DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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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 [*insert date 60 days after publication in the* **Federal Register**].

Compliance Dates: The compliance date is [*insert date 12 months after date of publication in the* **Federal Register**]; except that for small businesses employing fewer than 500, but more than 10 full-time equivalent employees, the compliance date is [*insert date 18 months after date of publication in the* **Federal Register**]; and except that for very small businesses that employ 10 or fewer full-time equivalent employees, the compliance date is [*insert date 24 months after date of publication in the* **Federal Register**].

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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 [*insert date 12 months after date of publication in the* **Federal Register**], except that the compliance date for small businesses employing fewer that 500, but more than 10 full-time equivalent employees is [*insert date 18 months after date of publication in the* **Federal Register**], and the compliance date for very small businesses that employ 10 or fewer full-time equivalent employees is [*insert date 24 months after date of publication in the* **Federal Register**].

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 [*insert date 12 months after date of publication in the* **Federal Register**]. Small businesses have [*insert date 18 months after date of publication in the* **Federal Register**] of this final rule to come into compliance with these regulations, and very small businesses have [*insert date 24 months after date of publication in the* **Federal Register**] 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 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)).* * *

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 & Dryers, Inc.*, supra.

Even before the Bioterrorism Act amendments, the term ''food'' was not given an identical meaning throughout the FD&C Act. For example, in construing the parenthetical ''(other than food)'' in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit noted that Congress meant to exclude only ''articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value'' and not all substances defined as food by section 201(f) of the FD&C Act. *Nutrilab, Inc.* v. *Schweiker*, 713

F.2d 335, 338 (7th Cir. 1983). Similarly, section 409(h)(6) of the FD&C Act 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,''

[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.

''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, 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