons who transport food in the United States.
- The following persons or facilities are excluded from the requirement to establish and maintain records in §§ 1.337 and 1.345 of subpart J of this final rule, but are subject to the record availability requirements in §§ 1.361 and 1.363 for existing records: (1) Fishing vessels not engaged in processing as defined in § 123.3(k) (21 CFR part 123.3(k)); (2) retail food establishments that employ 10 or fewer full-time equivalent employees; (3) nonprofit food establishments 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; and (4) persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart J of this final rule.
- Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J of this final rule as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J of this final rule as to the finished container, except §§ 1.361 and 1.363.
- Persons who distribute food directly to consumers are excluded from the requirement in § 1.345 to establish and maintain records to identify the immediate subsequent recipients as to those transactions. The term "consumers" does not include businesses.
- Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of subpart J of this final rule.
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of subpart J of this final rule.
- The regulations in subpart J of this final rule do not require duplication of existing records if those records contain all of the information required by the subpart. Furthermore, persons can supplement existing records with any new information required by this final rule instead of creating an entirely new record containing both existing and new information.
- Persons who manufacture, process, pack, distribute, receive, hold, or import food in the United States must establish and maintain the following records to identify the immediate previous sources and immediate subsequent recipients for all food they receive and release, unless otherwise excluded from the requirements of subpart J of this final rule:
  - Name, address, telephone number and, if available, fax number, and e-mail address of the immediate previous source and subsequent recipient;
  - Adequate description;
  - Date received or released;
  - For persons who manufacturer, process, or pack food, the lot or code number or other identifier;
  - Quantity and how the food is packaged; and
  - Name, address, telephone number and, if available, fax number, and e-mail address of the transporter who transported the food to and from you.
- Persons who have possession, custody, or control of food in the United States for the sole purpose of transporting the food, or foreign persons who transport food in the United States, regardless of whether they have possession, custody, or control of the food for the sole purpose of transporting that food (transporters), can meet the requirements of subpart J of this final rule by:
  (1) Establishing and maintaining the records listed in § 1.352(a); or
  (2) Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) contained in 49 CFR 373.101 and 373.103 as of the date of publication of this final rule; or
  (3) Establishing and maintaining specified information that is in the records required of rail and water interstate transporters by the DOT's Surface Transportation Board (STB) contained in 49 CFR 1035.1 and 1035.2 as of the date of publication of this rule; or
  (4) Establishing and maintaining specified information that is in the records required of international air transporters on air waybills by the Warsaw Convention as Amended at the Hague, 1995 and by Protocol No. 4 of Montreal, 1975 (Warsaw Convention); or
  (5) Entering into an agreement with a nontransporter immediate previous source (if located in the United States) or immediate subsequent recipient (if located in the United States) to establish, maintain, or establish and maintain, the required records in options 1 or 2 of the previous paragraphs. The agreement must contain certain elements specified in § 1.352(e).
- If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food.
- If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.
- If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.
- If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.
- Transporters of food (or specified persons who agree to establish and maintain required records under agreements with transporters) in the United States must retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food.
- Transporters of food (or specified persons who agree to establish and maintain required records under agreements with transporters) in the United States must retain records for 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the transporter receives or releases the food.
- Records must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request.
- Failure to establish or maintain records or refusal to permit access to or verification or copying of any record is a prohibited act under section 301 of the FD&C Act.
- The compliance date for the records establishment and maintenance requirements is December 9, 2005, except that the compliance date for small businesses employing fewer that 500, but more than 10 full-time equivalent employees is June 9, 2005, and the compliance date for very small businesses that employ 10 or fewer full-time equivalent employees is December 11, 2006.

B. Significant Changes FDA Made to the Proposed Rule

FDA made the following significant changes to the proposed rule:

- All foreign persons, except foreign persons who transport food in the United States, are excluded from all of the requirements in subpart J of this final rule. A foreign person transporting food in the United States is subject to the requirements for transporters in the subpart.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of subpart J of this final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food are excluded from all of the requirements of subpart J, except §§ 1.361 and 1.363.
- Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J of this final rule as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363.
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of subpart J.
- Transporters can meet their obligation to establish and maintain records in the following ways: (1) Keeping the records listed in § 1.352(a); (2) keeping the records listed in § 1.352(b), which contain information also currently required of roadway interstate transporters under the FMCSA regulations as of the date of publication of this final rule; (3) keeping the records listed in § 1.352(c), which contain information also currently required of rail and water interstate transporters under the STB regulations as of the date of publication of this final rule; (4) keeping the records listed in § 1.352(d), which contain information also currently required of international air transporters on air waybills under the Warsaw Convention; or (5) entering into an agreement with a nontransporter immediate previous source in the United States or a nontransporter immediate subsequent recipient in the United States to keep records for them. The agreement must contain certain elements specified in § 1.352(c). Intrastate transporters must also establish and maintain records under this final rule and can meet this obligation by complying with either § 1.352(a), (b), (c), (d), or (e).
- Foreign persons who transport food in the United States, whether or not

they have possession, custody, or control of the food for the sole purpose of transporting, must comply with § 1.352 of subpart J of this final rule.

- The exclusion for pet food not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (BSE rule) (62 FR 30935, June 5, 1997) has been deleted.
- 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.
- "Holding" has been defined and means "storage of food." Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
- "Packaging" has been defined and means "the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6))."
- Recipe has been defined to mean the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.
- The partial exclusion for retail food establishments has been replaced with a partial exclusion for persons who distribute food directly to consumers. Persons who distribute food directly to consumers are excluded from establishing and maintaining records required by § 1.345 to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. Persons who distribute food to businesses must establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients to the extent that information is reasonably available, for example when the purchaser has an established commercial account.
- The exclusion for retail facilities that are located in the same general physical location as a farm has been replaced with an exclusion for all retail food establishments that employ 10 or fewer full-time equivalent employees.
- An exclusion has been added for nonprofit food establishments.
- "Nonprofit food establishment" has been defined and means:

> * * * a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

- The requirement to record a "responsible individual" when identifying the immediate previous source, immediate subsequent recipient, and transporters has been deleted.
- The requirement to record "lot or code number or other identifier" has been deleted for all covered entities, except persons who manufacture, process, or pack food.
- The definition of perishable food has been deleted.
- The record retention periods for nontransporters have been changed to: (1) 6 months for food for which a significant risk or spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.
- The record retention periods for transporters (or specified persons who agree to establish and maintain required records under agreements with transporters) have been changed to 6 months for any food having a significant risk or spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk or spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.
- The record availability requirements have been changed from 4 hours/8 hours to "as soon as possible, not to exceed 24 hours from the time of receipt of the official request."
- The compliance date for these regulations has changed to December 9, 2005. Small businesses have June 9, 2005, of this final rule to come into compliance with these regulations, and very small businesses have December 11, 2006, of this final rule to come into compliance with these regulations.
- The qualifying language "food intended for consumption in the United States" has been removed from this final rule to ensure that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is intended for consumption are subject to this final rule unless otherwise exempt.

III. Comments on the Proposed Rule

FDA received approximately 212 timely submissions in response to the proposed rule, which raised approximately 220 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) Some comments state that it would be beneficial for the agency to provide the food industry with a model form that could be used to record all the required information, with the option for the industry to use this form or established recordkeeping systems. One comment requests that the agency develop and provide respective freeware that could be available as a compact disc (CD) or downloaded from the FDA Web site well in advance of the compliance date of the final rule. A few comments request that the regulations make clear that the model form is guidance and is not mandatory. One comment suggests that as a way to show that the model form is guidance, the agency should place the model form in an appendix to the regulations.

Several comments object to the inclusion of a model form in the regulations. The comments oppose using any "one-size fits all" generic form as an example or requirement. The comments suggest that affected businesses should decide the format in which the required records should be kept as dictated by specific business practices. The comments express concern that example forms might become informal requirements out in the field even though originally only meant as guidance.

One comment recommends that the agency provide further examples of scenarios, rather than model forms, where records would be in compliance and noncompliance with the final regulations.

In addition, several comments state that most food companies currently maintain the chain-of-distribution information that is required by these regulations. However, the diversity and complexity of the food industry means that the information is maintained in many different ways and formats, ranging from computerized records systems to file folders of paper records. The recordkeeping systems are designed to provide the necessary information to remove food from the market and prevent more food presenting the same risk from entering the market. The comments state that the regulations should not prescribe any specific manner or form of maintaining the information.

(Response) The provisions describe the specific information a covered entity must keep, but do not specify the form or type of system in which those records must be maintained. As stated in both the proposed and final § 1.330, these provisions do not require duplication of existing records if those records contain all of the information required by subpart J of this final rule. If a person subject to these provisions keeps records of all of the information as required by subpart J in compliance with other Federal, State, or local regulations, or for any other reason, e.g., as a result of its own business practices, then those records may be used to meet these requirements. Such records may include, but are not limited to, purchase orders, bills of lading, invoices, and shipping documents. Moreover, entities do not have to keep all of the information required by this final rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new data required by this final rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Our intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations. FDA received numerous comments, as discussed further in section III.G of this document on "Can existing records satisfy the requirements of this subpart?" that agreed with this approach to not specify the type and format of the records and to allow flexibility to use existing recordkeeping systems. In addition, comments state that individual companies are in a better position to decide in what format records are needed based on knowledge of applicable business practices and cost structures. For these reasons, FDA has not included a model form in this final rule.

(Comment 2) Several comments state that the food industry has repeatedly demonstrated the ability to identify and remove product from grocery store shelves very quickly. The comments suggest that the diversion of substantial resources that would be necessary to implement the agency's proposed regulations would not further food security, but instead would diminish the overall efficiency of the food distribution system, which is necessary to serve food safety and security needs and commercial purposes.

Further, some comments assert that the regulations are directed toward enabling the Government to trace a product, rather than ensuring that companies are able to trace the product through all the links in the chain of custody of a food ingredient or product. The comments state that the intent of the Bioterrorism Act was to ensure the existence of a system that fully engages the institutional knowledge and logical procedures that already enable the companies responsible for the production and distribution of food to maintain an orderly and efficient nationwide supply chain and that also currently make it possible to effect rapid recalls when necessary. The comments state that the proposed regulations fail to capitalize on the efficiencies of time and resources available through effective public/private coordination, exemplified by the efforts that currently support effective recalls.

(Response) FDA recognizes that some of the food industry currently has existing records that may satisfy all or part of these regulations; however, not all of the food industry is currently able to conduct such traceback investigations. Notwithstanding the ability of some of the food industry to conduct such investigations, Congress authorized FDA through the Bioterrorism Act to issue regulations requiring the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold or import food to enable FDA to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. FDA believes the information required to be established and maintained in records in these regulations is necessary to enable FDA to conduct an efficient and effective tracing investigation, independent of what the food industry may be able to do. FDA reiterates that it is not dictating the form or type of system to be used to satisfy these requirements in these regulations. If the food industry already keeps all of the information required by this final rule, then existing records can be used to comply with this final rule. Further, FDA anticipates working closely with the food industry in any tracing investigation.

In addition, recently FDA was significantly hampered in identifying the source of contaminated food during a trace back investigation following a Hepatitis A outbreak due to contaminated green onions. This outbreak involved a distributor who purchased green onions from a variety of firms in no predictable pattern and distributed them without recording brand and lot information. The distributor did not keep records of the previous sources of the green onions, which might have indicated a particular supplier of green onions during the specified exposure time period. It was impossible for investigators to determine, from the distributor, the identity of the supplier of the green onions that were sent to the implicated restaurant, and therefore FDA had to spend time investigating all potential suppliers of the green onions to identify the one supplier that supplied the restaurant. Speedy trace back would have enabled FDA to prevent further distribution of contaminated products sooner, thereby preventing more illnesses.

Further, 20 percent of all tracing investigations are prematurely terminated due to deficiencies in recordkeeping. A reduction of just one premature termination could prevent at least 53 people from becoming ill. Requiring adequate records to complete a tracing investigation reduces trace-back times by 8 days. This increased efficiency facilitates preventive action in 15 to 18 percent of outbreaks. The speed with which a tracing investigation can be conducted is of vital importance in reducing the number of people who could potentially become ill. Access to records that do not exist or that do not contain sufficient information (with no requirement to retain them or make them available in a timely fashion) is not an efficient and effective way to conduct a tracing investigation during a public health emergency involving

serious adverse health consequences or death to humans or animals.

(Comment 3) One comment states that established industry practice with regard to investigating product defects and conducting product recalls is consistent with the terms of the Bioterrorism Act allowing for the rapid identification of the immediate previous source and immediate subsequent recipient of foods. The comment asserts that the industry's response to the events of September 11, 2001, has strengthened these existing practices. The comment explains that as an inevitable result of industry's commitment to Responsible Care Security Code No. 7 and increased requests from customers, emphasis is now shifting from security at fixed plant sites and major distribution centers to security of products throughout the value chain. This shift in emphasis enhances industry's existing traceback capabilities. The comment asserts that the controls needed to effectively trace the source and recipient of foods are already in place.

(Response) As explained in the response to comment 2, these provisions are intended to help ensure that FDA has the information it needs to identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals.

(Comment 4) One comment asserts that when food presents a risk of serious adverse health consequences or death to humans or animals, a class I recall is used and can quickly eliminate problems, whereas recordkeeping, at best, will get a message to the retail locations where products were placed on sale to consumers. The comment questions the benefit of the copious amounts of information and possible implementation of an intricate new product tracking system required by the regulations. The comment asserts that class I recalls will continue to be the appropriate means by which a potential hazard is handled and that requiring the expenditure of significant resources to develop a new system in the absence of a Congressional mandate or a genuine need is questionable. The comment recommends that FDA continue to rely upon the proven capabilities of class I recalls and cooperation with the food industry. The comment suggests that FDA should develop a system to contact the appropriate companies to engage their assistance in addressing threats to the food supply, rather than requiring the onerous recordkeeping specified in the regulations.

(Response) This comment assumes that the contaminated food and its whereabouts are known completely, which may not always be the case. As such, the need exists for records to be able to trace forward fully to all locations where the food was shipped, as well as trace backwards to locate any similarly contaminated food shipped to all other locations. Moreover, class I recalls are voluntary measures only. In the Bioterrorism Act, Congress has given FDA the means both to establish requirements for establishment and maintenance of records, and to administratively detain, on its own initiative, food for which FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals (section 303 of the Bioterrorism Act). In addition, the records are needed not only to help remove contaminated food from the market place, but also to help identify the source of the contamination.

(Comment 5) A few comments state that, in the event of a serious product issue or life-threatening situation, the only responsible action to take is to warn the public through the media to prevent further use or distribution of the product. The communication vehicle used to disseminate the warning should be based on the severity of potential harm or health consequences. Use of the media also is necessary to influence facilities to check their store stock and for consumers to check their refrigerators and pantries for the affected product.

(Response) FDA agrees that the use of warnings to the public about specific products is important. Indeed, FDA has used this approach many times. Nonetheless, records will ensure that FDA can perform trace forward to remove the problem food from the market and traceback to identify the source of the problem. These recordkeeping requirements will also enable FDA to identify the problem food more specifically and, thus, FDA can target its public warnings on the specific problematic food.

(Comment 6) A few comments request that the agency add a "pipeline provision" that allows the use of NA (not available) in place of information where ingredient records were not maintained. The comments state that many ongoing processing operations will have some ingredients on site that have been purchased and housed in facilities for some time prior to the implementation of these regulations. In these cases, it would be a significant manpower burden (or perhaps not possible at all) to obtain or attempt to recreate all the required information on the source of those ingredients. The comments note that these ingredients have been used in food production without incident and it would be unlikely they would be involved in an act of terrorism.

(Response) There is no requirement to establish and maintain records for food ingredients you received before the compliance date of these regulations. Under that scenario, however, you must establish and maintain records of that food when you release it after the compliance date of the regulations. For example, if a commercial bread bakery receives flour, eggs, and salt before the compliance date of this final rule, it does not need to keep records of the immediate previous source of when it received that food. Once the bakery uses these ingredients to bake the bread and releases the bread to nonconsumers after the compliance date of the rule, the bakery must keep the records required by § 1.345 of this final rule regarding the immediate subsequent recipients of the bread.

(Comment 7) One comment recommends the use of United Code Council standards, a system of globally recognized and implemented standards that enables traceability of products and identification of trading parties/recipients, through all locations of the supply chain.

(Response) FDA does not agree. The agency has determined that the least burdensome way of issuing the recordkeeping requirements is to specify the information that must be contained in the records, but not the format in which the records are kept. Indeed, the agency received numerous comments that argued that covered entities should be allowed to use existing records and systems.

(Comment 8) One comment requests that source labeling, including country-of-origin labeling, be required as a component of an effective traceback program in the event of a food emergency. The comment states that some industries have already developed technologies such as barcodes, stamps, stickers, or tags to identify the source of produce as well as software to assist in more accurate traceback to the grower/packer level.

(Response) FDA does not agree. At this time, FDA does not believe this information is necessary to enable a traceback. FDA believes the requirements of the final regulations for the establishment and maintenance of records to identify the immediate previous sources and immediate subsequent recipients of food in order to address credible threats of serious

adverse health consequences or death to humans or animals are sufficient.

(Comment 9) Some comments ask that the agency generate more publicity on the regulations and provide the industry with educational materials and training. One comment states that because food wholesale distributors have no significant contact with FDA personnel and procedures, they have a limited understanding of the requirements. One comment asks that the agency help promote and educate the industry abroad on the recordkeeping regulations. Another comment asks that FDA provide materials in other languages. One comment asks that the agency develop a strong communications program to disseminate the new regulations once they become final because the fresh produce industry and its transportation partners are highly diverse and fragmented. The comment states that independent truckers in particular need to be made aware of the regulations because the fresh produce industry in the United States relies heavily on independent truckers to move fresh fruits and vegetables to market quickly.

(Response) FDA conducted extensive outreach on the proposed recordkeeping rule, including having relevant FDA staff attend 6 international meetings and more than 100 domestic meetings to ensure that affected parties were aware of the Bioterrorism Act requirements. On May 7, 2003, FDA held a public meeting (via satellite downlink) to discuss the recordkeeping and administrative detention proposed rules. See 68 FR 16998 (April 8, 2003) or *http://www.cfsan.fda.gov/~dms/fsbttraz.html*. Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later rebroadcast to Europe, Asia, Africa, and the Pacific (areas in different time zones). FDA has also provided transcripts of the broadcast in English, French, and Spanish (the three official World Trade Organization languages) on the agency's Web site. In addition to this outreach to the affected industry, FDA has conducted outreach on the proposed rule to States.

FDA plans similar outreach directed to stakeholders following publication of the final rule implementing the recordkeeping provisions of the Bioterrorism Act. Our outreach will include the following:

- Materials and events for the media;
- Domestic outreach meetings to States and industry;
- International outreach to U.S. trading partners;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and State and local government representatives of the new regulations and their requirements; and
- Cooperative arrangements with other Federal agencies to ensure that information on the final regulations and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included on FDA's Web site at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

(Comment 10) Several comments suggest that, to lessen the burden to the food industry, FDA needs to coordinate with other local, Federal, and State government security programs in establishing the final recordkeeping regulations.

(Response) In issuing these recordkeeping regulations, FDA has stated that records established and maintained as a result of local, State, or other Federal regulations, or as a matter of routine business practice, need not be duplicated if the records contain all the information required by these regulations. Further, if existing records contain some, but not all, of the required information, persons may supplement existing records with the additional information required under this final rule.

(Comment 11) One comment asks that the final rule require that upstream entities provide all the required information to downstream entities in the food distribution system. The comment states that distribution centers that receive and store food and retail outlets that hold and sell food do not know and should not be required to determine many of the information items required under the proposed regulation. The comment states that requiring that any information be passed through the system from the first point of distribution, preferably through electronic means, would alleviate some of the burden of the recordkeeping requirements on downstream entities.

(Response) The agency does not agree completely that distribution centers and retail outlets do not know many of the information items. The agency agrees, however, that including information pertaining to lot or code numbers of foods in the required records is not practical for distribution centers and retail outlets, given current business practices. FDA has, therefore, deleted this requirement. Instead, the final regulation now only requires that persons who manufacture, process, or pack food keep records on the lot or code number or other identifier of the food, and only to the extent this information exists. Moreover, to minimize the burden this regulation may have on affected parties, FDA is not specifying the form or format of the records that must be established and maintained and is not requiring electronic records.

(Comment 12) Several comments applaud the agency's efforts in proposing a rule that appears to be designed to work with the food industry as efficiently and effectively as possible to address credible threats without imposing undue burdens. One comment urges the agency to issue the final regulations as expeditiously as possible to enhance compliance with the provisions of the Bioterrorism Act. The comment states that, by finalizing the regulations in conjunction with the interim final rules entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (the registration interim final rule) (68 FR 58894, October 10, 2003) and "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (the prior notice interim final rule) (68 FR 58974, October 10, 2003), the education and training that will be necessary for compliance with the regulations can be done together and the internal policy and procedures for companies can be designed to meet all of the obligations under the final rule. The comment further states that this is the reason that Congress intended regulations to be issued within 18 months of the effective date of the Bioterrorism Act.

(Response) The agency has acted expeditiously in issuing all of the regulations under the Bioterrorism Act and has developed and published final regulations as quickly as possible. With respect to education and training, as stated previously, the agency intends to conduct extensive outreach to stakeholders for this final rule that is similar to outreach the agency conducted for the registration and prior notice interim final rules.

(Comment 13) One comment requests clarification regarding the level of recordkeeping that will be expected at each facility maintained by a vertically integrated company. The comment explains that a vertically integrated company has various facilities involved in the growing and processing of bulk ingredients as well as the manufacturing and marketing of finished products. Some of the requirements for recordkeeping could result in duplication of effort if each facility within the company is required to

maintain separate records, even though the overall records are available at company headquarters or some central location. One comment requests that the final rule clarify what is meant by the term "released" and the relationship of this term to holding legal title, or ownership of the food. Another comment suggests that FDA clarify that only at such time as the food leaves the possession and control of one firm and enters into the possession and control of another firm, whether or not via a transporter, would the recordkeeping requirement apply. The comment maintains that any other interpretation of the statute would impose a crushing burden of internal tracking systems and paperwork that would detract from most firms' abilities to do business and is well beyond the intent of the Bioterrorism Act.

(Response) The records required by these regulations are those that FDA needs for inspection to identify the immediate previous sources and the immediate subsequent recipients of food. "Immediate previous source" has been defined in § 1.328 of the final rule to mean "a person who owns food or who holds, processes, packs, imports, receives, or distributes food or food packaging, and that last had an article of food before transferring it to another person." Unless otherwise exempt (i.e., a farm), a "vertically integrated company" would be required to identify the sources of all food received from its immediate previous sources. Once the vertically integrated company receives the food and keeps information on its immediate previous sources, that vertically integrated company does not need to keep additional records until it releases the food to another person. Unless otherwise exempt, at the time the vertically integrated company releases the food, it is required to identify the immediate subsequent recipients of that food.

As an example, if a company buys food from its immediate previous source (company A), then the company further processes the food, holds the food, transports the food, and distributes the food to a grocery store, then the vertically integrated company would only have to keep records on its immediate previous source (company A) and its immediate subsequent recipient (grocery store). The vertically integrated company need not keep records of all the covered activities (manufacturing, processing, packing, transporting, etc.) conducted by that company while it has the food.

Of course, when the integrator has any records or other information available to FDA under sections 414 and 704(a) of the FD&C Act, then FDA would have access to those records if FDA has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

B. Foreign Trade Issues

(Comment 14) Several comments representing foreign governments and international associations agree in principle to the recordkeeping requirements provided the requirements are based on a sound risk assessment and do not restrict trade more than necessary to effectively address potential risks. Some comments note that there is no risk assessment provided to justify the proposed measures required by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement). Several comments representing foreign governments and businesses request that FDA work with foreign governments to develop common standards and requirements and to facilitate trade flow. Some foreign comments argue that the result of the onerous recordkeeping burden in the regulations will be the elimination of many legitimate and safe food distribution businesses and a serious reduction in global food trade. One comment suggests that the regulations will adversely impact trade, as they are likely to increase uncertainty and costs for foreign exporters. Small and medium sized foreign companies in particular may be prevented from continuing to export to the United States for these reasons. One comment is concerned that the regulations may lead to the unintended consequence of foreign countries imposing the same requirements of U.S. goods in foreign trade.

(Response) FDA considers that these foreign trade comments are now moot, given the scope of these final regulations. These final regulations do not apply to foreign persons, except foreign persons transporting food in the United States, who are treated no differently than domestic food transporters under these final regulations. FDA does not believe that foreign persons who transport food in the United States will incur additional costs as a result of these regulations, because FDA assumes that they will choose to comply with § 1.352 of this final rule by establishing and maintaining the records already required by FMCSA. See the response to comment 82, later in this document.

C. Comments on Who is Subject to This Subpart? (Proposed § 1.326)

1. General

(Comment 15) Several comments seek clarification on who is covered by the proposed regulation. Comments ask if the provisions of the regulations apply to port facilities, such as warehouses, or storage and inspection facilities in land, sea, or airports that belong to private companies and government bodies for food control in the country of shipping and/or origin.

(Response) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to these regulations. "Person" is defined in section 201(e) of the FD&C Act (21 U.S.C. 321 (e)) and includes any "individual, partnership, corporation, and association." Therefore, any person located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico who manufactures, processes, packs, transports, distributes, receives, holds, or imports food is included within the term "person". "Holding" has been defined in § 1.328 of the final rule to mean "storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks." Accordingly, port facilities, such as warehouses, or storage facilities that are located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico are subject to these regulations as they are "persons" who are holding food.

(Comment 16) One comment seeks clarification on whether the proposed regulation applies to a carrier's freight brokers. The comment states that, although these brokers never have actual physical possession of freight, they act as the middleman for carriers and shippers and have knowledge of where the freight came from and where it went. A few comments ask that FDA clarify that customs brokers are excluded from the regulations. The comment indicates that because § 1.326 of the proposed regulations applies to, inter alia, persons that "import" food, it could be interpreted to include customs brokers, who act only as agents for the importer. A comment notes that customs brokers have only the information needed to file an entry on behalf of the actual importer and to obtain release of the food from U.S. Customs and Border Protection (CBP). However, according to the comment, customs brokers do not own food or hold, process, pack, import, receive, or distribute food for purposes other than transportation. The comment notes that applying the recordkeeping requirements to customs brokers would cause redundant and burdensome recordkeeping requirements for them.

(Response) FDA clarifies that the recordkeeping requirements do not apply to brokers who act only to facilitate distribution, sale, or transportation of food by processing information or paperwork associated with these functions. Brokers who do not directly manufacture, process, pack, transport, distribute, receive, hold, or import food are not subject to the requirements of the regulation.

(Comment 17) One comment asks that FDA specify whether the regulation applies to the importer of record or to the initial U.S. recipient when the merchandise enters the country. The comment notes that this clarification could affect who is responsible for the establishment and maintenance of records.

(Response) The final rule applies to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States, unless the person qualifies for an exclusion in § 1.327 of the final rule. An importer of record or an initial U.S. recipient that is involved in one or more of the identified activities must establish and maintain the required records.

(Comment 18) Several comments express concern because the proposed regulation applies only to domestic, for-hire transporters, and foreign transporters that enter the United States, as well as domestic private transporters, are not covered. Comments state that the regulation should apply uniformly to all transporters, foreign and domestic, for-hire and private, to ensure that no group has an unfair competitive advantage.

(Response) All persons transporting food in the United States must meet the requirements of subpart J of this final rule, regardless of whether they are "for hire" or "private." FDA notes, however, that if a manufacturer located in the United States transports the food in its own company trucks, then it must comply with the recordkeeping requirements for nontransporters as opposed to those applicable to transporters because FDA does not need the facility to keep duplicative records of the food while it is in that facility's control. However, if a foreign person, such as a person who manufactures food, transports food in the United States, it must comply with the requirements for transporters, even if it transports the food in the United States itself. This ensures that FDA will have the ability to traceback the food that is transported in the United States, even if the facility from which the food originates is an exempt foreign facility under subpart J.

(Comment 19) One comment notes that CBP's current requirements apply to trucking companies that transport imported food into the United States. The comment suggests that FDA coordinate with CBP to get data from them in the event of a threat to the nation's food supply, rather than develop its own distinct recordkeeping regulations.

(Response) The records required to be kept by these regulations are those FDA needs to help identify the immediate previous sources and immediate subsequent recipients of food. Section 1.361 of the final rule allows FDA access to transporters' existing records when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. When conducting a traceback, FDA needs access to the required records at each point in the distribution chain for the implicated food. Thus, FDA will expect to obtain applicable records from transportation companies in the distribution chain. Although FDA may contact, and coordinate tracebacks with, other Federal agencies, including CBP, the agency expects transportation companies to comply with the recordkeeping and access provisions of these regulations. FDA notes that entities keeping records to satisfy CBP's regulations may use those same records to satisfy some or all of the requirements of this final rule if those records contain some or all of the information required by subpart J of this final rule. Entities also can supplement existing records with any new data required by this regulation, instead of creating an entirely new record containing both existing and new information.

(Comment 20) A few comments ask FDA to clarify what constitutes "holding" food, who FDA considers to be "holders of food," and under what circumstances food is being held in transport. The comment notes that the lack of clarity leaves a carrier's terminal operating facility, gas stations, truck stops, and even trucks themselves vulnerable to being considered as "holders of food" and thereby subject to burdensome reporting requirements. Comments also ask FDA to exclude trucks, truck terminals, and facilities from the definition of "holding," stating that this would be consistent with the intent of the law and the realities of the trucking industry's business practices. One comment asks whether food held for short periods of time in a trucking terminal during cross-dock operations meets the definition of "holding." One comment states that there are certain areas in the supply chain that provide temporary space for food during transit and that these areas should not be considered to be "holding" or "storing" food and subject to the recordkeeping requirements. The comment notes that some sites serve as transitory staging areas where produce is momentarily held before transportation and that, because of the perishable nature of the product and the desire to transport the fresh commodity rapidly, produce moves from these staging areas as quickly as possible.

(Response) "Holding" means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. The recordkeeping requirements in §§ 1.337 and 1.345 of this final rule apply to persons who "hold" food for purposes other than transportation. As defined in § 1.328 of this final rule, a "transporter" is:

* * * a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that person has possession, custody, or control of that food for the sole purpose of transporting the food.* * *

Truck terminals or similar facilities that are part of the transportation process and merely provide a location for trucks to transfer possession, custody, or control to another entity are not subject to the requirements in §§ 1.337 and 1.345 of the final rule, unless possession, custody, or control is transferred to that terminal or facility.

(Comment 21) One comment seeks clarification on whether a "customer," such as an office complex, would be required to maintain records if it receives and stores a food, such as bottled water, in the customer's own storage area for subsequent distribution to the various offices within the complex. The comment also asks whether, for bottled water, such a customer would also be the immediate previous source for bottles that are returned to the bottler for reuse.

(Response) FDA has added an exclusion to the final rule for persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food. This exclusion covers person such as a hotel concierge, the reception desk in an apartment building, and an office complex that

receives bottled water as described by the comment. FDA has added this exclusion because such persons are not parties to the transaction and records from such person are not necessary to identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death.

The comment also asks whether, for bottled water, such a customer would also be the immediate previous source for bottles that are returned to the bottler for reuse. A customer who returns bottles to the bottler would be the nontransporter immediate previous source of the bottles (§ 1.328 of the final rule). As with other sources of its bottles (e.g., a bottle manufacturer), the bottler would be required to keep records of bottles received from customers for reuse.

(Comment 22) One comment asks that FDA clarify in the regulation that domestic grain-handling, feed manufacturing/ingredient or processing facilities dedicated solely to exporting bulk or processed agricultural commodities to other countries are exempt from the recordkeeping requirement unless the commodities, products, or byproducts they handle are introduced into U.S. commerce. The comment states that this clarification would be consistent with the statutory language and FDA's proposed regulations.

(Response) The proposed rule applied to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for consumption in the United States, unless the person qualifies for an exclusion in § 1.327. This provision has been changed in the final rule. The Bioterrorism Act does not limit the recordkeeping authority to food that is consumed in the United States. FDA's intent in the proposed rule was to apply the recordkeeping provisions to the full reach of section 306 of the Bioterrorism Act with respect to domestic persons. In contrast, the registration interim final rule that FDA issued under section 305 of the Bioterrorism Act only requires those facilities that manufacture, process, pack, or hold food for consumption in the United States to register. The proposed recordkeeping rule inadvertently added the same qualifier as is in the registration interim final rule: That is, it only applied to food that was "intended for consumption in the United States." FDA is removing this qualifying language from the final rule to ensure that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to this final rule unless otherwise exempt. FDA believes this coverage is necessary because foods intended for export could easily be diverted into domestic commerce. In addition, not everyone in the food supply chain may know if the food is intended for consumption in the U.S. or intended solely for export. Therefore, such a limitation in this rulemaking could create holes in a tracing investigation. Further, FDA is concerned that exempting foods intended for export from the recordkeeping regulations could lead to such foods being targeted for tampering and reintroduction into domestic commerce because they would prove more intractable to tracing investigations.

(Comment 23) One comment asks whether small growers who provide a raw agricultural commodity to a cooperative must keep records and whether the cooperative must list all of the growers.

(Response) Growers of raw agricultural commodities that meet the definition of "farm" in § 1.328 are excluded from the requirements of subpart J of this final rule. A cooperative that accumulates raw agricultural commodities from growers, and does not meet the exemption for retail food establishments that employ 10 or fewer full-time equivalent employees in § 1.327(f) of the final rule, is subject to the requirements in § 1.337 of the final rule regarding the immediate previous sources of food. Distribution of food from the cooperative directly to consumers is excluded from the requirements of § 1.345 of the final rule regarding the immediate subsequent recipients of food.

2. Intrastate

(Comment 24) One comment agrees that the requirement for U.S. domestic firms, whether shipping interstate or intrastate, to establish and maintain records as provided in the proposed regulation will maximize FDA's capability to implement traceback procedures within the borders of the United States. Another comment states that a finding that a certain food is intentionally contaminated—even if only distributed or sold locally—could have widespread, nationwide, even international, economic implications. The comment states that the recent "mad cow" episode in Canada demonstrates that restrictions might be imposed on the distribution and sale of implicated products, or consumers across the country may decide not to buy the products thus impacting the economy as a whole. As a result, the comment states that FDA is correct in concluding that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food should be subject to the recordkeeping requirements whether or not they directly engage in interstate activities involving food.

However, another comment states that FDA's intent to assert jurisdiction over food, whether or not it enters interstate commerce, may be unconstitutional. The comment notes that this assertion of power to regulate food in intrastate commerce is inconsistent with limitations imposed by the Commerce Clause of the U.S. Constitution, which generally authorizes Congress to regulate purely interstate commerce only. The comment further states that FDA should have assumed that Congress did not intend to violate the Constitution, and should revise the proposed rule accordingly. Another comment states that the FDA is proposing that domestic persons must maintain appropriate records as stipulated by the proposed regulations regardless of whether their food enters interstate commerce. The comment adds that appropriate State, local, and municipal regulatory bodies have authority to regulate domestic persons who manufacture, process, pack, transport, distribute, receive, or hold food intended for human or animal consumption, when intended solely for intrastate commerce in the United States. The comment argues that the proposed regulations regarding recordkeeping should not be expanded beyond what has been set forth in the Bioterrorism Act.

Another comment states that the FMCSA has guidelines for determining whether carriers and drivers are engaged in interstate commerce and provides the following definition in 49 CFR part 390.5:

> Interstate commerce means trade, traffic, or transportation in the United States—(1) Between a place in a State and a place outside of such State (including a place outside of the United States);
>
> (2) Between two places in a State through another State or a place outside of the United States; or
>
> (3) Between two places in a State as part of trade, traffic, or transportation originating or terminating outside the State or the United States.

(Response) In the preamble to the proposed rule, FDA sought comments on its tentative conclusion that it has authority to require recordkeeping by persons engaged only in intrastate commerce. FDA also sought comments on how many intrastate persons would not be covered by one of the exclusions from the recordkeeping requirements (e.g., the farm or restaurant exemption). Based on consideration of the received comments and further review of the provision of the Bioterrorism Act that provides FDA with the authority to require the establishment and maintenance of records by all "persons" who engage in specified activities involving food, FDA has concluded that the Bioterrorism Act gives FDA authority to require persons to establish and maintain records, whether or not they engage in interstate commerce, as long as they fall within Congress's power to legislate in this area.

FDA is mindful that its interpretation of the Bioterrorism Act should not cast doubt on the constitutionality of the statute. (See *Solid Waste Agency of Northern Cook County* v. *U.S.*, 531 U.S. 159 (2001).) The agency has considered the relevant provisions of the Bioterrorism Act, the comments submitted on this issue, FDA's responsibilities in implementing the Bioterrorism Act, and the law interpreting the Commerce Clause of the Constitution (Article I, section 8). Based on these considerations, FDA is retaining § 1.326(b) as proposed, with the result that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States (unless otherwise exempt) must establish and maintain records, even if food from the facility does not enter interstate commerce.

The plain language of new section 414 of the FD&C Act does not exclude a facility from recordkeeping because food from such facility does not enter interstate commerce. Notably, sections 301 and 304 (21 U.S.C. 331 and 334) of the FD&C Act demonstrate that Congress has included a specific interstate commerce nexus (e.g., has explicitly required interstate commerce) in the provisions of the FD&C Act when that is its intent. Accordingly, it is reasonable to interpret the Bioterrorism Act as not limiting recordkeeping only to those persons with a direct connection to interstate commerce. Congress's power to legislate under the Commerce Clause is very broad. We acknowledge that such power is not without limits, see *United States* v. *Lopez*, 514 U.S. 549, 567 (1995); *U.S.* v. *Morrison*, 529 U.S. 598, 618 (2000), but these limits have to be construed in light of relevant and enduring precedents.

In particular, in Lopez, supra, the Supreme Court acknowledged the continuing vitality of *Wickard* v. *Filburn*, 317 U.S. 111 (1942), noting that:

> * * * although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.'* * * (*Lopez*, 514 U.S. at 556.) This principle applies squarely to the recordkeeping provision of the Bioterrorism Act. Accordingly, given the collective impact on commerce of intrastate manufacturing, processing, packing, transporting, distributing, receiving, or holding of food in the United States, FDA has concluded that the requirement to establish and maintain records should apply regardless of whether the food enters interstate commerce. Thus, FDA is retaining § 1.326(b) as proposed. See also response to comment 82 below for an expanded discussion of the collective impact on commerce of intrastate transportation of food.

This is consistent with section 709 of the FD&C Act (21 U.S.C. 379a), which states that, in any action to enforce the FD&C Act's requirements respecting foods, drugs, devices, and cosmetics, any necessary connection with interstate commerce is presumed. Likewise, this outcome is consistent with Congress's goal in enacting the Bioterrorism Act, because the potential harm from bioterrorist attacks or other food-related emergencies can be great, whether or not the food moves from one State to another. The usefulness of recordkeeping also can be significant in food emergencies where interstate shipment has not occurred.

3. Foreign Facilities

(Comment 25) Several comments assert that FDA lacks the statutory authority to apply the recordkeeping and records inspection provisions of the Bioterrorism Act to foreign facilities. According to the comments, section 306 of the Bioterrorism Act does not indicate, expressly or by inference, that Congress intended the provisions of that section to apply to overseas persons or facilities. They also contend that nothing in the legislative history of the Bioterrorism Act indicates Congress intended that section 306 of the Bioterrorism Act should apply to foreign facilities. The comments point out that there is a longstanding presumption in the law that legislation does not apply outside the borders of the United States, unless Congress clearly and expressly states such an intent. The comments state that, under governing case law, FDA may not infer legislative intent to give a statute extraterritorial reach.

A few comments indicated that FDA failed to provide legal justification for applying the regulation to foreign facilities. The comments pointed out that FDA's stated belief that this was the most efficient and effective strategy for obtaining needed information on food from foreign countries cannot overcome the clear indications that Congress did not intend section 306 of the Bioterrorism Act to apply to foreign entities.

One comment suggests that FDA clarify that the recordkeeping requirements do not apply outside of the United States, but serve only as a guideline to facilitate a rapid response through cooperation at intergovernment and international industry levels. One comment states that it has been acknowledged in the context of recent CBP initiatives that CBP has no jurisdiction in foreign countries. The comment notes that, consequently, mutual agreements on cooperation between CBP and some foreign governments have been reached to address together their shared security objectives. Comments suggested that FDA pursue a similar approach for safety and security of foods.

One comment asks what action FDA can take against foreign companies that do not establish and maintain the records required under section 306 of the Bioterrorism Act. A few comments state that the fact that section 306 of the Bioterrorism Act does not provide any mechanisms for enforcement of the recordkeeping and records access requirements against foreign persons supports the position that Congress did not intend that section to apply to foreign entities.

(Response) Because FDA has decided, for policy reasons, to exempt foreign facilities that do not manufacture, process, pack, distribute, hold, or import food in the United States from the requirements of the rule, FDA does not need to decide this jurisdictional issue. FDA is exempting all foreign persons (except for foreign persons who transport food in the United States) from the final regulation because FDA does not believe such records would be needed. Much of this information is available to the Secretary from facilities required to provide prior notice under part 1, subpart I. FDA intends to work with the competent authorities in foreign countries to access records during public health emergencies to obtain additional information, if necessary. However, the final rule explicitly provides that persons who transport food in the United States are subject to subpart J of this final rule.

(Comment 26) One comment questions FDA's determination that it can perform its Bioterrorism Act

mission of tracking shipments by exempting Mexican and Canadian motor carriers from the recordkeeping requirements while requiring U.S. motor carriers to comply with the recordkeeping requirements. The comment notes that, based on CBP figures for Mexico-domiciled carriers, referenced in the "Economic Impact Estimates" section of the proposed rule, 63,000 out of 80,000 carriers operating across the southern border are Mexico-domiciled. The comment points out that, therefore, the majority of cross-border FDA-regulated shipments at the southern border may be exempt from the requirements of the regulation.

(Response) FDA agrees. The final rule provides that foreign persons who transport food in the United States are subject to this final rule. A "transporter" is now defined as:

* * * a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, trail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether the foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.* * *

Thus, even if a foreign manufacturing facility transports its own manufactured food into the United States, it is considered a "transporter" under subpart J of this final rule and must comply with the requirements applicable to transporters.

(Comment 27) One comment seeks clarification regarding application of the recordkeeping requirements to certain ownership-partnership relationships involving a U.S. trucking company and a Canadian or Mexican trucking company. The comment asks, for example, whether a Canadian subsidiary of a U.S. trucking company is subject to the recordkeeping requirements. The comment states that a Canadian trucking company may be in partnership with a U.S. company, and the percentage of U.S. ownership is established in each partnership. Another example provided by the comment is that a Mexican motor carrier may have a contractual or interline relationship with a U.S. company. The comment asks whether the recordkeeping requirements apply to the foreign transporters with these U.S. relationships.

(Response) The final rule applies to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Thus, any person who transports food in the United States is subject to these recordkeeping requirements with respect to that food that enters the United States. The partnership or contractual status with a U.S. company does not affect the application of these requirements to a foreign person if they are transporting food in the United States, because such persons are already covered by this final rule by virtue of transporting food in the United States.

(Comment 28) One comment seeks clarification on whether residency in a territory of the United States affects applicability of the regulation. One comment questions FDA's authority to apply the proposed regulation to the Caribbean jurisdictions of the U.S. Virgin Islands and the Commonwealth of Puerto Rico. The comment contends that the regulations would be burdensome to grocery operators or other retailers in the Caribbean jurisdictions who do not export to the Continental United States, but would not deter bioterrorism acts in the Continental United States or in the Caribbean jurisdictions. The comment asserts that the proposed regulation will jeopardize the island economies of the Caribbean jurisdictions by increasing unnecessary expenses to the food retailing activity, which is already more expensive than in the Continental United States, by adding, among other expenses, the maritime transportation cost to the goods.

(Response) The final rule applies to persons that manufacture, process, pack, hold, transport, distribute, receive, or import food in the United States. Section 201(a)(1) of the FD&C Act defines the term "State" as, "any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico", and section 201(a)(2) of the FD&C Act defines the term "Territory" as, "any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone)." Accordingly, any person in the 50 States of the United States, or in any Commonwealth or Territory of the United States, that performs a covered activity is subject to the requirements of this final rule. This includes both Puerto Rico (because, for purposes of the FD&C Act, it is considered a State) and the U.S. Virgin Islands (because, as a U.S. territory, it is considered a State for purposes of the FD&C Act).

D. Comments on Who is Excluded From All or Part of the Regulations in This Subpart? (Proposed § 1.327)

1. General

(Comment 29) Several comments argue that because the Bioterrorism Act specifically excludes those foods under the jurisdiction of USDA, alcoholic beverages should also be excluded, as they are already regulated by the Department of Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) as well as by CBP. One comment requests that FDA secure a legislative amendment to the Bioterrorism Act that exempts wines and spirits and other alcoholic beverages from its application, in the same way meat, poultry, and egg products under the jurisdiction of the USDA are excluded from its scope.

Another comment states that the importer's records enable a product to be traced from the point of importation to its destination, as well as back to the producer/supplier. The comment states that substantial information about a product imported legally into the United States is already held in the TTB database.

(Response) Unlike products regulated under the exclusive jurisdiction of USDA under the FMIA, the PPIA, or the EPIA, Congress did not exempt alcoholic beverages from the scope of the recordkeeping requirements. FDA has not excluded alcoholic beverages from the scope of this final rule because FDA believes that these records are needed to help the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. Further, FDA reiterates that, to the extent that you already keep the information required by this final rule to comply with TTB requirements, or for any other reason, you do not need to establish and maintain duplicative records.

In addition, securing a "legislative amendment" to the Bioterrorism Act, as the comment suggests, is beyond the scope of this rulemaking.

(Comment 30) One comment suggests that FDA add an exclusion that covers persons who transport food for the U.S. military and U.S. Government agencies with respect to that food. Those entities are sophisticated and able to establish their own requirements. Transporters of food for those entities should not be subject to potentially duplicative FDA standards.

(Response) Congress did not provide for an exemption for food that is transported for the U.S. military or any other U.S. Government agency from the scope of the recordkeeping requirements. FDA believes that these records are needed to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. Again, with respect to the comment's assertion that transporters of food for those entities should not be subject to potentially duplicative FDA standards, FDA agrees. There is no requirement to keep duplicative records. FDA reiterates that to the extent that you already keep the information required by this final rule, you do not need to establish and maintain duplicative records.

(Comment 31) One comment questions whether there are provisions for the exemption of beekeepers who bottle and sell small amounts of honey and other beehive products, even if they keep their hives on the property of others, as is frequently done for pollination purposes or the production of honey from sites other than the beekeepers' own property.

(Response) Congress did not provide for an exemption for beekeepers who bottle and sell small amounts of honey and other beehive products. FDA believes that these records are needed to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. Unless these entities fall within a specified exemption, they are subject to the requirements of this final rule. For example, some of the beekeepers may fall within the exemption for farms or retail food establishments that employ 10 or fewer full-time equivalent employees. In addition, beekeepers are not required to keep records of sales directly to consumers.

(Comment 32) One comment requests clarification on how imported food samples that do not enter commerce will be handled based on the regulations. These food samples have the intended end use of analysis, experimentation, and/or subsequent destruction within approved company premises. The samples may be carried into the United States as personal baggage of company representatives or sent unaccompanied. The comment points out that food carried in personal baggage is exempt from the registration interim final rule only if the food is for personal enjoyment/use. Another foreign comment states that the recordkeeping requirement should not apply to commercial samples. The comment states that new exporters cannot be expected to engage in recordkeeping requirements concerning exports before testing marketing opportunities.

(Response) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is intended for consumption by humans or animals are subject to these regulations. The recordkeeping requirements would not apply to food samples that are used for quality assurance, research or analysis purposes, as long as the food samples are not consumed by humans or animals. Samples of food are considered to be for quality assurance, research or analysis purposes, rather than human consumption, when they are in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis, destroyed after analysis, or destroyed following a reasonable retention period after analysis. The analysis may include sensory examination, such as organoleptic examination for determining tea quality or detecting the presence of histamines. Evidence that an article of food is for quality assurance, research, or analysis purposes only might include, among other evidence, markings on the food and shipping documents. Food samples intended for consumption via test marketing, such as tasting at trade shows or product promotional tasting events, are subject to this subpart.

The recordkeeping rule, however, exempts all foreign persons, except foreign persons who transport food in the United States. Therefore, the foreign exporter of the samples mentioned by the comment's is not required to establish and maintain records under this final rule. With respect to the comments assertion that the registration interim final rule exempts food carried in personal baggage for personal use, FDA notes that it is the prior notice interim final rule (part 1, subpart I) that exempts these products, not the registration interim final rule (part 1, subpart H). The registration interim final rule applies to all domestic and foreign facilities that manufacture, process, pack, or hold food that will be consumed in the United States, unless otherwise exempted. This includes facilities performing covered activities with respect to commercial samples if those samples will be consumed in the United States. See response to comment 67 at 68 FR 58911 through 58912 (October 10, 2003). As detailed in the response to comment 22, this final rule does not distinguish between food consumed in the United States and food that is exported.

(Comment 33) One comment indicates that the proposal is silent as to whether firms producing finished food products or food additives and ingredients intended solely for export must comply with the recordkeeping requirements. The comment argues that because this regulation applies to foods for consumption in the United States, producers of such products should be exempt from the recordkeeping requirements.

(Response) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to these regulations. If the food is intended solely for export, the person producing that food in the United States would still be subject to these regulations with respect to that food.

2. Farms

(Comment 34) Several comments ask if foreign farms, including fish farms (aquaculture) fall under the regulation's farm exemption.

(Response) Section 306 of the Bioterrorism Act specifically exempts farms from these regulations. The definition of a farm includes aquaculture facilities. In addition, foreign persons (except for foreign persons who transport food in the United States), including foreign farms, are excluded from all of these regulations.

(Comment 35) One comment states that FDA has not clarified whether producers who ship live food animals to the United States will be required to keep records on their farm operations, as their products will be "finished" in another country, may have been raised on more than one farm, and may not be considered as going directly to the consumer for consumption. The comment strongly urges the FDA not to require farmers shipping live animals to the United States to incur the additional cost, time, and work involved in maintaining records, beyond those which are currently being maintained for their operations, solely for the purpose of this regulation.

(Response) Farms are excluded from these regulations, as are foreign persons, except for foreign persons who transport food in the United States. Therefore, foreign farmers who ship live food animals to the United States are exempt from this final rule (unless they transport the animals into the United States themselves). FDA notes, however, that although foreign exporters of food into the United States are exempt from these recordkeeping requirements, they must comply with the prior notice regulations issued under the Bioterrorism Act (part 1, subpart I). FDA also notes that an importer of live food animals into the United States would be required to establish and maintain records under these regulations given

that importers are not exempt from this final rule.

(Comment 36) One comment states that, although the proposed rule exempts farms, it may still result in a recordkeeping burden for them. The comment states that, in practice, the farmer will be expected to generate paperwork so that those delivering and dropping products off at the farm will be able to comply with the final rule. Although farms may be exempt on the face of the rule, the comment states that, in reality, farmers will have to generate large amounts of paperwork for their suppliers, truckers, and buyers. The comment states that the final rule needs to make clear that farmers will not be responsible, or expected to generate, paperwork for those complying with this rule.

(Response) Farms are specifically exempted from the requirements of these regulations. Only those persons subject to these regulations must establish and maintain records of the immediate previous sources and immediate subsequent recipients of food that they manufacture, process, pack, transport, distribute, receive, hold, or import. This final rule does not require a farm to establish or maintain records for those who are subject to this regulation.

3. Restaurants

(Comment 37) Several comments state that retail food stores offer a variety of services and conveniences to consumers, including foods that are prepared in-store and ready for immediate consumption, and that the restaurant-type facilities in the retail store should be excluded from the recordkeeping requirements.

One comment notes that the proposed rule includes an exemption for restaurants, which are defined as facilities that sell food directly to consumers for immediate consumption. The comment asserts that many convenience stores make such sales of prepared foods, but convenience stores are included in the proposed rule's definitions as an example of retail facilities. In the comment's view, convenience stores that sell food for immediate consumption should be exempt from the proposed rule. There is no reason why convenience stores that sell prepared foods should have greater regulatory burdens than any other type of entity that sells prepared foods. The comment further states that the restaurant exemption as currently proposed leads to results that are difficult to justify. The comment asks why, for example, should a convenience store that sells lunchmeat be required to comply with a costly system of recordkeeping, while a delicatessen that sells precisely the same product to the same consumer is exempt? The comment states that the only sensible answer to these unjustifiable inconsistencies is to exempt retailers that sell food to consumers for immediate consumption from the requirements of the regulation.

(Response) FDA agrees with these comments. Section 306 of the Bioterrorism Act exempts restaurants from recordkeeping requirements. There is no similar exemption in section 306 for retail facilities. In the proposed rule, FDA exercised the agency's discretion and proposed excluding retail facilities from the requirement to establish and maintain records of the immediate subsequent recipients of food when the food is sold directly to consumers (68 FR 25188 at 25192). As explained therein, the Bioterrorism Act expressly states that the Secretary may require the establishment and maintenance of records by persons who "distribute" food, and therefore retail facilities could be subject to all of the provisions in subpart J of this final rule if FDA thought it was necessary to address credible threats of serious adverse health consequences or death to humans or animals.

FDA recognizes that some facilities that are predominantly retail distribute some food to businesses (that then may further distribute the food before it is consumed) and that some facilities that are predominantly nonretail distribute some food to consumers. FDA concludes that to require such facilities to keep records of each individual recipient consumer would be too burdensome, and not necessary to help address credible threats of serious adverse health consequences or death to humans or animals. If a traceback or trace forward is necessary, FDA can learn from sickened consumers the sources of the food they purchased, or notify consumers generally about food that presents a threat. Therefore, FDA is changing the final rule from the proposal so that it does not require records of subsequent recipients for sales directly to consumers, regardless of whether the seller is a retailer or another type of entity. The final rule excludes persons who distribute food directly to consumers from keeping records of those transactions. Moreover, if a person prepares and sells food directly to consumers for immediate consumption, then those sales qualify for the restaurant exemption.

However, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

Furthermore, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J of this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363.

4. Fishing Vessels

FDA received no comments on this issue and has made no changes to the definition for fishing vessels or to the exemption in the final rule.

5. Retail Facilities

(Comment 38) One comment states that it operates a business that is essentially the same as any other retailer (although they sell to restaurants). Sales to its customers are recorded using a checkout register, and thus, it should not be required to keep records of individual items purchased by customers. Requiring such records from it, but not requiring retailers to keep such records, would be unfair and would be extremely burdensome.

(Response) The business described in the comment is not treated differently than other retailers. Persons who distribute food to businesses do not qualify for the exclusion for sales to consumers in § 1.327(d) of the final rule. Thus, sales of food to restaurants require the establishment and maintenance of records of the immediate subsequent recipient, as codified in § 1.345 of the final rule, to the extent that information is reasonably available to you. Information is reasonably available to you if you have a system in place to capture the information. FDA does not intend to require the reconfiguration of business operations. Thus, for example, information is reasonably available to you when the purchaser has an established commercial account to which the food purchases are charged in an identifiable manner. Accordingly, § 1.327(e) of the final rule provides that persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available. For purposes of this section, "retail food establishment" is defined to mean an establishment that sells food products directly to consumers as its primary function. The term "consumers" does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including 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 consumers exceeds the annual monetary value of sales of food products to all other buyers. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations.

In addition, a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements of this subpart, except the records access provisions for existing records under §§ 1.361 and 1.363. Given the large number of establishments that would be excluded and the significant cost reduction, FDA has analyzed the impact on its ability to efficiently and effectively conduct a tracing investigation to address credible threats of serious adverse health consequences or death. FDA believes the information as to the source of the food of concern sold at these establishments may be obtainable from a larger retail food establishment that is covered by the regulations and sold the same food. Specifically, many of the foods sold at very small retail food establishments are nationally distributed and are also sold at covered retail establishments. If there is an outbreak and product could also be traced to a covered retailer, then FDA could use that retailer's records to identify the source of the food.

Moreover, given the relatively small size of the exempted establishments, the exempted establishments are likely to have fewer products and suppliers than other retail establishments and are therefore more likely to be able to provide FDA with source information even if they are exempted from records establishment requirements. With larger retailers, the records of immediate previous sources are more critical to isolating quickly potential sources of food that poses a threat of serious adverse health consequences or death to humans or animals. The exclusion is based on the number of employees at each retail food establishment and not the entire company, which may own numerous retail stores.

(Comment 39) One comment argues that distributors for direct selling companies should be exempt from the requirement to maintain records concerning immediate subsequent recipients. The proposed regulation would have a significant impact on the direct selling industry. Independent distributors sell product not only to consumers, but also to other independent distributors in their network to support each others' businesses and enable them to fulfill customer orders.

In addition, FDA should acknowledge the unique, closed distribution model of the direct selling business and exempt independent distributors in a direct selling organization from the requirement to maintain records concerning the immediate previous source. In the closed distribution model of direct selling, the direct selling company is the source of all products sold by its distributors. Distributors typically obtain the products they redistribute directly from the direct selling company with which they are associated. Under the proposed regulations, the direct selling company will maintain records that identify the carriers and the distributors who are the immediate subsequent recipients of the product. Any records maintained by the distributor regarding the immediate previous source for such shipments would be wholly duplicative of the records held by the direct selling company.

(Response) Whether these "independent distributors" are subject to the requirement to establish and maintain records to identify the immediate subsequent recipients depends on the nature of their customers. Section 1.327(d) of this final rule excludes persons who distribute food directly to consumers from the requirement in § 1.345 of this final rule to establish and maintain records of the nontransporter and transporter immediate subsequent recipients. As discussed in response to comment 37, FDA concluded that to require such records would be too burdensome and not necessary to help address credible threats of serious adverse health consequences or death to humans or animals. Thus, independent distributors are not required to maintain records of subsequent recipients who are consumers. Independent distributors, however, are required to keep records of subsequent recipients who are not consumers. However, an independent distributor who qualifies as a retail food establishment under § 1.327(e) of the final rule that also distributes food to persons who are not consumers is required to identify the nontransporter and transporter immediate subsequent recipients as to those transactions only to the extent the information is reasonably available. FDA needs such records to quickly and effectively traceback and trace forward in the event of a food-related emergency. However, an independent distributor who qualifies as a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements in this subpart, except the record access provisions for existing records under §§ 1.361 and 1.363.

(Comment 40) One comment asserts that there is no added public health protection from requiring retailers to establish and maintain records of the immediate previous holder of a food product. The proposed rule ensures that all information desired by FDA (e.g., the product and lot number going to a particular retail store) is already recorded by both the distributor of the product and by the transporter of the product. Therefore, traceability of a product will exist without requiring the retailer to also keep that information. The comment believes that the added burden of requiring retailers to establish and maintain records on immediate previous sources of the food it receives is not necessary based on the limited public health and safety benefit that would result.

(Response) As discussed in response to comment 37 of this document, the Bioterrorism Act did not exempt retail food establishments from recordkeeping requirements. FDA decided to exclude persons who distribute food directly to consumers from the requirement to establish and maintain records of subsequent recipients because sick consumers can provide information as to where they obtained food in a traceback, and FDA can notify consumers of a food threat in a trace forward. In the case of a traceback from a retailer, the retailer's records of the immediate previous sources are needed by FDA to address credible threats of serious adverse health consequences or death to humans or animals. In a traceback, it is unlikely that a retailer's source for certain foods would be apparent. Accordingly, in order for FDA to be able to identify the retailer's immediate previous nontransporter and transporter sources, to gain access to those sources records and identify its sources or other recipients of the food, the retailer has to have records identifying those sources. Therefore, the final rule requires retailers to establish

and maintain records containing this information. However, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in subpart J of the final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 41) One comment states that a "retail facility" is defined as a facility that sells food directly to consumers only. Thus, a warehouse store or "cash and carry" store that sells food both to consumers and to commercial accounts would not qualify for this exemption. As the name implies, a "cash and carry" store sells food products to anyone who wishes to buy bulk quantities in cash transactions (e.g., from an individual consumer planning a party or providing for a large family to intermittent supply to restaurants). Such stores typically do not retain detailed records of cash sales. For cash and carry stores that do engage in regular commercial transactions, or which provide credit to commercial customers, ordinary business practices should normally generate records that could be tailored to serve the requirements of the proposed rule. FDA should clarify that, if an entity conducts both exempt and nonexempt activities at the same location, it would be required to retain records only with respect to its nonexempt activities. Under such a clarification, a "cash and carry" store that sells food to individual consumers would not be required to maintain records regarding its retail sales to consumers. The comment requests that the agency adopt and confirm this interpretation.

(Response) FDA agrees. Section 1.327(d) of the final rule excludes persons who distribute food directly to consumers from the requirement to establish and maintain records of the immediate subsequent recipients of food. Therefore, a "cash and carry" store is not required to maintain records regarding its sales to consumers. However, under § 1.327(e) of the final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to only those transactions involving nonconsumers and only to the extent the information is reasonably available. For purposes of this section of this document, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term "consumers" does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including 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 consumers exceeds the annual monetary value of sales of food products to all other buyers. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in subpart J of this final rule, except record access provisions for existing records under §§ 1.361 and 1.363.

(Comment 42) One comment states that, in the case of control state retail operations, keeping detailed information on the immediate subsequent recipients would impose an administrative burden. Although retailers are generally exempt from keeping records pertaining to their customers, the exemption is lost when, as is the case with control states, retail stores sell to other retailers, in this case restaurants, taverns, and bars who subsequently resell the alcoholic beverages being purchased to end-use customers. The retail store transactions are essentially the same type of "over the counter" transactions that take place between the stores and individual consumers. Some information is usually and customarily maintained (e.g., the information pertaining to the licensed purchaser and what is being purchased), although in some cases such information is not generally secured and retained. The comment further notes that some of the information sought (e.g., lot and other product identifiers) is neither generally secured, nor is it maintained.

(Response) Section 1.327(d) of the final rule excludes persons who distribute food directly to consumers from the requirement to establish and maintain records of the immediate subsequent recipients of food. As discussed in response to comment 37 of this document, such sales are excluded because FDA can learn from sickened consumers about the sources of food they purchased or notify consumers generally about food that presents a threat. However, this rationale is not applicable when, as described in the comment, retail stores sell to other retail stores. Under § 1.327(e) of the final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 of this final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to only those transactions and only to the extent the information is reasonably available. In addition, a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements in subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

In regard to lot identification numbers, retailers are not required to maintain this information. The final rule only requires that persons who manufacture, process, or pack food record lot or code numbers or other identifiers of that food (and only to the extent this information exists) (§§ 1.337(a)(4) and 1.345(a)(4) of the final rule).

(Comment 43) One comment argues that the proposed retail exemption (§ 1.327(d)) must be a complete exemption, including an exemption from recordkeeping regarding suppliers, identical to the exemption given to restaurants. The comment states that today retailers and restaurants compete in the burgeoning take home and carryout market. FDA's proposal gives an unfair and unnecessary advantage to restaurants, which are expanding out of in-restaurant dining into areas formerly served by retailers and carryout establishments. A full exemption for retailers presents no lessening of food safety safeguards.

(Response) "Restaurant" is defined to mean "a facility that prepares and sells food directly to consumers for immediate consumption." This means that an establishment that prepares and sells food that is capable of being eaten immediately, with no further preparation, is considered a restaurant. This definition and the corresponding exemption for restaurants in § 1.327(b) of the final rule includes activities such as a restaurant preparing and selling food to a consumer to be consumed at a later time, as long as the food is

capable of being immediately consumed without further preparation or processing. For example, a restaurant may prepare and sell pies from a counter that consumers purchase and take home for later consumption. This activity qualifies for the restaurant exemption as long as the food is prepared and sold directly to a consumer for immediate consumption.

In addition, a restaurant/retail facility is excluded from all of the requirements in subpart J of this final rule if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales. FDA notes that many facilities that otherwise would be excluded as restaurants under the final rule sell a small amount of food that they do not prepare for immediate consumption. For example, some restaurant/retail facilities have small packaged goods gift shop areas that sell food. The entire facility is excluded from all of the requirements in subpart J if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales. FDA exercised its discretion and excluded restaurant/retail facilities whose nonrestaurant food sales are less than 10 percent of their total food sales because many facilities that would otherwise qualify as restaurants make such sales as an incidental activity (Ref. 14). FDA believes that, were it not to provide such an exclusion, the exemption for restaurants would be undermined because many facilities that prepare and sell a high percentage of their food for immediate consumption also sell a small amount of packaged goods that they do not prepare themselves for sale to consumers (e.g., beverages, chips, candy, condiments, and sweeteners) and otherwise would be subject to the rule as to those sales.

Conversely, if a restaurant/retail facility's sales of food it does not prepare and sell for immediate consumption are 10 percent or more of its total food sales, FDA believes that such sales are a significant portion of the facility's activities. Such a facility's retail food sales are exempt only from the requirement to establish and maintain records of sales to consumers. The restaurant/retail facility's sales of food it prepares and sells for immediate consumption remain exempt from all of the requirements of subpart J of this final rule. As noted earlier, retail facilities are required to keep records of sales to nonconsumers only to the extent that information is reasonably available.

Section 306 of the Bioterrorism Act specifically exempts restaurants, but not retailers. FDA believes persons, including retailers, must establish and maintain records of immediate previous sources to ensure that FDA can quickly and effectively conduct a traceback in a food-related emergency. However, a retail food establishment that employs 10 or fewer full-time equivalent employees is excluded from all of the requirements of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 44) Several comments state that, although they make every effort to provide food to their customers in a timely and efficient manner, a small percentage of the food that is in a grocery store is sent to a reclamation center from which it is either returned to the manufacturer or sent to food banks. Reclamation centers are currently the largest single source of food donations for food banks. Food may be sent to reclamation centers if its packaging is damaged or if it is past the "best if used by" date. The system for sending food to reclamation centers is simple: The unsaleable products are collected in banana cartons and then shipped to the center where the food is sorted and either donated to charitable organizations, such as food banks, or returned to the manufacturers. No records are kept by the store of the foods shipped to the reclamation center.

The comment states that FDA's regulations should consider reclamation centers and food banks to be "consumers" for purposes of the recordkeeping regulations. Specifically, food retailers do not currently track the foods that are sent to reclamation centers, nor is there a mechanism available to do so. The requirement to develop and implement new recordkeeping systems would be a serious disincentive to corporate food donations and, again, would serve no purpose with respect to food security. If it is not necessary to track product to individual consumers to enhance food security, no purpose is served by monitoring those products that are sent through reclamation centers to consumers. Any products that are returned to the manufacturer are removed from the food distribution system so they will not reach consumers and their whereabouts need not be accounted for. Accordingly, FDA should broaden the exclusion for retailers to include food products that are routed to consumers through reclamation centers.

(Response) FDA agrees. FDA is exempting nonprofit food establishments 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. "Nonprofit food establishment" has been defined to mean:

> * * *a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes contral food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).* * *

Congress gave FDA the discretion to issue regulations regarding the establishment and maintenance of records under section 306 of the Bioterrorism Act. Charitable food establishments, such as food banks, stand in place of the consumer and FDA will treat them as consumers for purposes of this final rule. Therefore, grocery stores, catering facilities, and others giving a charitable donation of food to a food bank, soup kitchen, or other similar charitable entity are not required to keep records of the immediate subsequent recipients of the food, and the charitable food establishment does not need to keep records of the immediate previous sources of that food or the immediate subsequent recipients of that food. FDA has determined that it does not need records of food donated to food banks to address credible threats of serious adverse health consequences or death to humans or animals. In the event of a traceback investigation, FDA believes that it is likely to have the ability to trace the immediate previous source of contaminated food by other means. Unless the source of the contamination is at the food bank itself, other consumers of that same food obtained from a grocery store are likely to identify that grocery store as a link in the chain-of-distribution of the contaminated product. In the case of a trace forward investigation, records will likely exist from the donor of the food to the charitable food establishment. FDA believes that the likelihood of the existence of such records is great given the tax benefits available to the persons donating goods to establishments that are 501(c)(3) establishments under the Internal Revenue Code. Therefore, FDA does not believe that exempting such charitable entities from these requirements would interfere with the goals of the Bioterrorism Act or subpart J of this final rule.

With respect to the "reclamation centers" mentioned by the comment, FDA understands that most reclamation centers are actually owned by the

grocery store or grocery chain. Such reclamation centers will be treated as if they are part of the grocery store and must keep the records that must be kept by the grocery store. For instance, if food from the reclamation center is donated to a food bank, the exclusion described previously applies. If food is sold to consumers, the exclusion for foods sold directly to consumers applies. If food is returned to the manufacturer, or sold to another nonconsumer, the reclamation center must keep records of the immediate subsequent recipients of food, to the extent this information is reasonably available.

(Comment 45) Several comments state that, although retailers will not be required to keep track of foods sold to consumers, retailers will be required to keep records on those immediate subsequent recipients who are wholesalers or other retailers. The comments add that, unless the recordkeeping exclusion applies to all foods that are sold from the store, it is essentially meaningless. Food retailers do not know whether a person who comes into a store and buys food will be using the food for personal consumption or for a business purpose. To cover the possibility that a purchase was intended for business purposes would essentially require a retailer to record all consumer transactions. The comments state that this would not increase food security or consumer confidence. The comments also state that the trust of consumers is of tantamount importance and requiring documentation of all consumer transactions will diminish that trust without furthering the goal of food security.

(Response) Although retailers must keep records of immediate subsequent recipients of food who are not consumers, retailers are not required to do so unless that information is reasonably available, for example, when the purchaser has an existing commercial account. (See response to comment 38 of this document.) Retailers need not ask the status of each purchaser, and retailers will not be required to record every consumer transaction. Under § 1.327(e) of this final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of this final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only, and only to the extent the information is reasonably available.

FDA notes that there is an exclusion with respect to food that is manufactured, processed, packed, held, received, or transported for personal consumption. Such activities are excluded from the rule because if a traceback or trace forward investigation is necessary, FDA can learn from sickened consumers the sources of the food they purchased, or notify consumers generally about food that presents a threat. Whether food is for personal consumption depends on many factors, but FDA would consider food prepared in a private home and transported for other than business purposes to qualify for this exclusion. An example of food covered by this exclusion includes food prepared for "pot luck" suppers.

(Comment 46) One comment believes that direct marketing facilities should be explicitly exempted from maintaining records of immediate subsequent recipients. The comment believes that direct marketers that sell their food directly to consumers are functionally no different than brick-and-mortar retail establishments. Moreover, FDA's proposal already explicitly exempts other entities that sell food directly to consumers (farms, some roadside stands, and restaurants). Direct marketers thus should be exempt from another and different mandated recordkeeping protocol. Direct marketers already must meet the recordkeeping requirements of taxing authorities. Adding another enormous, needless recordkeeping requirement for consumers who purchase their food directly would do nothing to achieve the aims of the Bioterrorism Act at the expense of increased costs to marketers and, thus, their customers. The comment urges FDA to revise the exclusion for retail facilities by explicitly stating that direct marketing facilities are likewise exempt from the one-down requirements of § 1.345.

(Response) Neither the proposed nor final rule distinguishes between persons that sell to consumers as direct marketers, including those selling products over the Internet, and other persons selling to consumers from establishments. Therefore, if a direct marketer sells food directly to a consumer, he or she is exempt from establishing and maintaining records of the immediate subsequent recipients of that food. Under § 1.327(e) of this final rule, persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only, and only to the extent the information is reasonably available. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J of this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.) For a further discussion of "direct sellers" responsibilities under this rulemaking, see response to comment 50 in the following paragraphs.

(Comment 47) One comment states it is not clear in the proposed regulations whether retail bakeries and delicatessens are subject to these regulations. Although the registration requirements exempt them entirely, the recordkeeping rule only contains an exemption from establishing and maintaining records with the names of "immediate subsequent recipients of foods sold directly to consumers." This implies that they still need to keep track of ingredient lots used in each production. In such operations, production usually consists of a wide variety of products made daily and in very small quantities. Keeping track of ingredients used in each and every product made daily is virtually impossible, and if required, would financially break every retail bakery or delicatessen, most of which are already struggling to compete in the dwindling market being taken over by supermarket chains. The comment requests that FDA look seriously at totally exempting any retail food operation with 10 or less employees from any of the requirements of the proposed regulations, particularly recordkeeping. If this is not possible, the comment proposes that FDA consider an alternative choice if they do not keep records of ingredients used in products, that if any contaminated ingredient is found, or brought to their attention, that they agree to destroy all manufactured products currently in stock (made from this ingredient or not). This alternative would have the same safety effect, but would be a lot less costly than keeping records.

(Response) A bakery or delicatessen is excluded from all of the requirements in subpart J of this final rule if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

Food is for immediate consumption when the food is capable of being eaten immediately with no further preparation. However, if the bakery or delicatessen does not qualify for the restaurant/retail facility exclusion in § 1.327(b) of this final rule, there is also an exclusion for retail food establishments that may apply. Under § 1.327(f) of this final rule, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except the record access requirements for existing records. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(Comment 48) One comment states it appears that rather than exempting convenience stores that sell food for immediate consumption, FDA has proposed a partial exemption such that records need be kept only for the nonexempt activities, but that is not clear in the proposed rule. FDA should either take a functional approach that allows facilities that sell food to consumers for immediate consumption to have a full exemption, or FDA should clarify that convenience stores and other facilities that make sales for immediate consumption need not maintain records for that part of their operation.

(Response) Convenience stores and other covered facilities that sell to consumers are an example of a mixed-type facility. Food that the convenience store prepares and sells directly to consumers for immediate consumption (i.e., hot dogs, hot pretzels), is exempt from subpart J of this final rule under the restaurant exemption. Under § 1.337 of this final rule, the facility is required to keep records of the nontransporter and transporter immediate previous sources for all other food. The facility is not required to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients for sales of food to consumers, but must establish and maintain records to identify immediate subsequent recipients of food who are not consumers, as required by § 1.345 of this final rule, when such information is reasonably available, as discussed in response to comment 38. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 49) Some comments state they are engaged in marketing products directly to the consumer through direct sales, mail order, Internet sales, and/or retail sales and urge FDA to clarify the scope of "retail facilities" to include independent distributors in direct sales forces, mail order companies, or Internet sales operations, because it is apparent that neither Congress nor FDA intended for the recordkeeping requirement to encompass records of individual sales to consumers.

(Response) As described in response to comment 37, persons are not required to establish and maintain records to identify the nontransporter and transporter subsequent recipients of food distributed directly to consumers (§ 1.327(d) of this final rule). Further, as described in response to comment 50, these regulations do not distinguish between direct marketers and others selling food from a retail establishment. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

(Comment 50) One comment states that because direct sellers might also sell to other direct sellers either for consumption or for resale to other consumers, it is possible that the proposed recordkeeping requirements of the regulation might be construed to apply to them. The comment strongly suggests that were the requirements to apply to their businesses, many individuals would be discouraged from entering into direct sales. Individuals who are attracted to direct selling because of the ease of entry into the business would surely not welcome the additional paperwork and bureaucratic requirements necessitated by the proposal. Although perhaps appropriate for larger businesses, these requirements would provide a severe disincentive to their way of doing business. Additionally, given the sheer numbers of salespeople potentially involved, and the generally small size of the sales transactions consummated by direct sellers, the massive paperwork generated by direct sellers under the recordkeeping requirements could actually be counterproductive to efforts to enhance bioterrorism preparedness. The comment states that, given the unique, micro-entrepreneurial nature of operations of individual direct sellers and the questionable (at best) benefit to national security that might be achieved by applying this regulation to them, direct sellers should be exempt from the extensive recordkeeping requirements with respect to both immediate previous sources and immediate subsequent recipients. The comment also notes that other retailing operations are exempt (at least in part) from the proposed regulation, and believes that an exemption for direct sellers is consistent with the retailing exemption and the Bioterrorism Act.

(Response) "Direct sellers" are not required to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients for sales directly to consumers. Direct sellers that qualify as a retail food establishment under § 1.327(e) are required to establish and maintain records for sales to other direct sellers, when such information is reasonably available. FDA explains the rationale for distinguishing between sales to consumers and businesses in response to comment 40. Direct sellers, like other covered persons, are required to establish and maintain records to identify the nontransporter and transporter immediate previous sources of food, as required by § 1.337 of this final rule. However, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.) Thus, if a direct seller qualifies as a retail food establishment and employs 10 or fewer full-time equivalent employees, it is exempt from all recordkeeping requirements under this rule, except for the record access provisions for existing records.

(Comment 51) One comment states the Secretary has the full discretion to determine who shall be required to maintain records and what records shall be kept. Congress has clearly communicated its intention to protect small businesses by stating: "The Secretary shall take into account the size of the business in promulgating regulations under this section." The comment states that individual direct sellers who distribute nutritional or related products should be exempt from the requirement to maintain records under the proposed rule.

(Response) As stated in the proposed rule, FDA carefully considered the size of a business when developing these regulations. FDA found that most products and ingredients pass through

at least one very small business when moving through the distribution process. If FDA were to exempt all very small businesses with 10 or fewer employees, not just those in the retail sector, this would create a "Swiss Cheese" approach to trace back, as there would be a potential failure of entities to keep records throughout the distribution chain. The number of very small entities account for a large fraction of the total number of food establishments. We used U.S. Census data to estimate the percentage of the total number of food establishments that are very small, as well as their revenues, by sector and report them in table A of this document. The fraction of the total number of facilities that are very small ranges from an estimated 73 percent of convenience outlets to 90 percent of transporters.

TABLE A.—ESTIMATED TOTAL NUMBER OF VERY SMALL FOOD ESTABLISHMENTS

Sector	% of establishments That Are Very Small	% of Food Industry Revenue From Very Small Establishments
Manufacturers	77	15
Wholesalers	81	14
Transporters	90	16
Grocery outlets	88	18
Convenience outlets	73	18
Importers	82	14
Mixed-type facilities	82	15

Moreover, many of our failures in a typical trace back investigation (i.e., unclassified scenarios) have been at the wholesaler (distributor) level. As noted in the table A of this document, 81 percent of the wholesalers are considered very small. We also would have significant concerns if 90 percent of the transporters (as very small entities) were excluded from the requirements to establish and maintain records.

In light of the previous information, FDA does not believe we would have an effective recordkeeping system if we were to exempt all very small entities from the rule. Unlike the very small retailers who are at the end of the distribution chain only, a full exemption by size would create holes throughout the distribution chain and would not provide FDA adequate assurances that, in the event of a threat of serious adverse health consequences or death, FDA would be able to conduct an efficient and effective tracing investigation.

However, "individual direct sellers" as described in the comment who qualify as retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

In addition, FDA has considered the size of a business in establishing compliance dates for this final rule. Further, the final rule exempts direct sellers who are otherwise subject to the recordkeeping requirements of this rule and who sell food products directly to consumers from keeping records of the immediate subsequent recipients of that food.

(Comment 52) Several comments state FDA should interpret the exemption from maintaining records for immediate subsequent recipients of food to expressly include retail farm supply and feed stores that sell finished product directly to consumers and final purchasers. For instance, the comments note that many small rural feed manufacturers also have a retail outlet in their facilities that sell bagged feed, pet food, and feed ingredients/additives over-the-counter directly to consumers and to final purchasers for their own animals. These products are not resold by the purchaser-customer. Maintaining records of these sales is not common practice today, would represent a costly burden to such enterprises, many of which are small businesses, and would not demonstrably enhance human or animal protection from bioterrorism-related threats.

(Response) The exclusion in § 1.327(d) of this final rule from establishing and maintaining records of immediate subsequent recipients for food distributed directly to consumers applies to sales of bagged feed, pet food, and feed ingredients/additives over-the-counter directly to consumers and final purchasers for their own animals, unless the feed is to be used in animals that will be sold as food. If the feed is to be fed to food-producing animals, then the purchasers are not considered consumers since they are purchasing the food for a business (i.e., for the food-producing operation). The feed will remain in the food distribution system, and FDA needs records to help address credible threats of serious adverse health consequences or death to humans or animals. Therefore, under § 1.327(e), persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, for retail food establishments, the requirements in § 1.345 of this final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements of subpart J in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

6. Retail Facility/Roadside Stands

(Comment 53) One comment is concerned that the retail exemption only applies to facilities, such as roadside stands that employ 10 or fewer full-time employees, and that are located in the same general physical location as farms that sell unprocessed food grown or raised on those farms. The comments note that the exclusion does not apply to processed foods, even if they are sold directly to the consumers from the retail facility in the same general location as the farm, unless all the ingredients in that processed food were grown or raised on that farm. Consequently, persons handling processed foods, such as baked goods, jams, jellies, maple syrup, and "processed" items such as hams and sausages from animals grown and processed into meat products on the farm would fall under the provisions of the final rule. Also, any persons handling products that were "imported" from off the farm would be subject to the final rule. The processed food provision is a burden for those involved in roadside stands that operate outside of the normal seasonal harvest period or sell processed foods. They could not purchase goods from neighbors or bring in goods from other areas under the exemption or include ingredients from a nonfarm source. The comment asks that this limitation affecting farm markets be removed from the final rule.

(Response) FDA has changed the exclusion in proposed § 1.327(d)(2) and has now provided an exclusion for all retail food establishments that employ 10 or fewer full-time equivalent employees from all of the regulations in this final rule, except the record access provisions for existing records under §§ 1.361 and 1.363, regardless of whether the food being sold is processed or unprocessed. (See response to comment 38 of this document for a further discussion of FDA's rationale underlying this exclusion.)

7. Persons Under the Exclusive Jurisdiction of USDA

(Comment 54) One comment states that proposed §§ 1.327 and 1.328 distinguish between those foods that will be subject to the requirements of the final rule, and those foods that will be exempt. In doing so, the proposed rule refers to other federal statutes (e.g., the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act), as a means to provide the regulated community with the relevant details as to whether and when their conduct will come within the scope of the regulations being proposed. Although statutory references such as these may suffice to inform farms, food manufacturers, restaurants, and other food-related facilities that deal with these statutes on a daily basis whether and when they will be subject to FDA's final rule, that is clearly not the case with motor carriers. Therefore, the comment states that FDA should explain what food is subject to the final rule in layman's language to avoid any confusion. The comment further recommends that FDA attach a list of the applicable or the exempted foods as an appendix to the final rule.

In addition, a foreign comment states that meat, poultry, and eggs are exempt under the proposed rule because the United States deems current risk management systems associated with these products to be sufficiently stringent. The comment states that, in Australia, these products are subject to strict regulatory and certification requirements as "prescribed goods" under Australian legislation (the Export Control Act 1982), which the USDA audits. A range of other Australian products, such as milk and fish, are also prescribed goods and are subject to the same certification process. The comment, therefore, argues that all prescribed goods should qualify for an exemption on these grounds.

(Response) The rule does not impose any requirements with regard to food to the extent it is within USDA's exclusive jurisdiction under FMIA, PPIA, or EPIA. Under the FMIA, USDA regulates cattle, sheep, swine, equines, goats, and "meat food products." Under the PPIA, USDA regulates poultry and "poultry products." Under the Egg Products Inspection Act, USDA regulates some eggs and "egg products."

Any person that manufactures, processes, packs, transports, distributes, receives, holds, or imports some foods subject to exclusive USDA jurisdiction is exempt from these regulations with respect to that food while it is under USDA's exclusive jurisdiction.

FDA has decided not to attach an appendix to the final rules highlighting which foods are within the scope of this final rule. If questions remain, FDA will determine whether it needs to issue additional guidance on this subject.

With respect to the comment regarding Australian meat, poultry, eggs, milk, and fish, FDA notes that all foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of the final rule under § 1.327(h). However, domestic persons who import these foreign products are required to comply with these recordkeeping regulations to the extent that they are FDA-regulated food products.

(Comment 55) One foreign comment requests that FDA identify the list of persons that are excluded from all or part of the regulation in accordance with § 1.327.

(Response) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this final rule under § 1.327(h). The term "person" includes an individual, partnership, corporation, and association (section 201 of the FD&C Act (21 U.S.C. 321(e))).

8. Foreign Facilities if Food Undergoes Further Manufacturing/Processing

There were no comments received on this issue. However, FDA has decided to exempt foreign persons, except foreign persons who transport food in the United States, from this rulemaking. This is discussed in detail under section III.C of this document entitled "Comments on Who is Subject to This Subpart?" (Proposed § 1.326).

9. Pet Food

(Comment 56) Two comments requested clarification on whether the exemption from the recordkeeping requirements for non-BSE regulated pet food manufacturers applies to foreign manufacturing facilities.

(Response) All foreign persons, except foreign persons who transport food in the United States, are excluded from all of these regulations under § 1.327(h) of this final rule. In addition, the final rule deletes the proposed exclusion for non-BSE regulated pet food. Accordingly, all persons who manufacture, process, pack, transport, distribute, receive, hold, or import animal feed in the United States, including pet food, are subject to the requirements of this final rule, unless otherwise exempted.

(Comment 57) FDA received three comments from four national animal feed trade associations. One disagrees with the proposal to exempt pet food entities that are not subject to the BSE rule. It comments that it was an error to attempt to combine provisions of the BSE rule with a Bioterrorism rule. Because the BSE rule was solely designed to prevent the introduction and amplification of BSE, the comment is concerned that the recordkeeping requirements of the BSE rule do not fully address the recordkeeping provisions of the Bioterrorism Act. In addition, it comments that the health and safety of pets should not be compromised and, therefore, all animal food should be treated equally under the final rule and pet food companies should be required to maintain the same level of records as other animal feed companies. The comment also notes that creating an exempt category of food products (i.e., certain pet foods) could result in a gap in the recordkeeping

system established by the Bioterrorism Act.

Two additional animal feed associations submitted a combined comment that for simplicity FDA should adopt the same recordkeeping requirements for all animal food, pet food, and food intended for food-producing animals. One comments that entities already complying with the BSE rule should comply but all other animal feed and pet foods should be exempt from the recordkeeping requirement because of the low risk of serious adverse health consequence. Two comments state that they agree with FDA's risk assessments that animal feed and pet food have a lower risk and therefore needs fewer requirements than human food.

One other comment supports the proposed provision stipulating that BSE-regulated pet food entities should comply with the recordkeeping regulations. A foreign comment questions the need for the inclusion of any animal feed or pet food in the rule. Several comments, foreign and domestic, request clarification on which foreign establishments are subject to the recordkeeping requirements under the proposed non-BSE rule exclusion.

(Response) In the final rule, FDA has deleted the non-BSE pet food exclusions, and the final rule now requires all animal feed and pet food entities to establish and maintain records for 1 year. Therefore, the definition of pet food in the proposed rule is no longer needed and has been deleted. FDA was persuaded by the comments from three national trade organizations that: (1) Using the scope of the BSE rule as the criterion for exempting certain pet foods is inappropriate and would result in insufficient recordkeeping coverage to protect the public from bioterrorism; (2) creating an exclusion for certain pet foods could create a gap in the recordkeeping system; and (3) for simplicity, FDA should adopt the same recordkeeping requirements for all animal food, including pet food. FDA believes that contaminated animal food can be a link to human foodborne illness. People could be at risk through direct contact with animal food or through unintentional cross-contamination of cooking surfaces or utensils. Animals may also become infected and serve as a reservoir for exposing other animals and humans to disease. In 2002, dog chew treats were contaminated with *Salmonella enteritidis* (*Salmonella*) and became a vehicle to transmit *Salmonella* into homes. As a consequence, many pet owners became ill, and one person died (Ref. 15). Although FDA continues to believe that the consequences of a potential terrorist attack or food-related emergency are greater for food for food-producing animals than for pet food, compelling arguments have been raised against the proposal to create exclusions for certain pet food entities. Therefore, FDA believes that applying the recordkeeping requirements uniformly to all animal foods is most consistent with the intent of the Bioterrorism Act.

The final rule requires records for all animal food, including pet food, to be retained for 1 year after the dates you receive and release the food. FDA believes that a 1-year period of records retention is appropriate because food for food producing animals tends to have a faster turnover rate than many kinds of human food. In addition, since pet foods are typically the sole source of food for pets, such foods tend not to be stored as long as many human foods.

(Comment 58) One comment states that the recordkeeping requirements for animal food foreign establishments should be limited to the final establishment handling the product prior to export to the United States.

(Response) Section 1.327(h) of this final rule excludes all foreign persons, except foreign person who transport food in the United States, from all requirements in this final rule.

(Comment 59) One comment asks FDA to officially recognize its country's BSE regulations as equivalent to the U.S. BSE regulations.

(Response) FDA declines to respond to this request because it is outside the scope of this rulemaking.

(Comment 60) One comment asks that suppliers and transporters of animal food not be required to retain any additional information other than what is contained in their current records.

(Response) FDA agrees in part with this comment. This rule only requires additional records to be established and maintained to the extent the information does not already exist.

10. Food Contact Materials

(Comment 61) Several comments state that, although they agree with FDA's decision not to apply the proposed regulations to outer packaging, the same logic that supports that exclusion applies equally to food contact materials. One comment states that applying the recordkeeping requirements to food contact substances would create an unreasonable and unjustified burden on the industry and its suppliers. One comment states that, under FDA's proposed approach, there is no limit to the suppliers of components and precursor substances who would be required to establish and maintain records. Removing food contact facilities from the ambit of the recordkeeping regulations is consistent with the clear intent of the Bioterrorism Act and FDA's mandate to ensure the safety of the U.S. food supply in the least burdensome means possible.

Several comments state it is unrealistic to believe that a terrorist attack on the food supply will be carried out through food contact substances. As a technical matter, it would be virtually impossible to insert a poison in contact materials with a sustained release mechanism to contaminate food, without the full cooperation of the materials manufacturer. Even putting aside the technical and logistical complexities that would be involved, such an indirect approach would have virtually no impact before discovery. Food contact manufacturers and food processors have routine procedures in place to ensure that their contact materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage. Accordingly, there is no reason to believe that applying the recordkeeping requirements to food contact substances would further the purpose of the Bioterrorism Act or FDA's stated goal of the proposed regulations.

Another comment states that excluding outer food packaging from the requirements has little practical meaning because nearly all packaging companies handle both outer packaging and food contact substances. The comment further states that FDA's assumption that half of the manufacturers and distributors of packaging handle only outer packaging materials (68 FR 25188 at 25212) may be true for suppliers in other packaging segments, but is simply incorrect when it comes to the cartonboard segment of the industry. The comment states that packaging companies in that segment will find it more expedient to keep records on all materials—both outer packaging and contact substances—rather than to document only the food contact materials, because many of the same materials can be used for both purposes, and it would be prohibitively expensive to segregate these uses. The comment notes that this would result in a recordkeeping requirement for nearly all facilities that manufacture packaging and packaging components, and all of their suppliers, if FDA retains the proposed approach.

One comment states the inclusion of "immediate food packaging" and "food contact substances" in the definition of "food" creates a difficult and unnecessary compliance effort throughout the supply chain. The comment suggests that FDA remove the requirement to establish and maintain records on "immediate food packaging" and "food contact substances" after such materials are either accompanying or affixed to the food, thus eliminating duplicative tracking and burdensome paperwork. If records are kept on the food, the comment states that those same records could be used to trace the packaging and labeling materials to the farm and point of initial contact with the food. From there, the material's original manufacturing/processing facility can be identified, where detailed records on the immediate subsequent transporter and recipient (likely the farm) will be maintained according to the regulations.

(Response) FDA agrees with these comments in part. FDA is finalizing the definition of "food" as proposed and is not excluding food contact substances from the definition. As discussed in the following paragraphs and provided in §§ 1.327(i) and (j) of this final rule, however, FDA is using our discretion to exclude specified persons and activities from recordkeeping requirements for packaging and food contact substances.

These comments raise the question of what Congress intended "food" to mean for purposes of recordkeeping and access. In construing the recordkeeping and access provisions of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented (*Chevron* step one)? *Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have focused directly on the question presented and have articulated clearly its intention. *Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent. *Chevron*, 467 U.S. at 842–843. If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of "food," FDA may define "food" in a reasonable fashion (*Chevron* step two). *Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000).

The agency has determined that, in enacting section 306 of the Bioterrorism Act, Congress did not speak directly and precisely to the meaning of "food." The FD&C Act has a definition of "food" in section 201(f). It is a reasonable assumption that, when the term "food" is used in the Bioterrorism Act, section 201(f) applies. However, although there may be "a natural presumption that identical words used in different parts of the same Act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid* * *." *Atlantic Cleaners & Dyers, Inc.* v. *U.S.*, 286 U.S. 427, 433 (1932). Accord: *U.S.* v. *Cleveland Indians Baseball Co.*, 532 U.S. 200, 213 (2000). Thus, the same word may be given different meanings, even in the same statute, if different interpretations are what Congress intended. *Atlantic Cleaners & Dyers, Inc.*, supra.

Even before the Bioterrorism Act amendments, the term "food" was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical "(other than food)" in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit noted that Congress meant to exclude only "articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value" and not all substances defined as food by section 201(f) of the FD&C Act. *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983). Similarly, section 409(h)(6) of the FD&C Act defines a food contact substance as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding *food* if such use is not intended to have any technical effect in *such food* (emphasis added)." This definition makes sense only if "food" is interpreted to exclude materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.[1]

Thus, it is in this larger statutory context, that FDA has evaluated section 306 of the Bioterrorism Act to determine whether the meaning of the word "food" is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether Congress's intent is ambiguous. *Pharmaceutical Research & Manufacturers of America* v. *Thompson*, 251 F. 3d 219, 224 (D.C. Cir. 2001). Section 306 of the Bioterrorism Act amends the FD&C Act by adding section 414 to the FD&C Act. In section 414, "food" is used in conjunction with other words to describe which FDA-regulated articles are subject to recordkeeping and access requirements. In describing the conditions for record access by FDA, section 414(a) of the FD&C Act requires a reasonable belief as to an "article of food." In describing the purpose for which recordkeeping may be required, section 414(b) of the FD&C Act refers to "food, including its packaging." Elsewhere in the recordkeeping provisions, section 414 of the FD&C Act refers to "food," "food safety," "a food to the extent it is within the exclusive jurisdiction of [USDA]," and "recipes for food."

The Bioterrorism Act is silent as to the meaning of "food." Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other possibilities noted in the previous paragraph, or another meaning. Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole. *Martini* v. *Federal Nat'l Mortgage Association*, 178 F. 3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp.* v. *Cartier, Inc.*, 486 U.S. 281 (1988). Indeed, the analysis should not be confined to the specific provision in isolation because the meaning or ambiguity of a term may be evident only when considered in a larger context. *FDA* v. *Brown & Williamson Tobacco Corp.*, supra at 132 (2000).

FDA has considered other sections of the Bioterrorism Act and has concluded that the meaning of "food" in the Bioterrorism Act is ambiguous. FDA previously considered the meaning of "food" in section 305 of the Bioterrorism Act, governing registration of food facilities, and concluded that it is ambiguous (68 FR 58894). Section 305 of the Bioterrorism Act amends the FD&C Act by adding section 415 to the FD&C Act (21 U.S.C. 350d). In section 415(a)(1) of the FD&C Act, the word "food" is modified by the phrase "for consumption in the United States." It is not clear whether this modifying phrase limits the definition of "food" to food that is ingested, a narrower definition of "food" than that in section 201(f) of the FD&C Act. In addition, the definition of "facility" in section 415(b)(1) of the FD&C Act exempts "farms; restaurants; other retail establishments." It is not clear whether the phrase "other retail establishments" includes retailers of food contact materials; the legislative history indicates that it does not,

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

thereby giving rise to additional ambiguity about which definition of "food" applies to section 415.

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

FDA also considered the meaning of "food" in section 303 of the Bioterrorism Act, governing administrative detention, and concluded that it is ambiguous. FDA determined that use of the definition of "food" in section 201(f) of the FD&C Act is consistent with the language of section 303 of the Bioterrorism Act. Section 303 repeatedly uses the term "food" without adjectives, except for a reference to "perishable foods," which is not used to limit the reach of the section. FDA also determined that use of the definition of "food" in section 201(f) of the FD&C Act is consistent with the use of the term in judicial enforcement actions (e.g., seizures and injunctions) that may be instituted under administrative detention.

The ambiguity surrounding Congress's use of "food" in sections 303, 305, 306, and 307 of the Bioterrorism Act, coupled with the lack of a definition of the term in the Bioterrorism Act, support a conclusion that the meaning of "food" in the Bioterrorism Act is ambiguous. Having concluded that the meaning of "food" in the Bioterrorism Act and in section 306 of the Bioterrorism Act in particular is ambiguous, FDA has considered how to define the term to achieve a "permissible construction" of the records establishment and maintenance provisions. *Chevron, USA, Inc.* v. *NRDC*, Inc., supra at 843. In conducting this *Chevron* step two analysis, the agency has considered the same information it evaluated at step one of the analysis. *Bell Atlantic Telephone Co.* v. *FCC*, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC*, 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the records establishment and maintenance provisions, to use the definition of "food" in section 201(f) of the FD&C Act.

Use of the definition of "food" in section 201(f) of the FD&C Act is consistent with the language of section 306 of the Bioterrorism Act. Section 306 does not contain language qualifying the meaning of food. Furthermore, section 414(b) of the FD&C Act authorizes the Secretary to require certain records to identify the immediate previous sources and recipients of "food, including its packaging." In addition, section 306(b) of the Bioterrorism Act amended section 704(a) of the FD&C Act, governing factory inspections, to provide that in the case of persons engaging in covered activities with regard to "foods, the inspection shall extend to all records and other information described in section 414* * *." The inspection referenced in section 306(b) of the Bioterrorism Act is one of "any factory, warehouse or establishment in which [food] is manufactured, processed, packed or held* * *." FDA's longstanding interpretation is that "food" in section 704 of the FD&C Act has the same meaning as in section 201(f) of the FD&C Act.

Use of the definition of "food" in section 201(f) of the FD&C Act is also consistent with other sections of the Bioterrorism Act. Section 414(a) of the FD&C Act refers to an article of food that is "adulterated." "Adulterated" is defined in section 402 of the FD&C Act (21 U.S.C. 342), and "food" in that section has the meaning provided in section 201(f) of the FD&C Act. See, e.g., *Natick Paperboard Corp.* v. *Weinberger*, 525 F.2d 1103 (1st Cir. 1975). Furthermore, using the definition of "food" in section 201(f) of the FD&C Act for section 306 is consistent with the interpretation of "food" in section 303 of the Bioterrorism Act, providing for administrative detention. When the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA may need to administratively detain the food under section 303 of the Bioterrorism Act and access relevant records under section 306 of the Bioterrorism Act. FDA is therefore retaining its interpretation of "food" in section 306 of the Bioterrorism Act to mean "food" as defined in section 201(f) of the FD&C Act. Food subject to section 306 of the Bioterrorism Act thus includes, but is not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed (including pet food), food and feed ingredients and additives (including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients), infant formula, beverages (including alcoholic beverages and bottled water), live food animals (such as hogs and elk), bakery goods, snack foods, candy, and canned foods.

Although "food" for purposes of section 306 of the Bioterrorism Act means the same as in section 201(f) of the FD&C Act, FDA is using its discretion to exclude some food from the record establishment and maintenance provisions. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food are excluded from all the requirements of subpart J of this final rule, except §§ 1.361 and 1.363. Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except the record access provisions for existing records under §§ 1.361 and 1.363. FDA determined that requiring such persons to establish and maintain records is not necessary in order to address credible threats of serious adverse health consequences or death to humans and animals.

(Comment 62) One comment states that food packaging other than immediate food-contact packaging defined as "food" in the FD&C Act should not be included within the scope of this final rule. This appears to be consistent with FDA's intent in that the term "packaging" is neither defined nor used in the proposed rules.

One comment states that the inner packaging that is in direct contact with the food provides a barrier to contamination from outer packaging components. Therefore, the comment agrees with FDA's conclusion that shipping containers and outer packaging not in direct contact with food poses only a small risk from contamination and should be omitted from recordkeeping requirements.

One comment believes strongly that "packaging" is not "food" for purposes of the Bioterrorism Act. Even if FDA disagrees, the agency is urged to exclude from the recordkeeping obligation all materials that are separated from edible food by a "functional barrier." In other words, at a minimum, any materials that are separated from edible food by a functional barrier should be regarded as a type of "outer packaging" for which recordkeeping is not required. The comment states that FDA has long recognized the use of a functional barrier in determining what types of materials can be used in a packaging product. If a functional barrier (such as aluminum foil) is present in a packaging laminate, there is no expectation of migration of any material through the functional barrier. Therefore, the comment strongly requests that any materials on the exterior side of a functional barrier be excluded from the recordkeeping regulation. Because there is no expectation of migration of any material through a functional barrier, the likelihood that such materials could be used to adulterate food is extremely remote.

One comment states the reference to packaging does not mandate recordkeeping by packaging suppliers or transporters. Indeed, the reference to "packaging," in addition to "food," indicates a distinction between the two terms in the view of the drafters. The law and Congressional intent would be satisfied by a food processor maintaining records identifying the source of the finished packaging for the food product. In the unlikely event that food packaging is the target of terrorists, records in the hands of food processors regarding their packaging suppliers will allow FDA to follow the history of the packaging and its components. The regulation as proposed by FDA extends far beyond what was intended by Congress. To follow Congressional intent, the comment states FDA needs to revise the proposed regulation to provide only that food processors have records identifying the suppliers of their packaging.

(Response) FDA agrees with the comments in part. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 of this final rule (records access for existing records) with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of subpart J of this final rule. In addition, persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363 of this final rule. For example, a manufacturer and transporter of candy bar wrappers are not required to establish and maintain records as to the wrappers because they do not place food (candy bars) directly in contact with its finished container (wrappers). A manufacturer of candy bars, who places the candy bars in the wrappers, is required to keep records as to the sources of the wrappers and the recipients of the candy bars as a whole (not the candy bar and wrapper separately). Once the candy bar is placed in the wrapper, all persons who manufacture, process, pack, transport, distribute, receive, hold, or import the wrapped candy bar are required to keep records of the wrapped candy bar, but not to keep separate records with respect to the wrapper. FDA notes that the "food" in contact with the finished container refers to articles used by people in the ordinary way that most people use food primarily for taste, aroma, or nutritive value and not all substances defined as food by section 201(f) of the FD&C Act. The requirements for packaging and food contact substances are reflected in the following table.

TABLE B.—PACKAGING AND FOOD CONTACT SUBSTANCES

SUBSTANCE	ACTIVITY	COVERAGE
Packaging (Defined as the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances (§ 1.328).	Manufacture, process, pack, transport, distribute, receive, hold, or import	Excluded from all provisions of the rule unless person also engages in covered activity with respect to food, in which case subject to §§ 1.361 and1.363 (record access) (See § 1.327(i))
Food contact substance, other than the finished container that directly contacts food	Manufacture, process, pack, transport, distribute, receive, hold, or import	Excluded from all provisions of the rule, except §§ 1.361 and 1.363 (record access) (See § 1.327(j))
Finished container that contacts food	Place food directly in contact with its finished container	No exclusions, subject to record establishment, maintenance, and access (See § 1.327(k))
Finished container that contacts food	All other activities with respect to finished container	Excluded from all provisions of the rule, except §§ 1.361 and 1.363 (record access) (See § 1.329(k))

E. Comments on What Definitions Apply to This Subpart? (Proposed § 1.328)

1. General Comments

(Comment 63) One comment states that FDA should clarify the meaning of "responsible individual." The meaning of the term "responsible individual" is the same as other terms mentioned in other sections, such as "emergency contact." Moreover, it is not clear what responsibilities are included in this term.

(Response) FDA agrees with the comment that there is little utility for the record of each commercial transaction involving the distribution of food to contain the name of a responsible individual given that individuals change jobs within and among companies very often, making it unlikely that the person in the record will have responsibility for the food at issue when FDA seeks to effect a traceback. Therefore, FDA deleted the requirement that a name of a "responsible individual" be included in each record. To the extent this information is available, FDA will use the registration contact information for

facilities subject to registration requirements under § 1.232. FDA believes that, for facilities not subject to the registration interim final rule, an independent requirement to provide this emergency contact information with the records being kept will not be useful. The stated purpose of having such a contact name is to obtain help in accessing the records. However, to find that information, FDA would have already obtained the records without this emergency contact information.

(Comment 64) One comment states that FDA should clarify the meaning of "Adequate description." FDA must establish and publish the minimum parameters of the products description.

(Response) An adequate description of the food would include the brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce). This type of description saves time and resources during a tracing investigation because it allows FDA to narrow its focus to the appropriate product during the investigation.

(Comment 65) One comment requests that FDA clarify the meaning of "Holding."

(Response) FDA has defined "holding" in § 1.328 of this final rule to mean "storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks."

(Comment 66) One comment states that FDA uses the word "Importer" but does not define it.

(Response) The word "importer" does not appear in the final regulation. FDA will not define it for purposes of this regulation.

2. The FD&C Act

There were no comments on this issue.

3. Domestic Person

There were no comments on this issue; however, FDA has deleted the word "domestic" and instead defines the word "person" consistent with its definition in section 201(e) of the FD&C Act. FDA believes that the term "domestic person" is no longer needed because it is exempting foreign persons, except for foreign persons who transport food in the United States, from the requirements of subpart J of this final rule.

4. Farm

(Comment 67) Several comments assert that FDA's proposed definition of farm is too narrow and would require recordkeeping by farms that minimally process their produce for further marketing. The comments claim that many fresh produce farms incorporate packing and holding activities, and that minor manufacturing/processing activities should be considered incidental to the packing and storage activities. Accordingly, to give effect to the legislative intent to exclude farms, the comments argue that the definition of "farm" should include typical fresh produce post-harvest farming operations such as packing/packaging, washing, grading, waxing, sizing, cooling, application of inventory control items (e.g., price lookup stickers (PLUs) or universal product codes (UPCs)), conventional storage, controlled-atmosphere storage, transportation from the fields, transportation to storage or processing facilities, and transportation from the farm. According to the comments, these activities should be included in the definition of "farm" whether they are conducted in the field or in a packinghouse.

Some comments believe that the proposed definition of "farm" should be modified to include certain of the activities defined as manufacturing/processing, regardless of whether the foods that are the focus of these activities are consumed on that farm or one with common ownership or are offered for sale elsewhere, at least insofar as these activities relate to raw agricultural commodities. The comments state that the specific manufacturing/processing activities that should be included within the definition of "farm" are at least the following activities: Cutting, at least when this activity is applied to harvest of a farm crop; trimming; washing; labeling, at least when this activity is applied to containers that are not intended for direct consumer purchase; and packaging, at least when this activity is applied to containers that are not intended for direct consumer purchase. The comments also suggest that FDA should consider allowing farms to engage in milling and grinding without voiding the statutory exemption to section 306 of the Bioterrorism Act granted to farms, insofar as these activities are common farm activities.

(Response) In response to these comments and to ensure that FDA is fulfilling Congress's intent to exempt "farms," FDA has revised the definition of farm in the final rule to state that a "farm" means "a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both", and that "[w]ashing, trimming of outer leaves, and cooling produce are considered part of harvesting."

FDA considers several of the activities identified in the comments to be "packing or holding," including sorting, grading, wrapping, and boxing harvested food for the sole purpose of transporting this food off the farm. FDA also considers placing stickers on produce grown or consumed on a farm to be part of "packing." FDA notes that the definition of "farm" includes facilities that pack or hold food, provided all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. Thus, a farm that performs these packing and holding activities will not necessarily cease to be a farm and therefore cease to be exempt from these regulations. Similarly, FDA considers several of the activities identified in the comment (waxing, milling, and grinding) to be manufacturing/processing. A farm that performs these activities will not necessarily cease to be a farm because the definition of "farm" includes facilities that manufacture/process food, provided that all food used in these activities is consumed on that farm or another farm under the same ownership.

FDA is aware that a number of other activities may affect an establishment's status as a "farm" under this final rule. Thus, the agency is providing the following additional clarification. First, FDA considers application of a pesticide to a crop to be an integral part of growing and harvesting crops and therefore considers the activity to be covered by the "farm" definition. Therefore, an establishment devoted to the growing and harvesting of crops that applies a pesticide to its crops is a "farm" as defined in this final rule.

In addition, FDA recognizes that an activity such as placing a raw agricultural commodity directly into consumer-ready packages is likely to provide better protection to fragile produce, such as berries, than placing the produce into a larger bin or box for transport off the farm, with consumer packaging of the produce further down the distribution chain. "Manufacturing/processing" as defined in § 1.328 means "making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients." Thus, simply placing produce into containers (such as clamshells, baskets, mesh bags, or plastic bags) is more akin to packing, even if the containers are ultimately received by the consumer. Under § 1.328 of this final rule, a farm may engage in this packing activity so long as all of the involved produce is grown or consumed on the farm or a farm under the same ownership. Accordingly, a farm that simply places a raw agricultural commodity into containers, such as placing berries in clamshells, is not "manufacturing/processing."

Finally, a farm that transports its products from the field does not cease to be a "farm" because such transportation is considered incidental to traditional farming activities.

(Comment 68) One comment states that FDA's definition of "farm" should be size-neutral, and apply equally to integrated livestock and poultry facilities, as long as the activities engaged in at such locations are limited to "growing or raising" farm animals for human food, but do not extend to further processing of food-producing animals into meat, milk, or eggs (such as occurs at food processing and packing plants and rendering facilities) for subsequent commercial sale for humans or animals.

(Response) The proposed rule's definition of "farm" had no size limitation, and neither does the final rule's definition. FDA agrees that integrated livestock and poultry facilities are "farms," to the extent that these operations are devoted to raising animals for food, the growing of crops, or both, and otherwise engage in only those activities included in the farm definition. FDA considers milking cows and collecting eggs from chickens to be "harvesting" when applied to animals, because these activities are akin to harvesting crops.

5. Food

FDA received a number of comments regarding using the definition of "food" in section 201(f) of the FD&C Act, which includes food contact substances within its scope. These comments are addressed in section III.D.10, entitled "Food Contact Materials." For the reasons stated therein, FDA has decided to retain the definition of food as proposed; however, the final rule exempts persons who manufacture, pack, transport, distribute, receive, hold, or import food contact substances, other than the finished container that directly contacts the food, from all requirements of subpart J of this final rule, except §§ 1.361 and 1.363. Further, persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363 (regarding access to existing records).

6. Foreign Facility

(Comment 69) One comment asks whether "foreign facility" includes warehouses in ports belonging to shipping companies, land transport or air lines, sealed container deposits, public organization facilities of the foreign government and of other federal agency representatives (such as FDA or USDA) in the country of origin and/or shipment. Another comment states that FDA's definition of foreign facility is too inclusive. The comments suggest that only foreign manufacturers and exporters should be required to keep records of their partners, such as packing facilities and holding facilities.

(Response) FDA has deleted the definition of foreign facility in the final rule. FDA notes that foreign persons, except foreign persons who transport food in the United States, are excluded from all of these regulations in subpart J of this final rule.

7. Manufacturing/Processing

There were no comments on this issue.

8. Nontransporter

(Comment 70) Two comments state that many nontransporters own trucks or other vehicles and transport food as an incidental part of their operations. For example, many food distributors deliver food by truck to their customers and also may transport food returns. These entities should not be classified as transporters for their distribution practices that are incidental to the nontransporters' holding, processing, packing, importing, or receiving of food. The comments ask that the final rule clarify that an entity is either a transporter or a nontransporter, and that FDA will not consider the same entity a transporter for some purposes and a nontransporter for other purposes. The final rule should confirm that a food distributor is a nontransporter. A food distributor should not automatically be considered a transporter simply because it delivers food using its own truck fleet. If FDA were to consider the same company a transporter for some purposes and a nontransporter for other purposes, this would create tremendous confusion regarding what records are required to be retained.

(Response) Both the proposed and final rule define a transporter as a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food. A person who owns food, or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation is not a transporter, even if the person also transports food. In the example presented in the comment, a manufacturer that owned its own trucks to deliver food would not be considered a transporter. However, because FDA has exempted all foreign persons except those who transport food in the United States from this rule, foreign persons who transport food in the United States are subject to the requirements applicable to transporters regardless of whether that person has possession, custody, or control of the food for the sole purpose of transporting that food.

(Comment 71) One comment states that the proposed definition of "nontransporter" reads as follows: "Nontransporter means a person who owns food or who holds, processes, packs * * *" The same reference to a "person" is included in the definitions of "nontransporter immediate previous source" and "nontransporter immediate subsequent recipient." The comment asks whether the proposed rules apply to firms and other legal entities and/or physical persons. Any other solution would, in the comment's view, neither be appropriate nor practicable.

(Response) The maintenance and inspection of records provisions in section 306 of the Bioterrorism Act apply to "persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food." The term "person" has the same meaning as in section 201(e) of the FD&C Act and includes individuals, partnerships, corporations, and associations.

In addition, as explained further in response to comment 13, intra-company transfers of food are not subject to additional recordkeeping requirements. Once a covered person (including individuals, partnerships, corporations, and associations) receives food and keeps information on its immediate previous sources, that person or company does not need to keep additional records until it releases the food to another person or company. Unless otherwise exempt, at the time that person or company releases the food, it is required to identify the immediate subsequent recipients of that food.

9. Nontransporter Immediate Previous Source

There were no comments on this issue.

10. Nontransporter Immediate Subsequent Recipient

There were no comments on this issue.

11. Perishable Food

(Comment 72) Several comments propose that FDA use existing National Institute of Standards and Technology (NIST) Handbook 130 Regulations for Uniform Open Dating Definition for Perishable; Semi-Perishable and Long Term Shelf Life to define "perishable food." One comment states that the definition of "perishable food" proposed by FDA is inconsistent with prevailing regulatory definitions of that term. The NIST Handbook defines "perishable food" as "any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days of the date of packaging." "Semi-Perishable food" means "any food for which a significant risk for spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date of packaging." "Long Shelf-Life food" is defined as "any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than six months after the date of packaging, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container." These definitions have a history of use and acceptance by industry and government, and were developed 30 years ago by the National Conference of Weights and Measures, working in conjunction with state agencies responsible for the regulation of foods. The comments note that the National Conference undertook this task to assist in the establishment of a uniform method for presenting open code date labeling for foods. The definitions have since been adopted by numerous states and local jurisdictions with open date code regulations.

Several comments also question why records should be maintained for an additional 22 months after a product has been consumed. The comments state that 6 months is sufficient time to maintain records necessary for any traceback investigation related to food safety or security risks in the produce industry. One comment estimates that few, if any foods, would qualify as perishable as defined by FDA. The comment has identified only a few foods sold at retail that are "not heat-treated, not frozen and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions," namely bread, fish, and store prepared food.

One comment supports the following revised definition of the term "perishable food." Perishable food means food that may have been thermally processed or otherwise preserved in a manner so as to prevent the quality of the foods from being adversely affected if held for 90 days or less under normal shipping and storage conditions. The comment agrees with FDA's decision to divide the food products subject to the record maintenance requirement into perishable and nonperishable groupings, but disagrees with the 7-day aspect of the proposed rule's definition of perishable. In addition, the comment does not believe that whether a food has been subjected to heat treatment or thermal processing should be a factor in differentiating between perishable and nonperishable food. The comment's members consider as "perishable" those juice products that have a shelflife of 90 days or less. If 90 days was substituted for 7 days in the definition of "perishable," this would result in retention of records for perishable products for at least 4 times their shelflife.

One comment states that FDA should harmonize the Bioterrorism regulations with the other current regulatory provisions such as the Perishable Agricultural Commodities Act, where available. The definition for "perishable food" should include all fresh fruits and vegetables where the original kind or character has not been changed. The comment states that the effects of the following operations should not be considered as changing a commodity into a food of a different kind or character: Water, steam, or oil blanching; chopping; color adding; curing; cutting; dicing; drying for the removal of surface moisture; fumigating; gassing; heating for insect control; ripening and coloring; removal of seed, pits, stems, calyx, husk, pods, rind, skin, peel, etc.; polishing; precooling; refrigerating; shredding; slicing; trimming; washing with or without chemicals; waxing; adding sugar or other sweetening agents; adding ascorbic acid or other agents used to retard oxidation; mixing several kinds of sliced, chopped, or diced fruits or vegetables for packaging in any type of containers; or comparable methods of preparation. (For example, fresh iceberg lettuce, romaine and carrots would be included, as well as fresh-cut and packaged salads; fresh green beans would be included; frozen or canned green beans would not; fresh oranges would be included; frozen concentrated orange juice would not.)

One comment states that the proposed definition of "perishable food" excludes many products (including milk, which sometimes has a shelflife of up to 15 days) that are handled and treated as perishable in the food distribution system. The comment states that FDA should amend the definition so that perishable foods are those that are refrigerated or those that will be adversely affected if held longer than 20 days. The comment asserts that such a change would make the regulation more consistent with industry practice.

One comment states that the "perishable food" definition is confusing because the definition begins by stating that perishable foods are foods that are "not heat-treated, not frozen and not otherwise preserved * * * " Confusion arises because pasteurized milk is heat treated, and FDA's qualification of the three criteria is somewhat awkward and combined with an extensive use of negatives.

(Response) FDA agrees in part with the comments, but has decided not to define "perishable food" in this final rule. FDA defined perishable food in the proposal for the purpose of establishing a shorter record retention time for those foods as opposed to nonperishable foods. FDA has concluded that this objective can be achieved by inserting language directly in § 1.360(b) of this final rule using similar criteria as the NIST definitions for perishable, semi-perishable and long shelf-life food. FDA agrees that the proposed definition is too restrictive for purposes of these final regulations. Therefore, FDA has changed the record retention requirements in § 1.360(b) of this final rule to require record retention for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container. However, transporters, or nontransporters retaining records on behalf of transporters, are required to retain for 6 months records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving "perishable" food will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

(Comment 73) FDA requested comments on whether persons subject to the proposed rule always or usually know at the time a perishable food is released whether or not it is intended to be processed into nonperishable food. Two comments state that distributors have no way of knowing whether a perishable food will be processed into a nonperishable food by other parties. Buyers do not always disclose how the product will be used and may utilize it in more than one way. Therefore, producers of perishable food will have to retain records for the longer period, if they are held accountable for the further distribution and use of their products as nonperishable food.

(Response) FDA agrees with the comments that covered persons may not know at the time they release food if it is intended to be processed into a food that meets the 2-year record retention requirement. FDA clarifies that the retention period depends upon the status of the food at the time you release a food to your immediate subsequent recipient, regardless of whether it is intended or not to be processed into nonperishable food in the future.

12. Pet Food

There were no comments on the definition of pet food, however, FDA has decided to include all animal feeds, including pet food, under these regulations. Therefore, there is no longer a need to define the term "pet food" and FDA has deleted this definition from the final rule.

13. Recipe

(Comment 74) Three comments state that the proposed definition of recipe is internally inconsistent and ambiguous, and request clarification of its precise meaning. One comment characterizes the proposed definition as confusing and nearly nonsensical. The comment suggests that this definition be removed and that instead § 1.362 of this final rule be modified to add, for example, "Notwithstanding the exclusion of recipes for food from this subpart, all of the ingredients in a food are subject to this subpart."

Four comments state that the provisions in the proposed rule are inconsistent with the protection of recipes required by the Bioterrorism Act. The Bioterrorism Act and accompanying legislative history make it clear that the records authority does not apply to recipes. The comments urge FDA to further clarify that information on both the quantitative and qualitative ingredients in a proprietary formula are not covered by the proposed recordkeeping requirements or by the records access authority. According to the comments, in its ordinary meaning, a "recipe" includes three elements: The ingredients, the quantities, and the procedure. However, the fundamental element, and the one which in most cases is the most commercially sensitive, is the ingredient list. The comments state that it is not reasonable to define "recipe" to exclude the list of ingredients to obtain access to the list. The comments state that FDA is exceeding its statutory authority under the Bioterrorism Act.

Other comments are concerned about trade secret, sensitive, and/or proprietary information regarding recipe ingredients. One comment notes that food manufacturers are explicitly exempted from disclosing the specific contents of their flavor mixtures by section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)) and 21 CFR 101.4(b)(1) and 101.22(h)(1). The comment states that the purpose of this exemption is to protect a food manufacturer's trade secrets and excluding the identity of the individual ingredients of the food from the definition of "recipe" negates trade secret protection. The comment states that the complete lists of ingredients used in flavor formulas and seasoning blends are considered closely held trade secrets and should be considered part of the meaning of recipe. Flavors and spices are highly proprietary and, in many products, distinguish one manufacturer's product from another's. Disclosure on the label, or disclosure through the exercise of FDA's record access authority would be highly damaging to the food manufacturer whose "secret formula" entered the public domain. The comment states that it is unlikely that a product specific formulation would be relevant to an investigation. Therefore, the comment believes persons subject to the final rule should only have to establish and maintain records on nutrition facts.

Another comment similarly states that many products will be affected by the proposed definition, and ingredients and quantities must be protected. Many products are unique and were expensive to develop. Reverse engineering as well as trial and error can lead to duplication of products that can have very serious consequences for companies. FDA must find a solution to this challenge so as to not impede its investigations and at the same time protect the recipes of the involved companies.

(Response) FDA is changing the definition of "recipe" to clarify that a recipe consists of all three elements necessary to make a food: (1) A list of ingredients, (2) ingredient quantity information, and (3) instructions for combining the ingredients. Therefore, FDA is defining recipe to mean "the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe."

To address credible threats of serious adverse health consequences or death to humans or animals and to conduct tracing investigations, it is critical that FDA have access to the ingredients and the sources of the ingredients of food.

Some comments express concern about the disclosure of ingredients to the public. FDA understands the comments' concerns about protecting the confidentiality of nonpublic information. Several statutes and the agency's information disclosure regulations at parts 20 and 21 (21 CFR parts 20 and 21) govern the agency's ability to disclose information to the public. For example, section 301 of the FD&C Act prohibits any person from using to his own advantage or revealing, other than to the Secretary or other officers or employees of the Department, or to the courts, any information acquired under authority of section 414 and 704 concerning any method or process which as a trade secret is entitled to protection. Furthermore, the records provisions in the Bioterrorism Act recognize that FDA may obtain trade secret or confidential information and direct the Secretary to "take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of [such information]" (21 U.S.C. 414(c)). FDA is planning to reemphasize

in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained. Therefore, FDA disagrees that a manufacturer would be harmed by disclosing ingredient information to FDA.

Moreover, the FD&C Act currently requires manufacturers to disclose the ingredients they use to the public on food labels. One comment notes that section 403(i)(2) of the FD&C Act excludes spices, flavorings, and some colors from the label requirement. The exemption in section 403(i)(2) of the FD&C Act from disclosing specific spices, flavorings, and colors to the public on the label does not prohibit FDA from obtaining this information under the Bioterrorism Act. As previously discussed, if this information is legally protected from public disclosure, FDA will not release it to the public.

(Comment 75) A comment states that FDA's procedures for the exercise of its records access authority should embody recognition of the special status of confidential ingredients, as follows: First, FDA should provide that it will not routinely seek access to records that would require the disclosure of confidential ingredient information; second, if FDA concludes that it needs access to information about ingredients, it should present a written explanation to the custodian of the records that sets forth the basis for the agency's conclusion; and third, FDA should seek records access in an orderly manner, beginning with ingredients other than flavors and spices. The comment states that it will not be possible for FDA to assess simultaneously each ingredient in a product as the potential source of the problem that is being investigated. Given that flavor and spice information is highly confidential and that the low levels of use of those ingredients make it unlikely that one of them will be the source of the problem investigated, it is reasonable to provide that requesting information on flavors and spices will occur only as a "last resort." Finally, FDA should provide for special procedures to ensure that, when flavor and spice information is obtained, it is properly protected from disclosure, whether advertently or otherwise. The comment urges FDA to implement a system to adequately safeguard against the inadvertent release of proprietary and confidential information. Among other things, such information should be shared within FDA only to the limited extent necessary to conduct the particular investigation that resulted in the disclosure. The comment asserts that highly proprietary information about product formulas should not be widely distributed within the agency, and all persons who are made privy to the information should be reminded explicitly of the confidential nature of the information. Moreover, the comment states that FDA should amend its public information regulations to provide expressly that information obtained under the records access authority is exempt from disclosure under one or more of the exemptions under the Freedom of Information Act (FOIA) (5 U.S.C. 552).

(Response) FDA's procedure for accessing records is outside the scope of this final rule. FDA will consider these comments when it develops guidance for its investigations outlining how FDA intends to implement its access authority in section 414(a) of the FD&C Act. Such guidance will be subject to public comment under FDA's good guidance practice regulations (GGPs) § 10.115 (21 CFR 10.115).

14. Restaurant

(Comment 76) Many comments suggest that caterers supplying interstate conveyances are preparing meals for direct consumption by the consumer and should be excluded as restaurants. Some comments state that the manufacturer/processor of a sandwich should be treated the same, whether the sandwich is served in a restaurant, offered for sale in a vending machine, delivered as carryout, served on a hospital patient's tray, or served on a train or airplane. The comments note that, in the past, FDA has referred to "level playing fields." In this case, exempting of conveyance caterers is the only way to regulate even-handedly. If restaurants and retailers are to be exempt, these comments believe that caterers should also be exempt.

The comments further state that just because FDA has historically inspected the facilities providing food to interstate conveyances under the Public Health Service Act does not mean that these facilities should be considered processors under this security regulation. The comments view the proposed distinction between a snack bar on the train selling sandwiches to consumers for immediate consumption (considered an exempted restaurant) and a facility that provides the sandwiches to an airplane or train for later consumption (considered a covered processing establishment) as an arbitrary and illogical distinction, because they view the risk associated with that sandwich as the same between the two facilities.

The comments view their industry as similar to a large restaurant or hotel kitchen, which produces a wide variety of meals within a matter of hours. The comments state that inflight catering is not regulated under the same rules as a food processing plant because the same rules would not fit the inflight catering industry. Food in a processing plant may be prepared weeks to a year before consumption. The comments state that the only difference between the catering and the restaurant service is that the catering meals are generally consumed 1 to 4 hours after departing from the kitchen rather than immediately consumed, as in the restaurant industry.

(Response) FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not provide food directly to the consumer for immediate consumption. In fact, the food is prepared and provided to several possible intermediaries before reaching the consumer, such as the packer, transporter, and/or distributor, before reaching the interstate conveyance (e.g., airplanes, passenger trains, and cruise ships) that actually provides the food directly to the consumer for immediate consumption. FDA believes the risk is substantially higher when the food is not prepared and served directly to consumers for immediate consumption, but rather goes through a number of intermediaries before it reaches the consumer. In a traceback investigation, it is critical for FDA to be able to identify each entity that handled the suspect food. FDA would lose this ability if interstate conveyance caterers were exempted. In addition, this requirement is consistent with the registration interim final rule, which requires interstate conveyance caterers to register as manufacturers/processors.

(Comment 77) Several comments urge FDA to reconsider the proposed regulations for airline caterers. The comments state that these proposed requirements are onerous, unnecessary, and are being unfairly applied to that industry and would bury the industry in volumes of information. The comments note that the same rationale FDA used for partially exempting retail facilities should apply to airline caterers as well.

The comments further state that the airline catering industry currently must be in compliance with many Government regulatory agencies (FDA, Federal Aviation Administration (FAA), USDA, Environmental Protection Agency, Transportation Security Administration (TSA)), and that they have strict specifications for products and vendors, whereas most food service

operations do not. The comments also note that they currently employ security companies to monitor their staff, the food processes in which they prepare meals, the equipment the food items are loaded into, and the process of how it gets on board the aircraft. They also state that their customers have always expected traceability of all products used on their flights as part of their food safety and hygiene audits to resolve flight passenger complaints, food poisoning reports, and for other purposes, but not to the extent that is required by the proposed rule.

One comment states that it is a member of the International Flight Catering Association and International Inflight Food Service Association and adheres to practices of the "World Food Safety Guideline" as set forth by the two associations of inflight food services. Another comment states that all employees have been certified by the FAA through fingerprinting and 10-year background checks, and inhouse security personnel are responsible for checking what is placed on aircraft. Another comment maintains control of all inputs and outputs of production and states that documentation is in place for all items received and for all items produced.

(Response) For the reasons stated in response to comment 76 of this document, FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not provide food directly to consumers for immediate consumption. However, these final regulations state that duplication of existing records is not required if those records contain all of the information required by subpart J of this final rule. Therefore, if a covered person keeps records of all of the information as required by subpart J in order to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. As the comment notes, the airline catering industry currently has the capability to trace all food products on their flights. These regulations do not dictate the format or system in which the required records are maintained. The airline catering industry can use existing tracing mechanisms to comply with these regulations to the extent those mechanisms contain the required information.

(Comment 78) Some comments state that these proposed regulations would require a substantial and costly change in the way meals are delivered and processed. The comments urge FDA to consider whether the air and rail industries can bear the additional expense of these proposed regulations, as numerous ingredients are included in each meal that is prepared and boarded. The comments state that compliance with the traceability regulations depicted in the rule would require so many revamped processes and additional personnel that their organizations would likely not recover from the fiscal implications. The comments further state that they would have to completely change the way they produce and package meals for their customers, going to unprecedented lengths to ensure strict batch preparation. As an example, the comments note that with their current processes, they can determine shipment origin and location of the entire meal; however, it would be impossible to trace each individual ingredient going into the package. For example, meat from one lot number of ham could be put into sandwiches along with other ingredients from different sources and fruit or chips, and then loaded onto numerous flights. This level of batch control would make the production of these sandwiches and meals cost prohibitive.

The comments further state that the impact on the airline industry from September 11, 2001, has been tremendous. The airline industry is facing unprecedented challenges, and the way business is conducted has been altered forever. The comments note that reductions and bankruptcy filings by the various airlines have been extreme and have resulted in immense reductions in the airline catering business. The airlines' decisions to significantly cut back, eliminate food service, and reduce the load capacity on airplanes and number of flights continue to impact the interstate conveyance catering business. The comments urge FDA to consider these conditions because it will be difficult for the airline catering business to absorb the costs of proposed regulations into its current pricing structure. The comments conclude that they would be forced to pass these costs onto the already struggling airline industry.

(Response) For the reasons stated in the previous paragraphs, FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not prepare and sell food directly to the consumer for immediate consumption. However, the comment's concern about having to "go to unprecedented lengths to ensure strict batch preparation" misconstrues the proposed requirement. In the final rule, FDA deleted the requirement in § 1.337(a) for a nontransporter to provide information reasonably available to identify the specific source of each ingredient used to make every lot of finished product, and instead put that requirement in § 1.345(b) of this final rule because it is unlikely that a person would have that information reasonably available at the time records are created to identify the immediate previous sources of the food.

FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with outgoing product and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA's intent to mandate reengineering of long-standing existing processes. Accordingly, the final rule requires linking incoming with outgoing product only when this information is reasonably available.

Although the definition of restaurant has not changed from the proposed definition, FDA exercised its discretion and added language to the restaurant exclusion in § 1.327(b) of this final rule to account for incidental sales of food that a restaurant/retail facility does not prepare itself (e.g., food it purchases from a manufacturer for sale to consumers). See the discussion earlier in section III.E.14 of this document.

15. Retail Facility

As explained in response to comment 40 of this document, for purposes of § 1.327(e) of this final rule, "retail food establishment" is defined to mean an establishment that sells food products directly to consumers as its primary function. The term "consumers" does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including 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 consumers exceeds the annual monetary value of sales of food products to all other buyers. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from the requirements in subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of the document for a further discussion of FDA's rationale underlying this exclusion.)

16. Transporter

There were no comments on this definition. However, FDA is changing the definition to make clear that foreign persons that transport food in the United States are subject to these requirements regardless of whether they have possession, custody, or control of that food for the sole purpose of transporting that food.

17. Transporter's Immediate Previous Source

There were no comments on this definition.

18. Transporter's Immediate Subsequent Recipient

There were no comments on this definition.

19. You

There were no comments on this definition.

F. Comments on Do Other Statutory Provisions and Regulations Apply? (Proposed § 1.329)

There were no comments on this issue.

G. Comments on Can Existing Records Satisfy the Requirements of This Subpart? (Proposed § 1.330)

(Comment 79) Several comments state that the final rule requires additional or more detailed data than what is already maintained and recommend that the FDA and CBP work together with industry to avoid any unnecessary burdens. A few comments requested that we also work closely with TSA and FAA as those agencies consider modifications of their own rules. The comments urge close coordination between the FDA and those other agencies to avoid inconsistent or redundant regulations.

Several comments state that the proposed regulations do not strike a proper balance in that some of the data elements requested are unnecessary (redundant) and too burdensome on an industry already highly regulated by several agencies requiring the same or similar information. For example, the air cargo industry currently establishes and maintains industry air waybills, bills of lading and commercial invoices, which are required by CBP to be maintained for a period of 5 years. Moreover, CBP will be proposing a new set of mandatory advanced notice information, including other data elements, that could satisfy FDA in its effort to establish a complete tracing of activities.

(Response) FDA based the requirements of the final rule on what records are needed by the Secretary for inspection to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. Section 1.330 of subpart J of this final rule states that duplication of existing records is not required if those records contain all of the information required by subpart J. If a person keeps records of all of the information as required by subpart J to comply with other Federal, State, or local regulations (including those of TSA or FAA), or for any other reason, then those records may be used to meet these requirements. In addition, where a person currently has existing records that contain some, but not all, of the required information, only records for the nonexisting information needs to be created.

(Comment 80) One comment notes that CBP's current requirements would apply to a trucking company transporting imported food into the United States and manifest data would be maintained. The comment states that FDA could easily coordinate with CBP to get the data from them in the event a threat to the nation's food supply is discovered, rather than develop its own distinct recordkeeping regulations.

(Response) The Bioterrorism Act authorizes the Secretary (and, by delegation, FDA) to require the establishment and maintenance of records to address credible threats of serious adverse health consequences or death to humans or animals. As discussed in response to comment 79, subpart J of this final rule does not require duplication of existing records if those records contain all of the information required by subpart J. Therefore, to the extent information you keep for purposes of complying with CBP satisfies the provisions of subpart J, you do not need to keep duplicate records.

(Comment 81) One comment states that past situations have demonstrated that FDA already has a policy and good track record for finding and refusing adulterated products and products that could pose a problem to the American public. The comment questions how the final rule is going to improve upon existing recordkeeping.

(Response) As explained in the proposed rule (68 FR 25188), FDA has been involved in traceback investigations where not all necessary records were established and maintained to enable FDA to conduct a complete tracing investigation. By issuing these regulations, FDA believes that the likelihood of such a situation recurring will be reduced. As discussed in response to comment 93 of this document, for those covered persons already establishing and maintaining records that contain all of the required information in subpart J of this final rule, duplication of those existing records is not necessary. (See response to comment 2 of this document for further discussion on FDA's past experiences with traceback failures.)

(Comment 82) Several comments recommend that, for accuracy and regulatory consistency, the final rule should recognize that compliance with the bill of lading regulations of DOT's FMCSA will constitute compliance with the transporter's obligations under proposed § 1.352. The comments note that bills of lading and freight/expense bills for motor carriers are legal documents and contain sufficient information for the agency to be able to fulfill its Bioterrorism Act responsibilities. The information to be included on the bill of lading and freight/expense bills is prescribed by the United States Department of Treasury at 49 CFR 373.101 and 373.103.

(Response) FDA agrees in part with the comments. The final rule has been revised from the proposal. The final rule provides five alternatives for transporters to meet their obligation to establish and maintain records. First, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(a) of this final rule. Second, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(b) of this final rule, which are included within the current requirements for roadway interstate transporters under FMCSA regulations as of the date of publication of this final rule (49 CFR 373.101 and 373.103). Third, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(c) of this final rule, which are included within the current requirements for rail and water interstate transporters under STB regulations as of the date of publication of this final rule (49 CFR 1035.1 and 1035.2). Fourth, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(d) of this final rule, which are included with the current requirements for international air transporters under the Warsaw Convention. Fifth, transporters can meet the requirements of this final rule by entering into an agreement with a nontransporter immediate previous source in the United States or a nontransporter immediate subsequent recipient in the United States to keep records for them. Such agreements must

contain the elements specified in § 1.352(e) of this final rule. Failure by the immediate previous source or immediate subsequent recipient who enters into an agreement under § 1.352(c) of this final rule to keep such records is a prohibited act under § 1.363 of this final rule.

FDA notes that the FMCSA and STB regulations only apply to interstate transporters, and this final rule applies to both interstate and intrastate transporters. Intrastate transporters will be subject to the requirements of this final rule because FDA has determined that imposing such requirements on intrastate transporters comports with the Constitution, and these requirements are necessary to allow FDA to identify the immediate previous sources and immediate subsequent recipients of food in order to address credible threats of serious adverse health consequences or death. Intrastate transporters can meet this obligation by complying with either § 1.352(a), (b), (c), (d), or (e) of this final rule.

As a practical matter, because the final rule's requirements for interstate shipments can be satisfied by existing records relating to interstate shipments, the final rule only establishes new requirements for (1) *intrastate transporters*; and (2) *intrastate shipments* conveyed by *interstate transporters*. FDA estimates that there are approximately 115,000 intrastate carriers, and based on DOT data, almost one million commercial drivers report intrastate travel. In reviewing the truck tonnage by commodity, approximately 12 percent of the intrastate shipments are of FDA-regulated food products. The average distance these products are shipped is 231 miles, which means many shipments are intrastate, especially in the larger western states.

For some foods, distribution may be limited primarily to intrastate transportation, depending on the time of year and state. Many businesses have their own delivery trucks that are used intrastate, several use employee vehicles for deliveries, and many rent vehicles to deliver product. These vehicles are used to deliver all types of food products—refrigerated, cooked, as well as fresh food and produce, and grocery items. Some local firms pick up their own merchandise from "warehouse" facilities to stock their own locations. Many of these "warehouses" (commonly referred to as "bin warehouses") may receive product via interstate transporter and subsequently deliver to a variety of intrastate retail customers via many different intrastate means.

Data on the volume of foods that move in intrastate commerce are maintained by individual state Departments of Agriculture and by DOT. For example, from CA, LA, TX alone, DOT reports over 12 percent of intrastate truck tonnage is FDA-regulated products. Past traceback investigations provide examples of the need to regulate intrastate transport. For example, in 2003, there were two produce-associated outbreaks that occurred in CA from intrastate shipments. There were also two *Salmonella enteritidis* outbreaks in WI associated with intrastate shipments of eggs. Other foods, such as pasteurized milk, nearly all raw products, seafood, and sprouts, may be shipped either intrastate or interstate depending on the production or processing site.

Most seafood consumed in FL is transported only intrastate, but in OK, most seafood is transported interstate. In 2002, there was an outbreak in NJ and FL linked to seafood. Intrastate records assisted us in pinpointing the portion of the Indian River, FL that was causing the problem. In reviewing egg tracebacks from 1996 to 2003, 35 percent of the tracebacks that resulted in farm investigations were intrastate. This past summer, the state of Oregon (OR) was able to stop a sprout-associated outbreak from becoming a serious one by tracing back to a WA sprouter just over the border from OR after some initial cases but before the *Salmonella* serotype had been identified. The sprouts were recalled. If the sprouter had been located in OR so that the sprouts were not transported interstate, it would have been problematic to a traceback investigation for FDA to be limited to records only from interstate transporters.

The NC green onion traceback investigation in 2003, which was part of the largest Hepatitis A outbreak that has ever occurred in the United States, is another example of the importance of intrastate records. There, the amount of time spent on the traceback within that State was twice as long as the other three tracebacks done in other states because the distributor in NC did not have records. Traceback from the TN outbreak took over a month, the GA traceback took a month, and Pennsylvania (PA) traceback took a week. Because we had no intrastate records in the NC outbreak, the traceback was determined to be inconclusive after two months, which meant that we would not have been able to identify the farms involved if it had not been for the other outbreaks.

This year, there was an *Escherichia coli* (*E. coli*) O157:H7 outbreak associated with bagged lettuce product in CA that was only in intrastate commerce. That traceback might have been lost had records not have been available. Exempting intrastate transporters could significantly impede FDA's ability rapidly and effectively to respond to a public health emergency involving a food transported within a state, particularly if the adulteration occurred during transport and the food was delivered to multiple sources within the State. In scenarios where time is of the essence to prevent serious injuries or death on a large scale, having records available becomes even more critical. In addition, not only must FDA be able to rapidly obtain records, it is imperative that FDA be assured that those records contain certain essential information to allow FDA to prevent further harm in an efficient and effective manner.

Additional examples of circumstances involving food products that have significant intrastate manufacturing/processing or distribution are provided in the following paragraphs:

- An intrastate sandwich/snack food company that sells to retail outlets for consumption had an outbreak of *Listeriosis* or *Salmonellosis* that was traced back to the sandwiches. The product was completely distributed using the company trucks within the state. FDA was unable to determine which sandwiches caused the outbreak. The sandwiches were delivered to retail customers, and it was impossible to track which sandwiches went to which retailer. The transporter did not track which product was delivered to which location. In this case, the firm had to recall all of its products.
- Retail stores regularly purchase food, especially locally grown produce, from "truck farmers." These farm trucks travel from store to store within a state, sometimes selling an entire truckload to a store, other times a portion. There is no manifest or record other than a bill of sale—e.g., 200 cantaloupes from Farmer Brown. If the contamination occurred on the truck, FDA would not have a record from the truck of all other delivery sites.
- Several days into the investigation of a Hepatitis A outbreak from chicken salad in one city, FDA learned that the chicken was "cubed" at another facility in another city within the state, and transported to the "manufacturing facility." The source of the outbreak was the site where the chicken was "cubed" by an ill employee; however, there were no records to indicate when the cubed product was shipped or received by the salad manufacturing facility.

(Comment 83) One comment suggests that the final regulation should clarify that "transportation record" includes the various documents that may be developed by a company that contain the information specified in the regulation. They do not believe that it would be necessary to include all of this information in one shipping document. The comment notes that industry currently collects much of the data that would be requested by FDA but these data are not found in one document, and in some instances, may be found at various locations within the manufacturing facility. Significant time and expense could be involved in making the modifications to the company's computer and recordkeeping systems to have a system that develops a transportation record that contains all of this information on one form. Such a requirement would be unreasonably onerous, particularly if the company's system is designed to make certain that the company can provide all of this information to the agency within the specified time. The respondent asks the agency to clarify in the final rule that it is not necessary to develop one transportation record that contains all of the information in a single form.

(Response) FDA confirms that it is not necessary to develop one record that contains all of the information. FDA's intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations. The final regulation has been clarified to explicitly provide in § 1.360 that you must create the required records when you receive and release food, except to the extent that the information is contained in existing records. FDA is requiring that specific information be kept by a covered person, but is not specifying the form or type of system in which those records must be maintained. The required information may be contained entirely in one record or spread among many different records. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records are available to FDA under the record availability requirements in § 1.361 of this final rule.

(Comment 84) A few comments note that the recordkeeping requirements under existing FDA regulations, such as Substances Prohibited From Use in Animal Food or Feed (21 CFR part 589), Current Good Manufacturing Practice for Medicated Feeds (21 CFR part 225), and Fish and Fishery Products (seafood Hazard Analysis Critical Control Point (HACCP)) (21 CFR part 123) should be sufficient and deemed adequate to meet the requirements under the Bioterrorism Act and that FDA should not introduce additional, stand alone, recordkeeping systems.

(Response) As discussed in response to comment 79, § 1.330 of the final regulation states that duplication of existing records is not required if those records contain all of the information required by subpart J of this final rule. That includes records kept under the regulations identified in the comment.

(Comment 85) One comment states that it would be beneficial if FDA announced the suitability of records kept under existing requirements well ahead of the implementation deadline under the Bioterrorism Act.

(Response) FDA is not able to determine what records currently exist throughout the entire food industry that satisfy these regulations due to the diversity and complexity of the food industry and the various existing Federal, State, and local regulations that require recordkeeping, as well as varying business practices. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records are available to FDA under the record availability requirements in § 1.361 of this final rule. FDA points out that the earliest compliance date of this final rule is December 9, 2005, and that many persons are not required to comply with this final rule for up to 2 years after publication. Therefore, FDA believes that it has provided sufficient time for persons to determine what, if any, additional information must be kept to comply with these provisions well ahead of the compliance date of this final rule.

(Comment 86) A few comments note that most food companies currently maintain the chain of distribution information that FDA proposed, but the diversity and complexity of the food industry means that the information is maintained in many different ways and formats, ranging from computerized records systems to file folders of paper records. The comments state that it should be of no concern to FDA and, therefore, not the subject of the regulations to prescribe any specific manner or form of maintaining the information.

(Response) As discussed in response to comments 1 and 83 of this document and in the proposed rule, FDA's intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations. FDA is requiring specific information be kept by a covered person, but not specifying the form or type of system in which those records must be maintained. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records be made available to FDA under the record availability requirements in § 1.361 of this final rule. To satisfy the requirements in this final rule, paper or electronic records or a combination of the two may be used.

H. Comments on What Information is Required in the Records You Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Sources and Immediate Subsequent Recipients? (Proposed §§ 1.337 and 1.345)

1. General Comments

(Comment 87) Several comments state that the information required by the recordkeeping regulations exceeds the information required by the Bioterrorism Act, thereby exceeding FDA's statutory authority. Some of these comments state that according to the Bioterrorism Act, the regulations need to provide that those persons subject to the recordkeeping requirement maintain the "one-up and one-back" information in a records maintenance system in which the information is reasonably accessible to FDA upon request. The comments ask that FDA consider the diversity and complexity of the food industry and allow for more flexibility. They contend that the name and address of the person from whom an article of food was received or to whom it was shipped and a description of the article of food should be sufficient. The comments further suggest that not all companies require or need the same type of identification as other members in the food chain, e.g., lot numbers and identity preserved ingredients. They request that, because of this diversity in the supply chain, the agency not define rigid identification requirements. The comments contend that this flexibility is in keeping with the intent of the Bioterrorism Act and will avoid dramatic changes to what are currently efficient and effective business practices.

(Response) FDA disagrees that the information required by the rule exceeds FDA's authority under the Bioterrorism Act. The Bioterrorism Act authorizes FDA to require records needed to "allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death in humans or animals." FDA believes the information it is requiring to be

established and maintained meets this standard.

Information such as the specific name of the food will allow FDA to limit its investigation to the implicated food. For example, if FDA has a reasonable belief that a shipment of cheddar cheese is contaminated, traceback or trace forward would be better facilitated if the records contained the identifier "cheddar." This would help FDA narrow its investigation and increase the speed of the trace. The information would also help the involved firm limit the scope of any recall, should it be necessary. However, FDA does recognize the diversity of the food chain and has allowed for flexibility in the final rule. For example, the requirement to record lot/code number or other identifier applies only to persons who manufacture, process, or pack food and only to the extent that information exists. Also, the final rule allows covered persons to use existing abbreviations or codes currently used to identify the food. However, if these abbreviations and/or codes are used, they must be readily deciphered for FDA upon request so that an "adequate description" of the food is recorded.

(Comment 88) One comment questions the need for the extensive recordkeeping requirements in the regulations and suggests that much of the facility information required in the recordkeeping rule is already required in the registration interim final rule. The comment gives as an example the duplicate requirements that the nontransporter must maintain a record of the responsible individual, fax number, and e-mail address for: (1) The facility that shipped product to your facility, (2) the transportation company that delivered the product, (3) the transportation company that picked up product from your facility, and (4) the facility where your product is being shipped.

(Response) FDA does not agree that much of the information required under this recordkeeping rule is already required under the registration interim final rule. Information required under the registration interim final rule pertains to the facility itself, including information about the general food product categories that the facility manufactures/processes, packs, or holds. Information that this final rule mandates be established and maintained in records is information pertaining to food that will assist FDA in identifying the immediate previous sources and the immediate subsequent recipients of all food that is received and released by a person. In addition, to complete the tracing investigation, the identity of the transporters who transported the food to and from the sources and recipients is required, which is not covered by the facility registration. Moreover, the scope of section 305 of the Bioterrorism Act (registration) is not as broad as section 306 of the Bioterrorism Act (establishment and maintenance of records). Specifically, registration applies only to facilities that manufacture, process, pack, or hold food for consumption for humans or animals in the United States. Recordkeeping applies to these facilities, as well as those who transport, distribute, receive, or import food. Recordkeeping also applies to all food regardless of whether it will be consumed in the United States or exported.

However, FDA has deleted the requirement that persons subject to subpart J of this final rule identify a responsible individual in the records. Instead, for those facilities required to register under part 1, subpart H, FDA will use the emergency contact telephone number provided by those facilities. For other facilities, FDA does not believe requiring such facilities to provide an emergency contact telephone number is needed to assist the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, since that telephone number would be contained in the very records FDA would be seeking assistance in locating.

(Comment 89) One comment states that it is unreasonable to require nontransporters to have a record of the intermediate transporters, i.e., transporters who do not have direct contact with the nontransporters.

(Response) Neither the proposed rule nor the final rule requires nontransporters to establish and maintain records identifying intermediate transporters. With respect to transportation records, § 1.337(a)(6) of this final rule only requires nontransporters to establish and maintain records of the transporter that brought the food to them. Similarly, § 1.345(a)(6) of this final rule only requires nontransporters to establish and maintain records of the transporter that took the food from them. The transporters are required to keep records that identify intermediate transporters.

(Comment 90) One comment states that some firms use carriers such as United Parcel Service, Federal Express, and the United States Postal Service to deliver their products and conduct all their transactions with these carriers via the Internet. The address and fax numbers of these carriers are not relevant. The comment requests that FDA revise the section on identifying information of the transporter to require only "sufficient identifying information."

(Response) FDA disagrees with this comment. In the event that FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, FDA would need to determine from the source and recipient records who transported the subject food to complete the tracing investigation. Although the transportation may be arranged over the Internet, companies such as those mentioned in the comment have fixed addresses, such as a corporate headquarters, that would need to be included in the record so that if FDA had to access their existing records under section § 1.361 of this final rule, FDA would know where to go.

(Comment 91) One comment states that wines produced in France are sold by someone other than the producer and that the producer never knows the destination of the wine. The comment states that the recordkeeping requirement is an unnecessary burden on the producer because much of the producer's wine may be sent to destinations other than the United States.

(Response) There is no requirement for a person that manufactures or processes food to know the ultimate destination of its product. A person subject to subpart J of this final rule is only required to establish and maintain records to identify the transporter and nontransporter immediate previous sources and transporter and nontransporter immediate subsequent recipients of food. Further, FDA notes that it has excluded all foreign persons, except foreign persons who transport food in the United States, from all of the regulations in subpart J.

(Comment 92) One comment requests clarification on the records requirements for products produced before the regulations take effect.

(Response) Covered persons are required to establish and maintain records to identify the immediate previous sources and the immediate subsequent recipients of all food as of the compliance date of this final rule, keeping in mind the staggered compliance dates provided in § 1.368 of this final rule. If a food was received before the compliance date of this final rule, then there is no obligation to keep records of the immediate previous sources of that food. If a food is released on or after the compliance date of this final rule, you must establish and maintain records of the immediate

subsequent recipients of the food, regardless of when that food was produced or received.

2. Information Reasonably Available to Identify the Specific Source of Each Ingredient

(Comment 93) A few comments state that the requirement to keep records that identify the specific source of each ingredient to a lot of finished product exceeds the intent of the Bioterrorism Act. One comment adds that the language in the Bioterrorism Act clearly authorizes a regulation to require the maintenance of records that show the person from whom a product is received and the person to whom a product is sent. The comment states that there is nothing in the language of the Bioterrorism Act or in its legislative history that would support including a requirement that products received be directly associated with products that are shipped.

(Response) FDA does not agree with these comments. Section 306(b) of the Bioterrorism Act expressly states that the Secretary

* * * may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, *which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging*, in order to address credible threats of serious adverse health consequences or death to humans or animals" (emphasis added).* * *

Thus, the Bioterrorism Act clearly gives FDA the authority to determine what records are needed to achieve this objective.

The final rule contains those requirements that FDA has determined are necessary to help FDA identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals. If FDA cannot immediately narrow its tracing to a specific source, tracing becomes much more difficult and time-consuming, there is an increased risk to consumers, and some food sources may be unfairly implicated. FDA notes, however, that the final rule (§ 1.345(b)) only requires nontransporters to identify the specific source of each ingredient that was used to make every lot of finished product to the extent such information is reasonably available.

(Comment 94) A few comments state that they are not able to provide information that ties the specific source of each ingredient to a lot of the finished product. Several comments agreed with FDA's decision to require identification of the specific source of an ingredient in a finished product only when the information is "reasonably available." Some comments request that the agency make clear in the final rule that, in many instances, it will be impossible to identify the specific source of a material that is held in bulk and that multiple sourcing information in recordkeeping is to be anticipated for raw materials that are held in bulk form.

Several other comments state that, because their ingredients are commingled, they are unable to provide FDA with information that ties the specific source of each ingredient to a lot of the finished product. Certain bulk products such as flour, shortening, vegetable oil, fructose syrup, and milk cannot be identified as ingredient lots. Other comments state that the ability to identify specific sources of ingredients will vary based on many factors. One comment states that produce is often commingled to meet marketplace needs. A few comments state that some processors commingle ingredients in their processing operations, which makes it impossible to trace the specific source of ingredients to a lot of finished product. One comment states that most companies would only be able to produce possible sources of ingredients in batches of final products. The comment asserts that companies should only be required to do so in a crisis.

(Response) FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with outgoing product and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA's intent to mandate reengineering of long-standing existing processes. For this reason, the final rule requires the identification of the specific source of each ingredient that was used to make every lot of finished product only when the food is released and only if this information is reasonably available. With respect to the comment that companies should only be required to produce records during a crisis, the agency notes that FDA will request access to the records under section 306 of the Bioterrorism Act only when it has reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 95) One comment requests that the agency accept testing of each delivery of incoming product as a substitute for the requirement to tie the specific source of each ingredient to a lot of the finished product. The comment asserts that this testing provides the needed safeguards and would ensure that the ingredient is not contaminated chemically, physically, or biologically.

(Response) The agency does not agree with this comment. The comment fails to specify the nature of the chemical, physical, or biological tests being proposed, or what sampling scheme would be conducted to ascertain that the incoming ingredient is not contaminated. Moreover, only nontransporters are required to identify the specific source of each ingredient that was used to make every lot of finished product, and they are required to do so only if this information is reasonably available. FDA also notes that it has deleted this provision from § 1.337(a) of this final rule and instead inserted it in § 1.345(b) of this final rule. The agency believes records are more likely to be reasonably available to persons when they release food made from the ingredients than when the persons receive the ingredients under § 1.337 of this final rule.

(Comment 96) A few comments request that the agency treat processing aids and incidental additives as it does commingled ingredients. The comments state that they are able to identify the source(s) in use in a facility when specific food products were produced, but are not able to identify the source of the processing aid or incidental additive used to produce a specific lot of food.

(Response) The recordkeeping requirements in these regulations apply to all food unless specifically exempted. Processing aids may be food additives or a generally recognized as safe ingredient. In either case, they fall within the definition of food and are subject to these regulations. If the manufacturing process is such that a processing aid was used to make a specific lot of a finished food product, then the specific source of each processing aid should be identified in the records to the extent that information is reasonably available.

(Comment 97) Several comments ask that the agency clarify the term "reasonably available" and provide guidance on what the agency considers is "reasonably available." One comment suggests that the agency use hypothetical case studies as guidance.

(Response) What is "reasonably available" is going to depend on the particular circumstances. To illustrate this point in the proposed rule, FDA used a hypothetical case of a cookie maker. (See 68 FR 25188 at 25197.) A company that bakes cookies may source flour from five different companies rather than depend on a single company as its supplier. The flour from the five companies may be stored in one common silo before being used in the manufacture of the cookies. In this scenario, the manufacturer could identify, depending on the date the flour was received from each company and placed in the silo and when the silo was emptied, the various companies that were the sources of the flour. Under this situation, the information is not reasonably available to determine a single source of the flour used in a particular lot of cookies. The information reasonably available to the manufacturer would be the identity of all of the potential sources of the flour for each finished lot of cookies. However, if the manufacturer had dedicated silos for each supplier of flour, then the information would be reasonably available to the manufacturer to specify the specific source of the flour for each finished product. If we determine that additional guidance is needed, FDA will consider issuing guidance in the future to explain this requirement further. Again, FDA notes that this requirement now appears in § 1.345(b) of this final rule and has been deleted from § 1.337(a) of this final rule.

(Comment 98) One comment states that manufacturers of packaging face the same issues as processors who deal with commingled ingredients. The comment explains that, during the manufacture of multiple-layer packaging products, it is common to use multiple lots of raw material within a master roll of semifinished or finished product. An example of this condition would be a paper/foil lamination where one roll of foil and three to four rolls of paper are used in the same production run. In this situation, the lot numbers of the raw materials and the lot numbers of the finished products may be known, but it cannot be determined with precision which lot of the input materials is in an individual roll of finished product.

(Response) Manufacturers of packaging (the outer packaging of food that bears the label and does not contact the food) are excluded from all requirements of subpart J of this final rule unless such persons also manufacture, process, pack, transport, distribute, receive, hold or import food in the United States, in which case they are subject to §§ 1.361 and 1.363 of this final rule as to the food's packaging. Manufacturers of food contact substances, whether or not the substances are the finished container that directly contacts the food, are excluded from all of the requirements of subpart J, except §§ 1.361 and 1.363 of this final rule. Therefore, such manufacturers are not required to know which lot of the input materials is in an individual roll of finished product.

(Comment 99) Several comments request that the agency clarify the term "ingredient" with respect to distilled spirits that have innumerable sources of ingredients dependent upon the category and particular brand. The comments state that there is a question of interpretation as to what is meant by ingredients, given that the distilling process changes substantially the character and chemical composition of the raw materials and some of them may even be absent from the final product.

(Response) Alcoholic beverages are within the definition of "food" in § 1.328 of this final rule. A manufacturer of alcoholic beverages is required under § 1.337 of this final rule to identify the source of each ingredient that was received to make the alcoholic beverage, regardless of whether it later changes character and chemical composition.

(Comment 100) One comment suggests that the agency reconsider the requirement for immediate previous sources of bottled water. The comment asserts that the detail of records required under the regulations will not exist in many cases because the bottled water source will be directly out of the ground and that the bottler will capture any potential concerns of a serious threat of adverse health consequences. The comment suggests that water be viewed as other primary agricultural food ingredients.

(Response) Bottled water is within the definition of food as defined in § 1.328 of this final rule. If water is obtained from a public water system, then the public water system is the immediate previous source. If ground water is used, then the location where the water was extracted should be provided.

(Comment 101) One comment recommends that, in requiring a record of the raw material of a product, the agency should limit its requirement to that of major ingredients of the product.

(Response) FDA does not agree with the comment. The comment neither explains what distinguishes a major ingredient from a minor one, nor why the agency should limit its requirement to "major" ingredients only. Even if an ingredient is present only in small quantities, it may pose a risk and could be the focus of an intentional attack (e.g., the deliberate addition of a chemical toxin or pathogens), which would further contaminate food products to which they are added.

3. Requirement to Record Responsible Individual

(Comment 102) Several comments object to the requirement to name a responsible individual as duplicative of a requirement in the registration interim final rule. The majority of these comments ask that FDA use the emergency contact information required in the registration interim final rule in place of the responsible individual. The comments suggest that using the emergency contact information would give the agency rapid access to the information and provide the industry with flexibility. The comments state that there is no demonstrated need for the record of each commercial transaction involving the distribution of food to contain the name of a responsible individual, and that the requirement for a responsible individual is too rigid, as there is a high turnover of employees in many companies and the naming of a specific person as the responsible individual would require frequent updating.

(Response) FDA agrees with the comments that there is little utility from requiring that the record of each commercial transaction involving the distribution of food contain the name of a responsible individual, due to the fact that individuals change jobs within and among companies very often, making it unlikely that the person named in the record will have responsibility for the food at issue when FDA seeks to effect a traceback. FDA further notes that, for those facilities required to register under part 1, subpart H, FDA already has the emergency contact designated in the registration under §§ 1.232(d) and (e) and 1.233(d) or § 1.233(e). As explained previously, FDA does not believe this information is necessary for those facilities not required to register under 21 CFR part 1, subpart H, because including an emergency contact telephone number in records being kept will not assist the Secretary in locating the records because FDA would not have the emergency number until it had already accessed the records.

(Comment 103) Some comments suggest that, rather than requiring a specific individual, the agency require a department such as a quality assurance department.

(Response) As explained in response to comment 63 of this document, FDA has deleted the proposed requirement that a responsible individual be listed in each record.

4. Adequate Description of Type of Food

(Comment 104) One comment notes that "specific variety" is not appropriate