Federal Register

Thursday,
December 9, 2004

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11

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and Response Act of 2002; Establishment and Maintenance of Records for Foods; Notice of Public Meeting; Availability of Draft Guidance for Records Access Authority; Final Rules and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. 2002N–0277]

RIN 0910–AC39

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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

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

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

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Legal Authority
II. Highlights of the Final Rule and Summary of the Significant Changes Made to the Proposed Rule
A. Highlights of This Final Rule
B. Significant Changes FDA Made to the Proposed Rule
III. Comments on the Proposed Rule
A. General Comments
B. Foreign Trade Issues
C. Comments on Who is Subject to This Subpart? (Proposed § 1.326)
D. Comments on Who is Excluded From All or Part of the Regulations in this Subpart? (Proposed § 1.327)
E. Comments on What Definitions Apply to this Subpart? (Proposed § 1.328)
F. Comments on Do Other Statutory Provisions and Regulations Apply? (Proposed § 1.329)
G. Comments on Can Existing Records Satisfy the Requirements of this Subpart? (Proposed § 1.330)
H. Comments on What Information is Required in the Records You Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Source and Immediate Subsequent Recipients? (Proposed §§ 1.337 and 1.345)
I. Comments on Who is Required to Establish and Maintain Records for Tracing the Transportation of All Food? (Proposed § 1.351)
J. Comments on What Information is Required in the Transportation Records? (Proposed § 1.352)
K. Comments on What Are the Record Retention Requirements? (Proposed § 1.360)
L. Comments on What Are the Record Availability Requirements? (Proposed § 1.361)
M. Comments on What Records Are Excluded From this Subpart? (Proposed § 1.362)
N. Comments on What Are the Consequences of Failing to Establish and Maintain Records or Make Them Available to FDA as Required By This Subpart? (Proposed § 1.363)
O. Comments on What Are the Compliance Dates for This Subpart? (Proposed § 1.368)
IV. Analysis of Economic Impacts—Final Regulatory Impact Analysis
A. Summary of the Costs and Benefits of the Final Rule
B. Description of Proposed Rule
C. General Comments
D. The Tradeoff Between Costs and Risk Reduction
E. Estimating the Benefits
F. Costs
G. Summary of the Costs and Benefits of the Final Rule and Policy
V. Final Regulatory Flexibility Analysis
VI. Unfunded Mandates
VII. SBREFA
VIII. Paperwork Reduction Act of 1995
IX. Analysis of Environmental Impact
X. Federalism
XI. References

I. Background and Legal Authority

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

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

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

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

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

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

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

A. Highlights of this Final Rule

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

- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in part 1 (21 CFR part 1) subpart J of this final rule (i.e., recordkeeping and access requirements);
- The following persons or facilities are excluded from all of the regulations in subpart J of this final rule: Farms; restaurants; those performing covered activities when the food is subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*); and foreign persons, except foreign persons who transport food in the United States.
- The following persons or facilities are excluded from the requirement to establish and maintain records in §§ 1.337 and 1.345 of subpart J of this final rule, but are subject to the record availability requirements in §§ 1.361 and 1.363 for existing records: (1) Fishing vessels not engaged in processing as defined in § 123.3(k) (21 CFR part 123.3(k)); (2) retail food establishments that employ 10 or fewer full-time equivalent employees; (3) nonprofit food establishments that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States; and (4) persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart J of this final rule.
- Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J of this final rule as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J of this final rule as to the finished container, except §§ 1.361 and 1.363.
- Persons who distribute food directly to consumers are excluded from the requirement in § 1.345 to establish and maintain records to identify the immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.
- Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of subpart J of this final rule.
- Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of subpart J of this final rule.
- The regulations in subpart J of this final rule do not require duplication of existing records if those records contain all of the information required by the subpart. Furthermore, persons can supplement existing records with any new information required by this final rule instead of creating an entirely new record containing both existing and new information.
- Persons who manufacture, process, pack, distribute, receive, hold, or import food in the United States must establish and maintain the following records to identify the immediate previous sources and immediate subsequent recipients for all food they receive and release, unless otherwise excluded from the requirements of subpart J of this final rule:
- Name, address, telephone number and, if available, fax number, and e-mail address of the immediate previous source and subsequent recipient;
- Adequate description;
- Date received or released;
- For persons who manufacturer, process, or pack food, the lot or code number or other identifier;
- Quantity and how the food is packaged; and
- Name, address, telephone number and, if available, fax number, and e-mail

address of the transporter who transported the food to and from you.

• Persons who have possession, custody, or control of food in the United States for the sole purpose of transporting the food, or foreign persons who transport food in the United States, regardless of whether they have possession, custody, or control of the food for the sole purpose of transporting that food (transporters), can meet the requirements of subpart J of this final rule by:

(1) Establishing and maintaining the records listed in § 1.352(a); or

(2) Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) contained in 49 CFR 373.101 and 373.103 as of the date of publication of this final rule; or

(3) Establishing and maintaining specified information that is in the records required of rail and water interstate transporters by the DOT's Surface Transportation Board (STB) contained in 49 CFR 1035.1 and 1035.2 as of the date of publication of this rule; or

(4) Establishing and maintaining specified information that is in the records required of international air transporters on air waybills by the Warsaw Convention as Amended at the Hague, 1995 and by Protocol No. 4 of Montreal, 1975 (Warsaw Convention); or

(5) Entering into an agreement with a nontransporter immediate previous source (if located in the United States) or immediate subsequent recipient (if located in the United States) to establish, maintain, or establish and maintain, the required records in options 1 or 2 of the previous paragraphs. The agreement must contain certain elements specified in § 1.352(e).

• If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food.

• If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

• If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

• If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

• Transporters of food (or specified persons who agree to establish and maintain required records under agreements with transporters) in the United States must retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food.

• Transporters of food (or specified persons who agree

to establish and maintain required records under agreements with transporters) in the United States must retain records for 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the transporter receives or releases the food.

• Records must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request.

• Failure to establish or maintain records or refusal to permit access to or verification or copying of any record is a prohibited act under section 301 of the FD&C Act.

• The compliance date for the records establishment and maintenance requirements is December 9, 2005, except that the compliance date for small businesses employing fewer that 500, but more than 10 full-time equivalent employees is June 9, 2005, and the compliance date for very small businesses that employ 10 or fewer full-time equivalent employees is December 11, 2006.

B. Significant Changes FDA Made to the Proposed Rule

FDA made the following significant changes to the proposed rule:

• All foreign persons, except foreign persons who transport food in the United States, are excluded from all of the requirements in subpart J of this final rule. A foreign person transporting food in the United States is subject to the requirements for transporters in the subpart.

• Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of subpart J of this final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food are excluded from all of the requirements of subpart J, except §§ 1.361 and 1.363.

• Persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J of this final rule as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363.

• Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of subpart J.

• Transporters can meet their obligation to establish and maintain records in the following ways: (1) Keeping the records listed in § 1.352(a); (2) keeping the records listed in § 1.352(b), which contain information also currently required of roadway interstate transporters under the FMCSA regulations as of the date of publication of this final rule; (3) keeping the records listed in § 1.352(c), which contain information also currently required of rail and water interstate transporters under the STB regulations as of the date of publication of this final rule; (4) keeping the records listed in § 1.352(d), which contain information also currently required of international air transporters on air waybills under the Warsaw Convention; or (5) entering into an agreement with a nontransporter immediate previous source in the United States or a nontransporter immediate subsequent recipient in the United States to keep records for them. The agreement must contain certain elements specified in § 1.352(c). Intrastate transporters must also establish and maintain records under this final rule and can meet this obligation by complying with either § 1.352(a), (b), (c), (d), or (e).

• Foreign persons who transport food in the United States, whether or not

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

• The exclusion for pet food not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (BSE rule) (62 FR 30935, June 5, 1997) has been deleted.

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

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

• ''Holding'' has been defined and means ''storage of food.'' Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

• ''Packaging'' has been defined and means ''the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)).''

• Recipe has been defined to mean the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

• The partial exclusion for retail food establishments has been replaced with a partial exclusion for persons who distribute food directly to consumers. Persons who distribute food directly to consumers are excluded from establishing and maintaining records required by § 1.345 to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. Persons who distribute food to businesses must establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients to the extent that information is reasonably available, for example when the purchaser has an established commercial account.

• The exclusion for retail facilities that are located in the same general physical location as a farm has been replaced with an exclusion for all retail food establishments that employ 10 or fewer full-time equivalent employees.

• An exclusion has been added for nonprofit food establishments.

• ''Nonprofit food establishment'' has been defined and means:

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

• The requirement to record a ''responsible individual'' when identifying the immediate previous source, immediate subsequent recipient, and transporters has been deleted.

• The requirement to record ''lot or code number or other identifier'' has been deleted for all covered entities, except persons who manufacture, process, or pack food.

• The definition of perishable food has been deleted.

• The record retention periods for nontransporters have been changed to: (1) 6 months for food for which a significant risk or spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

• The record retention periods for transporters (or specified persons who agree to establish and maintain required records under agreements with transporters) have been changed to 6 months for any food having a significant risk or spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk or spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

• The record availability requirements have been changed from 4 hours/8 hours to ''as soon as possible, not to exceed 24 hours from the time of receipt of the official request.''

• The compliance date for these regulations has changed to December 9, 2005. Small businesses have June 9, 2005, of this final rule to come into compliance with these regulations, and very small businesses have December 11, 2006, of this final rule to come into compliance with these regulations.

• The qualifying language ''food intended for consumption in the United States'' has been removed from this final rule to ensure that all persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is intended for consumption are subject to this final rule unless otherwise exempt.

III. Comments on the Proposed Rule

FDA received approximately 212 timely submissions in response to the proposed rule, which raised approximately 220 major issues. To make it easier to identify comments and FDA's responses to the comments, the word ''Comment'' will appear in parentheses before the description of the comment, and the word ''Response'' will appear in parentheses before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

(Comment 1) Some comments state that it would be beneficial for the agency to provide the food industry with a model form that could be used to record all the required information, with the option for the industry to use this form or established recordkeeping systems. One comment requests that the agency develop and provide respective freeware that could be available as a compact disc (CD) or downloaded from the FDA Web site well in advance of the compliance date of the final rule. A few comments request that the regulations make clear that the model form is guidance and is not mandatory. One comment suggests that as a way to show that the model form is guidance, the agency should place the model form in an appendix to the regulations.

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

One comment recommends that the agency provide further examples of

scenarios, rather than model forms, where records would be in compliance and noncompliance with the final regulations.

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

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

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

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

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

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

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

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

serious adverse health consequences or death to humans or animals.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Foreign Trade Issues

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

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

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

1. General

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

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

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

transportation. The comment notes that applying the recordkeeping requirements to customs brokers would cause redundant and burdensome recordkeeping requirements for them.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Intrastate

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

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

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

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

(Response) In the preamble to the proposed rule, FDA sought comments on its tentative conclusion that it has authority to require recordkeeping by persons engaged only in intrastate commerce. FDA also sought comments on how many intrastate persons would not be covered by one of the exclusions

from the recordkeeping requirements (e.g., the farm or restaurant exemption). Based on consideration of the received comments and further review of the provision of the Bioterrorism Act that provides FDA with the authority to require the establishment and maintenance of records by all ''persons'' who engage in specified activities involving food, FDA has concluded that the Bioterrorism Act gives FDA authority to require persons to establish and maintain records, whether or not they engage in interstate commerce, as long as they fall within Congress's power to legislate in this area.

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

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

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

> * * * although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not 'enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.'* * *

(*Lopez*, 514 U.S. at 556.) This principle applies squarely to the recordkeeping provision of the Bioterrorism Act. Accordingly, given the collective impact on commerce of intrastate manufacturing, processing, packing, transporting, distributing, receiving, or holding of food in the United States, FDA has concluded that the requirement to establish and maintain records should apply regardless of whether the food enters interstate commerce. Thus, FDA is retaining § 1.326(b) as proposed. See also response to comment 82 below for an expanded discussion of the collective impact on commerce of intrastate transportation of food.

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

3. Foreign Facilities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. General

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

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

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

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

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

(Response) Congress did not provide for an exemption for food that is transported for the U.S. military or any other U.S. Government agency from the scope of the recordkeeping requirements. FDA believes that these records are needed to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or

animals. Again, with respect to the comment's assertion that transporters of food for those entities should not be subject to potentially duplicative FDA standards, FDA agrees. There is no requirement to keep duplicative records. FDA reiterates that to the extent that you already keep the information required by this final rule, you do not need to establish and maintain duplicative records.

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

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

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

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

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

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

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

2. Farms

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

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

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

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

that importers are not exempt from this final rule.

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

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

3. Restaurants

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

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

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

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

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

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

4. Fishing Vessels

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

5. Retail Facilities

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

(Response) The business described in the comment is not treated differently than other retailers. Persons who distribute food to businesses do not qualify for the exclusion for sales to consumers in § 1.327(d) of the final rule. Thus, sales of food to restaurants require the establishment and maintenance of records of the immediate subsequent recipient, as codified in § 1.345 of the final rule, to the extent that information is reasonably available to you. Information is reasonably available to you if you have a system in place to capture the information. FDA does not intend to require the reconfiguration of business operations. Thus, for example, information is reasonably available to you when the purchaser has an established commercial account to which the food purchases are charged in an identifiable manner. Accordingly, § 1.327(e) of the final rule provides that persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in subpart J of this final rule. However, the requirements in § 1.345 of the final rule to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Response) FDA agrees. FDA is exempting nonprofit food establishments that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the United States. ''Nonprofit food establishment'' has been defined to mean:

> * * *a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes 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,'' ''food safety,'' ''a food to the extent it is within the exclusive jurisdiction of [USDA],'' and ''recipes for food.''

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

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

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

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

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

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

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

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

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

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

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

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

One comment believes strongly that ''packaging'' is not ''food'' for purposes of the Bioterrorism Act. Even if FDA disagrees, the agency is urged to exclude from the recordkeeping obligation all

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

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

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

TABLE B.—PACKAGING AND FOOD CONTACT SUBSTANCES

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

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

1. General Comments

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

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

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

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

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

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

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

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

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

2. The FD&C Act

There were no comments on this issue.

3. Domestic Person

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

4. Farm

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

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

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

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

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

In addition, FDA recognizes that an activity such as placing a raw agricultural commodity directly into consumer-ready packages is likely to provide better protection to fragile produce, such as berries, than placing the produce into a larger bin or box for transport off the farm, with consumer packaging of the produce further down the distribution chain. ''Manufacturing/processing'' as defined in § 1.328 means ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.'' Thus, simply placing produce into containers (such as clamshells, baskets, mesh bags, or plastic bags) is more akin to packing, even if the containers are ultimately received by the consumer. Under § 1.328 of this final rule, a farm may engage in this packing activity so long as all of the involved produce is grown or consumed on the farm or a farm

under the same ownership. Accordingly, a farm that simply places a raw agricultural commodity into containers, such as placing berries in clamshells, is not ''manufacturing/processing.''

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

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

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

5. Food

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

6. Foreign Facility

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

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

7. Manufacturing/Processing

There were no comments on this issue.

8. Nontransporter

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

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

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

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

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

9. Nontransporter Immediate Previous Source

There were no comments on this issue.

10. Nontransporter Immediate Subsequent Recipient

There were no comments on this issue.

11. Perishable Food

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

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

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

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

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

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

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

or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

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

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

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

12. Pet Food

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

13. Recipe

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

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

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

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

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

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

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

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

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

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

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

14. Restaurant

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15. Retail Facility

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

16. Transporter

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

17. Transporter's Immediate Previous Source

There were no comments on this definition.

18. Transporter's Immediate Subsequent Recipient

There were no comments on this definition.

19. You

There were no comments on this definition.

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

There were no comments on this issue.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. General Comments

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

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

established and maintained meets this standard.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Response) What is ''reasonably available'' is going to depend on the particular circumstances. To illustrate this point in the proposed rule, FDA used a hypothetical case of a cookie maker. (See 68 FR 25188 at 25197.) A company that bakes cookies may source

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

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

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

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

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

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

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

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

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

3. Requirement to Record Responsible Individual

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

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

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

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

4. Adequate Description of Type of Food

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

for many food ingredients and should be changed to ''common name.''

(Response) FDA is requiring an adequate description of the type of food received or released to include brand name where applicable and specific variety where applicable (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce). FDA agrees that ''specific variety'' may not apply in all cases, but should be provided where it applies because it will help narrow the investigation and help FDA identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse health consequences or death to humans or animals.

(Comment 105) Some comments recommend that the agency allow the use of company specific codes or an existing abbreviation system. One comment states that commercial documents often incorporate code numbers and abbreviations that identify the food products very specifically. The comments add that, as long as these codes and abbreviations can be deciphered readily for FDA in the event of an agency request for records, the product descriptions should be considered sufficient in their present form.

(Response) As discussed in response to comment 103 of this document, in keeping with FDA's intention to ensure these regulations are not unnecessarily burdensome, FDA agrees that covered persons may use existing abbreviation or code systems that identify the food very specifically, provided the abbreviations or codes can be readily deciphered at the time the records are made available to FDA following an agency request.

(Comment 106) Some comments who represent warehouses state that they rely on the customer's description of the product as the food comes to them in shrink-wrapped pallets and cartons and the warehouse is not permitted to open the packaging.

(Response) It is not clear from the comment what the ''customer's description'' entails; however, FDA is requiring an adequate description of the type of food to be able to narrow the scope of the implicated food in the event of a public health emergency. For this reason, each entity within the chain of distribution of the food must establish and maintain records that adequately describe the type of food received and released so that FDA can identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse consequences or death to humans or animals. It is the responsibility of the covered entity to revise its recordkeeping system so that it establishes and maintains records containing all required information. In the previous example, the warehouse may need to require its customers to provide it with a more detailed description when food is delivered or released than it currently receives.

5. Date Food Received or Released

(Comment 107) One comment agrees with the proposed requirement. Another stated that the term ''released'' is ambiguous in a commercial environment and asked for clarification.

(Response) Under §§ 1.337 and 1.345 of this final rule, if you are a nontransporter, you must establish and maintain records to identify the date you received and released food. Food is ''released'' when it moves from one covered activity to another covered activity (unless both activities are conducted by the same person). For example, an article of food is released from the manufacturer when it is given to the transporter. The food is released again when the transporter delivers the food to a grocery store. Where the manufacturer transports its own food to the grocery store, however, the food is not released when the manufacturer loads his trucks, but rather when the manufacturer delivers the food to the grocery store.

6. Lot or Code Number/Other Identifier

(Comment 108) Several comments state that some products do not have lot numbers (e.g., bulk produce and restaurant foods). The comments state that ''character/number string'' on the package may be hard to identify as a lot code; food product with closed lot codes requires deciphering; lot codes may be on nonvisible portions of the packaging or on the invoice; the integrity of the lot code may be compromised or unreadable if the outer packaging is damaged; and this requirement potentially forces the manufacturer either to stop using or to shorten the lot codes, which would be counterproductive to addressing public health concerns in this initiative. Another comment states that the requirement to record lot or code number/other identifier would be time inefficient and time consuming. One comment states the agency should require lot number tracing when information is ''reasonably available.''

(Response) FDA recognizes the difficulties in some situations of recording lot/code number or other identifiers of food. FDA has revised the final rule to only require that persons who manufacture, process, and pack food to record lot/code numbers or other identifiers. *See* §§ 1.337(a)(4) and 1.345(a)(4) of this final rule. Furthermore, this requirement only applies to the extent the information exists. FDA has learned through comments that tracking lot/code numbers or other identifiers throughout the manufacturing/processing and packing of food is not a problem, because in most cases it is currently being done or capable of being done. It is during the transporting, distribution, and holding of food (e.g., from the warehouse distribution centers to the retail store or restaurant) that such tracking becomes a problem. FDA also learned that the food industry is moving in the direction of being able to track the lot or code number or other identifier throughout the entire food chain, but that the current technology has not made such tracking cost efficient.

(Comment 109) Several comments state that the requirement to record lot/code number or other identifier would cost the industry millions of dollars in operational changes. They state that more warehouse space would be required to separate food by lot number, expensive computer system upgrades would be needed to handle lot code information, and the industry would incur significant administrative and labor costs to enter lot code information into the system. Comments further state that bar code tracing/scanning or radio frequency identification (RFID) systems are costly, and the RFID technology is new. The food distribution business will be affected every minute of every day compared to the infrequent costs associated with investigating food safety issues as the need arises. RFID is being studied and involves placing tagging chips in packaging. It may not be necessary to invent an elaborate system of paper recordkeeping if RFID proves to be useful in the future.

(Response) As discussed in response to comment 108 of this document, FDA recognizes the difficulties in tracking lot/code numbers or other identifiers throughout the entire food distribution chain. This final rule accounts for those difficulties. FDA is aware that technology is developing that will enable lot/code number tracking in the future to be cost efficient for all of the food industry.

(Comment 110) One comment states that food is not sorted by lot code identification. One pallet/bin, slot, or stockkeeping unit may contain multiple lot numbers.

(Response) The final rule does not require warehouse distribution facilities

to track lot/code number or other identifiers in these final regulations.

(Comment 111) A comment states that lot numbers are not scannable or machine readable, and manual transcription of these numbers would introduce errors. The comment states that small businesses would be buried in a mountain of paperwork and this would make it impossible for them to track products accurately.

(Response) As explained in response to comment 108, FDA recognizes the difficulties in tracking lot/code numbers or other identifiers. This final rule reflects those considerations. FDA has balanced the need to provide information that would expedite a traceback in a food-related emergency with the ability to record lot numbers. Because food almost always passes through at least one small business in the distribution chain, FDA cannot exempt small businesses entirely from this important requirement. The final rule, however, does give small and very small businesses more time to comply with its requirements. FDA is aware that technology is developing that will enable lot/code number tracking in the future to be cost efficient for all of the food industry.

(Comment 112) Some comments state that if foods are distributed to the store via direct store delivery (DSD) (i.e., baked goods, breads, soda, snack foods, beer/wine, ice, and milk) the vendor provides the food directly to the store and sometimes stocks the shelves. DSD has no system to track the information the FDA will require.

Several comments note that protecting public health does not necessitate the maintenance of records in every step of the distribution process. The comments state that the current recall system is the most efficient and practical way to identify and remove product from distribution. These comments state that consumers typically return all products in a recall with no regard to the lot code, and that this is the most appropriate response in the event of a terrorist attack. In these comments' opinion, complex lot numbers may slow or substantially limit the recall of contaminated food. Additionally, requiring distributors to compromise the integrity of food packaging to determine lot codes defeats the purpose of the proposal. Some comments state that this requirement represents a disproportionate burden to packaged food distributors.

Some comments state that food manufacturers may use independent delivery persons who pick up product from several manufacturers for delivery to retailers. There may be as many as 75 to 100 different products on each truck. The independent delivery person has no capability to capture the lot numbers of the products of several different manufacturers.

(Response) (Response) The final rule does not require distributors to track lot/code numbers or other identifiers. DSD vendors will not be subject to the lot code requirement in § 1.345(a)(4) for activities other than manufacturing, processing, and packing food. Thus, activities such as holding and transportation are not subject to the requirements.

(Comment 113) Many comments request clarifications for the terms ''other identifiers'' and ''to the extent information this information exists.''

(Response) FDA acknowledges that most firms use lot or code numbers to identify specific batches of their products. However, some may use other technologies such as barcodes. The term ''other identifier'' is intended to capture any other methods that the food industry may be using to identify specific lots of product. FDA is mandating that this information be captured in the records, where required, to the extent this information exists. It is conceivable that certain sectors of the industry may not use lot or code numbers, or other identifiers to identify specific lots of products. In this case, the regulations do not specify that these sectors start using such identifiers. The identifiers are required only to the extent that they already exist.

(Comment 114) A number of comments suggest that, in lieu of lot numbers, purchase orders numbers would serve as acceptable identifiers.

(Response) To the extent that a purchase order contains all required identifiers of food received or released, the purchase orders may be used to satisfy the requirement. To the extent that a purchase order only contains some of the required information, those records will need to be supplemented to satisfy all the requirements contained in §§ 1.337 and 1.345 of this final rule.

FDA notes that the final rule only requires that persons who manufacture, process, or pack food maintain lot or code number or other identifier of the food, and only requires this information to the extent that the information exists. Furthermore, FDA is not specifying the form or the format of the information that is required to be established and maintained.

(Comment 115) One comment states the FDA should standardize lot codes.

(Response) FDA does not agree. The agency has determined that the least burdensome way of issuing the recordkeeping requirements mandated by the Bioterrorism Act is to specify the information that must be contained in the records, but not the format in which the records are kept. As indicated by other comments summarized previously, persons subject to this final rule already have various means to identify food, including lot numbers. The final rule allows such persons to use lot numbers or other appropriate identifiers, including abbreviations, provided such information can readily be decoded to identify particular foods if FDA makes an appropriate request to access records.

7. Quantity and How the Food is Packaged

(Comment 116) A few comments recommend that FDA allow quantity of products in bulk containers to be expressed in gross quantity, e.g., 1 to 5,000 gallon (gal) tank load; 5 to 1,000 gal totes.

(Response) FDA agrees with this comment that, when recording quantity of bulk food, the gross quantity, or weight, (e.g., 5,000 gal) is acceptable. To satisfy the requirement to record how the food is packaged, ''tank load'' or ''totes'' is acceptable. FDA has revised §§ 1.337(a)(5) and 1.345(a)(5) of this final rule accordingly.

(Comment 117) One comment representing warehouses recommends that the final rule require that the information relating to quantity and how a food is packaged be maintained by the warehouse customer.

(Response) FDA disagrees with this comment. Warehouses ''hold'' food and are, therefore, subject to all of the regulations in subpart J of this final rule. The comment has not explained why a warehouse would not know or could not obtain information regarding the quantity of food received and how it is packaged. FDA believes it is necessary to maintain this information at each step of the distribution chain to be able to effectively and efficiently conduct a tracing investigation.

8. Name, Responsible Individual, Address, Telephone Number, Fax Number, E-Mail Address of Transporters Who Transported the Food To You and From You

(Comment 118) Several comments state that the identity of the transporter is known to the shipper but is not typically known to the receiver. The comments assert that it is unreasonable to expect the receiver to have, seek, or maintain information on the identity and related contact information for the transporter that delivered the product, especially if multiple transporters may have been involved. The comments state

that such information would be available from the shipper that arranged the transport. One comment states that it is not usual business practice for distributors to keep records about the transporter who delivers food.

(Response) FDA believes that excluding a source from keeping records on the immediate previous source if that immediate previous source is a transporter would hinder a traceback investigation. The proposed and final rule require nontransporters to identify the name of the firm, address, telephone number and, if available, the fax number and e-mail address of the transporter who transported the food to and from them. See §§ 1.337(a)(6) and 1.345(a)(6) of this final rule. These provisions however, do not require the nontransporter to record transactions to which they were not a party, e.g., where multiple transporters are involved.

I. Comments on Who is Required to Establish and Maintain Records for Tracing the Transportation of All Food? (Proposed § 1.351)

(Comment 119) Several comments stated that foreign transporters are not included in the definition of ''foreign facilities'' and that the final rule should be applied to foreign transporters as it is to domestic transporters.

(Response) FDA has excluded all foreign persons, except foreign persons who transport food in the United States, from all of the regulations in subpart J of this final rule. Therefore, foreign transporters are subject to the same requirements as ''domestic'' transporters when transporting food in the United States.

(Comment 120) A number of comments noted that many ''nontransporters'' own trucks or other vehicles and transport food or feed as an incidental part of their operations. They express concern that they would be required to keep two sets of records, one as a nontransporter, and the other as a transporter. One comment recommends that the final rule be applicable to both private and ''for-hire'' transporters.

(Response) ''Transporter'' is defined in § 1.328 of this final rule to mean 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 that food. If a person is considered a nontransporter under the rule, then the person is not subject to the transporter provisions when transporting food, but must comply with the requirements applicable to nontransporters. The final rule applies to transporters regardless of their status as private or for-hire. For example, if a U.S. manufacturer hires a company to deliver its food, the delivery company is subject to the transporter provisions whether or not it is private or for-hire.

If a person is considered a nontransporter under the final rule, then the person is not subject to the transporter provisions when transporting food. For example, a U.S. manufacturer that delivers its food to a grocery store must only keep the records required of a nontransporter. In this situation, the immediate previous sources of the manufacturer are the sources and transporters of the ingredients, and the immediate subsequent recipient of the manufacturer is the grocery store.

(Comment 121) A number of comments note that the specific records being required of transporters are duplicative of the information being required of the immediate prior sources and the immediate subsequent recipients with respect to each other and that such redundancy is unnecessary because the agency could get the information from either or both of the immediate prior sources or immediate subsequent recipients.

(Response) The requirements in the final rule ensure that transporters have records that would assist FDA in a tracing investigation. For example, if a manufacturer of a food product sends 300 boxes of that product to its buyer (the immediate subsequent nontransporter recipient), and the recipient only receives 200 boxes, records created by the transporters (or multiple transporter companies if more than one is used to transfer food between the nontransporter immediate previous source and the nontransporter immediate subsequent recipient) will be the only means of enabling FDA to learn how and when the remaining 100 boxes were diverted, and to where. In addition, under a similar scenario where a manufacturer of a food product sends 300 boxes of that product to its buyer and the recipient receives 400 boxes, transportation records will be the only means of enabling FDA to determine when the additional 100 boxes were introduced into the system and where they came from. Further support for requiring transporters to establish and maintain records is provided in response to comment 82 of this document.

J. Comments on What Information is Required in the Transportation Records? (Proposed § 1.352)

(Comment 122) Several comments recommend that FDA exempt transporters from all recordkeeping elements except the immediate source and immediate subsequent recipient. They note that the cost of complying is not proportional to the risk.

(Response) FDA disagrees with this comment. FDA, however, has taken steps to minimize the burden on transporters by including five alternatives to meet their obligations to establish and maintain records under this final rule. FDA notes that transporters also are subject to the records access requirements in §§ 1.361 and 1.363 of this final rule. This will ensure that FDA has access to all applicable records that will enable FDA to perform a tracing investigation quickly and effectively. Additionally, to ensure there are no gaps in transporter coverage in a traceback investigation, the final rule applies to both interstate and intrastate transporters of food.

(Comment 123) Comments arguing for exemption of transporters state that it is difficult or impossible for the crew of the transporter to open each container of food, contaminate it, repackage it, replace seals, and arrive on time without leaving any trace of their intervention. Other comments suggest that a known and trustworthy transport company will not risk their business by doing something of this nature.

(Response) FDA disagrees that the transportation process is any less vulnerable to attacks on the food supply than any other part of the food industry. FDA believes that recordkeeping requirements are necessary for transporters, but, as discussed previously, it has taken steps to minimize the burden on transporters.

(Comment 124) A number of comments state that the transporter has no access to detailed information about the shipment and is dependent on the information listed on the bill of lading provided by the shipper. Therefore, the information required of transporters should be limited to the information on the bill of lading. One comment states that a bulk shipper, for example, has a 5,000 gal shipment of orange juice and has access to only this information, and detailed descriptive information such as brand names, specific variety, and package types are not applicable to bulk loads. Several comments state that transporters are frequently provided with preloaded and/or sealed vehicles for transport, and the transporter does not have knowledge of the contents

other than what is on the bill of lading prepared by the shipper. They argue that they cannot access the sealed cargo to obtain specific information to confirm or supplement the bill of lading information. Similarly, other comments advise that they cannot verify bill of lading information for food contained in shrink-wrapped pallets. These comments believe that the carriers responsibility should be limited to the description provided by the shipper.

(Response) As discussed in response to comment 82 of this document, transporters are not required to establish and maintain the detailed information about a particular shipment of food that nontransporters are required to establish and maintain under §§ 1.337 and 1.345 of this final rule. The final rule provides five alternatives for interstate and intrastate transporters to meet their obligation to establish and maintain required records.

(Comment 125) One comment notes that air transporters may have a record of the consignee (immediate subsequent recipient), but may not have a record of the truck transporter the consignee sent to pick up the freight. The comment believes that the consignee who arranged for the pickup should be responsible for the record, not the air transporter who released the shipment to the agent of the consignee.

(Response) The final rule provides five alternatives for transporters to meet their obligation to establish and maintain records. Failure by the immediate previous source or immediate subsequent recipient who enters into an agreement under § 1.352(e) of this final rule to keep such records is a prohibited act. The requirements for transporters in the final rule ensure that FDA has records identifying how a food traveled between a nontransporter supplier and nontransporter recipient when multiple transportation companies or multiple modes of transportation are used. FDA does not believe that the nontransporter will always have this information. For example, if a trucking company that picks up the food from a manufacturer in State A for delivery to a grocery store in State B subcontracts with an airline and subsequent trucking company to deliver the food to the grocery store, the manufacturer may have no knowledge that the food was transported on the airline and subsequent trucking company. Similarly, the grocery store is aware that the second trucking company delivered the food, but may not be aware that before that, the food was transported on an airline and a different trucking company.

In the event that FDA has a reasonable belief that food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, such records could be critical to determining whether such adulteration occurred during transportation, and if so, during which leg.

(Comment 126) One comment observes that the Bioterrorism Act does not mention ''transporters'' in providing the Secretary with record access. The comment concludes that Congress chose not to give the Secretary access to the records of transporters and asks why there is a recordkeeping requirement for those transporters.

(Response) FDA disagrees with this comment's assertion that the statute does not provide FDA with access to transporters' records. Section 306 of the Bioterrorism Act amends section 704(a) of the FD&C Act, Factory Inspection, to read:

> * * * In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, *transports*, distributes, holds, or imports foods, the inspection shall extend to all records or other information described in section 414 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 * * *. (Emphasis added.)

FDA is imposing a record establishment and maintenance requirement on transporters to ensure that transporters have records that would assist FDA in a tracing investigation in a food-related emergency.

(Comment 127) Numerous comments state that a requirement for specificity as to brand names, specific variety names (e.g., ''romaine lettuce'' rather than ''lettuce''), lot numbers, and the way the food is packaged would require information neither readily available to transporters, nor routinely recorded by transporters. They further state that, if needed, such information could be obtained from both the shipper and receiver. They contend that these requirements are not necessary to effectuate the purposes of the statute. Other comments state that air carriers typically rely on information from those tendering the freight and, in some instances, shipments may not even be identified as containing food, particularly since chewing gum and pet foods are included in the definition of food.

(Response) The final rule does not require transporters to establish and maintain records with brand name or lot numbers. However, FDA believes it is necessary to obtain some information about the shipment of food from transporters to conduct tracing investigations. Transporters are responsible for knowing that they are transporting food.

(Comment 128) Some comments state that requiring brand name descriptions raises cargo security concerns because having more detailed descriptions on paperwork will increase the risk of theft and make it easier for bioterrorists to target certain shipments.

(Response) FDA does not agree with this comment. Interstate transporters are already required to keep similar records under the DOT regulations, and FDA is not aware of these records presenting a security risk; thus, there should not be any increased security risks as a result of this rulemaking. Furthermore, FDA notes that the final rule does not require transporters to establish and maintain records of brand name, specific variety names, or lot numbers.

K. Comments on What are the Record Retention Requirements? (Proposed § 1.360)

(Comment 129) Many comments state that because an infrastructure for long-term record retention does not exist to the extent FDA envisions, more reasonable time requirements for retention of records should be established. Another comment states that, although the proposed record retention periods seem simple and straightforward, in practice, they are difficult and confusing for some companies to apply because of the other record retention requirements of varying lengths with which they also must comply. The comment urges FDA to review the recordkeeping retention periods now in effect for specific food categories (e.g., acidified foods, low acid canned foods, bottled water, juices, seafood, and milk) and work to harmonize the proposed record retention requirements with those periods. A few comments question the value of a 2-year record retention period for a product with a shelflife of 60 days, particularly in light of the additional costs associated with the extended retention requirements for perishables. Another comment states that the proposed timeframes for maintaining records for all food products, based solely on whether a food has a shelflife of 7 days, does not appear to utilize sound risk management principles.

(Response) FDA agrees in part with these comments and has revised the record retention requirements in the final rule. FDA used similar criteria as the NIST definitions for perishable, semiperishable and long shelf-life food. The record retention requirements in § 1.360(b) of this final rule now require record retention of: (1) 6 months for

food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydration, or being placed in a hermetically sealed container.

Transporters, or nontransporters retaining records on behalf of a transporter, are required to 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 food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

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

(Comment 130) Comments from the transportation industry indicate that FDA should revise the record retention requirements for transporters to be the same for both nonperishable and perishable food shipments, rather than the 1 and 2-year periods FDA proposed, and that the final rule should adopt the FMCSA 1-year retention period required for bills of lading.

(Response) FDA agrees with this comment and has revised the final rule accordingly. Section 1.360(f) of the final rule requires transporters, or nontransporters retaining records on behalf of a transporter, to 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 food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

(Comment 131) One comment suggests that records retention timeframes should be based on a simple partitioning of shelf perishable and shelf stable products, e.g., retain records for products with a shelflife up to 90 days for 1 year and retain records for products with a shelf life greater than 90 days for 2 years from the time of manufacture.

(Response) As stated previously in response to comment 129 of this document, FDA has considered various options and has chosen to require record retention based on criteria similar to the NIST definitions for perishable, semi-perishable and long shelf-life food. FDA is convinced such an approach is the most efficient and effective because the food industry already is familiar with classification of foods into these three categories due to existing regulations and practices; and it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage or significant loss of value occurs within 60 days will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

With regard to the comment's statement that records be retained from the time of manufacture, FDA does not agree. The record retention periods begin at the time the food is received and released. Under § 1.360(a) of this final rule, you must create the required records at the times you receive and release food, except to the extent that the information is contained in existing records.

(Comment 132) One comment suggests that retaining records for 6 months after the product expiration date should be more than adequate for investigations for potential threats associated with the food. The comment indicates that expanding system capacity to accommodate much longer record retention is a major cost associated with implementing the proposed regulation and that FDA should either justify the value for longer record retention periods against the increased burden being placed on the industry or substantially decrease the number of records that must be retained for longer duration.

(Response) As previously noted in response to comment number 129, FDA has considered various options and has chosen to require record retention based on criteria similar to the NIST definitions for perishable, semiperishable and long shelf-life food. FDA is convinced such an approach is the most efficient and effective because the food industry already is familiar with classification of foods into these three categories due to existing regulations and practices; and it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods.

FDA notes that a traceback may not begin until well past the time the food has been consumed, as explained in the response to the following comments.

(Comment 133) A few comments contend that a shorter record retention time, such as 3 to 6 months, should be sufficient time for retention of records because any harmful effect directly related to a perishable food would be detected well within the life expectancy of the food.

(Response) FDA does not agree that harmful effects directly relating to perishable foods always can be detected within the shelflife of the food. FDA has experienced some situations in which the health hazard was not immediately apparent, but only emerged several months after the food was consumed. Also, FDA recognizes the potential for serious adverse health consequences caused by novel contaminants or novel food sources for known contaminants. In such situations, it may take months to identify the source of contamination, or the contaminant itself.

(Comment 134) Several comments suggest that record retention be based on three categories of food, i.e., perishable, semiperishable, and long shelflife, as defined by NIST. NIST defines perishable food as any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days of the date of packaging. The corresponding time frames for semiperishable and long shelflife food are 60 days to 6 months, and greater than 6 months, respectively. Several comments suggest the record retention time should be 6 months for perishable food; 12 months for semiperishable food and 18 months (or product shelflife plus 12 months or 24 months, whichever is greater) for long shelflife food.

(Response) FDA agrees with this comment. FDA has concluded that this objective can be achieved by inserting language directly in § 1.360(b) of this final rule using similar criteria as the NIST definitions for perishable, semi-

perishable and long shelf-life food. Therefore, FDA has changed the record retention requirements in § 1.360(b) of this final rule to require record retention by nontransporters for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

Transporters, or nontransporters retaining records on behalf of transporters, are required to retain for 6 months records for food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and for 1-year records for all food having a significant risk of spoilage, loss of value, or loss of palatability after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

(Comment 135) One comment states that records should be retained for 2 years from the date they are created, and not for 2 years from the date of shipment of the product. The comment points out that wine may be shipped several years after it has been manufactured, and that establishing the timeframe from the date of shipment of the product would be an unwarranted burden. One comment suggests that the minimum record retention periods should be stated as time from the date of production, e.g., a minimum of 2 years after the date of production of the food, except perishables, and a minimum of 1 year after the date of production for perishables.

(Response) FDA does not agree with the comment's suggestion, as this will not ensure that FDA has access to the requisite records at the time of a traceback investigation. Often, a traceback begins after consumers become sickened or die. In the comment's example, if the wine was adulterated and presented a threat of serious adverse health consequences or death to humans, FDA may not know this until the wine has been consumed, i.e., after the product was released by the manufacturer into commerce and consumers became seriously ill. If the record retention period began at the time of production, but the wine was aged at the manufacturer's facility 2 years before distribution into commerce, the record retention period would have expired before the wine entered commerce. In the final rule, FDA retains the requirement that records required under subpart J must be established at the time food is received or released and maintained from that time until the end of the time period specified in § 1.360 of this final rule.

(Comment 136) One comment notes that mechanisms for keeping records updated have not been established. The comment asked what should be done if a record's 2-year deadline expires, e.g., is there a requirement to open a new record?

(Response) The final rule does not mandate specific mechanisms, systems, or processes for establishing and maintaining the required records, only the information that must be kept. The record retention period is from the time the food is received or released. Persons are not required to update, modify, or transfer information in a record to a new record after the end of the required retention period.

(Comment 137) One comment expressed concern that, under the proposed regulation, persons who do not know if perishable food is intended for processing into nonperishable food would have to assume it is and maintain records for 2 years. A few comments state that persons, such as distributors, carriers, farms or orchards, roadside stands, and small collection centers generally have no way of knowing whether a perishable food will be processed into a nonperishable food by other parties. A few comments ask FDA to clarify that companies selling perishables can rely on the applicability of the 1-year records retention period unless they have actual knowledge at the time of sale that the perishables will be used for processing into nonperishable foods.

(Response) Section 1.360 of the final rule specifies retention periods based on the type of food being received or released, not on the end use of the food being delivered.

(Comment 138) One comment states that the proposed requirements are more burdensome than is necessary to enable food producers to respond quickly and appropriately to a food safety emergency. The comment further states that the proposal does not take into account the sheer volume that retail grocery stores deal with on a daily basis. According to the comment, the average retail grocery store currently is capable of retaining such records for only approximately 1 week. The comment concludes that the requirement to maintain records for 2 years is completely unworkable and will not serve in the interest of public health in times of crisis.

(Response) FDA has revised the record retention periods for nontransporters to 6, 12, and 24 months as discussed in response to comment number 129. FDA believes that these timeframes are within the period Congress believed appropriate because the Bioterrorism Act gives FDA authority to require records to be retained for up to 2 years. Moreover, Congress did not exempt retailers (e.g., retail grocery stores) from the recordkeeping requirements, as they did in section 305 of the Bioterrorism Act (registration of food facilities). FDA believes that the benefit to FDA and consumers in conducting an efficient and rapid traceback in a public health emergency justifies the burden to industry.

For the final rule, FDA has changed the record retention requirements in § 1.360(b) to require record retention by nontransporters for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

Transporters or nontransporters retaining records on behalf of a transporter are required to retain 6 months records for food having a significant risk of spoilage, loss of value,

or loss of palatability within 60 days after the date the food is received or released and 1 year all food having a significant risk of spoilage, loss of value, or loss of palatability after a minimum of 60 days after the date the food is received or released.

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage or significant loss of value occurs within 60 days under normal shipping and storage conditions will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

In addition, FDA has excluded the distribution of food directly to consumers from the requirement to keep records of immediate subsequent recipients of food because FDA can obtain information from consumers and notify them when necessary. Often, consumer illness is the first common indicator that food may be adulterated and present a threat of serious adverse health consequences or death. Requiring retailers to retain records for only weeks or months would greatly impede FDA's ability to conduct a rapid and effective traceback. FDA has selected those timeframes for record retention based on the amount of time perishable and nonperishable food may remain in commerce, and thus, may be the subject of a traceback investigation. FDA further notes its understanding that many retailers currently maintain records for 2 years.

Also, retail food establishments that employ 10 or fewer full-time equivalent employees are now excluded from all of the requirements in this subpart, 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 139) A few comments state that the requirement to maintain records for 2 years is very burdensome for those who obtain a variety of fresh produce from a large number of small farmers and commingle lots of produce for distribution.

(Response) FDA notes that these foods for the most part would fall into the category of foods for which a significant risk of spoilage or significant loss of value occurs if held longer than 60 days under normal shipping and storage conditions for the food. As stated previously, the record retention period for this category of foods in this final rule is 6 months.

(Comment 140) A few comments state that, for alcoholic beverages and distilled spirits, retention of records for a period of only 2 years would be inadequate to trace a matured product back to the source. They suggest that FDA should rely on alcoholic beverage importers' and producers' own existing record systems to facilitate tracebacks.

(Response) Although retaining records for 2 years may not be enough for products with long shelflives, the agency notes that the Bioterrorism Act sets the maximum time the agency can mandate record retention at 2 years. FDA further notes, however, that 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, any records and other information accessible to FDA under section 414 or 704(a) of the FD&C Act must be readily available for inspection and photocopying or other means of reproduction. Therefore, as a practical matter, FDA may be able to access additional information about food products after the 2-year retention period required by subpart J of this final rule has elapsed.

(Comment 141) Several comments offer suggestions on where the required records should be maintained. One comment recommends that, for intracorporate transfers, companies should be permitted to make all required records accessible at one location. The comment states that this would not delay, and could even enhance, efficiencies in an FDA traceback investigation. Several comments state that companies should have flexibility for determining where to maintain the required records. The comments note that it should be sufficient that the records are maintained and are accessible at some location, including the headquarters office for specific locations within a company. One comment requests clarification on whether records may be stored in separate locations, as long as the combined records adequately provide the required information. The comment notes that confidentiality requirements may cause records that contain part of the required information to be maintained in different locations.

One comment states that, in the context of air transportation of food, the location where the activity occurred may be difficult to determine, and may not be a feasible place to store records or to make them available to FDA at a future date. According to the comment, the option to store records offsite, combined with the flexibility to maintain records in an electronic format, is critical to ensuring prompt access to the records.

(Response) FDA requires in the final rule that the required records must be retained at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. The agency clarifies that the intent of this provision of the regulation is to provide flexibility for a company to determine the most efficient and readily accessible means of storage, consistent with the company's business practices. Access to the records may be provided to FDA electronically, by facsimile, or by other appropriate means consistent with the availability requirements in § 1.361 of this final rule, once FDA makes a written request under section 414(a) or 704(a) of the FD&C Act. Each individual company may determine the appropriate location for maintaining the required records and for ensuring that the record availability requirements can be met.

L. Comments on What Are the Record Availability Requirements? (Proposed § 1.361)

(Comment 142) Some comments state that the proposed time is reasonable for record production if the requested records are onsite and of recent transactions (i.e., within the last 3 months). One comment urges the agency to clarify that, although companies must make the records available within 4 hours, the agency does not expect companies to link the sources of each ingredient with every finished lot of product within that timeframe. Another comment states that, within the 4-hour proposed time, a firm will not be able to make records available that are stored offsite and currently are subject to contracts that allow the vendors to deliver records on the next business day. The comment recommends that FDA consider the possibility of allowing records stored offsite to be produced at locations more convenient than the manufacturing facility, such as FDA offices, headquarters, or other locations mutually agreed upon to expedite record examination.

Some comments also state that the cost of renegotiating record storage contracts would cost thousands of dollars, more than the $151 per firm cost that FDA estimated. They recommend that FDA allow companies to provide records ''within a reasonable period of time'' or that the final rule

give companies 24 hours to make records available to FDA from the time of receipt of FDA's official request. Several comments state that the proposed time does not reasonably reflect the following: The scope of requested records; the accessibility, degree of compatibility and number of recordkeeping systems involved; the limitations on record maintenance of some systems; the limited physical access to nonelectronic records; and the presence or absence of a quality assurance system. Comments further state that, with millions of foods transported annually, many firms utilize various data systems and have implemented records maintenance procedures to meet their specific company needs. Compliance with this new rule requires establishing new protocols and developing new database systems, which would require a substantial capital investment.

Comments also note that the proposed rule does not consider the time required to verify the completeness and accuracy of records, transmission of data to appropriate authorities and the availability of knowledgeable personnel to access specific records. They suggest that FDA should focus on the information contained in the records, rather than on the records themselves. Comments suggest FDA change the proposed language to include: As soon as possible within 24 hours from the time the request is made. Other comments state that the proposed time is not enough, particularly if the request for record is made late during the day, or on Friday, or on a day (Sunday) when the location where records are maintained is closed and insufficient staff is available to retrieve the requested records. Comments urge FDA to allow companies to provide records as quickly as is practicable, given the nature of the recordkeeper's operations.

(Response) FDA agrees with these comments in part and has amended the proposed records availability requirements in this final rule. Section 1.361(a) of this final rule states: ''* * * Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of an official request * * *.'' FDA notes that, although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

(Comment 143) Other comments suggest that records be available within 12 hours regardless of what time of day the FDA request is made or the next business day, in the event the next day falls on a weekend or a holiday. Some suggest a timeframe within 24 hours if the request is made during a working week and within 72 hours if a request is made during a weekend.

Several comments state that the majority of businesses, especially small businesses, store records that are older than 3 weeks ''offsite'' where many storage facilities are not open on weekends and holiday. Comments also state that more than 24 hours is needed to retrieve such records and to impose criminal liability for noncompliance is unworkable and unfair. Comments urge FDA to allow companies to provide records within a reasonable period of time or that the final rule gives companies 24 hours to make records available to FDA from the time of receipt of an official request.

(Response) FDA agrees with these comments in part. In this final rule, FDA is requiring that records be made available as soon as possible, but not more than 24 hours from the time of receipt of an official request. FDA does not agree with the comments' suggestion that more time be made available if a request for records is made outside of the working week. FDA notes that it would only access the records if 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. Under these circumstances, it is critical for FDA to move as quickly as possible to trace backwards to identify the source of any such adulteration and trace forward from that source to remove all similarly adulterated food from commerce to protect the public health. FDA notes that although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

(Comment 144) Several comments urge FDA to reconsider its proposed definition of work hours (8 a.m. to 6 p.m.). The comments state that in most ports of entry, the hours of operation of the trade community are established to mirror the hours of the commercial operations of CBP. If FDA requests records outside of those hours of operation, FDA could encounter difficulty in contacting the appropriate parties from whom to request records. Comments suggest that FDA use the phrase ''during times in which a firm is operating'' or ''during a firm's normal business hours.''

(Response) FDA is no longer defining work hours, and has modified its proposed records availability requirement to ''as soon as possible, not to exceed 24 hours from the time of receipt of the official request.''

(Comment 145) Some comments state that the agency has not considered difficulties of compliance in the real world where there are different time zones within the United States and foreign countries. According to these comments, mandating an unattainable compliance time may cause great confusion globally and may actually impede the information gathering process. Comments urge FDA to allow for records to be provided to FDA within a timeframe not to exceed 24 hours or other timeframe appropriate to the scope of records being sought. Others suggest 24 hours for domestic and 36 hours for foreign facilities.

(Response) FDA agrees in part with these comments. FDA has deleted the 4-hour and 8-hour requirements. The final rule requires all records to be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request. With respect to the comments suggestion that foreign facilities be given 36 hours, FDA notes that foreign persons (except for foreign persons who transport food in the United States) are not subject to these final recordkeeping regulations.

(Comment 146) Many foreign governments express concern that FDA does not have authority regarding recordkeeping and record access when a firm is located in a foreign country. One foreign government urges FDA to recognize the role of another competent authority with respect to records access as provided for under the World Trade Organization Agreement on Sanitary and Phytosanitary Measures. Foreign governments request that FDA operate under agreements with these governments so that FDA will convey its request to the competent authority in that country. The competent authority can then carry out investigations on behalf of FDA and provide FDA with any resulting relevant information.

(Response) Foreign persons, except those who transport food in the United States, are not subject to these final recordkeeping regulations. If FDA needs to access food records that are established and maintained by foreign persons, FDA will work with the relevant competent authorities in those countries to do so.

(Comment 147) One comment notes that the proposed rule does not take into account the time required to translate into English records in other languages that are obtained from firms located in foreign countries.

(Response) Foreign persons, except those who transport food in the United States, are not subject to these final recordkeeping regulations. In the event FDA needs to access records kept by foreign persons, FDA intends to work

with the relevant competent authorities in those countries to do so.

(Comment 148) One comment states that, for rurally-located industry, it is difficult for primary agricultural dealers from any location to meet the proposed requirements, because, in some of these small businesses, one person assumes many responsibilities.

(Response) FDA has considered this and other comments and has changed the record availability requirement from the proposed rule. Under this final regulation, records shall be made available as soon as possible, but not to exceed 24 hours after FDA has made the request. In the circumstances in which FDA would access the records, it is critical for FDA to move as quickly as possible to trace backwards to identify the source of any such adulteration and trace forward from that source to remove all similarly adulterated food from commerce to protect the public health. FDA notes that, although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

(Comment 149) One comment states that the proposed time for records access is problematic for small-scale exporters that do not have any representation in the United States; hence, they need special treatment.

(Response) Foreign persons are not subject to these final recordkeeping regulations, except to the extent they transport food in the United States.

(Comment 150) Several comments state that the Bioterrorism Act only provides authority to access and copy records for the purpose of determining whether a food believed to be adulterated is actually so and for conducting a tracing investigation in regard to such an adulterated food. Comments express concern over possible unlawful conduct and abuse of discretion by FDA field inspectors and other officials. They urge FDA to clearly define legal violations concerning recordkeeping and record access requirements so corporate officers can make responsible decisions. They also urge FDA to integrate the constitutionally required safeguards into the regulations.

Comments recommend that FDA establish procedural safeguards to protect manufacturers and their customers by providing the affected company with a reasonable written notice that explains how the ''reasonable belief'' standard is being met and identifies the type of records being requested. According to comments, this would inform the affected company which records are being sought and the legal basis for the request. Several comments also request that FDA develop procedures requiring that the written notice be examined and approved by the District Director in whose district the implicated food is located, or by any FDA official senior to such District Director. They urge FDA to develop guidelines to define ''reasonable belief'' and base a decision to access records on laboratory analyses confirming adulteration and/or on an affidavit sworn under penalty of perjury.

Other comments state that FDA should issue interim final regulations with an opportunity for comment on the procedural protections that will be utilized to implement the record maintenance and inspection provisions of the Bioterrorism Act. Specifically, the comments state that the regulations should at least delineate agency procedures for authorizing the review, those officials who are permitted to review the documents, the standard for when such review may occur, an appellate procedure for those who disagree with the agency's determination, and the reasonable times, limits and circumstances to which the Bioterrorism Act limits FDA's review, as well as the procedures FDA must implement to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by FDA under the Bioterrorism Act. Others urge FDA to incorporate these procedures into regulations and ask that the public be granted an additional 60 days to comment.

(Response) FDA's record access authority under sections 414(a) and 704(a) of the FD&C Act became effective upon enactment of the Bioterrorism Act on June 12, 2002. The record access provisions of the Bioterrorism Act do not require FDA to issue implementing regulations. FDA intends to issue guidance to FDA personnel regarding FDA's exercise of this provision in accordance with FDA's GGPs regulations (§ 10.115). The previously stated comments will be considered as FDA develops the agency's guidance. FDA does not agree that these procedures need to be codified.

(Comment 151) One comment observes that, depending on the length of the distribution chain involved in a contamination event, FDA may need to examine records of numerous food handling facilities. As a result, it could still take FDA several days to obtain needed records. The comment suggests that source labeling could help FDA determine the ultimate source faster.

(Response) The comment's suggestion is outside the scope of the proposed rule. The authority granted in section 306 of the Bioterrorism Act relates to establishing requirements for records to identify immediate previous sources and recipients of food, not establishing labeling requirements.

(Comment 152) One comment requests specific guidelines and an opportunity to object to providing the records for a period before access of the records.

(Response) FDA disagrees. FDA does not currently provide a period of time in which a person subject to an inspection may object prior to that inspection. As discussed in response to comment 171 of this document, FDA plans to issue a guidance document regarding the record access provisions.

M. Comments on What Records Are Excluded From This Subpart? (Proposed § 1.362)

(Comment 153) Several comments express concern that information that FDA would view, copy, or otherwise access could contain confidential information, such as confidential commercial or trade secret information. Two comments ask FDA to permit a person subject to the requirements of section 414 of the FD&C Act to redact what they consider to be nonpublic information from records properly sought by FDA. One comment asks FDA to permit a person to create a separate document containing only that information FDA is entitled to inspect. Examples of confidential information that comments have described include formulas, recipes, information about their businesses, where the product was purchased or sold, product development information, and location and business operations of farms.

One comment requests that FDA allow the affected person to either redact confidential information from the source records (purchase orders, bills of lading, etc.), or create separate records containing the information required by section 414 of the FD&C Act, but not including the information excluded by § 1.362 of this final rule or any other confidential information.

(Response) FDA understands the comments' concerns about protecting the confidentiality of nonpublic information. If a person wishes to create separate records that do not contain certain confidential information, the person may do so, as long as the records are created at the time the food is received or released and the records contain the information required by the regulations. In addition, section 306 of the Bioterrorism Act excludes many types of confidential data from the record requirements: Recipes for food (see § 1.328 for the definition of recipe),

financial data, pricing data, personnel data, research data, and sales data (other than shipment data regarding sales). Section 306 of the Bioterrorism Act, however, does not allow other types of confidential data to be withheld from FDA even if they are confidential. The laws governing FDA's activities, however, require it to protect certain trade secret and confidential information. See responses to comments 74 and 154 of this document.

Further, because timely information is critical to a tracing investigation, records and other information must be made available to FDA as soon as possible, not to exceed 24 hours from the time of a request (§ 1.361 of this final rule). If the provision of information and records to FDA is delayed so that information can be redacted, the information and records may not have been provided ''as soon as possible.''

(Comment 154) Comments ask that FDA take steps to maintain the confidentiality of the information it receives. One comment asks that FDA develop and inform the public of procedural safeguards it will follow to obtain the information needed without jeopardizing the confidentiality of business information. Two comments ask that FDA provide guidance about its information disclosure procedures. Other comments ask how FDA will ensure the confidentiality of sensitive business information.

Comments ask that FDA provide for special procedures to safeguard the confidentiality of the identities of flavors and spices and other secret ingredients in a recipe. Two comments request that FDA issue a regulation and another comment suggests that FDA issue an interim final regulation concerning the statutory requirement under section 414(c) of the FD&C Act to prevent unauthorized disclosure of any trade secret or confidential information.

A comment asks that FDA provide a paragraph in a regulation requiring that FDA maintain the confidentiality of nonpublic information. That comment expresses concern about information FDA might receive from an ''unaffected source,'' ''incorrectly implicated sources'' in the distribution chain, or the identity of a food company that was the victim of ''food contamination in premeditated form.'' A comment asks that FDA amend its public information regulations to provide that information obtained under the records access authority is exempt from disclosure under FOIA.

(Response) As discussed in response to comment 74, several statutes and the agency's information disclosure regulations at parts 20 and 21 govern the agency's ability to disclose information to the public, including information obtained under section 306 of the Bioterrorism Act. For example, section 301 of the FD&C Act prohibits any person from using

> * * * to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts * * *, any information acquired under authority of [section 414 or 704] concerning any method or process which as a trade secret is entitled to protection * * *.

FDA already has procedures in place to ensure that FDA staff follow these laws. See, e.g., FDA Staff Manual Guide sections 2280.10, 3250.15, and 3291.5. Furthermore, the record provisions in the Bioterrorism Act recognize that FDA may obtain trade secret or confidential information, and direct the Secretary to ''* * * take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of [such information] * * *'' (21 U.S.C. 414(c)). FDA is planning to reemphasize in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained.

FDA has previously issued information disclosure regulations applicable to information FDA obtains, and these regulations are applicable to information FDA obtains under the Bioterrorism Act (parts 20 and 21). FDA notes that these regulations are applicable regardless of whether the person supplying the information is ultimately determined to be an ''unaffected source,'' ''incorrectly implicated source,'' or the victim of ''food contaminated in premeditated form.'' Therefore, it is not necessary for FDA to issue additional information disclosure regulations.

Moreover, FDA routinely reviews, evaluates, investigates and maintains confidential, trade secret information that encompasses sophisticated, cutting edge technologies, as well as confidential records that contain formulations and other trade secret information. Based upon FDA's track record of consistently ensuring the confidentiality of this type of information, we have attained the trust of the pharmaceutical, medical device and biologics industries. Moreover, the utilization of such information by an FDA employee for his or her own advantage, or the revelation of such information to outside parties beyond the scope allowed by the FD&C Act, is a prohibited act (21 U.S.C. 331(j)) subject to criminal prosecution.

(Comment 155) One comment asks that FDA not disclose personal details (name of responsible person) about secondary suppliers. The comment notes that disclosure of personal details of secondary supplies might be contrary to international and European privacy regulations. One comment notes that disclosure to the public of the names of the firm and the responsible individual might conflict with foreign confidentiality rules of law. Other comments express concern about protecting personal privacy information. Another comment states that farmers are concerned about the effect of possible information disclosure on the personal and physical security of their farms where they reside with their families.

(Response) Foreign persons, except for those who transport food in the United States, are exempt from all of the requirements in subpart J of this final rule. Farms are also exempt. FDA follows Federal statutes (e.g., FOIA, the Privacy Act) and its regulations (e.g., parts 20 and 21) in determining the proper treatment of information it receives, including personal information. FOIA, for example, contains exemptions that allow FDA to withhold personal information from the public in certain circumstances (5 U.S.C. 552(b)(6) and (b)(7)).

(Comment 156) A few comments ask what assurances FDA can give to a person subject to the Bioterrorism Act that the information will not be subject to unauthorized disclosure. Other comments ask that CBP and FDA guarantee nondisclosure of the information. A comment asks how FDA can guarantee the confidentiality of confidential and secret information such as formulas.

(Response) FDA complies with Federal law (e.g., the FD&C Act, FOIA, Trade Secrets Act) and regulations (e.g., parts 20 and 21) regarding the dissemination of the information it receives. FDA employees are subject to criminal penalties for disclosing information in violation of section 301(j) of the FD&C Act or the Trade Secrets Act. FDA plans to reemphasize to its field personnel the importance of current protections and legal requirements against unauthorized disclosure of any protected information FDA obtains.

(Comment 157) A comment concerned about adverse publicity asks with whom might FDA share information.

(Response) FDA is authorized to share certain nonpublic information with others. For example, FDA may share confidential commercial information with a sister agency within the

Department of Health and Human Services, a State government agency official whom FDA has commissioned to act on its behalf under section 702 of the FD&C Act (21 U.S.C. 372) (§ 20.84), its contractors (§ 20.90), other Federal government agencies (§ 20.85), or foreign government agencies (§ 20.89). Procedural and other safeguards must be followed for FDA to share nonpublic information with other persons. For FDA to share confidential commercial information with CBP under § 20.85, CBP must sign a written agreement that it will not further disclose the information except with FDA's written permission.

(Comment 158) Several comments express concern about the risk of disclosure of information about a formula or recipe. One of these comments noted that, even if the complete formula may not be disclosed, listing the source of each ingredient in a product would reveal the recipe for that product. Other comments ask how FDA would handle commercially sensitive information that might be derived if FDA provides information about a ''one-up'' source nontransporter for each of the ingredients in a recipe.

(Response) As discussed in response to comment 74 of this document, several statutes and the agency's information disclosure regulations at parts 20 and 21 govern the agency's ability to disclose information to the public, including information obtained under section 306 of the Bioterrorism Act. For example, section 301 of the FD&C Act prohibits any person from using

> * * * to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts * * *, any information acquired under authority of [section 414 or 704] concerning any method or process which as a trade secret is entitled to protection * * *.

FDA follows these laws in determining the proper treatment of the information it receives.

N. Comments on What Are the Consequences of Failing to Establish and Maintain Records or Make Them Available to FDA as Required by This Subpart?'' (Proposed § 1.363)

(Comment 159) Three comments state that imposition of criminal liability would be inappropriate and excessive if they performed to the best of their abilities. The comments state that taking time beyond 4 hours to locate, compile, and provide records on a detained article's manufacture should not be viewed as a prohibited act.

(Response) As noted previously, FDA has changed the proposed times in § 1.361 of this final rule for responding to a request for access to records to a requirement that all records 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.

(Comment 160) One comment states that the rules on recordkeeping are not enforceable outside the United States. The comment states that any legal proceedings based on failure to comply with the final rule that could result in confiscation of assets held in the United States or action against foreign executives visiting U.S. territory would be considered by a foreign country to be a very grave step. This would be unworkable in practice and problematic in terms of bilateral relations. The comment requests that FDA clarify that no enforcement action will be taken against foreign persons outside the United States.

(Response) Foreign persons, except those who transport food in the United States, are not subject to subpart J of this final rule and thus, for the most part, the concerns raised by the comment are moot. If FDA needs to access records kept by foreign persons, FDA intends to work in cooperation with the relevant competent authorities to do so.

(Comment 161) One comment encourages FDA not to use incidental infractions of its final recordkeeping regulations as a pretext for bringing additional enforcement actions for alleged violations of other agency regulations that are outside the scope of the Bioterrorism Act.

(Response) Nothing in the proposed or final rule suggests that FDA would take such actions.

O. Comments on What Are the Compliance Dates for This Subpart? (Proposed § 1.368)

(Comment 162) Many comments strongly urge FDA to revise the compliance dates in the proposed rule. The comments state that given the scope of the proposed requirements it is not possible for industry to be in compliance within the 6, 12, or 18 months proposed by FDA. The comments state that each of the new requirements imposes programming, training, and business practice adjustments that FDA must take this into account in setting an appropriate effective date for the regulation. The recommendations that FDA received from comments are as follows: 9 to 12 months for larger businesses; 1 year regardless of the size of the business; 18 months regardless of the size of the business; 18 months for large firms and 24 to 30 months for smaller firms, depending on their numbers of employees; an additional 1 year for each entity group; and 2 to 7 additional years.

(Response) FDA has carefully considered these comments and agrees that businesses should be given additional time to comply in view of the programming, training, and business practice adjustments that will be needed. Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance within December 9, 2005. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance within June 9, 2005, and very small businesses that employ 10 or fewer full-time equivalent employees must be in compliance within December 11, 2006. The extended compliance times for small and very small businesses are based on the total number of full-time equivalent employees within the entire business, not just at each individual establishment. FDA does not believe that extending more time is appropriate given the need for the regulations to help improve FDA's ability to address credible 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 enable FDA to notify more quickly the consumers and/or facilities that might be affected by the outbreak.

Further, the Bioterrorism Act directs FDA to take into account the size of a business in promulgating regulations. Consistent with this provision, FDA has: (1) Provided a full exemption for very small retailers based on the rationale stated previously; (2) provided a partial exemption for small (11 to 500 employees) and large (more than 500 employees) retailers from having to establish and maintain records as to immediate subsequent recipients; and (3) provided extended compliance times for very small businesses and small businesses in all sectors.

(Comment 163) Some comments state that the transportation chain information requirements, by themselves, are so complex they simply cannot be developed in such a short timeframe even if industry were not dealing with several other major security-related regulatory efforts under the Trade Act of 2002 and the Maritime Transportation Security Act of 2002.

The comments ask FDA to require more reasonable timetables that would be less costly and have a more realistic chance of successful compliance.

(Response) As stated in the response to the comment 162, FDA has modified the compliance timeframes proposed. The final rule gives covered persons 12, 18, or 24 months after the date of publication to come into compliance, depending on the size of the business. The extended compliance times for small and very small businesses are based on the total number of full-time equivalent employees within the entire business, not just at each individual establishment.

(Comment 164) Several comments state that the food distribution chain is comprised of multiple links or components, some of which will qualify as small or very small businesses, such as independent truck operators or some DSD operations. For example, some large national baked goods companies deliver products directly to stores through individuals who function as independent businesses (e.g., they own their own trucks, purchase the food from the vendor and sell it to the store, and hold licenses to the particular delivery routes). The comments state that, if these businesses are covered by the small business exemption, they will not be required to provide the information that larger businesses will be required to retain. The comments recommend that FDA either extend the exemption through all subsequent links in the distribution chain, or else recognize the interconnectedness of the systems and impose a single, more realistic compliance date with which all in the food distribution chain will be able to comply, e.g., establish a universal compliance date for the regulations of June 9, 2005.

(Response) FDA does not agree that all businesses should be subject to a universal compliance date. FDA has considered the interconnectedness of the food distribution system and contractual relationships that exist between very small, small, and large businesses. FDA has determined that large, small, and very small businesses will have 12, 18, and 24 months, respectively, from the date of publication of this final rule, with which to comply. These timeframes represent an extra 6 months over the timeframes in the proposed rule for all business sizes to come into compliance. FDA believes that many large businesses and possibly many small businesses already establish and maintain records that contain most or all of the information required by these regulations, and thus should not require longer than 12 and 18 months, respectively, to come into compliance. Very small firms would have 24 months to comply.

FDA anticipates that the very small and small businesses will be able to lower their compliance costs by learning from the experience of the large businesses. The extended compliance times for small and very small businesses are based on the total number of full-time equivalent employees within the entire business, not just at each individual establishment.

(Comment 165) One comment notes that small businesses doing business with large businesses would have to comply with the large business timeframe and asks FDA to reconsider this exception, and allow small businesses to comply on the 12 and 18 month schedule.

(Response) FDA has considered the interconnectedness of the food distribution system and contractual relationships that exist between very small, small, and large businesses. FDA has determined that small and very small businesses will have 18 and 24 months, respectively (not the 12 and 18 months that were proposed that the comment alludes to) to comply with the regulations, regardless of whether they are engaged in doing business with large firms.

(Comment 166) Several comments express support for the different implementation dates based on the size of a business. The comments state that the extra time will ensure that small businesses have adequate time to understand the new rules, reorganize their administrative recordkeeping, and spread the costs of the new rules over a greater volume of their (limited) production. In addition, within the first year of implementation, the comments note that the larger companies and FDA will resolve many of the problems that will arise with the new rules. The comments maintain that large companies are better able to adjust to any problems than are small businesses.

(Response) FDA agrees with this comment, and for the reasons stated in the preceding paragraphs, has modified the compliance dates and extended each of the proposed compliance dates by an additional 6 months.

(Comment 167) Several comments request that FDA clarify the method used to determine business size for deciding the timeframe for compliance. The comments ask whether a company's size is determined based on all employees of the parent company, the entire corporation as a whole, or upon each individual enterprise or location or manufacturing facility. The comments also question how full- and part-time employees are counted.

(Response) The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(Comment 198) Some comments state that the criterion used to determine small and very small businesses is the number of employees, whereas in other countries, especially the developing ones, other criteria are used to better reflect the nature of the businesses. The comments ask FDA whether the value of investment and value of assets can be considered as other criteria in determining if a business meets the definition of a small or very small business in order to be allowed extended time to comply with the regulations. The comments also ask FDA to consider factors such as production capacity and production value for labor-dense firms such as in China, where the production rate per person is lower than that in the United States.

(Response) FDA continues to believe it is appropriate to use the number of full-time-equivalent employees as a criterion to differentiate between very small, small, and large businesses. This is consistent with other regulations the agency has issued where staggered compliance dates were utilized, e.g., the juice HACCP regulation (21 CFR 120.1(a)).

(Comment 169) Two comments ask FDA to phase in enforcement of these provisions once the regulations are in effect, especially as to the critical elements of the regulation. One of the comments requests that FDA allow a grace period of 1 year before enforcing any of the rule's requirements against any organization that is taking good faith steps to achieve compliance.

(Response) Rather than phase in enforcement, FDA has extended the compliance dates for all covered persons subject to this final rule. The earliest that covered persons would have to be in compliance is 1 year for large firms, and the latest is as much as 2 years for very small firms.

(Comment 170) Two comments ask whether the staggered timeframes apply to foreign businesses of varying sizes.

(Response) Foreign persons, except for those who transport food in the United States, are not subject to the recordkeeping regulations in this final

rule. For foreign persons who transport food in the United States, the staggered compliance dates based on size of business applies.

(Comment 171) Two comments ask how the proposed rule affects long shelflife products prepared before the introduction of the new rule still in storage when full compliance is required. Is the rule retroactive or does it apply to food manufacturers from the date of full compliance?

(Response) Once applicable compliance dates occur, covered persons must establish and maintain records. As explained previously, records must be created at the times you receive and release the food. Persons do not need to keep records of the immediate previous sources of food if that food is received before the compliance date of the rule. Likewise, persons do not need to keep records of the immediate subsequent recipients if that food is released before the compliance date of subpart J of this final rule.

(Comment 172) One comment states that implementation may prove to be a major barrier to foreign shipments due to the additional strains and demands upon communication systems, port and airport facilities, and on the inspection infrastructure. The comment also states that it may overlap with the beginning of the fresh fruit export season.

(Response) Foreign persons, except those who transport food in the United States, are not subject to this final rule; however, persons that import food from foreign countries are subject to the rule. FDA believes that the compliance timeframes specified in § 1.368 of this final rule give all persons subject to this final rule, including importers, sufficient time to determine what steps are needed to be able to comply with the final rule, and to be in compliance on their respective compliance dates, while allowing FDA to meet its statutory objective of ensuring that persons that manufacture, process, pack, hold, transport, distribute, receive, or import food in the United States establish and maintain records that will significantly improve FDA's ability to address credible threats of serious adverse health consequences or death to humans or animals.

(Comment 173) One comment states that the proposed delay in the compliance date for small businesses does not adequately address small business needs. One comment states that FDA should provide businesses with additional assistance with compliance.

(Response) FDA has increased the compliance period for small businesses from 12 months to 18 months, and for very small businesses from 18 months to 24 months. With respect to additional assistance, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), FDA plans to publish a small entities compliance guide to assist small and very small businesses with complying with the recordkeeping requirements. As described previously, FDA also plans to conduct outreach activities to explain the requirements of this final rule to affected entities.

(Comment 174) One comment states that the phase-in for small and very small businesses is not a good idea because if the consequences are as grave as FDA claims, everyone must be required to comply at the earliest possible time, allowing for systems and procedural development and employee training. The comment states that a phase-in of the regulations would pose a threat to public health and safety, should not be part of this regulation, and would be against the public interest.

(Response) The Bioterrorism Act specifically states that, in issuing these regulations, the Secretary shall take the size of a business into account. FDA considered reduced requirements for, or even exempting, small businesses. However, most food products and ingredients pass through at least one small business during commerce. In addition, more than 80 percent of the covered entities are considered very small businesses. If FDA were to exempt small businesses from these regulations, permit shorter record retention periods, or subject them to reduced records requirements, FDA's tracing investigations would be severely compromised. Given the foregoing, FDA believes it is appropriate to give small and very small businesses additional time to come into compliance with the regulations.

(Comment 175) A few comments point out that the burden for maintaining records is proportionately similar for large transporter companies and small independent transporters. Therefore, according to the comments, the relative regulatory burden for small, independent transporters is no greater than for large companies. The comments contend that all carriers, regardless of the size of the company, should be required to comply with the same requirements on the same timetable.

(Response) As stated previously, the Bioterrorism Act specifically states that, in issuing these regulations, the Secretary shall take the size of a business into account. FDA believes it is appropriate to give small and very small businesses additional time to come into compliance with the regulations.

IV. Analysis of Economic Impacts—Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

This final regulatory impact analysis reflects changes made in the regulation from the proposed rule to the final rule, as well as changes in estimates in response to comments. It also includes responses to comments on the preliminary regulatory impact analysis (PRIA) (see 68 FR 25188). Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA for a fuller explanation of the estimates over which there were no significant comments or changes. As noted in the previous section of this preamble, FDA received 212 submissions in response to the proposed rule, which raised over 200 issues. We continue with the discussion of the comments and FDA's responses to those comments using the same presentation as in section III of this document, focusing here on the comments FDA received on the PRIA. Accordingly, the word ''Comment'' again will appear in parenthesis before the description of the comment, and the word ''Response'' will appear in parenthesis before FDA's response.

A. Summary of the Costs and Benefits of the Final Rule

We revised the estimated costs of the final rule in response to comments on the proposed rule and to account for the changes between the proposed and final rules. The final rule will cover more

than 1 million entities at a cost of approximately $1.41 billion in present value with a 7-percent discount rate. With a discount rate of 3 percent, the estimated present value of the costs is approximately $1.94 billion. Costs for learning, records redesign, and planning for records access requests are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the rule beginning in the second year for large and small firms, and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. The total cost estimate can be computed by summing the costs estimated for learning, records redesign, additional records maintenance, records retention, and planning for a records access request. The annual and total costs of the final rule are reported in table 1 of this document. The recurring annual costs of the final rule (the sum of additional records maintenance and learning for new firms) are about $123 million. The annualized costs of this final rule are $108,000 using a 3-percent discount rate and $110,000 using a 7-percent discount rate.

TABLE 1.—ESTIMATED ANNUAL AND TOTAL RECORDKEEPING COSTS[1]

21 CFR Section	Costs (in dollars)
1.337, 1.345, and 1.352 (learning)	$85,082,000
1.337, 1.345, and 1.352 (records redesign)	$205,239,000
1.337, 1.345, and 1.352 (additional records maintenance)	$114,701,000
1.337, 1.345, and 1.352 (learning for new firms)	$8,508,200
Discounted present value of total costs[2]	$1,406,356,000

[1] The annual costs are reported in undiscounted terms. Records access planning costs and records retention costs are estimated to be zero and are not reported here.
[2] The reported discounted present value of total costs assumes a 7-percent discount rate and a 20-year time horizon over which annual costs are summed.

The final rule will help reduce the numbers of people who become ill during foodborne outbreaks by reducing the time required for preventive action. Furthermore, the final rule will eliminate the recurrence of outbreaks that may have been prevented had poor records quality not resulted in prematurely terminating the initial traceback investigation. The number of illnesses prevented (excluded those associated with food security will be approximately 1,204. The food safety benefits reported in the table are the values of averted illnesses from increased food safety. Averted illnesses are valued by low, middle, and high cost of illness estimates for both $5 million and $6.5 million values of a statistical life. The estimated annual benefits from enhanced food safety range from $7 million to $25 million. These estimates should be interpreted as the minimum benefits from this final rule because they do not include the benefits from enhanced food security.

TABLE 2.—VALUE OF AVERTED ILLNESSES FOR THE FINAL RULE

	Low[2]	Medium[3]	High[4]
VSL[1] = $5 million	$7,388,685	$15,905,182	$24,421,229
VSL = $6.5 million	$8,199,494	$16,715,991	$25,232,038

[1] Value of a statistical life used to value the averted deaths.
[2] A value of $100,000 was used to value a year in good health.
[3] A value of $300,000 was used to value a year in good health.
[4] A value of $500,000 was used to value a year in good health.

B. Description of Proposed Rule

The proposed rule required the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States and also by certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The proposed regulations would implement section 306 of the Bioterrorism Act. FDA expected that the requirements the agency proposed would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

C. General Comments

(Comment 176) FDA received a number of comments that asserted that the costs of the proposed rule were incorrectly estimated.

(Response) If the comment asserted costs or benefits were incorrectly estimated without specifying which costs or benefits, there was not sufficient information for FDA to respond. Comments that specified which costs or benefits the comments believed were incorrectly estimated are addressed in later sections of this analysis.

(Comment 177) There were several general comments that the costs that result from the rule are too high and would result in the failure of enterprises and small businesses.

(Response) In the PRIA, FDA estimated the impacts of the costs of compliance on small businesses using FDA's small business model using a cash flow metric (Ref. 1). In this

analysis, we use the small business model to calculate the effects on small businesses using the difference between revenue and variable cost as the metric. A finding that firms incur costs greater than revenues as a result of this rule can be interpreted to mean that they may be driven out of business. We incorporated both the annualized value of one-time costs and the recurring costs for computing the effects of this final rule on small firms.

We computed the effects for firms manufacturing dietary supplements, candy, and ready-to-eat foods, including breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes in current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will incur negative cash flows (defined as revenues less than variable costs) as a result of this rule. The percentages of firms predicted to incur negative cash flows range from 0.2 percent to a high of 1.9 percent for the ready-to-eat food manufacturing industry. These findings strongly suggest that very few firms, if any, will be driven from business as a result of this rule.

D. The Tradeoff Between Costs and Risk Reduction

(Comment 178) Many comments argue that the benefits from the rule do not justify the costs to the food industry. Another comment states that it remains doubtful that the benefits from the regulation justify the costs, while another comment expressed the need for a proper model to compare the costs of the recordkeeping provisions with a measure of the risks averted from the provisions.

(Response) FDA agrees that the measure of the net benefits used to justify the regulation remains uncertain. A large portion of the uncertainty arises from FDA's inability to quantify the benefits from the regulation. In the PRIA, we used epidemiological evidence from four outbreaks to suggest qualitative results.

In the final rule, we develop a more comprehensive and detailed model to estimate the food safety benefits using information generated from FDA outbreak investigations (Ref. 2). We use this information to estimate the number of illnesses averted as improved recordkeeping practices lead to faster traceback investigations and higher rates of successful traceback completions. These estimates understate the true expected benefits from the rule, because they are derived solely from food safety data and do not take into account the expected benefits of this rule to food security. The estimate of strictly food security benefits is based on classified data and is not used in this analysis. A qualitative description of the security benefits is provided below under section IV.E.1 of this document, entitled ''Bioterrorism Considerations''.

Although benefit-cost analysis is primarily a quantitative exercise, the existence of non-quantified benefits and costs, as well as uncertainty around the quantified measures, means that assessing whether costs justify benefits entails a qualitative element. Decision aids such as uncertainty analyses are used to help decision makers in these instances.

(Comment 179) There were several comments stating that the costs of compliance for specific sectors, including foreign facilities, food contact suppliers, and transportation facilities, did not justify the benefits of reducing the risks of contamination posed by those sectors.

(Response) In the final analysis that follows, we refine the analysis of the benefits of selected policy options including those expected from foreign firms, food contact substance suppliers, and transportation facilities.

(Comment 180) One comment states the need to measure benefits from the regulation against the existing traceback and recall capability of the industry. This comment questions whether the provisions in the recordkeeping rule would improve response times for removing product from the market, and potentially reduce the number of illnesses from a foodborne outbreak. The comment suggests that FDA should consider what the savings would be in anticipated response times and records recovery times, as well as how this would translate into a reduction in illnesses and enhanced product recovery. Finally, the comment states that the burdensome exercise to produce records could actually slow and hinder the objectives of recalling a suspected product.

(Response) FDA agrees with the comment that a model is needed to determine the savings in investigation traceback times, and the numbers of illnesses that would be avoided from this regulation. FDA has developed a model of the benefits, which is described later in this section. However, FDA does not agree that the benefits should be compared to the current system for recalling products since few investigations result in recalls. Instead, FDA believes that benefits from this final rule will primarily be from faster investigations leading up to preventive actions, including recalls. A recall or other preventive action is made only after a product has been implicated. The benefits from the recordkeeping rule are to improve the accuracy and speed with which a product is implicated. If recalls or other preventive actions are made too quickly and cover too wide a range of products, there is the very real danger of a recurrence of the outbreak if the source is not investigated. For that reason, the benefits from the regulation include not only faster traceback investigation times, but also higher rates of completed traceback investigations, and the commensurate reduction in outbreak recurrences.

(Comment 181) One comment states that the analysis failed to meet Office of Management and Budget (OMB) guidelines for regulatory impact analysis by failing to do the following: (1) Adequately consider the need and consequences of the regulation and (2) show that the benefits outweigh the costs of the regulation. In addition, the comment states that the purpose of the regulation is to expand the agency's jurisdiction, rather than to maximize the net benefits to society, and that alternatives with the highest net benefits (including the alternative not to regulate) were not chosen. Finally, the comment states that the analysis failed to consider the condition of the affected food industries, potential future regulatory actions, and the weak state of the national economy as required.

(Response) In the PRIA, we stated that the need for these regulations is to enable FDA to respond to, and help contain, food for which the agency has a reasonable belief that it is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. In the final rule we bolster the explanation of the need for the regulation by analyzing vulnerabilities due to shortfalls in current recordkeeping practices. These shortfalls are shown to inhibit current outbreak investigation efforts and, by extension, efforts to mitigate serious adverse health consequences or death to humans or animals. The perceived vulnerability of the U.S. food supply to an attack, as articulated by Congressional passage of the

Bioterrorism Act, elevates the importance of addressing these shortfalls.

The analysis of the benefits of the final rule uses characteristics of conventional outbreaks and investigations to more clearly identify and quantify shortfalls in existing recordkeeping practices and how each is addressed by the recordkeeping regulation. We measure the effects in terms of the number of illnesses averted due to reductions in the duration of outbreak investigations and reductions in the number of investigations that are prematurely terminated because of poor records quality. When an investigation is prematurely terminated, there is both a loss of data that might prevent recurrences of the outbreak and a decrease in the effectiveness of any preventive action. The need for this regulation is underscored when the potentially large sizes of outbreaks from intentional attacks on the food supply are considered. Although the probability of such an intentional attack is unknown, the size of the benefits from this regulation are larger, the larger the size of such an outbreak.

We estimate benefits using data from FDA outbreak investigations. We then compared estimated benefits for a number of regulatory options. In this way, the benefits of each regulatory option can be compared to its costs. While the costs and benefits of the policy alternative ''not to regulate'' are not considered in the final rule, they were analyzed in the proposed rule. We did not estimate the effects of potential future regulatory actions because we do not anticipate any such actions that would affect the estimated costs or benefits of this final rule.

In response to the comment that we have not shown that benefits exceed costs, the Executive Order requires that costs must be justified by benefits. We believe we have done so in this analysis. Finally, in the PRIA, FDA addressed the state of the national economy by examining the impact of the final rule on the most vulnerable firms in the industry, through simulations using our small business model (Ref 1.), and also in the Unfunded Mandates section by examining the impact of the rule on all consumers as well as producers in the food economy in general.

In this analysis we use the small business model to calculate the effects of the costs of this final rule on the survival of small businesses. We incorporated both the annualized one-time costs and the recurring costs for computing the effects on cash flows. We computed the effects for firms manufacturing dietary supplements, candy, and ready-to-eat foods, including breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes to current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will shut down as a result of this rule. In the Unfunded Mandates section of the PRIA, we also consider the impacts of the proposal on food prices and conclude that any effect would be negligible.

E. Estimating the Benefits

The benefits from the recordkeeping rule will be from illnesses averted due to faster traceback components of outbreak investigations, and an increased ability to complete investigations that previously would have been prematurely terminated due to poor records quality. Because of this new recordkeeping rule, a greater number of traceback investigations will be completed, and traceback investigations will take less time because of shorter records access times and better records quality.

The benefits estimated in this analysis are realized only in the event of a foodborne outbreak (intentional or unintentional) because the probability of a terrorist attack is unknown. However, the estimated costs are incurred at all times regardless of whether there is an outbreak investigation underway, as well as by all facilities, regardless of whether they are implicated in the outbreak.

1. Bioterrorism Considerations

Interviews with FDA traceback personnel indicate that traceback and source investigations involving fresh produce find that the contamination often occurs at the farm level (Ref. 2). The interviews suggest that bioterrorism scenarios envision possible intentional contaminations on the farm, in distribution, at processing, and at retail. Moreover, fresh products may be more likely targeted for intentional contamination when they are at intermediate levels of processing than when they are at the farm level.

The benefits from the recordkeeping rule are from enhanced food safety and enhanced food security. We can estimate the food safety benefits, but we cannot estimate the food security benefits, as the probability of the occurrence of a deliberate outbreak is unknown. The tangible benefits from the recordkeeping rule occur after an outbreak of food-related illness. With the records required by this rule, the agency can investigate outbreaks more quickly and will not be forced to terminate an investigation because of poor or nonexistent records. The speeding up of investigations generates benefits in some cases because the information from the records will enable the agency to take actions to reduce the size of the outbreak. Both the increased completion rate and faster investigations may reveal more sources of outbreaks and help to prevent recurrences.

The food security benefits of recordkeeping come from mitigating a terrorist attack on the food supply, and preventing unnecessary expense in the event of a hoax or a small terrorist event. While we are unable to estimate the benefits from such scenarios, we can point to investigative speed as a principal mechanism for mitigating their costs. The first benefit—mitigating the effects of an attack—is similar to the food safety benefit. Investigations will be quicker because of better records. Investigation speed may be crucial in the early period after a terrorist attack to more quickly determine the likely scope and scale of the contamination. With quicker investigations, the government can act sooner to reduce the public health and other effects of a terrorist attack on the food supply. These benefits should be qualitatively the same as in the case of an accidental outbreak of food-related illness, but we expect them to be potentially larger for a terrorist attack on the food supply.

The second counterterrorism benefit from recordkeeping is also difficult to quantify but may be important: the ability to identify quickly a potential food security hoax. The hoax could be completely false, or it could be a small event masquerading as a large event. For example, a terrorist could contaminate a single container of some food and send out an Internet message stating that the entire national stock of that food was contaminated. If the goal is to spread terror rather than to cause mass illness, then a small attack or even an Internet announcement with no contaminated products could persuade consumers that the risk is real.

With a sufficiently plausible background story implicating a widely-consumed food, the hoax might lead to

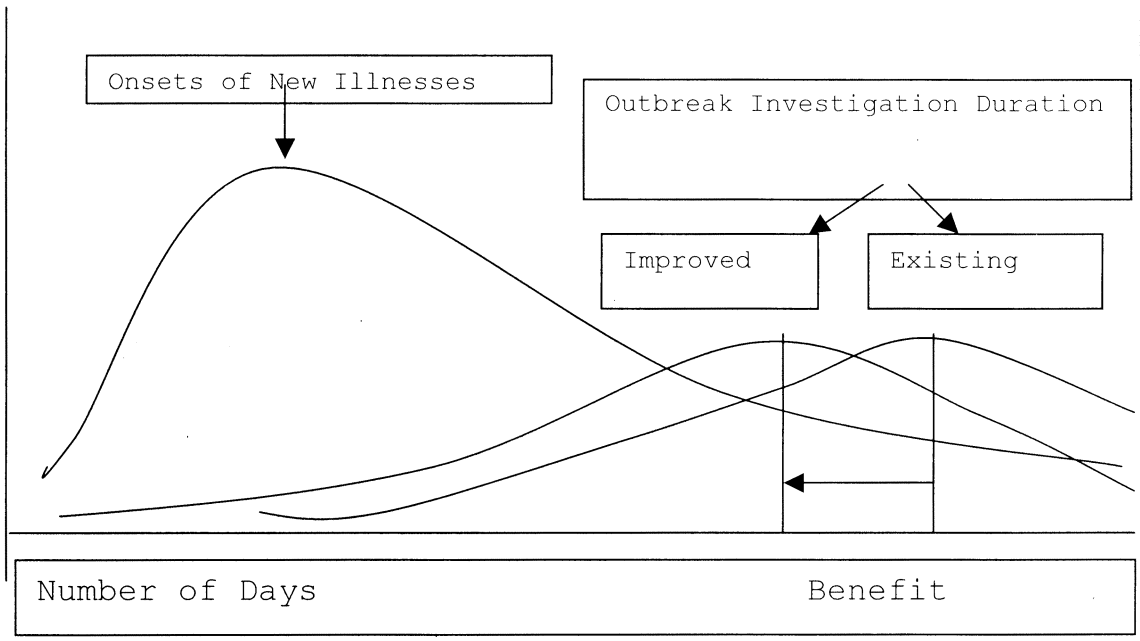
extensive protective efforts by businesses and consumers. Consumers might take costly preventive actions, such as throwing away food, stopping their consumption of the suspect food item, or visiting physicians or emergency rooms to determine if they have been exposed to some hazard. Producers and distributors might destroy inventories of the suspect food as a preventive measure. If there is widespread uncertainty about the extent of contamination, this protective behavior could easily generate high costs. If the terrorist attack on a food is a small-scale event masquerading as a national event, a full system of records will allow the agency to trace the suspect foods through the food chain to determine the extent of contamination. The government could quickly narrow down the range of suspect foods and, if the risk is absent, reassure the public that the suspect foods are indeed free of contamination by terrorists. The ability to move quickly and authoritatively will possibly generate real benefits by preventing costly defensive actions by businesses and consumers.

2. Benefits: Model Framework

The primary food safety benefits from this rule are from the number of illnesses averted due to improved recordkeeping practices. Improved recordkeeping practices result in faster traceback investigations and higher traceback completion rates, which will reduce the expected number of illnesses from intentional and unintentional outbreaks.

The following diagram visually depicts the benefits from faster traceback times from the recordkeeping rule. The number of onsets of new illnesses and outbreak investigation duration curves overlap to estimate the number of days that an investigation is likely to reduce the duration of an outbreak. With faster traceback times, the distribution of the durations of outbreak investigations shifts to the left from ''existing'' to ''improved,'' reducing even further the number of days of an outbreak. This diagram assumes the outbreak is still going on at the time the traceback investigation begins. The reduced number of days of an outbreak can then be translated into a reduced number of illnesses from an outbreak.

Figure 1: The Distributions of the Onsets of New Illnesses Over Time During an Outbreak, and the Duration of an Outbreak Investigation.



There are two ways that the recordkeeping rule speeds up traceback investigations: (1) Higher records quality means that traceback investigators spend less time trying to find and analyze information that might have been missing or incomplete had there been no rule and (2) the rule makes failure to provide records within the required time period a violation, thus increasing cooperation with investigators who need rapid access to records. Greater traceback speeds result in more recalls (if the product is still in the marketplace), administrative detentions (under section 303 of the Bioterrorism Act), import actions, closures, and other preventive actions that reduce the number of illnesses during an outbreak. The following is a description of the model used to measure the benefits from the recordkeeping rule.

i. *Given the speed of the initial recognition and epidemiological investigation of an outbreak, the benefits from the recordkeeping rule*

depend on the following factors: (1) the average duration of a traceback investigation, (2) the average number of traceback investigations prematurely terminated for reasons of poor records quality, and (3) the distributions of outbreak durations and sizes.

ii. *The average duration of a traceback investigation depends on the number of point-of-service and distributor investigative visits per traceback investigation, and the average duration of an investigative visit*. The quantity of records that needs to be reviewed is an important determinant of the duration of a traceback investigation. However, we assume that the change in the quantity of records requested is much smaller than the change in the quality of the records requested as a result of this final rule. We therefore omit the quantity of records reviewed during a traceback investigation as a modeling consideration when measuring the impact of the final rule.

iii. *Because traceability information, such as lot codes, may be readily identified on the label of packaged products but is largely absent for fresh produce, the average number of investigative visits per outbreak may depend on the food category (e.g., fresh and packaged) of the contamination source*.

iv. *The average duration of an investigative visit depends on the following factors*: Average records access times, which depend in part on how records are stored and maintained; average travel times and overnight stays required to complete an investigative visit; and average records analysis times. The time required to analyze records depends on the quality of the records.

v. *The rate that traceback investigations are prematurely terminated due to poor records quality will decline as the average quality of records improves*. This improvement will reduce the number of outbreaks that result from recurring contaminations that may otherwise have been prevented.

vi. *The size, contaminating agent, and duration of an outbreak determines the number of illnesses averted from faster preventive action and higher success rates of traceback completion*. The value of the averted illnesses is the averted medical expenses, and the averted loss in welfare, including pain, suffering, and productivity that would otherwise result from the illness.

Thus, the model may be summarized as the following:

i. *Benefits are determined by*: (1) The sizes of outbreaks, and the nature of contaminating agents, which determine the baseline number and severity of illnesses potentially averted; (2) the reduced time needed to complete a traceback investigation, which reduces the number of illnesses by allowing faster preventive action; and (3) the increased rates of successful traceback completion, which reduce the number of illnesses that result from outbreak recurrences.

ii. Time to complete a traceback investigation is determined by the time needed to complete an investigative visit, and the number of investigative visits.

iii. *Time to complete an investigative visit is determined by the record access times, and the record analysis times*.

iv. *Record analysis times are determined by records quality (we ignore the quantity of records requested on the assumption that the changes in the quantity resulting from this final rule will be negligible compared with changes in the quality)*.

v. *The rate of successfully completed traceback investigations is determined by the quality of the records*.

vi. *The value of the averted illnesses is computed by adding together the estimated value of averted healthy life days lost, and the averted medical expenses due to the illness*.

3. Data on Outbreak Sizes, Durations, and Contaminating Agents

Data used to estimate the numbers of illnesses, contaminating agents, and outbreak durations are taken from FDA information documenting investigations monitored by the agency from 2000-2003 (Ref. 2). The investigation information is drawn from multiple, non-standardized sources that irregularly document different aspects of investigations. The number of investigations reported in the table is not exhaustive; more investigations may be documented elsewhere. Moreover, it is possible that the information does not perfectly reflect the universe of FDA outbreak investigations because the methods for its collection and distribution are non-standardized. Nevertheless, we believe the information is sufficiently accurate, and that the list of outbreaks is sufficiently exhaustive for purposes of estimating the benefits from the recordkeeping final rule.

The outbreak duration is calculated as the time between the first and last illness, and the sizes of the outbreaks are calculated as the numbers of known illnesses attributed to an outbreak. The charts that follow depict the sizes and durations of the outbreaks from 2000 to 2003 as estimated from FDA outbreak investigation data.

Chart 1:

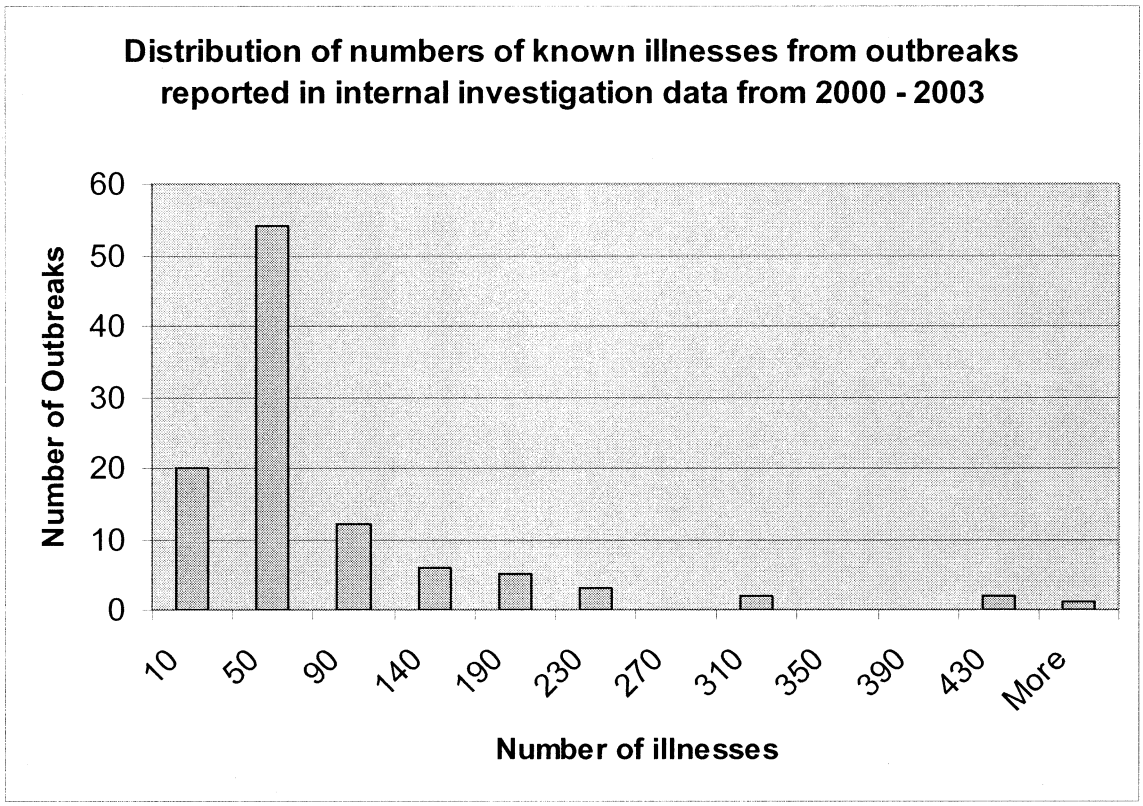
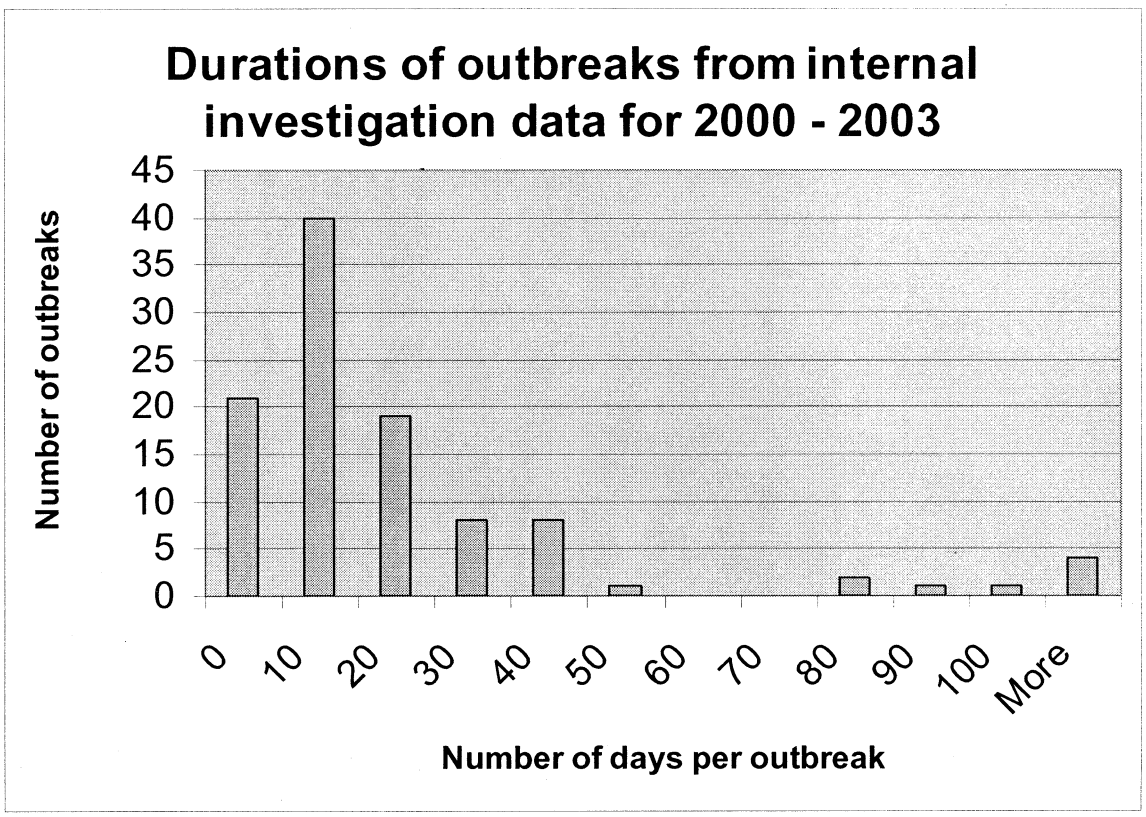
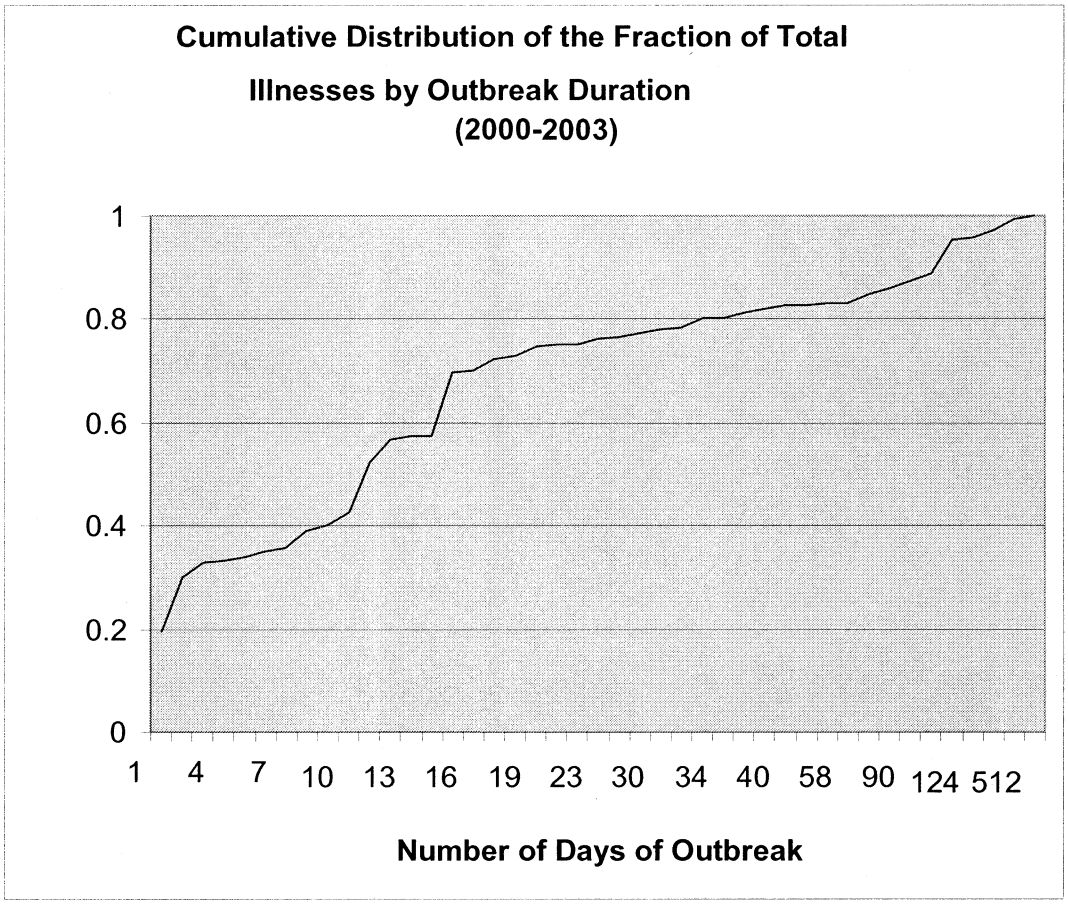

Distribution of numbers of known illnesses from outbreaks reported in internal investigation data from 2000 - 2003
Number of Outbreaks
60
50
40
30
20
10
0
10
50
90
140
190
230
270
310
350
390
430
More
Number of illnesses

Chart 2:



The next diagram combines information from the two preceding diagrams and depicts the cumulative distribution by outbreak duration of the percent of all onsets of illnesses. The horizontal axis in the following diagram gives the number of days that outbreaks lasted, and the vertical axis gives the fraction of all illnesses that occurred during outbreaks of a given duration. The diagram shows that approximately 80 percent of illnesses were from outbreaks that lasted for 33 or fewer days, and 20 percent of all illnesses were from outbreaks that lasted more than 33 days.

Figure 2:



Estimates of the durations and magnitudes of outbreaks based on FDA outbreak investigation information may overestimate the true average outbreak magnitudes and durations. The outbreaks monitored by FDA may be the most difficult to investigate because they involve interstate commerce (so illnesses are geographically dispersed), and may sicken a greater number of people. Consequently, the duration and magnitudes of the outbreaks may be longer and more severe than the average duration and magnitude of all investigations, which includes investigations at the local level in addition to the national level. However, as indicated earlier, the estimates presented here are based on food safety considerations and may understate the benefits of this final rule when the possibility of bioterrorism (food security) is considered.

4. The Total Number of Illnesses

The following table 3 of this document reports agents, illnesses, and deaths taken from the FDA outbreak investigation information. The 129 outbreaks from approximately 21 agents resulted in reports of 8,325 illnesses, 444 hospitalizations, and 21 deaths. The data reported in the table are drawn from multiple, non-standardized, sources that irregularly document different aspects of investigations.

TABLE 3.—THE DISTRIBUTION OF ILLNESSES BY AGENT FROM OUTBREAKS MONITORED BY FDA FROM 2000 TO 2003

Agent	Number of Outbreaks Attributed to the Agent	Number of Known Illnesses Attributed to Outbreak Agents	Number of Illnesses That Were Known to Be Hospitalized
Bacteria			
Campylobacter	1	20	0
E. coli 0157:H7	13	287	45
Listeria	2	51	10
Salmonella	59	4,411	253
Shigella	3	672	30
Vibrio P.	4	124	0

TABLE 3.—THE DISTRIBUTION OF ILLNESSES BY AGENT FROM OUTBREAKS MONITORED BY FDA FROM 2000 TO 2003—Continued

Agent	Number of Outbreaks Attributed to the Agent	Number of Known Illnesses Attributed to Outbreak Agents	Number of Illnesses That Were Known to Be Hospitalized
Chemical			
Ammonia	1	141	42
Methomyl	1	26	0
Sodium nitrite	1	5	0
Parasitic			
Cryptosporidium	1	19	0
Cyclospora	4	78	3
Toxin			
Ciguatera or Ciguatoxin	3	26	3
Histamine	3	26	7
Saxotoxin	1	17	0
Scromboid	2	14	4
Star Anise	1	20	0
Toxin	1	78	0
Viral			
Hepatitis A	4	945	18
Norovirus	18	1,246	11
Viral or Vitri	1	35	4
Unknown	5	84	14
Total	129	8,325	444

The number of illnesses reported in table 5 of this document represents only the known cases, cases that have been recorded elsewhere in the public health system. For each reported illness, there are many illnesses that are unreported, so the actual number of illnesses from outbreaks is much larger than the reported number. For example, CDC states that the ratio of total (unreported plus reported) illnesses to reported sporadic illnesses from *Salmonella* is 38 (Ref. 3).

To estimate the number of unreported illnesses from outbreaks that FDA monitors, we assume the same pathogen-specific hospitalization rates as those used in the CDC estimates for the burden of foodborne illness (Ref. 3). For example, CDC assumes a 0.295 hospitalization rate for all illnesses caused by the pathogen *E. coli* 0157:H7. Moreover, CDC assumes that about one-half of hospitalizations related to foodborne illnesses are reported or diagnosed (Ref. 3). Consequently, we estimate that there were 90 hospitalizations due the *E. coli* pathogen from outbreaks monitored by FDA 2000 to 2003 (i.e., twice the number of hospitalizations from *E. coli* 0157:H7 reported in table 3 of this document). Based on the CDC hospitalization rate for *E. coli*, we estimate that the total number of illnesses (reported and unreported) from outbreaks caused by *E. coli* contamination is approximately 305 (i.e., 90 divided by 0.295, the hospitalization rate for illnesses caused by *E. coli* 0157:H7).

In order to characterize uncertainty in the estimates, we assumed that the total number of unreported illnesses from outbreaks for almost all pathogens would be distributed as a negative binomial with the parameters defined by the case hospitalization rates, and twice the reported number of hospitalizations. The estimated total number of illness for each agent is extrapolated from the estimated number of hospitalizations, with two exceptions: Estimates obtained of the total number of illnesses from *Listeria monocytogenes* and *Vibrio parahaemolyticus* were less than the reported total from those pathogens, so we used the reported total instead of the estimated total.

Case hospitalization rates for chemical poisoning and for other toxins are not reported in the CDC report, and (because such cases are unusual and characterized by severe acute distress) we assumed that half of such cases would be hospitalized. Finally, we assumed that the total number of illnesses from unknown agents is the same fraction of the estimated total summed over all pathogens, as the reported total summed over all pathogens. The estimated ratio of the total number of illnesses to reported illnesses was computed by dividing the estimated total by the reported total summed of all pathogens.

The average estimate of the ratio of total illnesses to reported illnesses from all pathogens, as well as the high and low estimates representing the 95 percent and 5 percent levels are reported in the following table. We estimate a total of 71,928 reported and unreported illnesses from outbreaks monitored by FDA from 2000 to 2003. This total reflects 8,325 illnesses that were reported, and approximately 63,603 that were estimated to be unreported.

TABLE 4.—ESTIMATED RATIO OF THE TOTAL NUMBER OF ILLNESSES TO REPORTED NUMBER OF ILLNESSES

Mean	Low (greater than 5% of the range)	High (greater than 95% of the range)
8.64	7.89	9.51

5. The Costs of Each Illness

We estimate the direct medical costs as well as the indirect costs of illnesses from outbreaks monitored by FDA. The direct medical costs include the costs of any doctor visits and hospitalizations that are required. Indirect costs are from the loss in productivity and quality of life as a result of the symptoms and severity of the illness. We estimate the indirect and direct costs of each illness for mild, moderate, and severe cases.

Mild cases are assumed to remain untreated with no direct medical costs. We assume that persons with moderate cases visit a physician and that those with severe cases require hospitalization. The average costs of $64 for a physician visit was obtained from the online source, Medical Economics (Ref. 4), and hospitalization costs were obtained from the Health Cost and Utility Project's (HCUP) Nationwide Inpatient Sample (Ref. 5) by type of illness.

The numbers of days that symptoms persist for each illness and severity were estimated from the FDA-Center for Food Safety and Applied Nutrition (CFSAN) Bad Bug Book (Ref. 6), CDC's National Center for Infectious Diseases, Infectious Disease Information fact sheets (Ref. 7), and from a CFSAN report entitled ''Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act'' (Ref. 8). These estimates were assumed to be uniformly distributed with the means reported in table 5 of this document.

TABLE 5.—DURATION OF THE ILLNESS FOR MILD, MODERATE, AND SEVERE CASES

Mild	Moderate	Severe	
Bacteria			
Campylobacter	4	8	8
E. coli 0157	3	8	18
Listeria	4	30	37
Salmonella	4	12	16
Shigella	3	11	18
Vibrio P.	2	2	3
Chemical			
Ammonia	3	5	7
Methomyl	3	5	7
Sodium nitrite	3	5	7
Parasitic			
Cryptosporidium	17	22	60
Cyclospora	17	22	60
Toxin			
Ciguatera or Ciguatoxin	2	5	19
Histamine	2	5	19
Saxotoxin	2	5	19
Scromboid	2	5	19
Star Anise	2	5	19
Toxin	2	5	19
Viral			
Hepatitis A	22	22	28
Norovirus	2	2	6
Viral or Vitrio	2	2	6

The distributions over mild, moderate, and severe cases for most of the illnesses were estimated from the CDC (Ref. 3), and a CFSAN report entitled ''Modeling the Effects of Food Handling Practices on the Incidence of Foodborne Illness'' (Ref. 9). The case distributions over mild, moderate, and severe cases were estimated for chemical and marine toxin poisoning from a study by Brevard et al. (Ref. 10), and a study reported by CDC (Ref. 11).

The indirect costs of an illness are the loss in welfare measured as a loss in life quality or, in the extreme case, death from the illness. This loss in quality of life also includes lost worker productivity while ill. Estimates of the indirect costs will vary depending on the symptoms of the illness and their severity. We use a quality of well-being scale for a typical gastrointestinal illness to adjust the well-being of a person with mild, moderate, or severe symptoms (Ref. 12). The well-being scale assumes a value of 1 for a person in good health, and is reduced according to the

symptoms and impaired mobility, reduced physical activity, and reduced social activity that result from the illness.

We compute an index of lost quality adjusted life days (QALD) by subtracting the individual's health status when ill from one and then multiplying that fraction by the number of days the illness lasts. The result represents the number of health days lost from an illness; we estimate the loss for varying severities for each illness. The QALD losses for an average foodborne illness are reported in the following table 6 of this document.

TABLE 6.—LOST QALDS DUE TO AN AVERAGE CASE OF FOODBORNE ILLNESS

Severity of Illness	Symptom	Mobility	Physical	Social	Quality Adjustment	QALDs Lost
Mild	-0.29	-0.062	-0.077	-0.061	0.51	0.49
Moderate	-0.29	-0.062	-0.077	-0.061	0.51	0.49
Severe	-0.29	-0.090	-0.077	-0.061	0.48	0.52

To reflect uncertainty in the literature, FDA uses a range to estimate the values of the health days lost. We use a low estimate of $100,000 for the value of a life year. This is consistent with that proposed by Garber and Phelps, who suggest a value of approximately twice the annual income (Ref. 13). U.S. Census data reports that the median family income in 2001 was approximately $51,000 (Ref. 14).

Middle and high estimates of the value of a health day are derived from estimates reported in the literature of the value of a statistical life. A value of a statistical life of $6.5 million is consistent with the findings of a literature survey of the premium for risk observed in labor markets, reported by Aldy and Viscusi (Ref. 15). We derive middle and high estimates of the value of a health day by annualizing the value of a statistical life of $6.5 million over 35 years at discount rates of 3 percent and 7 percent. These computations yield middle and high estimates for the value of an additional year of life of about $300,000 and $500,000. We estimated the range in values of a health day by dividing each of the estimates of the value of an additional year of health by 365, which yields estimates of $274, $822, and $1,370.

To calculate the indirect costs of mild, moderate, and severe cases of the illnesses, we multiplied the low, middle, and high estimates of the value of a health day by the QALD estimated for each illness and severity. Consistent with OMB's guidance on the use of multiple values for a statistical life, we used values of $5.0 million and $6.5 million to compute the value of a death from an illness.

The estimated range of the average cost of an illness resulting from outbreaks monitored by FDA from 2000 to 2003 is reported in the following table. The averages reported in table 7 of this document are weighted by the total number of reported and unreported illnesses from each agent, as well as the assumed distributions of mild, moderate, and severe cases, including deaths, from those illnesses. As explained earlier, we valued statistical deaths at $5 million and $6.5 million, and the low, medium, and high estimates assume values of a healthy year of $100,000, $300,000, and $500,000.

TABLE 7.—AVERAGE COST OF AN ILLNESS ACROSS OUTBREAKS

	Low	Medium	High
VSL = $5 million	$6,136	$13,209	$20,282
VSL = $6.5 million	$6,810	$13,883	$20,955

6. The Stages of an Outbreak Investigation

There are four stages in an outbreak investigation. The first stage is the preliminary investigation of laboratory results and epidemiological evidence used to determine the parameters of the outbreak, including the following: number ill, food vehicle contaminated, microbial or other agent responsible, potential commercial sources of contamination, as well as the degree of confidence in the information on each of these parameters. The second stage of the outbreak investigation is the decision making part, when FDA determines what resources will be committed to proceed further in the investigation. The third stage is the traceback investigation, which is conducted to do the following: (1) Identify the source and distribution of the implicated food and remove the contaminated food from the marketplace; (2) distinguish between two or more implicated food products; and (3) determine potential routes and sources of contamination in order to prevent future illnesses, or to treat persons sooner for the identified contaminants. The traceback investigation involves investigative visits by FDA inspectors to points of service, which are the facilities where consumers had purchased the contaminated food, and also distribution facilities.

A fourth stage is the source investigation of the specific practices at the farm, transportation, or other facility that may have led to the outbreak. For many outbreaks, the source investigation occurs well after any preventive action can be taken to limit the number of illnesses. This would be true for outbreaks from contaminated foods with short shelf lives that no longer are in circulation at the time of the source investigation, or from contaminations occurring at banquets, parties, or other one-time events where the source investigation cannot limit the size of the outbreak. For these outbreaks, the improved recordkeeping practices specified in the final rule would not improve FDA's current ability to limit the size of the outbreak, or prevent additional illnesses.

However, for certain products such as eggs, sprouts, and other fresh products, additional illnesses due to conditions at the source may continue if shipments from contaminated facilities continue. The same may also be true for perishable foods imported on a frequent basis from contaminated facilities. For these kinds of outbreaks, the ability to more rapidly implicate a contaminated farm or manufacturing source will improve FDA's ability to limit the size of the outbreak, or prevent its recurrence.

7. The Duration of Traceback Investigations, and Numbers of Premature Terminations

FDA outbreak investigation personnel estimate that a full outbreak investigation lasts at least 3 to 5 weeks, with a most likely duration of 2 to 6 months, and a maximum duration of 10 months (Ref. 2). The numbers of outbreak investigations and investigative visits come from internal interviews with investigation personnel and from other data maintained by FDA (Ref. 2).

The annual numbers of outbreaks investigated, investigative visits, and investigations that are prematurely terminated for reasons of poor records quality are reported in table 8 of this document. A traceback is defined to be prematurely terminated for records quality reasons if investigators noted in summarizing information that data quality impeded the investigation which ended before investigators were able to determine the specific cause of the outbreak. We used the simple averages over the 4 years reported in the table to estimate the annual numbers of outbreaks investigated, the annual numbers of investigative visits per outbreak investigated, and the annual rates of investigations prematurely terminated for reasons of poor records quality. We characterized the uncertainty of these estimates as normal distributions with means and standard deviations taken from the data on annual numbers of outbreaks and investigative visits per outbreak. For the annual rate of prematurely terminated investigations, we characterized the uncertainty with a beta pert distribution using the average, low and high values reported in the table 8 of this document.

TABLE 8.—OUTBREAK INVESTIGATION DATA

Year	Number of Outbreaks Investigated	Number of Investigative Visits per outbreak	Rate of records quality related premature terminations
2000	9	12	0.11
2001	9	11	0.33
2002	18	7	0.06
2003	17	6	0.00

The recordkeeping requirements of this final rule will improve the quality of records established and maintained by persons that manufacture, process, pack, transport, distribute, receive, hold, or import food. For options that provide comprehensive coverage of all food facilities, we estimate that the number of investigations prematurely terminated because of poor records would fall to zero. For options that provide less than comprehensive coverage, the reduction in premature terminations is reduced in proportion to the coverage.

Because outbreaks whose investigations are prematurely terminated may recur, the benefits from reducing that number may be high (if many people continue to become ill as a result of the recurrence). Based on FDA outbreak investigation information, the average number of reported illnesses in outbreaks that occurred between the years 2000 and 2003 was approximately 65. However, many illnesses from outbreaks go unreported, so the average total number of illnesses from an outbreak is much larger than the reported number. Using the estimated average ratio of total illnesses to reported illnesses reported earlier, we estimate that by avoiding just one outbreak recurrence, approximately 559 persons would avoid becoming ill.

Traceback durations may be different for processed food sold in packages with labels with identifying barcodes than for fresh food items sold in packages with no labels. Eggs and fresh produce account for 90 percent of all outbreaks investigated by FDA, while labeled packaged foods account for only 10 percent (Ref. 2). To determine the likely length of time it takes to investigate a packaged food product, we use a range that includes the low end, where investigators are able to obtain the exact package that contains the identifying barcodes, and the high end that assumes the package, with the identifying barcodes, is not available. In the latter case, any subsequent recalls would likely include more foods than the implicated lot.

The final rule relaxes the proposed requirement for lot codes to be established and maintained on all records. If FDA were to require all persons, including distributors, transporters, and retailers, to include lot numbers in the records they establish and maintain under this final rule, the traceback durations for many products would be reduced and would be comparable to those currently reported for tracebacks of packaged products that contain barcode information. If all retailers and distributors were required to establish and maintain lot codes for all processed products, then the duration of the traceback component of an outbreak investigation for many products could be reduced to 1 to 14 days. Examples of reported traceback times for fresh products and for packaged products that contain lot code information in bar code format are reported in table 9 of this document.

TABLE 9.—DURATION OF THE TRACEBACK COMPONENT OF AN OUTBREAK INVESTIGATION[1]

	Most Likely	Low	High
Eggs and fresh produce	6 to 8 weeks	2 to 5 weeks	12 weeks

TABLE 9.—DURATION OF THE TRACEBACK COMPONENT OF AN OUTBREAK INVESTIGATION[1]—Continued

	Most Likely	Low	High
Packaged products	3 days	1 day	14 days

[1] Estimates reported in Ref. 2 of this document.

8. The Duration of Investigative Visits

The main delays in traceback investigations are long travel times and overnight stays, slow and poor cooperation from recordkeepers, and inconsistent and incomplete records. Many recordkeepers may not be inclined to devote sufficient labor to providing records to inspectors during business hours because that is a costly time of day to reallocate resources. Furthermore, sometimes companies follow time-consuming procedures before approving FDA's request for records access. The legally binding provision in this rule will expedite cooperation from recordkeepers and reduce access times. When we take into account the requirement in the rule that access be provided on weekends, we estimate a substantial amount of time saved due to the records access provision—especially when there are multiple point of service or distributor visits.

The inconsistency and incompleteness with which some records are maintained are also important causes for delay in an investigative visit. Records from approximately 50 percent of access requests require additional information from the recordkeeper. Examples of information that may be incomplete include supplier contact information, a description of a product received or shipped, or date of receipt or shipment. This information is used by analysts located at headquarters, along with inventory rotation and control information, to determine precisely what was shipped, by whom, and when it was received. Often, many similar products from different suppliers are received during the course of the day by any given receiver.

Frequently, records document transactions from regular suppliers or customers where the identity of the shipper and description of the product can be determined readily based on the regularity and composition of the shipments. Sometimes, an entity will receive an unusual shipment (especially during holiday seasons), or it may receive multiple shipments of similar products from different suppliers, making it difficult to precisely link an incoming product with an outgoing shipment. Other times, descriptions of products received differ from how they are referenced on the shipping documents, making it difficult for the analyst to link the incoming product with an outgoing shipment.

Each category of incidents may result in confusion on the part of the analyst located at central headquarters and require an additional visit by the field inspector to the recordkeeper for further clarification. Because travel times account for a significant amount of time in a traceback investigation, and an estimated 20 percent of all point of service or distributor visits require an overnight stay, we estimated that the final rule would result in substantially reduced traceback durations.

Including travel time, 1 full day is usually required to obtain records after a request. A second full day is required when the records are not available on the first day. Furthermore, although records analysis times are typically only 7 to 10 hours, approximately 50 percent of all investigative visits require a return trip to clarify inconsistencies in the records, or to obtain additional information to compensate for incomplete records. In addition to slow compliance with records access requests, the unavailability of personnel and flight schedules may necessitate an overnight stay and an extra day of travel by an FDA investigator. Approximately 20 percent of all investigative visits require an overnight stay.

The duration of each component of an investigative visit, both inclusive and exclusive of travel times, is reported in the following table. We assume a uniform distribution of between 1 and 3 days including travel times for obtaining requested records. We assume that the times for records analysis are uniformly distributed between 0.8 and 1.6 days, including travel times. The lower bound reflects the time for records analysis when documents are able to be quickly transferred to headquarters. The upper bound reflects 1 full day of travel with 50 percent requiring an additional follow-up and 20 percent requiring an overnight stay.

TABLE 10.—DURATION OF THE COMPONENTS OF AN INVESTIGATIVE VISIT

		Including Travel Time and Overnight Stays
Obtaining requested records	4 to 48 hours	Uniformly distributed between 1 and 3 days
Records analysis	7 to 10 hours	Uniformly distributed between 0.8 to 1.6 days

We estimate the time for a traceback investigation by multiplying the duration of an average investigative visit by the number of investigative visits per traceback investigation. We estimate the duration of an investigative visit by adding the time to comply with a records access request to the time required to analyze those records. If obtaining requested records takes 1 to 3 days (i.e., 1 to 2 days to comply with the access request and 1 day of travel) and records analysis, inclusive of travel, takes between 0.8 and 1.6 days (i.e., 50 percent require return trips and 20 percent of trips require an overnight stay), the duration of an investigative visit is assumed to be uniformly distributed between 1.8 and 4.6 days (i.e., 1 to 3 days plus 0.8 to 1.6 days), with a simple average of 3.2 days.

From annual data we assume that the number of investigative visits per outbreak for the years 2000 to 2003 is normally distributed with a mean of approximately 9 visits and standard deviation of approximately 3 visits per traceback investigation. Using just the mean numbers of visits in a traceback investigation and visit durations, we estimate that the traceback component of an outbreak investigation takes approximately 29 days (the duration of an investigative visit multiplied by the number of investigative visits per outbreak).

9. Adjustments to Account for Records Requests Made on the Weekends

If there are 4 sets of weekends during the 29 day traceback time period in which records are inaccessible, then the estimated calendar duration (including weekends) of a current traceback investigation becomes much longer. To allow more accurate comparison of the time savings between current traceback times with those projected under alternative policy options requiring 4 and 8 hours, and up to 24 hours records access, we adjust the estimate of current traceback times to account for requests that would be made on weekends following issuance of this final rule. Most current records requests are made during the week, because establishments may not be open or key personnel may be absent on weekends. However, this final rule requires records access when requests are made on either weekdays or weekends. Consequently, we assume that there is a 1 in 7 chance of requesting records on a Saturday, and a 1 in 7 chance of requesting records on a Sunday if FDA were conducting a traceback investigation of a food for which it had a reasonable belief the food was adulterated and presented a serious threat of serious adverse health consequences or death to humans or animals.

A 24-hour records access requirement would improve current traceback times by allowing weekend records access requests. We assume that a records access request that would be made on a Saturday or Sunday following issuance of this final rule, would currently not be made until the following Monday. Taking this assumption into account, we estimate that the current time to satisfy a records request made on a Saturday to be 3 to 5 days (i.e., 2 days, plus 1 to 3 days), or an average of 4 days for 1/7 of all access requests (i.e., records requested on a Saturday), and 2 to 4 days (i.e., 1 day, plus 1 to 3 days), or an average of 3 days for 1/7 of all access requests (i.e., records requested on a Sunday).

With the average of 1.2 days for records analysis times, the adjusted estimate of the total time for satisfying a records access request and records analysis is an average of 5.2 days (1.2 days, plus an average of 4 days) for requests made on a Saturday, and 4.2 days (1.2 days, plus an average of 3 days) for requests made on a Sunday. The adjusted estimate of current traceback times is computed as an expectation of traceback times taking into account the probabilities of records requests made on weekdays and weekends. Assuming nine investigative visits per traceback investigation, the adjusted estimate of the current traceback time is approximately 33 days (((3.3 days x 5/7) + (4.2 days x 1/7) + (5.2 days x 1/7)) x 9 visits). The adjusted estimate of the current traceback duration is reasonably consistent with the current traceback durations reported by traceback personnel of between 6 and 8 weeks for eggs and fresh produce, and 3 days for packaged products that contain lot code information on the labeling.

10. Estimate of the Time Required Before Preventive Action

We estimated the time required before taking preventive action using FDA outbreak investigation information. We estimated the time required for a preventive action as the time that elapsed between the onset of the first reported illness and the first action taken by FDA or a commercial or state entity. In 11 of 26 traceback investigations considered from 2000 to 2003, an average of 78 days had elapsed between the time of the onset of the first illness in the outbreak and any initial preventive measure.

The estimate of the time required for a preventive action may be overstated because for those investigations that had entries reporting an initial action, but did not report a specific date of the action, we used the information entry date to approximate the date of the initial action. The information entry date is the date on which the initial action is recorded by FDA. Consequently, this procedure likely overestimates the time to preventive action because the information entry date is later than the date of the initial action it approximates, and in some cases may be significantly later than that date.

Moreover, many investigations do not involve any preventive action that would limit the magnitude of the outbreak, because either the investigation lasts longer than the shelf life of the implicated food product (so that there is no longer any implicated food in circulation), or the implicated source of the outbreak is determined to be an isolated event with no possible preventive action that would limit the size of the outbreak. Because information from such observations is not used in the analysis, the resulting estimate of the investigation duration is likely to be shorter than what would otherwise be obtained.

Based on the outbreak data used to create figure 2 of this document entitled ''Cumulative Distribution of the Fraction of Total Reported Illnesses by Outbreak Duration,'' we estimate that between 15 and 18 percent of all illnesses were from outbreaks that lasted more than 78 days. This implies that, with an average of 2,081 reported illnesses per year, the faster tracebacks could potentially prevent up to a maximum of 312 to 374 (reported) illnesses per year. The average duration of outbreaks that last longer than 78 days is approximately 121 days, for an average net excess of 43 days (121 days minus 78 days). By dividing the maximum number of known illnesses per year, by the average duration of outbreaks that persist beyond 78 days, we estimate a maximum daily average of 8 to 9 illnesses that occur each day after the 78 day threshold.

We characterize the uncertainty in the estimate of the time for preventive action as a Beta-Pert distribution with the most likely value of 78 and the minimum and maximum values (taken from the data) of 6 days and 150 days. The Beta-Pert distribution is a Beta distribution that has been re-scaled to run between values other than 0 and 1. The Beta-Pert uses a minimum, maximum, and most likely value to generate a distribution running from the minimum to the maximum, with a mean equal to (minimum + (4 times the most likely) + maximum) divided by 6. We use the Beta-Pert distribution since it is less sensitive to extreme values and generates more outcomes close to the mean than a Triangular distribution. We assume that the average duration of outbreaks that persist beyond the time for preventive action is distributed normally with a mean of 121 minus the time for preventive action, and a standard deviation (computed from the data) of 17. We assume a uniform distribution with a range between 0.15 and 0.18 in the estimate in the portion of annual illnesses that potentially could be averted by faster preventive action.

11. Estimating the Impact on Traceback Performance for Options With Different Coverage

Our framework for estimating the impact on baseline traceback speeds and completion rates for policy options with alternative levels of coverage uses the number of facilities in each sector to weight the sectoral contribution to baseline traceback performance. We adjusted the weights of the transportation, warehouse, and mixed-type facilities sectors to account for special considerations related to their contributions to traceback speeds and completion rates. For options that distinguish between very small and large facility coverage, we also adjusted

the contributions to traceback performance by facility size.

We estimated that options with the most comprehensive coverage will lead to the greatest decrease in times for preventive action, and eliminate the largest number of investigations that are prematurely terminated for reasons of poor records quality or nonexistent records. Options with more limited coverage will have a more limited impact on traceback speeds and completion rates. The factors used to scale baseline traceback speeds and rates of premature terminations are described by the following expression:

Total baseline performance = contribution by grocery outlets, given that contamination occurred further up the supply chain + contribution by wholesalers and importers, given that contamination occurred further up the supply chain + contribution by warehouses, given that contamination occurred further up the supply chain + contribution by manufacturers, given that contamination occurred further up the supply chain + contribution by transporters, given that contamination occurred further up the supply chain + contribution by mixed-type facilities.

The contribution to baseline traceback speeds by each sector is adjusted to reflect the probability that the food was contaminated further up the supply chain. Based on conversations with traceback personnel, we estimated that 10 percent of outbreaks requiring traceback records are from contamination at manufacturing facilities, and 90 percent are from contamination at the farm facilities (which may include mixed-type facilities subject to the recordkeeping requirements of this final rule).

a. *Adjustments to traceback performance for the grocery sector*. The baseline contribution from the retail sector to traceback performance is composed of contributions from both the restaurant and grocery sectors. The contribution to traceback performance from grocery outlets represents only a fraction of the total contribution of the retail sector. We adjust the probability of requiring traceback records from grocery outlets downward to account for the possibility that initial traceback from retail could begin at a restaurant as well as at a grocery outlet. For the adjustment we use the estimated number of restaurant locations of approximately 900,000 reported in a recent survey conducted for the National Restaurant Association (Ref. 16).

b. *Adjustments to traceback performance for transportation and warehouse facilities*. We adjusted estimates of the contributions to traceback performance by warehouse and transportation facilities to reflect the ''checks and balances'' nature of traceback records from these facilities for many investigations. Manufacturers and third party warehouses are both important links in the supply chain and are required to keep records under the provisions of this regulation. This requirement allows FDA to determine whether what was sent at each stage is what was received, and if not, to be able to locate the unaccounted-for food. It is critical that FDA be able to locate and remove from commerce any adulterated food that presents a credible threat of serious adverse health consequences or death to humans or animals.

We assume that there is a uniform likelihood between zero and one that there are more than two transportation or warehouse facilities used in the provision of a transportation or storage service. For these cases there is no adjustment to the value of records from such facilities during a traceback investigation. When two or fewer facilities provide transportation and warehouse services (estimated to be approximately half of the total number of such services) we adjust downward the value of records to acknowledge their role of verifying, rather than identifying, the buyer or seller of the food. For these cases we adjust the value of records to traceback performance by a factor of 0.5.

c. *Adjustments to traceback performance for large and very small facilities*. We adjusted the contributions by large and very small facilities to traceback performance to reflect the substantially different quantities of food each facility size is responsible for. While the number of very small facilities accounts for a large fraction of the total number of facilities, the quantity of food for which these facilities are responsible is relatively small. Consequently, estimates of the contributions to traceback performance should reflect the lower likelihoods of investigative visits at very small businesses.

For options that differentiate between coverage by facility size, we used estimates of the quantities of food passing through very small establishments and the quantities of food passing through all other sized establishments to scale each sector's contribution to traceback performance. In this way we were able to estimate the contribution by very small size establishments and other size establishments to traceback performance for each sector. We used U.S. Census data (Ref. 17) 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 the chart below. 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. In contrast, the percentage of total convenience store revenues from very small facilities is an estimated 18 percent, while very small transporters are responsible for an estimated 16 percent of total revenues from that sector.

TABLE 11.—THE PERCENTAGE OF VERY SMALL FOOD ESTABLISHMENTS THAT MAKE UP EACH SECTOR AND THE PERCENTAGE OF THE TOTAL SECTOR'S FOOD FOR WHICH THEY ARE RESPONSIBLE

Sector	% of Establishments That Are Very Small	% of Food Sector Revenue From Very Small Establishments
Manufacturers	77	15
Wholesalers	81	14
Transporters	90	16
Grocery outlets	88	18
Convenience outlets	73	18

TABLE 11.—THE PERCENTAGE OF VERY SMALL FOOD ESTABLISHMENTS THAT MAKE UP EACH SECTOR AND THE PERCENTAGE OF THE TOTAL SECTOR'S FOOD FOR WHICH THEY ARE RESPONSIBLE—Continued

Sector	% of Establishments That Are Very Small	% of Food Sector Revenue From Very Small Establishments
Importers	82	14
Mixed-type facilities	82	15

Source: U.S. Census, 1997 Economic Census.

In addition to a lower probability of an investigative visit at very small compared with other size facilities, records quality or records access times might also be different for very small and other size facilities. However, conversations with FDA investigative personnel revealed that there are no differences in records quality or records access times across business sizes. Consequently, we estimate the duration of an investigative visit to be the same for very small and other size businesses.

12. Estimating the Benefits When Selected Sectors Are Excluded

In this section we describe the estimated reduction in benefits that would be incurred from excluding certain sectors. We will provide additional quantitative information on this later in the analysis. We selected specific sectors for analysis in this section based on comments received on the proposal. The reduction in benefits from excluding foreign persons, transport persons, and food contact substance persons (including the finished container that contacts the food) from establishing and maintaining records are estimated as affecting traceback performance and the number of outbreak victims. The final rule excludes food contact substance and foreign facilities from recordkeeping maintenance requirements. As stated earlier, these estimates all account for food safety benefits based on traceback investigations currently performed and do not consider food security benefits, which are based on classified information.

a. *Excluding foreign facilities*. One policy option excludes approximately 225,000 foreign persons from all recordkeeping requirements. Although it is impossible to estimate the likelihood of intentional contamination at foreign facilities compared with domestic facilities, in this analysis we assume that there is no difference between the probabilities of foodborne outbreaks originating at foreign and domestic facilities. Consequently, the estimated reduction in benefits from excluding foreign persons is based solely on the number of facilities that are excluded, and the likely importance of their records for traceback performance. Because foreign facilities are close to the beginning of the supply chain for U.S. domestic consumption, the importance of their records during a traceback investigation is moderate while the costs to obtain those records during a traceback investigation are high.

b. *Excluding persons that manufacture, process, pack, hold, transport, distribute, receive, or import food contact substances*. Another policy option excludes food contact substance suppliers, estimated to be 37,000 manufacturers and distributors of the finished container that contacts the food, from the requirement to establish and maintain records. Because of the small number of manufacturers and distributors of the finished container that contacts the food compared with the total number of foreign suppliers, their exclusion from recordkeeping requirements would have a relatively small impact on traceback performance (if we ignore the possibility that excluding packaging suppliers increases their profile as potential targets for terrorist activities). Moreover, because manufacturers and distributors of the finished container that contacts the food occupy up-stream positions along the supply chain relative to foreign entities, we estimate the reduction in benefits from excluding them to be less than that from excluding foreign entities. Finally, if the requirements of section 306(a) of the Bioterrorism Act were satisfied, FDA would have access to existing records at these facilities.

c. *Excluding transporters*. One policy option would exclude all transporters from the requirement to establish and maintain records. FDA determined, however, that the qualitative and quantitative impact on benefits in the classified and unclassified scenarios would greatly eliminate the effectiveness of the rule and FDA's ability to timely and efficiently respond to a threat of serious adverse health consequences or death to humans or animals. As a practical matter, because the final rule's requirements for interstate shipments can be satisfied by compliance with existing requirements for interstate shipments, the final rule only establishes new requirements for the following: (1) Intrastate transporters; and (2) intrastate shipments conveyed by interstate transporters. FDA estimates that there are approximately 115,000 intrastate carriers, and based on DOT data, almost one million commercial drivers report intrastate travel. In reviewing the truck tonnage by commodity, approximately 12 percent of the intrastate shipments are of FDA-regulated food products. The average distance these products are shipped is 231 miles, which means many shipments are intrastate, especially in the larger western states.

For some foods, distribution may be limited primarily to intrastate transportation, depending on the time of year and state. Many businesses have their own delivery trucks that are used intrastate, several use employee vehicles for deliveries, and many rent vehicles to deliver products. These vehicles are used to deliver all types of food products—refrigerated, cooked, as well as fresh food and produce, and grocery items. Some local firms pick up their own merchandise from ''warehouse'' facilities to stock their own locations. Many of these ''warehouses'' (commonly referred to as ''Bin warehouses'') may receive product via interstate transporter and subsequently deliver to a variety of intrastate retail customers via many different intrastate means. Data on the volume of foods that move in intrastate commerce are maintained by individual state Department of Agriculture and by DOT. For example, from CA, LA, and TX alone, DOT reports over 12 percent of intrastate truck tonnage is from FDA-regulated products (ref. 18). Past traceback investigations provide examples of the need to regulate intrastate transport. For example, in 2003, there were two produce-associated outbreaks that occurred in CA from intrastate shipments. There were also two *Salmonella enteritidis* outbreaks in WI associated with

intrastate shipments of eggs. Other foods, such as pasteurized milk, nearly all raw products, seafood, and sprouts, may be shipped either intrastate or interstate depending on the production or processing site.

Most of the seafood consumed in Florida is transported only intrastate, but in Oklahoma most seafood is transported interstate. In 2002, there was an outbreak in New Jersey and Florida linked to fish. Intrastate records assisted us in pinpointing the portion of the Indian River, Florida that was causing the problem. Information on egg tracebacks from 1996–2003 indicates that 35 percent of the tracebacks that resulted in farm investigations were intrastate. This past summer, the State of Oregon was able to stop a sprout-associated outbreak from becoming a serious one by tracing back to a Washington sprouter that was just over the border from Oregon after some initial cases before the Salmonella serotype had been identified. The sprouts were recalled. If the sprouter had been located in Oregon so that the sprouts were not transported interstate, it would have been problematic to a traceback investigation limited solely to interstate transporters.

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

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

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

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

Having transporter documents would be critical if there was an intentional or unintentional contamination of the product while en route. Because of our limited experience, we cannot anticipate how much additional time it would add to our investigation, should records not be available.

The probability that a traceback investigation will require records that document the movements and packaging of food items between transportation facilities is uncertain. At least one outbreak involving the contamination of dairy products while inside a truck that had previously carried non-pasteurized eggs is estimated to have infected about 224,000 persons (Ref. 19). This example illustrates only one potential way that food may be contaminated while in the possession of transporters, and suggests that these risks of contamination can be considerable.

13. Options With Different Access and Retention Requirements and With Different Compliance Dates

a. *24 hour and 4- and 8-hour records access requirements.* For options with comprehensive coverage (and using simple average numbers), when compared with current traceback times, we would save an estimated 10 days for the proposed option requiring 4 and 8 hour records access, and 5 days for the option requiring 24 hour records access. When travel times are included, the provisions of the recordkeeping rule will significantly reduce the records access as well as the records analysis times. When travel times are included, the 4 and 8 hour records access times in the proposed rule would reduce the range of records access times to 1 to 2 days. The final rule requires records access within 24 hours of a request, which would reduce records access times by a smaller amount than with the proposed 4 and 8 hour requirement. Because current records access times are between 1 and 3 days including travel times, we assume that relaxing the requirement to 24 hours would only speed up compliance for records requested on the weekends. The proposed records access times of 4 and 8 hours would result in estimated records access times of between 1 and 2 days, and a records analysis time of 1 day (because the improved records quality would preclude the need for return investigative visits).

We assume that a 10-day reduction in the duration of the traceback component of an outbreak investigation would reduce the time required to take an initial preventive action by 10 days as well. A savings of 10 days would reduce the average amount of time required to take a preventive action to 68 days (based on the estimated current time of 78 days), and a savings of 5 days would reduce the time required to take a preventive action to 73 days. From data used to generate the cumulative distribution displayed earlier in this document in figure 2 entitled ''Cumulative Distribution of the Fraction of Total Illnesses by Outbreak Duration (2000–2003),'' we find that between 15 and 18 percent of all outbreak victims became ill from outbreaks that lasted more than 65 days. Consequently, the benefits from

reducing traceback times by either 10 days for the 4-and 8-hour records access requirement, or 5 days for the 24-hour records access requirement can be considerable. We assume that with comprehensive coverage, the number of traceback investigations that are prematurely terminated because of poor records quality will fall to zero under either the 24-hour records access requirement, or under the proposed 4- and 8-hour records access requirement.

The reduced durations of traceback investigations computed in the previous paragraphs are based on the assumed comprehensive coverage of the proposed recordkeeping rule. Excluding certain persons from all or part of the requirements of the regulation results in a reduction in the benefits as measured by reduced times for traceback investigations. The extent of the reduction in benefits from reduced traceback durations depends on the number of persons (and facilities for which the persons are responsible) that may be excluded from the regulation and the position along the supply chain of the excluded facilities. The position along the supply chain influences the probability of contamination, as well as the probability of losing the paper trail. We assess the relative benefits of excluding certain sectors as policy options later in this document.

Finally, if there is a deliberate attack on the food supply, with catastrophic consequences, then the duration of the preliminary and decision making parts of the outbreak investigation will likely be substantially compressed, and the importance of the traceback investigation in preventing additional illnesses from an outbreak will be elevated. If firms fully understand the seriousness of an outbreak, their reaction times may be compressed as well, which would tend to reduce the computed benefits from this rule. However, we expect FDA to be more likely than all firms to fully understand the seriousness of an outbreak.

As an example computing how compressed preliminary investigation and decision making times affect the benefits from faster tracebacks, we estimate the duration of the preliminary and decision making parts of the outbreak investigation to currently be approximately 55 days (i.e., the difference between 78 days for an initial preventive action and 33 days for the traceback investigation). If we assume a 50 percent reduction in the times for the preliminary and decision making components of an outbreak investigation, then a 10-day reduction in traceback times would result in preventive measures taken after approximately 56 days (28 days, rounding up, for the preliminary and decision making investigations plus 28 days for a traceback investigation) compared with the current 78 day duration. For a 75 percent reduction in the duration of the initial parts of an outbreak investigation, a 10-day reduction in traceback times would result in preventive measures being taken after approximately 42 days (14 days for preliminary and decision making investigations plus 28 days for a traceback investigation) compared with the current 78 days.

b. *Records retention requirements of 6 months, 12 months, and 24 months based on three NIST definitions*. Many comments suggested that product shelf lives as defined by the NIST should determine which product records would be subject to retention requirements of 6 months, 12 months, and 24 months. We estimate a negligible reduction in costs (which we estimate to be zero) and benefits associated with reducing retention times in the final rule.

The provision specifying the shorter retention requirements of 6 months, 12 months, and 24 months may result in the destruction of records earlier than would be the case for the longer retention requirements. While we estimate the reduction in benefits from the reduced retention times to be negligible, we explain the logic behind the perverse incentive for the early destruction of records, and its potential impact on traceback performance. The benefits from the records access requirements cannot be realized without the records retention requirements. If records no longer exist, there is nothing for FDA to access.

Given the records access requirement, the records retention requirement in both the proposed and final rules may create a perverse incentive for entities to destroy records, even though we estimate that this incentive will lead to the actual destruction of very few records, and very small reductions in investigative speed. Private firms are quite reluctant to share their private records with outsiders such as federal regulatory agencies. Facilities may choose to destroy records once legal retention requirements have been met rather than risk the possibility of sharing them with FDA. Consequently, there is a nonzero probability that facilities will destroy records subject to the retention requirements shortly after the legal retention requirement has been met, and that those records would not exist in the event of an FDA records access request.

The incentive to destroy records due to the access requirement will likely result in the destruction of a very small fraction of records because of the private utility from retaining records, and also the costs of destroying them. Because of the perverse nature of this incentive, it is informative to estimate its impact on the benefits from final rule—especially since the costs of the 1 and 2 years records retention provisions were estimated to be zero because the retention time periods are the same as or shorter than current business practices.

We used outbreak investigation data to estimate the reduction in benefits when retention requirements are redefined to be 6, 12, and 24 months based on NIST definitions of shelf lives. Investigations that remained open 6 months after initial exposure were considered possible candidates for continued investigative visits. From FDA investigation information, we estimated that about 20 percent of all FDA investigations from 2000 to 2003 remained open 6 months after initial exposure to the pathogen. However, it is likely that most of these investigations did not require access to a firm's records after 6 months.

We assume that a maximum of 20 percent of all traceback investigations are candidates for a records access request 6 months after initial exposure to the pathogen. We assume that half of the investigative visits in one of these candidate investigations requires access to records after 6 months, and that 1/3 of these access requests are for records subject to the 6 month retention period (i.e., a 1/3 probability for 6 months, a 1/3 probability for 12 months and a 1/3 probability for 24 months). Consequently, 3.3 percent of records requests for records subject to the 6 month retention time are estimated to be made after 6 months (20 percent x 1/2 x 1/3).

We assume that the potential records destroyed (after retention requirements have been met) as a result of the access requirement would be from the set of establishments with the poorest food safety practices. To determine the percent of firms with the poorest food safety practices, we obtained information from FDA personnel indicating that inspections of approximately 3 to 4 percent of all FDA-regulated food and cosmetic facilities from 2001 to 2003 were classified as official action indicated (Ref. 20). Based on this information, we assume that the incentive for records destruction will result in approximately 3 to 4 percent of firms destroying their records after 24 months, with destruction taking place shortly after retention commitments have been met.

We assume that the private utility of records decreases over time, and that the rate at which records subject to 6 months retention are destroyed shortly after meeting the retention requirement is half that for records subject to 12 months retention, which is half that for records subject to 24 months retention. Consequently, an estimated 0.5 percent of records subject to the 6 month retention time are assumed to be destroyed shortly after the 6 months have been met (i.e., the solution for ''X'' when solving the algebraic problem, 3.5 percent = X + 2X + 4X, where 3.5 percent is the midpoint between 3 and 4 percent and the rate at which all records are destroyed, X is the rate that records subject to the 6 month retention requirements are destroyed, 2X is the rate that records subject to 12 month retention requirements are destroyed, and 4X is the rate that records subject to the 24 month retention requirements are destroyed.). The destruction of records is estimated to affect about 0.02 percent of access requests (i.e., 0.5 percent records destruction rate x 3.3 percent of records requests made after 6 months). Finally, we assume that records destruction will slow down and terminate traceback investigations at the same rates at which the destruction takes place. Consequently, we estimate that both traceback speeds and rates of successful traceback completions will decline by 0.02 percent because of access requests when the requested records had been destroyed because of retention requirements.

c. *Extending the compliance dates.* Another policy option considers extending each of the proposed compliance dates by 6 months: Large, small, and very small firms would be required to be in compliance with the regulation 12, 18, and 24 months, respectively, after publication of the final rule instead of the proposed 6, 12, and 18 months after publication. The longer compliance dates reduce the time savings for a preventive action for 50 percent of the annual number of traceback investigations, and lead to a 50 percent increase in the annual number of outbreak investigations prematurely terminated for records quality reasons. Unlike the reduction in the benefits from the other policy options considered, these are one-time decreases in the benefits, because the option only extends the initial baseline compliance times by 6 months.

d. *Exemption of all very small entities.* FDA also considered whether it should exempt all entities with ten or fewer employees, not just those in the retail sector as is provided in the final rule; however, 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.

Moreover, many of our failures in a typical trace back investigation (i.e., unclassified scenarios) have been at the wholesaler (distributor) level. As discussed above, we would have significant concerns if 90 percent of the transporters (as very small entities) would be excluded from the requirements to establish and maintain records, particularly if these are predominantly intrastate transporters that are not currently subject to DOT's requirements. (FDA notes that intrastate shipments carried by interstate transporters also are not subject to DOT's requirements.)

In light of the above, 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 to humans or animals, FDA would be able to conduct an efficient and effective traceback investigation.

F. Costs

1. Estimates of the Number of Facilities Affected By the Final Rule

In the PRIA, FDA estimated the number of transporters and packers from data in the 2000 County Business Pattern statistics (Ref. 21) and the 1999 Nonemployer statistics (NES) (Ref. 22). We assumed that local and long distance specialized freight carriers devoted exclusively to transporting food were about 20 percent of the total of the specialized freight category. In the PRIA, FDA requested comments on the assumption that 20 percent was appropriate for this estimate.

(Comment 182) Several comments suggest that the number of trucking entities covered by the rule was substantially underestimated. One comment suggests that while 20 percent of the specialized carriers transport food products at any specific time, most specialized carriers transport food at one time or another. Another comment suggests that FDA's estimate of the number of covered trucking entities was low; the comment cites information obtained from the U.S. DOT that indicated close to 600,000 operating authorities on file, which includes Mexican, Canadian, and domestic carriers. Moreover, the comment suggests that if half of the general carrier population (600,000 carriers) transports food on an occasional basis, then over 300,000 companies would be affected. These numbers suggest an estimate of covered trucking facilities much larger than FDA's estimate. To support the assertion of an underestimate, the comment suggests that FDA-regulated Mexican carriers alone likely account for 12,000 facilities. Another comment states that individual transporters, not only transportation firms, will hold food while it is in transit and that transportation vehicles do not appear to be exempt from the recordkeeping requirements.

(Response) FDA agrees with the concerns underlying many of these comments and revises its estimates of the number of transportation entities in a way that is consistent with the data and framework used in the PRIA. Although FDA does not dispute the comment that most specialized carriers transport food items at one time or another, the ease with which transporters enter and leave the food industry is considered in the PRIA. That analysis already accounts for the additional learning, records access, and planning costs incurred by new entrants. In the PRIA, FDA estimated that there would be approximately a 10 percent rate of entry and exit of new and existing firms for all sectors. FDA calculated the startup costs for these new entrants and added them to the compliance costs incurred by existing facilities.

The County Business Pattern and NES used by FDA in the analysis include all potentially covered transporters (except foreign-based carriers that transport food in the United States), including individual carriers. However, in the PRIA, FDA neglected to include the number of establishments under North American Industry Classification System (NAICS) code 4841 for general freight trucking as well as for NAICS code 488510 for freight transportation arrangement. In the analysis of the final rule, we include entities that fall under both of these categories.

The combined data from the County Business Pattern and NES contain 384,358 establishments under code 4841 for general freight trucking. In addition, the County Business Pattern data contain 15,177 establishments for code number 488510 for freight transportation arrangement. To estimate the number of facilities under code 488510 in the NES data, we calculated

the ratio of the number for code 488510 to the total number for code 488 in the County Business Pattern data, and then applied that ratio to the number of establishments under code 488 in the NES data. We assumed a uniform distribution of food and nonfood carriers under the general freight trucking category and estimated the number of establishments that transport food products under code 4841 to be half of the total for that category. We assumed the number of establishments under code 488510 that arrange freight transportation for food products to be 20 percent of the total for that category. We assumed that the same percentage applies to the total assumed for specialized freight carriers dedicated to the food industry. As a result of these changes, the total number of domestic transportation and packing facilities is revised upward from 16,773 facilities used in the PRIA to 234,980. The numbers of establishments by code are reported in table 12 of this document.

TABLE 12.—NUMBER OF TRANSPORTATION ESTABLISHMENTS BY NAICS CODE

NAICS Code	Description	CBP 2000	NES 99
481112	Scheduled freight air transportation	584	2,413
481212	Nonscheduled chartered freight air transportation	217	
483111	Deep sea freight transportation	485	4,754
483113	Coastal and Great Lakes freight transportation	546	
483211	Inland water freight transportation	402	
4841	General freight trucking	27,937	164,242
48422	Specialized freight (exclusively used) trucking, local	6,499	4,946
48423	Specialized freight (exclusively used) trucking, long distance	2,580	8,189
488320	Marine cargo handling	607	2,415
488510	Freight transportation arrangement	3,035	3,814
488991	Packing and crating	1,315	

Foreign transportation carriers that cross the northern and southern U.S. borders are not counted in the County Business Pattern and NES data, because they are foreign based. All of these carriers are subject to DOT regulations, and the costs of compliance for these facilities are assumed to be zero because the final rule allows a transporter to meet its obligations by keeping the records currently required by DOT. However, foreign transportation carriers that cross the northern and southern U.S. borders are assumed to incur learning costs associated with this final rule.

FDA estimates the number of Mexican carriers that are subject to DOT regulations from a study conducted for DOT by Economic Data Resources under the auspices of the International Association of Chiefs of Police (Ref. 23). Using 1999 U.S. Customs and Border Protection data on the use of annual decals and per-trip payments by commercial vehicles at Southwest border crossings, that study estimated the total number of vehicles that cross the Southwest border to be approximately 76,177. Furthermore, using 1998 data on Mexican interstate commercial vehicle registrations, the DOT study estimated the number of commercial carriers of Mexican origin that use the Southwest border crossings to be approximately 63,000, or approximately 83 percent of the total. If one half of the total number of these trucks carry food items, then approximately 31,500 carriers of Mexican origin are subject to this final rule and would not be counted in the CBP or NES data.

In order to estimate the number of commercial carriers of Canadian origin that would be covered by this final rule, from the DOT study we obtain an estimate of approximately 79,643 carriers that purchase annual decals at the Northern border. We assume the same ratio of the total number of trucks that purchase annual decals for Southwest border crossings as that for northern border crossings (42 percent) and estimate the total number of trucks that cross the northern border to be approximately 191,167. Furthermore, we assume the percentage of these carriers that are of Canadian origin is the same as that used to estimate Southwest border crossings by Mexican carriers (83 percent). This assumption yields a total of 158,099 carriers of Canadian origin that are subject to DOT regulations. If one half of the total number of these trucks carry food items, then approximately 79,050 carriers of Canadian origin are subject to this final rule and would not be counted in the CBP or NES data. The number of transport facilities is revised upward by 110,550 (i.e., 79,050 plus 31,500) to account for the number of foreign based transporters that are subject to the final rule and not counted in the NES or CBP data.

(Comment 183) One comment states that direct selling businesses are clearly not accounted for because there are millions of such entities involved on either a full or part-time basis, while the combined estimate of domestic retailers and wholesalers used in the analysis is only slightly more than 300,000. Furthermore, the comment states that the burden on these retailers would be higher than for other retailers.

(Response) FDA does not agree that there are millions of direct marketers of food in the United States. Nor does FDA agree that the burden on direct marketing retailers would be greater than for other retail establishments. However, FDA does agree that the data sources used in the PRIA may not account for many small direct marketers that may not have filed as a sole proprietorship business with the Internal Revenue Service (IRS). While these direct marketers may have been omitted in the PRIA, they are considered exempt in the final rule and are not included in the cost estimates in this analysis. Nevertheless, in order to respond to comments and to estimate the cost of policy options that include very small retailers, FDA does revise its estimate of the number of retail establishments to account for direct marketers that may not have been included in the PRIA.

FDA found estimates of 10 million (Ref. 24) and 12 million (Ref. 25) direct marketers in the United States, but these estimates included all the direct marketers of both nonfood and food products in the United States. FDA does not have a complete census of the number of marketers of food versus nonfood products. To approximate the percentage of direct marketers selling food, FDA divided the number of direct marketing companies selling food by the number selling all types of products, using data from the directory of companies on the Web site of a large direct selling trade organization (Ref. 25). Of the 141 companies in the directory, approximately 5 market food or beverages, or approximately 3.5 percent of the total.

The number of direct marketing establishments should be captured by the NES, which are generated chiefly from administrative records of the IRS. These data are primarily composed of sole proprietorship businesses filing IRS Form 1040, Schedule C (Ref. 22). Many of the nonemployer businesses are very small, and many are not the primary source of income for their owners. Furthermore, nonemployers account for 75 percent of all businesses.

There is the possibility that direct marketers are included in the estimate of the number of direct marketers cited earlier and excluded in the NES if they are casual market participants, and have temporarily left the industry, or if they do not file as a sole proprietorship business with the IRS. Casual market participants might be included in the estimate of the total number of direct market facilities even if they are not active members. This would tend to inflate the total number of direct marketers to include both active and inactive members. Because of the ease of entry and exit by these firms, casual direct marketers that have temporarily left the industry are assumed to be approximately half of the number of direct marketers of food, or 1.75 percent of all direct marketers. This assumption leaves an estimated 1.75 percent (175,000) of direct marketers that are not counted in the NES statistics because they did not file as a sole proprietorship business with the IRS. We use this estimate of the number of direct food marketers that did not file as a sole proprietorship business with the IRS to revise our estimate of the total number of retail facilities.

Direct marketers that did not file as a sole proprietorship business with the IRS are assumed to be part-time suppliers and to sell mostly at the retail level. Furthermore, because these are very small businesses that only sell food products on a part-time basis, the additional records maintenance costs for these facilities will be considerably less than that for larger, full-time businesses. We estimate the additional records maintenance costs for these part-time facilities to be one half that for other retailers. The learning costs, records redesign costs, and records access planning costs for these facilities are assumed to be the same as for other facilities.

FDA does not agree that the burden of the rule would be higher for direct marketers than for other retailers. In the PRIA, FDA estimated that about 88 percent of retailers classified as very small firms have fewer than 10 employees. FDA believes it is reasonable to assume that compliance costs for direct marketers would be about the same as for other very small firms.

(Comment 184) One comment suggests that FDA underestimated the number of mixed-type facilities that engage in nut farming. The comment states that, in the almond industry, there are about 360 hullers and processors who are also growers, while FDA estimated that there were only 290 mixed-type facilities that engage in all categories of nut farming. Furthermore, because there are about 6,000 almond growers, the comment states that this implies that 6 percent of all almond growers would be classified as mixed-type facilities, compared to FDA's estimate of 2 percent of all nut farms.

(Response) FDA acknowledges considerable uncertainty in the estimates of the numbers of mixed-type facilities that engage in farming and is receptive to comments from industry that can improve them. There is likely to be more uncertainty in the estimates of the number of mixed-type facilities that engage in any individual category of nut farming than that for the estimate of the number of mixed-type facilities that engage in nut farming over all categories of nuts. FDA will use the estimate provided by the comment to revise its estimate of mixed-type facilities that engage in nut farming from 2 percent to 6 percent. The total number of mixed type facilities that engage in farming is revised upward to 31,077 from 30,497 used in the PRIA.

Table 13 of this document is a revised table of mixed-type facilities that engage in farming.

TABLE 13.—MIXED-TYPE FACILITIES ENGAGE IN FARMING

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Farms
Pig farms (feed mixing)	46,353	1.5%	695
Cattle (feed mixing)	785,672	1.0%	7,857
Poultry (feed mixing)	36,944	1.0%	369
Other animal production (feed mixing)	110,580	1.0%	1,106
Dairy	86,022	1.1%	903
Grain, rice, and beans	462,877	1.0%	4,629

TABLE 13.—MIXED-TYPE FACILITIES ENGAGE IN FARMING—Continued

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Farms
Apples	10,872	1.5%	163
Oranges	9,321	1.5%	140
Peaches	14,459	1.5%	217
Cherries	8,423	1.5%	126
Pears	8,062	1.5%	121
Other fruit	29,413	1.5%	441
Nuts	14,500	6.0%	870
Berries	6,807	1.5%	102
Grapes	11,043	10.5%	1,160
Olives	1,363	3.5%	48
Vegetables and melons	31,030	0.5%	155
Organic vegetables	6,206	50.0%	3,103
Honey	7,688	50.0%	3,844
Syrup	4,850	100.0%	4,850
Herbs	1,776	10.0%	178
Total			31,077

(Comment 185) One comment states that FDA mistakenly omitted the number of food grade warehouses that are subject to the regulation included in NAICS code 49311. Consequently, FDA's estimate that a total of 76,952 wholesaler and public warehouse companies are affected by the regulation is too low, and these additional warehouses should be included in the cost calculation of the final rule.

(Response) FDA agrees that public warehouses included in NAICS code number 49311 were omitted from the count of total warehouse facilities. Table 14 of this document describes the primary activities performed by the warehouses included in this classification.

TABLE 14.—DESCRIPTION OF PRIMARY ACTIVITIES PERFORMED BY WAREHOUSES BY NAICS CODE

NAICS	SIC	Corresponding Index Entries
493110	4225	Bonded warehousing, general merchandise
493110	4225	General warehousing and storage
493110	AUX	Private warehousing and storage, general merchandise
493110	4225	Public warehousing and storage (except self storage), general merchandise
493110	4226	Warehousing (including foreign trade zones), general merchandise
493110	4225	Warehousing and storage, general merchandise

There are a total of 4,415 of such facilities listed in the County Business Pattern data. In the NES statistics, there are 4,700 reported for the aggregate NAICS code of 4931. To estimate the number of warehousing facilities that would be included in NAICS code 49311 in the NES statistics, we scaled the aggregate number in the NES statistics by the ratio of the numbers reported for code 49311 to the total of those reported under code 3931 in the County Business Pattern. When the imputed NES numbers for code 49311 are added to the reported County Business Pattern numbers for code 49311, the total number of facilities in the NAICS code is 7,328 facilities. We adjust the total number of warehouses by one half of the total number of facilities reported for code 49311 by assuming that half of the total number of facilities included in that code handle food items. The number of warehouse facilities is revised upward to 6,089 from the 2,425 in the PRIA. The facilities-to-firm adjustment factor used for the facilities listed in NAICS code 49311 is the average of that used for the

other two warehouse codes in the analysis.

(Comment 186) One comment requests clarification as to whether all members of the International Bottled Water Association were included in the number of facilities covered by the regulation.

(Response) The NAICS code 3121 used in the PRIA includes all beverage manufacturers and specifically includes bottled water manufacturers. All other bottled water suppliers are included in the various NAICS codes used to count wholesalers and retailers, and other food suppliers.

Finally, the changes to the costs and benefits of the final rule due to the expanded coverage to include persons that export food for consumption outside of the United States are estimated to be small. We assume that the export of food and feed occurs at the manufacturing and wholesaling levels, with retailers unlikely to engage in export. The U.S. Census Bureau's 1997 Economic Census (Ref.17) indicates that approximately 4 percent of wholesale trade in all grocery and related products (NAICS code 4224) was from export sales. We assume that the same percent also applies to exports in the manufacturing sector and also to the numbers of facilities in those sectors. An estimate of 4 percent likely overstates the true incremental cost of covering exported food and feed since most, if not all of the establishments engaged in export are also likely to be engaged in domestic commerce and consequently would not incur additional learning and records redesign costs. Moreover, firms that export and also engage in domestic commerce are unlikely to incur additional maintenance costs because it is unlikely that they would follow two sets of recordkeeping practices. Consequently, only firms that are exclusively exporters will incur incremental recordkeeping costs as a result of expanded coverage. We assume that half of all wholesale and manufacturing establishments estimated to engage in export, or 2,736 facilities, are exclusively exporters and will incur recordkeeping costs as a result of expanded coverage to include export of food and feed.

The incremental benefits from expanding the coverage to include exported food and feed are from the possibility that some of these shipments may be diverted for domestic consumption, and their coverage may enhance traceback investigations should they be necessary. The food safety (but not food security) benefits from expanded coverage are likely to be negligible since the likelihood of diversion is small, and the likelihood that a diverted shipment is accidentally contaminated is also small. However, the food security benefits, while not quantifiable, include classified scenarios that could include diversion of food and feed. Further, FDA is concerned that exempting foods intended for export from the recordkeeping regulations could lead to such foods being targeted for tampering by terrorists and reintroduction into domestic commerce as they would prove more intractable to tracing investigations. Including the revisions described previously, we estimate that a total of 707,672 facilities will be covered by this final rule. This represents a reduction of 96,642 facilities compared with the number estimated in the analysis of the proposed rule.

2. High Cost of Tracking by Lot Code

(Comment 187) Many comments state that lot codes are not currently used in tracking products at the distributor and retailer levels, and that requiring lot codes to be recorded by these entities would represent a large change in business practice. One comment states that only 10 percent of food distributors currently use lot numbers to track their food products. One comment states that its facility tested the proposed requirement to establish records of lot numbers in its daily operations and concluded that there would be an 80 percent loss in productivity as a result of the requirement. Another comment states that labor costs for unloading a truck at a distributor would increase by a factor of 15 under an exhaustive check of shipper and lot code information. The comment further states that a conservative estimate of the unloading costs would be a threefold increase in current costs if a less exhaustive spot check of the lot codes is required.

Other comments illustrate the dramatic change in current business practices that would result from requiring lot codes to be included in records. However, several comments indicate that although the technology to maintain lot codes in bar code format does not currently exist, the industry is moving in that direction and such a requirement might be feasible in 5 to 7 years.

(Response) In estimating the costs of the rule, FDA assumed that all required information provided for in the regulation represented only small deviations from current business practice. The comments received strongly suggest that the cost estimates for maintaining records on lot codes for distributors and retailers were substantially understated. The results reported by one comment of an experiment that tested the requirement in their daily operations indicated an 80 percent loss in productivity. Other estimates of the increase in labor costs that would result from this requirement ranged from three-fold to fifteen-fold. FDA revises the estimates of the costs to maintain records on lot codes by assuming an 80 percent loss in productivity for retailers and distributors from compliance with this provision. For other policy options included in this analysis as well as in the final rule, the requirement to establish and maintain records containing lot codes is relaxed to be consistent with current feasibility.

3. Records Retention Costs

(Comment 188) Several comments address the costs of records retention. Several comments suggest that records are often stored off site or at corporate headquarters, with a nonzero cost for retrieval. Another comment recommends that we review our estimate of records retention costs of zero. The comment states that firms that handle products not covered by the juice HACCP regulation (part 120) may not have a records retention strategy and may have to implement a new strategy for records retention and recovery. Several comments express uncertainty with regard to the appropriate records retention time of either 1 year or 2 years for the products that they handle. These comments suggest definitions of ''perishable'' that would be more consistent with the terminology used in the trade, which is different from the definition in the proposed rule. Recommended records retention times ranged from a low of 6 months for perishable foods, up to 2 years for other foods.

(Response) In the PRIA, we used information from preliminary outreach to tentatively conclude that requirements for records retention of 1 year for perishable products, and 2 years for all other foods were consistent with current industry norms. The respondents to the outreach were not necessarily subject to the recordkeeping requirement of the juice HACCP rule, and we assume that the understanding of the term ''perishables'' by the respondents to that outreach was based on the conventional use of the term, rather than the definition of the term used in the PRIA.

In response to comments, the record retention requirements for nontransporters in the final rule now provide: (1) 6 months for food for which a significant risk or spoilage or significant loss of value occurs within

60 days under normal shipping and storage conditions for that food; (2) 1 year for food for which a significant risk of spoilage or significant loss of value occurs within 61 days to 6 months under normal shipping and storage conditions for that food; and (3) 2 years for food for which a significant risk of spoilage or significant loss of value occurs greater than 6 months under normal shipping and storage conditions for that food.

(Comment 189) One comment suggests that the estimates of zero storage costs from records retention are too low. The comment estimates that offsite storage and recovery costs range between $2.50 and $3.50 per cubic foot per year.

(Response) The costs for records storage and retrieval are not zero, but the additional storage costs likely to be incurred by covered entities as a result of this regulation are assumed to be zero. We assume that the private benefits from retaining records for the 1 and 2 years time frames required by this rule exceed the private costs of doing so. The range of comments to the proposal suggests that this assumption is reasonable. The private benefits of retaining records include enhancing a firm's ability to do the following: (1) file claims for shortages in quantities or qualities of products received, (2) respond to claims for shortages in quantities or qualities of products shipped, (3) sue suppliers for damages resulting from products received, and (4) respond to suits filed by downstream users for damages resulting from products shipped. FDA also believes that most firms retain these records for at least two years for income tax purposes. Therefore, FDA is not persuaded by the comment that most firms do not currently retain these records.

Evidence gathered from interviews with FDA traceback investigation personnel indicate that current records retention practices in the food industry have not been a major obstacle to successful traceback investigations. In addition, comments suggest that records retention requirements should be linked to the shelf life of the product (which is presumably the current practice), and suggest retention times of 6 months to 2 years, depending on the shelf lives of the products. FDA interprets this evidence to indicate that even in the absence of records retention requirements, the private incentives to retain records would result in records retention times in excess of those required in the regulation.

(Comment 190) One comment draws comparisons of the proposed records retention burden on small and large trucking firms. The comment contains a calculation of the number of records that would be required to be retained by a typical owner and operator of a single truck. The comment states that a 2 year retention requirement would obligate an owner and operator of a single truck to have on hand approximately 598 sets of load documents at any given time. If the average set of documents contained 20 pages, then this person would be required to retain approximately 11,960 pages at any given time. The comment suggests that this amount of documentation could be easily kept inside the truck in a side box and later transferred to an office corner or file cabinet at the owner's convenience. By assuming the number of documents to be retained by a firm is commensurate with the number of trucks owned by the firm, the comment argues that the proposed retention requirement would require large firms to retain an unreasonable amount of paperwork requiring substantially more storage space.

(Response) FDA notes that we computed the retention costs of the proposed rule on a per-facility basis and that we assumed that costs did not differ significantly from those of current business practices. The example documented in the comment illustrates the small amount of storage space that is required per facility. In the PRIA, FDA assumed that all firms keep most of the proposed records so that larger firms with a larger quantity of records may find it necessary to retain off-site records storage. In the final rule, FDA has revised the recordkeeping retention and other requirements for transporters to be consistent with current requirements for interstate transportation. Consequently, the retention requirements from this final rule should impose no extra burden on these facilities.

(Comment 191) One comment from an association of wholesalers states that its members typically retain invoices and shipping records for approximately 6 months and will find it difficult to find the storage space to retain records under the proposed requirements. The comment states that a 2-year retention requirement would constitute a dramatic change in distributors' operations and lead to a substantial increase in data storage costs.

(Response) FDA does not agree that the retention requirements from this final rule will impose a large burden on food businesses. Only a small fraction of information is required to be added to existing records. Furthermore, based on preliminary research, a survey of dietary supplement manufacturers, and our interpretation of most of the comments to the proposed rule, the retention requirements in this final rule do not differ substantially from the industry norm. We believe that any change in practice from wholesalers that generates costs is mostly included in the estimated redesign and other set-up costs.

4. Records Access Costs

(Comment 192) One comment states that a 4 and 8 hour records access cost is an additional cost, because it requires retrieval on the weekends, which may require companies to renegotiate storage contracts to allow for weekend access.

(Response) FDA researched typical records storage contracts and found that at least one company's standard records retention contract explicitly provides that ''unscheduled or emergency delivery of records'' was to be charged on a ''per event'' basis (Ref. 26). FDA assumes this to be the norm in the industry. For both the proposed and final rules, FDA does not estimate the probability of a records access request, and weekend access is assumed to be charged on a per-event basis, which is considered a cost of performing a records access request. Because the records access costs are estimated to be the private costs of planning for a records access request, rather than for performing a records access request, the estimates for planning for a records access request in the analysis of the final rule do not change.

(Comment 193) Many comments assert that the cost estimates for requiring 4 and 8 hour records access were too low or inappropriate. Comments support this assertion by citing factors ranging from the additional staffing requirements necessary to respond to a records request at such short notice, to the burden of a records access request being dependent on the number of records, and to the length of time covered by the records requested. Some comments state that a 48-hour records access requirement would be reasonable, and some comments state that 24 hours would be reasonable.

(Response) FDA acknowledges the difficulties faced by firms complying with the 4 and 8-hour records access requirements. This final rule requires providing access to records as soon as possible, but no later than 24 hours after an FDA request. The costs for 4 and 8 hours and 24 hours are analyzed as policy options later in this document. In the PRIA, we estimated the records access costs as the costs for planning for a records access request. FDA assumed

that the 4-and 8-hour response time required would compel business practices to change as firms developed preemptive emergency plans, while a 24-hour response requirement would not compel firms to modify their current business practices. Interviews with FDA traceback personnel suggest that firms are able to comply with a 24-hour records access request. Many comments support the notion that a 24-hour response time is not an unreasonable requirement given current business practices. Consequently, FDA maintains the assumption that a 24-hour records access requirement is reasonable under current business practices and that a 4 and 8 hour records access requirement would require additional planning for a records request.

Relaxing the records access requirement from 4 and 8 hours to 24 hours leads to an estimated cost savings relative to the PRIA. The access planning cost estimate assumed that 6 hours of administrative labor per firm (lowered to 3 hours per convenience store firm) would be a one-time requirement for each firm. FDA estimated that new businesses would also have to incur records access costs. As a result of relaxing the records access request time to 24 hours, these costs will no longer be incurred.

5. Additional Records Maintenance and Redesign Costs

The cost estimates assume that the information a covered entity must keep is specified, but that the form or type of system in which those records are maintained is not specified; we expect that firms will collect the additional information not currently included in their existing records. Furthermore, FDA assumes that firms will choose to comply with any new requirements in the manner most economically feasible for them, including modifying shipping or purchase records, such as bills of lading, invoices, or purchase orders.

(Comment 194) Several comments question the format for presenting the additional required information and whether existing records could satisfy the requirements. These comments cite specific types of transactions to illustrate the difficulties in maintaining the required information on one form. In addition, several comments state that the required information is typically available. One comment states that it is already standard business practice to maintain all required information on bills of lading in the trucking industry. Several comments state that FDA should maintain flexibility in the information required, as well as the type of forms maintained.

(Response) Neither the proposed nor final rule specifies the form or format in which records are to be established and maintained. There are no restrictions on the kinds of forms maintained. Commercial invoices, bills of lading, packing lists, and other forms commonly used when executing business transactions can all be used to record the information required by the regulation. We assume that most of the required information is already maintained on forms ordinarily used in conducting business. Persons subject to this final rule can choose to record the required information in one record or to use existing and newly created supplemental records to capture the required information.

(Comment 195) One comment requests clarification that ''transportation record'' includes the various documents that may be developed by a company and that it is not necessary to include all of this information in one shipping document. Furthermore, the comment asks us to clarify that existing records can be used to satisfy the requirements, even if they are not in the same location within the manufacturing facility (i.e., all required information is there, but not in the same location).

Others comment that the proposed regulation is not practical or reasonable, and fails to consider the business practices currently in place for food protection.

(Response) FDA believes that most of the information required by this regulation is currently collected as a matter of normal business practices and that any changes to current business practices as a result of this final rule are small. The revised language in the final rule removing the requirement to record lot codes for distributor and retail facilities increases the agency's belief that changes to existing recordkeeping practices will be small.

(Comment 196) One comment states that the need for both manufacturers and third party warehouse or wholesalers to keep the records is redundant.

(Response) Manufacturers and third party warehouses are both important links in the supply chain and are required to keep records under the provisions of this regulation. It allows FDA to determine whether what was sent at each stage is what was received, and if not, to be able to locate the unaccounted-for food. In a traceback investigation, it is critical that FDA be able to locate and remove from commerce any adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(Comment 197) Several comments suggest that the information required by the proposed regulation is excessive and that it would require significant changes in business practices to collect and maintain the required information. One comment suggests that requiring records of names, addresses, and telephone numbers of each supplier for each transaction is excessive. A comment suggests that its firm has no way to capture all of the proposed data elements through current sources of transaction documentation.

(Response) FDA assumes, and comments agree, that most of the information required by this regulation is already collected and maintained through currently used transaction documents. The final rule requires lot codes or other identifiers only of persons who manufacture, process, or pack food, and only to the extent this information exists. The final rule also does not require that a responsible individual be identified for the immediate previous source and immediate subsequent recipient for each transaction, as was required by the proposed rule. Accordingly, FDA does not modify its assumptions underlying the estimate of the costs of establishing and maintaining records.

6. Estimates of Additional Records Maintenance Costs Too Low

In the PRIA, FDA assumed that the burden of maintaining and collecting additional information would be shared among more than one facility.

(Comment 198) Comments state that FDA's estimates of recordkeeping burden obtained from the juice HACCP rule are inappropriate. The comments state that using the juice HACCP model substantially underestimates time requirements because most other types of firms would require more resources to achieve the proficiency required under the HACCP rule.

(Response) The juice HACCP cost estimates that we used to estimate costs in the PRIA were published before the juice HACCP rule took effect. The cost estimates for that rule were for firms that were not yet in compliance. FDA continues to believe that those cost estimates are an appropriate reference for this final rule, because they represent a precedent for cost estimates of activities similar to those required in this regulation.

(Comment 199) According to numerous discussions with those who are subject to HACCP regulations, the time and money estimates of the costs FDA provided in the seafood HACCP

rule were about 1/10 the actual values. This represents a big underestimate of the true costs of the regulation.

(Response) The costs estimated in the PRIA use cost estimates of the juice HACCP rule as a reference, not those of the seafood HACCP regulation. FDA has also received information that costs for compliance with the seafood HACCP rule were underestimated. FDA developed the estimates for the juice HACCP rule much later than those for the seafood HACCP rule. In addition, the burden for the additional records maintenance required in this final rule is considerably less than that required by the juice HACCP rule, particularly because FDA has relaxed the requirement for maintaining lot code information in the final rule and removed the requirement to record and maintain contact information for each transaction.

(Comment 200) Some comments state that FDA failed to account for the effect of higher transaction costs (as a result of the regulation) on reducing arbitrage opportunities. Food arbitrage is a line item in most food distributors' and retailers' financial statements. The comments assert that this final rule will result in fewer arbitrage opportunities, because the cost of a transaction will rise, which will cause a substantial reduction in profits, encourage layoffs, and raise consumer prices.

(Response) FDA agrees that the recordkeeping provisions in this regulation may increase the costs of transactions, thereby decreasing the total number of transactions. FDA believes, however, that transactions will be only slightly costlier and the effect on consumer prices and arbitrage opportunities will be small.

(Comment 201) One comment urges FDA to clarify and confirm that it would not consider records identifying producers of coffee cherry for traceback purposes as information that would be considered to be ''information reasonably available.'' The comment states that it would be prohibitively costly to link the identities of individual coffee cherry growers to any processed food item, because the cherries from many growers are typically mixed upon delivery to a processing facility.

(Response) Both the proposed and final rules require incoming ingredients to be linked specifically to outgoing food products only if that information is reasonably available (as discussed previously). What is reasonably available is determined on a case-by-case basis and depends on the operating practices of a specific facility. FDA does not intend the rule to require covered entities to reconfigure their operations. If cherries from many growers are typically mixed (i.e., commingled), then full information linking ingredient source to final product may not be reasonably available. If, however, the cherries are in separate bins based on supplier or easily can be separated and identified, then full information linking source to final product may be reasonably available. In the PRIA, FDA acknowledged the prohibitive cost of a policy option requiring producers to be able to link specific ingredients to specific food products (option 13 in the proposal). That option was ultimately rejected, in part, because of the high cost of identifying the producers of traditionally commingled raw commodities. Instead, both the proposed and final rules required linkage only when the linkage is reasonably available.

7. Labor Cost Estimates

(Comment 202) Several comments suggest that the wage rate used by FDA in the PRIA of $25.10 is too low. One comment suggests that an hourly wage of $33 would be more appropriate for the analysis, because it would reflect the need for higher-level personnel involvement due to complexities in the proposed rule. Another comment suggests that the $25.10 wage is reasonable, but that the hour estimates are too low.

(Response) FDA disagrees with the suggestion to increase the wage rate used in the analysis because the implied annual wage and overhead cost of more than $52,000 seems more than reasonable, as suggested in another comment.

(Comment 203) One comment argues that there is no evidence that the wage of $25.10 used in the analysis has been doubled to account for overhead in any of the calculations.

(Response) The hourly wage of an administrative worker reported by the Bureau of Labor Statistics of about $12.55 was doubled in the computations to account for overhead costs. FDA acknowledges that this was not clearly stated in the PRIA.

8. Learning Costs

(Comment 204) Some comments state that FDA's estimate of 3 hours for learning costs is low. The comments state that access to the Internet and lack of fluency in English are not the only costs. The comments maintain that learning cost estimates did not include the time for an FDA explanatory video and did not include adequate time for evaluating the information in the rule.

(Response) Although the comment states that 3 hours is too low an estimate, the comment did not indicate how the learning cost estimates as a whole, or any of the component cost estimates, can be improved. FDA explicitly incorporates the costs of searching, learning, and comprehending the rule in the PRIA. Learning cost estimates are composed of costs for searching for a copy of the requirements, and reading and understanding them. Because of the approximate nature of the calculation, FDA rounds up to the nearest half hour to 3 1/2 hours for the time required for reading and comprehending the requirements of this final rule for all English reading users. Although the cost of viewing the explanatory video was not explicitly included in the PRIA, such a viewing was assumed to reduce the burden from other searching and learning activities. Consequently, in the analysis of the final rule, FDA maintains the learning costs estimates used in the PRIA.

9. Specific Sector Cost Estimates

a. *Transportation and warehouse sector.* (Comment 205) At least one comment states that trucking companies already maintain the required records to comply with another Federal regulation and therefore additional Federal requirements would be duplicative.

(Response) FDA has included several options in this final rule for transporters to comply with their obligations to establish and maintain records under this final rule. One option is for transporters to keep some of the records currently required by the FMCSA regulations as of the date of publication of this final rule. The FMCSA regulations already require interstate transporters to establish and maintain transportation records, and we assume that interstate transporters who already comply with the FMCSA recordkeeping requirements will choose to comply with this final rule by maintaining such records. However, the FMCSA regulations cover only interstate common carriers, while this regulation covers all persons who transport food, including intrastate carriers. Moreover, domestic air carriers, and interstate transporters of low-value packages may not be required to comply with FMCSA regulations. Consequently, as a result of this final rule, intrastate carriers, intrastate shipments by interstate carriers, domestic air cargo carriers, and transporters of low-value packages may incur recordkeeping costs, in addition to learning costs, as a result of this final rule.

To estimate the costs incurred by intrastate carriers, domestic air cargo carriers, and transporters of low value

packages, we first estimate the number of facilities that engage in only intrastate food transportation. Then, we adjust this number to account for domestic air cargo carriers of food shipments and carriers of low-value food packages. Additional records maintenance costs incurred by interstate carriers of intrastate shipments are estimated to be zero since it is unlikely that a transportation establishment would use two sets of recordkeeping practices.

To determine the number of intrastate carriers subject to this final rule but not subject to FMCSA requirements, we take a weighted average of the ratios of local to total general freight trucking in the CBP data under NAICS code 4841, and the local to total specialized freight trucking in the County Business Pattern data under NAICS code 4842. Weights are applied to reflect the importance of local specialized and local general freight in all local trucking to estimate the overall number of intrastate carriers. This computation estimates that 50 percent of all freight carrying trucks are intrastate carriers. Consequently, we assume that 50 percent of all transportation facilities are not already subject to recordkeeping requirements under FMCSA, and will incur the full records redesign and additional records maintenance costs of this regulation.

The total number of domestic air cargo carriers of food packages is estimated from NAICS code 481112 in the CBP and NES data which was used for estimating the total number of transporters in the PRIA. Since not all of the carriers reported under NAICS code 481112 transport food items, we used a factor of 50 percent to scale data from the CBP and the NES to estimate the number of air cargo carriers that have a significant portion of their business transporting food items. The resulting estimate of the number of air cargo carrier facilities that transport food items is approximately 1,825 or 0.078 percent of the total number of transporters. These facilities will incur records redesign costs and additional records maintenance costs, in addition to learning costs as a result of this final rule.

The number of carriers of low-value food items is estimated using the number of couriers under NAICS code number 49211, which was not included in the PRIA. According to the U.S. Census Bureau, this NAICS includes establishments primarily engaged in providing air, surface, or combined courier delivery services. From the CBP and NES statistics there are approximately 141,931 establishments engaged in courier services. Since this includes courier services that use both air and surface transportation, we reduce this number by 50 percent, under the assumption that only establishments engaged in surface courier services are likely to carry food items, resulting in an estimate of 70,965 surface courier facilities.

Most surface courier services may carry food items as an incidental part of their business and will incur learning costs as a result of this rule. However, only a small fraction will carry food items as a significant part of their business and will incur additional records maintenance and records redesign costs. We estimate that 10 percent of surface couriers services will ve more than an incidental portion of their business transporting food items and will incur records redesign and additional maintenance costs in addition to learning costs. This is consistent with the fraction of restaurants that report retail sales as a secondary activity of their establishment (Ref. 29). The resulting estimated number of surface transporters of low-value packages of food items that would incur additional records maintenance and records redesign costs is 7,097 facilities.

(Comment 206) Several comments suggest that transportation carriers have only a limited knowledge of the contents of the packages that they carry and should not be held liable for much of the information. These comments suggest that transporters have detailed information on sources and recipients of the products that they carry but do not have the capacity to track other details of the contents of the packages, such as lot codes and other details. For example, one comment states that air carriers typically rely on the shippers for information, and shipments may not be identified as containing food. Others comment that because carriers lack knowledge of the contents of packages, the default records retention times for all shipments will be the longer required time of 2 years, even if the contents are perishable products. The comments state that this 2-year default retention time will only add to the records retention burden already faced by many trucking firms.

(Response) FDA acknowledges that, currently, the transporter may have limited knowledge of the contents of the packages that it carries and that an undue records retention burden would result if the default would be the longer retention period. FDA notes, however, that under this final rule transporters must know that they are transporting food and be able to record a description of that food. Nonetheless, FDA has relaxed the records retention requirement for transporters from the proposed rule to this final rule. Transporters, or nontransporters retaining records on behalf of a transporter, are required to 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 food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released. FDA also has codified in this final rule an option for transporters to comply with recordkeeping requirements of this final rule by keeping records already required by the existing bill of lading requirements applicable to interstate transporters.

(Comment 207) One comment expresses concern that differing knowledge of the contents of food packages between transporters and nontransporters would require standards of information exchange to be created to coordinate the contents of records maintained by the two types of entities. The comment suggests that without such standards, the coordination costs may be high, because certain records maintained by nontransporters would need to be exchanged with transporters for them to have the full knowledge of the contents and extent of the packaging. Failure to create these standards would result in elevated costs for transporters.

(Response) FDA acknowledges the limited knowledge that transporters currently may have about the contents of the packages that they carry. FDA has included less detailed information requirements in the final rule to respond to these comments; however, FDA believes the information it is requiring is necessary to allow the FDA to conduct a tracing investigation efficiently and effectively. In addition, FDA included an option whereby transporters can fulfill their recordkeeping requirements by keeping records already required for interstate transporters. Furthermore, the final rule provides an option allowing transporters to enter into a contractual arrangement with the non-transporter immediate previous source located in the United States or with the non-transporter immediate subsequent recipient located in the United States; any contractual arrangements would redistribute the burden of establishing and maintaining transportation records between transporters and non-transporters but would not change the total recordkeeping costs since the same number of records would be established

and maintained under all negotiated arrangements. FDA assumes that current business practices are the low-cost arrangement for the establishment and maintenance of records and does not revise its estimate of recordkeeping costs to account for higher coordination costs between transporters and nontransporters.

(Comment 208) Some comments state that FDA's estimated cost per facility in the public warehousing sector is likely to be incorrect because of the apparent assumption that costs incurred would be similar for both a public warehouse and a wholesaler. The comments argue that, because wholesalers own a product, they are more knowledgeable about its contents and packaging than are warehouse facilities. The comment notes that a warehouse is a third party provider of warehousing, storage, and other value added services; does not have direct knowledge of where a product originates; and may not have full knowledge of the contents and packaging of a product, or of the product's next destination. Another comment states that the information asked for in the proposal is reasonable, but that this information will be difficult, costly, or impossible to obtain for public warehouse facilities.

(Response) FDA acknowledges that warehouse facilities and wholesalers perform different functions. FDA has accounted for the differences in its cost estimates. The NAICS definition of the wholesale trade includes, ''* * * selling merchandise, generally without transformation* * * to other business* * *.'' The definition also characterizes wholesalers as normally operating from a warehouse or office (Ref. 27). In contrast, the NAICS defines the warehousing and storage sector as providing facilities to store goods but not sell the goods that they store. In addition, warehouse facilities may also provide logistical services for the goods that they store (Ref. 27).

Although the warehouse and wholesaler functions are clearly different, FDA assumes that both kinds of facilities would have records giving an immediate previous source and an immediate subsequent recipient of the product. Because warehouse facilities do not take ownership of the products that they handle, they may not have specific information about the products and their packaging.

In the course of their day-to-day business dealings, warehouses may not be privy to a description of the type of food or details of its packaging sufficient to satisfy this regulation. To acquire this knowledge and maintain the required records, warehouses may incur costs in addition to those that would be incurred by the owners of the product. FDA assumes that as part of their normal business practices, warehouse facilities may be required to maintain a limited amount of information on the immediate previous source and immediate subsequent recipient of a comparable magnitude to that of the owners of the products. However, the detailed information on the product and its packaging required by the regulation may be more costly to obtain for warehouse personnel than for the owners of the product. For some products, warehouse facilities are assumed to have the same required knowledge of the required information on the stored product and its packaging as that of the owner of the product. For other products, the warehouse personnel's knowledge of the required information on the stored product and its packaging is less than that of the owner. We estimate that, for half of all food products stored, warehouse personnel have the same amount of the required knowledge of the food and its packaging as the owner of the product, and that the additional records maintenance costs would be comparable to those incurred by the product owners. For products for which warehouses currently lack the required knowledge, we assume that the additional records maintenance costs for warehouse facilities would be approximately 50 percent higher than those for owners of the products. Much of the extra cost may involve contracting with product owners to provide the required information.

b. *Interstate conveyances and catering services sector*. (Comment 209) Several comments suggest that the costs to the interstate conveyance catering industry were greatly underestimated and that this sector should be excluded from the regulation. One comment states that for airline caterers, each flight typically includes hundreds of individual foods from scores of different sources and suppliers. The comment further states that this industry is further complicated by the large number of special meal requests by individual passengers on each flight.

(Response) In the PRIA, we assumed that persons subject to this final rule may be required to add a limited amount of new information to existing transactions records, such as bills of lading, commercial invoices, and other shipping documents. We did not model the costs of compliance for each sector in the food economy, and assumed that the private incentives to maintain most, if not all, of the required information were sufficient. Examples of private incentives to maintain the required records are provided in our response to comment 189. Moreover, we do not require that the information be in any particular form or format, which further reduces the potential costs of compliance.

c. *Pet foods sector*. (Comment 210) Some comments suggest that FDA eliminate requirements for pet food because the risk of exposure through that sector is small. Other comments acknowledge potential targets and impacts from terrorist attacks through the pet food sector and encourage FDA to require all in the pet food sector to be subject to the final rule.

(Response) In the proposed rule, pet food not subject to the BSE rule was excluded from the requirement to establish and maintain records. In this final rule, all animal feed entities, including all pet food entities, are subject to all requirements of the rule, but have a records retention requirement of 1 year. There are approximately 19,600 facilities that were excluded in the proposed rule and that have been included in this final rule. In the PRIA, rather then estimate the cost savings from excluding these facilities from complying with the regulation, we noted that the costs were overestimated because pet food facilities were included in the estimates. In the final rule, pet food entities are subject to the regulation and are included in the cost estimates.

d. *Food contact substances and the packaging sector*. (Comment 211) FDA received many comments that FDA underestimated the number of facilities covered by the definition of substances and components of substances that contact food. One comment states that FDA does not include the ''upstream'' manufacturers that make ingredients and components that go into food packaging who would be required to comply with the recordkeeping provisions of this regulation. The comment further states that there is no logical conclusion to this chain. Some other comments assert that FDA did not account for warehouses that hold articles that can migrate to food from food packaging, or other articles that contact food.

Another comment states that FDA's count of the number of domestic facilities is overly inclusive if FDA's intention is to include only finished packaging and that the Operational and Administrative System for Import Support (OASIS) database used for the count of foreign facilities does not include suppliers of food contact articles. Other comments indicate that FDA understated the number of

facilities covered by the regulation by not identifying transporters of food contact materials, and that the 20 NAICS codes do not cover all food packaging manufacturers and distributors. Several comments state that all packaging firms handle both outer packaging and food contact substances, and for all practical purposes, will have to track all products they produce, because they may not know if a shipment is destined for food or nonfood use. One comment states that FDA's count of foreign facilities from OASIS did not include all imported food contact substances.

(Response) The final rule does not require persons who manufacture, process, pack, transport, distribute, import, receive, or hold packaging (the outer packaging of food that bears the label and does not contact the food) to establish or maintain records. However, these persons are subject to the records access requirements with respect to any existing records if they also engage in another regulated activity with respect to the food in, or to be placed in, such packaging. 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. Moreover, 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 establishment and maintenance requirements with regard to the finished container, and are only subject to the records access provisions for existing records under §§ 1.361 and 1.363.

In the final rule, records access costs are estimated to be zero and we assume that the only costs incurred by persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are learning costs. Because the economic burden on these facilities in the final rule has been substantially reduced from that estimated in the PRIA, we assume that the impact on costs of any possible underestimation of their numbers will be very small.

e. *Foreign facilities and related impacts*. (Comment 212) There were many comments that state that the expansion of requirements to foreign facilities would have a large impact on international trade by making imports more expensive. Some comments state that costs for compliance by developing countries were underestimated in the PRIA because their labor and technology are so different from those that prevail in developed countries.

(Response) In the final rule, all foreign persons are excluded from all requirements in this rule, except for foreign persons who transport food in the United States. Because all foreign persons who transport food in the United States are currently subject to FMCSA regulations as interstate transporters, and can meet the requirements of transporters in subpart J of this final rule by keeping records already required by FMCSA, the costs of compliance for these facilities, including the costs for the records access requirement, are assumed to be zero.

(Comment 213) One comment questions the implied assumption in the PRIA that foreign transporters share the cost burden with other foreign facilities when foreign transporters are not covered by the rule.

(Response) Foreign persons who transport food in the United States are covered by this final rule. The revised costs of compliance by these facilities to establish and maintain records are assumed to be zero because they will be in compliance with this final rule if they keep the records currently required by FMCSA for interstate transporters.

10. Compliance Dates

Several comments suggest changes in the compliance dates. In the design of the regulation, the compliance dates are used primarily to address regulatory flexibility considerations. Consequently, these comments are treated in the regulatory flexibility section of the final analysis.

G. Summary of the Costs and Benefits of the Final Rule and Policy Options Considered

The revisions to the cost estimates based on comments to the proposed rule and on changes in records requirements between the proposed and final rule result in estimated costs of approximately $1.41 billion expressed in present value terms, using a 7-percent discount rate. Using a discount rate of 3 percent, the estimated costs of the final rule expressed in present value terms are approximately $1.94 billion. Costs for learning, records redesign, and planning for records access requests are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs and records retention costs are incurred each year following publication of the final rule, beginning in the second year for large and small firms and in the third year for very small firms. Learning costs and records access planning costs for new entrants are also incurred each year following publication of the final rule beginning after the second year. The details of the assumptions used to estimate the costs are provided in the PRIA. The estimated total cost is computed by summing the costs estimated for learning, records redesign, additional records maintenance, records retention, and planning for a records access request. The annual and total costs of the final rule are reported in table 15 of this document.

TABLE 15.—ESTIMATED ANNUAL AND TOTAL RECORDKEEPING COSTS[1]

21 CFR Section	Costs (in dollars)
1.337, 1.345, and 1.352 (learning)	$85,082,000
1.337, 1.345, and 1.352 (records redesign)	$205,239,000
1.337, 1.345, and 1.352 (additional records maintenance)	$114,701,000
1.337, 1.345, and 1.352 (learning for new firms)	$8,508,000
Discounted present value of total costs[2]	$1,406,356,000

[1] The annual costs are reported in undiscounted terms. Records access planning costs and records retention costs are estimated to be zero and are not reported here.

[2] The reported discounted present value of total costs assumes a 7-percent discount rate and a 20-year time horizon over which annual costs are summed.

The final rule will help reduce the numbers of people who become ill during a foodborne outbreak by reducing the time required for preventive action. Furthermore, the final rule will reduce the recurrence of outbreaks that may have been prevented had nonexistent or poor records quality not resulted in prematurely terminating the initial traceback investigation. In addition to relaxing elements of the requirement for records to contain lot code information, the reduction in benefits from the final rule compared to the proposal results from excluding foreign facilities except those that transport food in the United States, relaxing recordkeeping requirements for food contact substance facilities, relaxing recordkeeping requirements for very small retail facilities, adopting retention requirements based on the NIST food shelf life definitions, and relaxing the records access requirement from 4 and 8 hours to as soon as possible, not to exceed 24 hours.

The estimated costs and benefits of many policy options considered in this section summarize the details of the analyses based on the comments FDA received and are reported in the following tables. The costs for the options are reported in present value terms for both 7 percent-and 3-percent discount rates. We summed the discounted annual costs over a 20 year horizon to obtain the estimate of the total costs. A 20-year horizon for measuring the costs from the regulation is reasonable, given uncertainty in the regulatory environment and technological change. The reduction in benefits relative to the proposal from each modification is based on the impact that each option would likely have on traceback times and the rates of traceback completions. Again, the benefits are based solely on food safety concerns (i.e., typical traceback scenarios with which FDA has been involved) and do not take into account food security concerns.

In table 16 of this document we compare the costs of the options considered to the baseline option of the proposed rule, with the caveat that the provision requiring all records to contain lot code information, which was included in the proposed rule, is no longer in the baseline. All other provisions included in the proposed rule are in the baseline for this analysis.

All options consider relaxing one provision, or excluding one sector from the recordkeeping requirements. In that way, a comparison of the cost of a policy option with the cost of the baseline yields the marginal cost savings from either relaxing a provision in the baseline, or reducing the coverage by one sector relative to the baseline. The columns containing the absolute amount and percentage cost savings show the savings relative to the baseline. In the final rule reported in table 18 of this document, the provisions requiring lot code information, 4- and 8-hour records access, and short compliance dates are all relaxed to yield cost savings relative to the baseline. Additional cost savings result from excluding the following: (1) Foreign persons, except for foreign persons who transport food in the United States; (2) persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances except the finished container that directly contacts the food; and (3) persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished containers that directly contacts food except for those who place food directly in contact with its finished container.

The option to relax the requirements for all records to contain lot code information when feasible saves more costs relative to the baseline than any other option. The cost savings from relaxing the lot code information requirement is approximately $13 billion in present value terms with a 7 percent discount rate, and $18 billion with a 3 percent discount rate. Based on detailed information in the comments, requiring lot code information to be contained in all records by retailers and distributors would result in approximately an 80 percent loss in productivity for distributors and retailers.

Excluding many foreign persons and relaxing the 4- and 8-hour records access requirement also result in significant cost savings. By excluding all foreign persons except those who transport food in the United States, approximately 225,000 facilities would not have to establish and maintain records relative to the baseline. This exclusion results in a cost savings of approximately $770 million, or 19 percent, relative to the baseline in present value terms when a 7-percent discount rate is used, and a savings of $1 billion when a 3 percent discount rate is used. A 24-hour records access requirement results in a cost savings of approximately $260 million relative to the baseline with a 7-percent discount rate, and $318 million with a 3-percent discount rate.

Extending the compliance dates and broadening the scope of foods subject to the limited 1-year records retention period relative to the baseline are all provisions in the final rule. Cost savings from extending the compliance dates by 6 months relative to the baseline result from reductions in inventory losses and discounts in the costs realized when incurred 6 additional months into the future. These cost savings are approximately $271 million relative to the baseline with a 7-percent discount rate, and $163 million with a 3 percent discount rate. Adopting retention requirements based on NIST definitions based on shelf life is not assumed to increase costs, but will reduce the benefits by a negligible amount.

Throughout the analysis, we have estimated costs based on the number of facilities, and assume that this number, whenever used, approximately reflects the number of persons covered by the regulation. The revised number of facilities covered by the final rule is estimated to be 707,672 (including persons who manufacture, process, pack, transport, distribute, receive, hold, or import food, and foreign based transporters that transport food in the United States). Learning costs are assumed to be incurred by all facilities and persons 2 years following enactment of this final rule and are computed by multiplying the number of facilities by the cost of learning per facility. Based on details outlined in the proposed rule, learning costs are computed using a $25.10 wage rate and 4.5 hours spent learning for Internet users (approximately 71 percent, and 5.5 hours spent learning for non-Internet users). The total learning costs are computed to be $85,082,000.

Records redesign costs are assumed to be incurred by approximately 101,153 large and small firms 2 years following issuance of this final rule and by 222,316 very small firms after 3 years following issuance of this final rule. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that contacts food, and foreign based transporters that transport food in the United States are assumed not to incur records redesign costs. In this analysis, FDA assumed that all sizes of firms will bear the $1,365 per-firm records redesign cost estimate that was used in the proposal as the most likely records redesign cost for small and very small firms. The redesign costs are $53,508,000 after the second year and $151,731,000 after the third year following issuance of this regulation.

FDA assumes the additional records maintenance costs to be incurred by 110,081 large and small facilities 2 years following issuance of this final rule and by 379,493 facilities after 3 years and for all subsequent years following issuance of the final rule. Persons who

manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that contacts food and foreign based transporters that transport food in the United States are assumed to not incur additional records maintenance costs. FDA assumes the 34,634 convenience store facilities will spend 2.5 hours per year and that persons who directly market food are excluded from the rule. All other facilities (344,859) will spend 13 hours per year on additional records maintenance at an hourly cost of $25.10. The undiscounted total additional records maintenance costs 2 years following enactment of the rule are $70,745,000. After 3 years, and for each subsequent year, the undiscounted additional records maintenance costs are $114,701,000. The annual costs for records access planning and for records retention for all persons are assumed to be zero in the final rule.

The following table includes the estimated reduction in benefits relative to the proposal from policy options that would exclude select sectors from recordkeeping requirements, or that would relax certain provisions, which are considered in detail earlier in this analysis. The benefits from each policy option are ranked by size, so that policy options that would result in large reductions in benefits relative to the proposal are ranked highest, where a ranking of one represents the largest reduction in benefits relative to the proposal.

The reduction in benefits from relaxing the requirement for all persons to establish and maintain records containing lot numbers is very high. With lot codes contained on all records, the duration of a traceback investigation for many products would likely be between 1 and 14 days (estimated current times for many packaged products that contain all lot code information on the package). Relaxing the lot code requirement may increase the traceback times of these products to between 6 to 8 weeks (estimated current times for many fresh products not accompanied by lot code information). Relaxing the requirement for all records to contain lot code information leads to the largest reduction in benefits relative to the baseline.

The reduction in benefits from excluding all foreign persons except those who transport food in the United States is considerable because the large number of excluded entities increases the likelihood of hampering traceback investigations. Moreover, the risk of contamination (unintentional) is generally higher for many products earlier in the supply chain. In addition, enforcement costs for foreign persons would likely be prohibitively high—decreasing the likelihood of obtaining records required for a traceback even if these persons were covered. When compared to the eight other individual options considered for the final rule, the large number of excluded foreign persons ranks third highest of the reductions in benefits relative to the baseline considered. This reduction in benefits, however, is mitigated in one respect: The risk of not being able to complete traceback investigations due to this exclusion is considered low because most of these foreign entities occupy positions early in the supply chain.

The reduction in benefits from relaxing the recordkeeping requirements for persons who manufacture, process, pack, transport, distribute, import, receive, or hold food contact substances other than the finished container that directly contacts the food, and who manufacture or process the finished container that directly contacts the food, as estimated by the number of applicable facilities, is small. Although relaxing requirements for these persons may expose a ''soft target'' for intentional contamination, the probability of foodborne illness from unintentionally contaminated food contact substance and finished container material is low. Furthermore, the likelihood of needing records from food contact substance and finished container facilities during traceback investigations is also low. When compared to the other issues considered for the final rule, relaxing the requirements for these persons ranks only seventh in the reductions in benefits relative to the baseline.

The reduction in benefits from relaxing the requirement to access records within 24 hours from 4- and 8-hour requirement would be substantial. We estimate that relaxing the records access requirement would increase the amount of time for any preventive action to be taken during a traceback investigation by about 5 days relative to the baseline, if all persons subject to an access request took the full 24 hours to respond. The loss of time relative to the baseline would limit the preventive benefits for 15 percent to 18 percent of outbreaks. Relaxing the record access requirement from 4 and 8 hours, to within 24 hours ranks second in reductions in benefits relative to the baseline.

The reduced benefits from extending the compliance period by 6 months for each person subject to the final rule are a twofold increase in the number of outbreak victims relative to the baseline in the first year only. Baseline benefits reduce the impact of 15 percent to 18 percent of outbreaks and eliminate the problem of prematurely terminated investigations because of poor records quality (i.e., about 10 percent of the total number of traceback investigations estimated from FDA outbreak investigation information). Extending the compliance dates by 6 months ranks sixth in the reductions in benefits relative to the baseline.

We estimate that allowing transporters to comply with this final rule by complying with existing requirements (e.g., records already required by FMCSA) will have a negligible impact on the benefits relative to that from the more comprehensive requirements of the proposal. Option 7 in table 16 of this document incorporates a 24-hour access provision, 6, 12, and 24 month retention requirements, extension of the compliance dates, and adjusted recordkeeping requirements for transporters based on existing requirements. In table 18 of this document, the costs and benefits of the final rule are compared with those from the adjusted comprehensive coverage of option 7 in table 16 of this document.

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
Baseline[1]: Proposed rule except requirement for all records to contain lot codes is relaxed.	$4.0 billion	$5.27 billion		

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS—Continued

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
(1) Baseline except existing interstate transporter requirements are sufficient.	$3.78 billion	$4.97 billion	No reduction[2]	1
(2) Baseline except retention of 6, 12, and 24 months per NIST standards	$4.0 billion	$5.27 billion	Negligible reduction	2
(3) Baseline except food contact entities are excluded.[3]	$3.92 billion	$5.16 billion	Exclude 37,000 facilities near the top of supply chain. Low risk of contamination and low risk of loss of the paper trail.	3
(4) Baseline except compliance dates are extended by 6 months.	$3.73 billion	$5.10 billion	An estimated one-time, two-fold increase in the number of victims compared with the baseline in the first year only.	4
(5) Baseline except foreign facilities are excluded.	$3.23 billion	$4.26 billion	Exclude 225,000 facilities near the beginning of the supply chain. Very high cost of enforcement and access.	5
(6) Baseline except relax records access from 4 and 8 hours, to 24 hours.	$3.74 billion	$4.95 billion	Adds a maximum of about 5 days to the time for preventive action during an outbreak.	6
(7) Adjusted comprehensive coverage	$2.59 billion	$3.57 billion	Incorporates all policy options and adjusted numbers of facilities	

[1] Note that option 1 is used as the baseline in the descriptions of all other options. The variation of the proposed rule with the relaxed lot code requirements is used as the baseline in this table because the high cost of requiring lot codes on all records ($16.58 billion) is overwhelming. While the reduction in benefits from relaxing the lot code requirements is also large, we thought that the inclusion of that option in this table would confuse the presentation and add little practical value to the policy analysis.

[2] Because this chart only reflects food safety, it does not include classified food security scenarios which envision intrastate shipments being targeted for tampering.

[3] This option overstates the cost reduction from provisions in the final rule that exclude food contact substance entities since it assumes that they will not have to incur learning, records redesign, and additional records maintenance costs. In the final rule these entities will incur learning costs since they will still be subject to access requirements for records that they keep during the course of normal business activity.

We constructed the policy options reported in the following tables to provide a range of net benefit and cost effectiveness measures for alternative coverage options. The records access, retention, and compliance date provisions, as well as the requirements for transporters for all options reported in the following tables, are the same as those reported for option 7 in the previous table. In addition, coverage for the option entitled ''all entities'' is the same as that for option 7 in the previous table. Persons handling the finished container that contacts food are excluded from all of the following coverage options for the policy reasons stated previously. However, while persons handling the finished container that contacts food other than those who place food directly in contact with the finished container, are not required to establish and maintain records in the final rule, they are required to provide access to FDA to existing records if the conditions for access are satisfied. This requirement is implicit in all of the options with different coverage reported in the following tables.

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
Option						
Adjusted Comprehensive	All	All	All	All	All	All

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS—Continued

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
A		All				
B	All					
C		All	All			
D		All	All	All		
E		All	All	All	All	
F		All	All	All	All	All
G (final rule)	Exclude very small	All	All	All	All	All
H	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small
I	Exclude very small	All	All	All	All	Only interstate

Note: Very small firms are defined as those with fewer than 10 full-time equivalent employees.

In the following table, costs, food safety benefits, and cost effectiveness measures are reported for each of the coverage options described in the above table, and the final rule. Costs are reported in terms of annualized costs and incremental costs using a 7-percent discount rate over a 20-year horizon. Benefits are reported in terms of the annual number of food safety illnesses averted (reported and unreported), and the incremental number of illnesses averted. The estimates of the numbers of averted illnesses should be interpreted as minimum values because they relate to only the food safety benefits; bioterrorism considerations are not incorporated into the estimates. Cost effectiveness measures are in terms of the incremental costs per averted illness, and the average cost per averted illness.

The incremental cost per averted illness is used to measure the relative cost effectiveness of an option when compared with successively more stringent requirements. It is computed by dividing the incremental costs from the option by the incremental benefits. Since option H averts a larger number of illnesses at lower cost then options A through F, option H dominates the other options and they can be eliminated from further consideration in an incremental cost effectiveness analysis. Thus, the cells for computing the incremental costs per averted illness for those options are left blank in table 18 of this document. Similarly, through the principle of weak (or extended) dominance, option I can be eliminated from the incremental cost effectiveness analysis. (For a full discussion of extended dominance in cost-effectiveness analysis, see Gold, M.L., J.E. Siegel, L.B. Russell, and M.C. Weinstein, ''Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine, Oxford University Press,'' New York, p. 286, 1996). Consequently, only options H, the final rule, and the adjusted comprehensive coverage are used to measure the incremental cost effectiveness. We assume that bioterrorism considerations would not alter the relative order of the number of illnesses averted across all options.

The average costs per averted illness reported in table 18 of this document are calculated by dividing the annualized costs by the total number of illnesses averted for each option. The average costs per averted illness is the cost-effectiveness of each option relative to the baseline. For the final rule, the average cost-effectiveness expressed in costs per illness prevented is $110,000 discounted at 7 percent and $108,000 discounted at 3 percent.

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option A	$40,975,852		245			$167,248
Option C	$56,753,102		316			$179,598
Option D	$67,712,296		355			$190,739
Option E	$69,902,094		359			$194,713
Option B	$135,636,340		572			$237,126
Option F	$119,792,995		621			$192,903

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS—Continued

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option H	$30,610,378	$30,610,378	1,067	1,067	$28,688	$28,688
Option I	$106,138,020		1,072			$99,009
Final Rule	$132,750,092	$102,139,714	1,204	137	$745,545	$110,258
Adjusted Comprehensive	$244,134,086	$111,383,994	1,282	78	$1,428,000	$190,432

The distribution of the number of illnesses averted due to faster traceback investigations and more successfully completed traceback investigations for each policy option are also reported in the following tables. Of the 800 annual food safety illnesses averted due to improved recordkeeping practices, about 600 can be attributed to more successfully completed tracebacks, and about 200 from faster tracebacks. The sum of averted illnesses from faster tracebacks, plus that from more successfully completed tracebacks may differ from that reported in the table of totals because of rounding in the computations.

TABLE 19.—ALL AVERTED (REPORTED AND UNREPORTED) FOOD SAFETY ILLNESSES PER YEAR

	Mean	Low	High
Adjusted Comprehensive	1,282	0	6,400
Option A	245	0	1,079
Option B	572	0	2,660
Option C	316	0	1,452
Option D	355	0	1,612
Option E	359	0	1,750
Option F	621	0	2,846
Final Rule	1,204	0	6,061
Option H	1,067	0	5,372
Option I	1,072	0	5,504

TABLE 20.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM FASTER TRACEBACK INVESTIGATIONS

	Mean	Low	High
Adjusted Comprehensive	451	0	2,692
Option A	83	0	513
Option B	206	0	1,278
Option C	111	0	691
Option D	122	0	755
Option E	124	0	763
Option F	184	0	1,078
Final Rule	425	0	2,532
Option H	387	0	2,307
Option I	396	0	2,414

TABLE 21.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM MORE SUCCESSFULLY COMPLETED TRACEBACKS

	Mean	Low	High
Adjusted Comprehensive	826	0	3,024
Option A	161	0	605
Option B	364	0	1,296
Option C	203	0	778
Option D	232	0	864
Option E	234	0	864
Option F	434	0	1,728
Final Rule	775	0	2,592
Option H	676	0	2,592
Option I	673	0	2,592

The next table shows the food safety benefits as the number of averted illnesses valued by the low, middle, and high cost of illness estimates, and for the $5 million and $6.5 million estimates of the value of a statistical life. These are estimated annual food safety benefits and should be interpreted as minimum benefits from this final rule because food security benefits are not included.

TABLE 22.—VALUE OF AVERTED FOOD SAFETY ILLNESSES FOR THE FINAL RULE

	Low[2]	Medium[3]	High[4]
VSL[1] = $5 million	$7,388,685	$15,905,182	$24,421,229
VSL = $6.5 million	$8,199,494	$16,715,991	$25,232,038

[1] Value of a statistical life used to value the averted deaths.
[2] A value of $100,000 was used to value a year in good health.
[3] A value of $300,000 was used to value a year in good health.
[4] A value of $500,000 was used to value a year in good health.

V. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the final rule on small entities. FDA finds that this final rule may have a significant economic impact on a substantial number of small entities.

We estimate that more than 75 percent of all businesses covered by this final rule are small or very small. The undiscounted per-facility costs for small and very small businesses are reported in the following table. Costs for learning and records redesign are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs are incurred each year following publication of the final rule beginning in the second year for large and small firms, and in the third year for very small firms.

TABLE 23.—ESTIMATED PER FACILITY RECORDKEEPING COSTS

21 CFR Section	Costs
1.337, 1.345, and 1.352 (learning)	$120.00
1.337, 1.345, and 1.352 (records redesign)	$411.00
1.337, 1.345, and 1.352 (additional records maintenance)	$219.00

Comments Summary

Comments cover topics such as reasons why staggering compliance dates will not achieve regulatory flexibility objectives, suggestions of regulatory alternatives that would achieve regulatory flexibility objectives, appeals to consider the cumulative costs of all four bioterrorism regulations together when considering the impact on small businesses, appeals for exclusion of certain categories of small businesses, as well as other general topics. The different categories of comments are summarized in the following paragraphs.

(Comment 214) One comment finds the definition of ''small business'' uncertain and asks whether it is based on either the number of employees at a

firm or the number of employees at a facility.

(Response) The U.S. Small Business Administration (SBA) establishes small business definitions (or size standards) by industry (Ref. 28). The most common SBA size standard applicable to manufacturers covered by this final rule is 500 employees. Other pertinent SBA size standards include 100 employees for wholesale distributors, $21.5 million in receipts for transporters, and $6 million or $23 million in receipts for retailers, depending on the type of store. After discussions with the SBA, we define a small business in the food industry as having more than 10 and fewer than 500 full-time equivalent employees, and we define very small firms as having 10 or fewer full-time equivalent employees.

Firm size, rather than facility size, is used in the cost estimates for regulatory flexibility purposes whenever the data permit. For purpose of the compliance dates, the firm size governs. For purpose of the retail exclusion, the number of employees at the facility applies.

(Comment 215) Several comments suggest that the recordkeeping requirements are so onerous that compliance periods should be extended to as many as 7 years.

(Response) In the PRIA, FDA assumed that the recordkeeping provisions required a limited amount of additional information over current business practices. Comments suggest that this may not be true for certain provisions. In the final rule, we have relaxed some of the more costly provisions, such as the requirement for records to contain lot code information for all persons subject to the final rule, and we have relaxed the records access requirement to 24 hours. We have also revised the requirements applicable to transporters so that they have multiple options for complying with the final rule. These modifications should reduce the costs of compliance for small businesses. In addition, we have extended the compliance dates of the final rule by 6 months to 12, 18, and 24 months for large, small, and very small businesses. The extension should further reduce the costs of compliance with the final rule because the costs of the required changes in records quality and records access fall as compliance time increases. Moreover, given the purpose of the Bioterrorism Act, FDA believes a 7-year compliance period is excessive.

(Comment 216) One comment states that large carriers account for only 0.28 percent of all carriers and that 0.28 percent of all carriers should not be unfairly burdened to comply with regulations 1 year before the rest. Another comment states that across-the-board compliance dates of 18 months better serves the purposes of the Bioterrorism Act, because it reflects the large volume of food that moves through big business.

(Response) The Regulatory Flexibility Act requires that special consideration be given to small businesses when such flexibility does not compromise the efficacy of the regulation. In the PRIA, FDA considered several other potential flexibility options and found that the policy of staggering the compliance dates and exempting very small retailers were the only ones that did not appreciably compromise the effectiveness of the regulation.

(Comment 217) Several comments state that large businesses would likely pass the costs of the regulation on to smaller firms. In addition, the proposed regulatory flexibility from staggered compliance dates would largely be ineffective, because large businesses will require their small suppliers to comply with the regulation to ensure their own compliance. Another comment suggests extending the compliance dates to 18 months for large businesses and 36 months to small businesses but acknowledged that staggering compliance dates would complicate business practices.

(Response) FDA acknowledges the difficulties in addressing regulatory flexibility considerations with staggered compliance dates. Nevertheless, FDA has decided that staggering the compliance dates is a viable mechanism to address regulatory flexibility considerations without compromising the effectiveness of the regulation as intended by Congress when it enacted section 306 of the Bioterrorism Act. However, to address the concerns expressed by these comments without compromising the effectiveness of the regulation, in the final rule compliance dates for all size businesses have been extended by 6 months to 12 months for large, 18 months for small, and 24 months for very small businesses. FDA further notes that small and very small businesses are not required by FDA to comply earlier than these timeframes even if they are doing business with larger businesses that have earlier compliance dates.

(Comment 218) At least one comment suggests that requiring the same compliance date for all firms and excluding small businesses from complying with the regulation compromises the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations. Such a compromise is contrary to the intent of the Regulatory Flexibility Act.

(Response) In the PRIA, FDA considered three regulatory flexibility options: (1) Exempting small business from all regulatory requirements, (2) offering small business exemptions from parts of the regulation, and (3) specifying longer effective compliance dates for small businesses. We found that specifying longer compliance dates for small businesses was one option that would not appreciably compromise the purpose of the regulation.

(Comment 219) Several comments state that the 4 and 8 hour provision for records access is more onerous for small businesses and suggest either flexibility in the extent of the records to be made available in that time period for small businesses, or extending the records access time requirements for small businesses. One comment suggests that the rule requires firms to keep more records than is necessary and that FDA should consider relaxing the level of detail in the small business records required to be made available in the 4 and 8-hour records access times. One comment states that the burden on a small firm from devoting a single employee, who generally performs multiple tasks, to accessing requested records is greater than that on a large firm devoting an employee who may generally perform only one task.

(Response) The proposed rule required large and small firms to provide access to records up to 4 hours after a request made during business hours, and up to 8 hours after a request made after business hours. FDA's current experience is that access to records generally takes 2 to 3 days and the requirements in the regulation will considerably increase the speed of traceback investigations. To acknowledge the concerns addressed by these comments, FDA has relaxed the records access requirement to as soon as possible, but within 24 hours. This longer requirement should provide regulatory relief to small businesses; however, FDA reiterates that it expects all businesses to provide access as soon as possible, given that an access request would only be made in a food-related emergency.

(Comment 220) Several comments request an exemption for some specific categories of small business, because they believe the estimated costs of compliance for small businesses are inadequate. Furthermore, one comment states that the regulatory flexibility provisions in the proposed rule did not satisfy SBREFA obligations.

(Response) FDA addresses SBREFA's regulatory flexibility issues by

exempting very small retailers, and by staggering compliance dates so that small and very small businesses would have 18 and 24 months to comply with the regulation. Because food in commerce generally passes through at least one small business before reaching consumers, excluding small businesses in every sector from compliance with the regulation would risk severely compromising the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations.

(Comment 221) Some comments argue that FDA should address the relatively large burden on small businesses due to the cumulative cost of the four bioterrorism regulations when considered together. The comments state that the proposed registration rule estimated that approximately 16 percent of foreign businesses might cease to export to the United States as a result of that rule. The comments note that this figure was used in the sensitivity analysis in the proposed recordkeeping rule to estimate the costs of the rule with 16 percent fewer foreign facilities. However, the comments stated that FDA did not consider the costs of all the bioterrorism regulations combined on small (or other) businesses.

(Response) The cumulative costs of multiple regulations are rarely considered in regulatory impact analyses. However, costs of the other three regulations were analyzed in their respective regulatory impact analyses. To estimate the cumulative costs of the regulation one could add together the costs determined for all four regulations.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule will include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112,300,000. FDA has determined that this final rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates have been fulfilled in the Executive Order 12866 analysis in the PRIA. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future Costs

The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after promulgation of the final rule. These costs will be incurred by all domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food except very small retail facilities.

Recurring costs from collecting new information as well as the learning costs for new entrants will be incurred in each future year. An hourly burden of 30 minutes a week was estimated for the additional monitoring and recordkeeping that will be required from this final rule. This hourly burden estimate was modified for convenience stores to allow for structural differences assumed in their operations. Refer to the PRIA for a fuller illustration of the future costs of the final rule.

TABLE 24.—FUTURE COSTS

	Mean	Low	High
Year 3 and later years	$123,209,200	$121,980,000	$125,788,000

Particular Regions, Communities, or Industrial Sectors

The costs of the establishment and maintenance of records will be shared among all domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, except very small retail facilities that are exempted from the final rule. The higher costs incurred by domestic suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Because consumer demand for food is highly inelastic, almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food.

National Productivity, Economic Growth, Job Creation, and Full Employment

Although this regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports

This rule requires additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs will increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of United States exports could reduce the quantity of United States exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the final rule, the increases in the price of United States exports (and resulting decreases in quantity demanded) will be quite small.

VII. SBREFA

SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is a major rule for the purpose of congressional review.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirement are shown below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Establishment and Maintenance of Records

Description: The Bioterrorism Act contains a provision authorizing the Secretary to establish requirements regarding the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food which are needed to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequence or death to humans or animals.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce. FDA received several comments about the hourly burden imposed by the rule on respondents.

(Comment 222) One comment states that the cumulative effect of the regulation is a staggering amount of required paperwork that needs to be organized and made available.

(Response) This comment is not directly responding to any specific request for comments but is a general comment. The duplication of records is unnecessary as long as existing records contain all of the required information. In this analysis we use the FDA small business model to calculate the effects on small businesses using the difference between revenues and variable costs as the metric. We incorporated both the one-time costs and the recurring costs to compute the effects on small businesses. The effects were computed for firms in the dietary supplements industry, candy manufacturing, and the ready-to-eat food manufacturing industry, including firms that manufacture breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes to current recordkeeping practices, the findings from the small business model indicate that virtually no small businesses will incur negative cash flows as a result of this rule. The percentages of firms predicted to incur negative cash flows are range from 0.2 percent to a high of 1.9 percent for the ready-to-eat food manufacturing industry. These findings strongly suggest that very few firms, if any, will be driven from business as a result of this rule. In the Unfunded Mandates section of the PRIA, we also consider the impacts of the proposal on food prices and conclude that any effect would be negligible.

(Comment 223) One comment states that the PRA was adopted to prevent the burden of collecting unnecessary information that has little practical utility or benefit. The comment further states that FDA needs to realign the benefits with the costs of the regulation.

(Response) This is a response to the request for comments on whether the information required in the proposal would have any practical utility. Compared with the description of the costs in the proposal, the benefits were not as well defined. In the final rule, the benefits of each provision are more clearly identified, which facilitates greater realignment of costs with the benefits of the regulation. As stated previously, however, the benefits are underestimated because they only consider food safety concerns and do not address food security concerns, which are based on classified information.

(Comment 224) One comment suggests that FDA should reduce the paperwork burden by integrating the paperwork requirements from this regulation with current U.S. CBP process so that only one form needs to be completed.

(Response) The final recordkeeping regulation excludes all foreign persons, except for foreign persons who transport food in the United States so that many foreign persons do not have to establish or maintain records. Moreover, neither the proposed nor final rules specify the form or format of required records. Accordingly, existing records used for U.S. CBP purposes may be used if they contain all of the information required by this final rule and are retained for the required time period.

Burden: FDA estimates that the paperwork burden of this final rule will be incurred by approximately 707,672 facilities owned by 581,943 firms. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food as well as foreign persons who transport food in the United States. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 of this final rule includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the registration interim final rule (68 FR 58894). The learning burden presented in table 25 of this document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following issuance of the final rule.

The records redesign burden presented in table 25 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the proposed rule. The burden from this activity is reported in table 25 of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning in each subsequent year following enactment of the final rule. These burdens for new

firms are reported in table 26 of this document.

TABLE 25.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—FIRST AND SECOND YEARS[1]

21 CFR Section	No. of Record keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352 (learning)	707,672	1	707,672	4.790		3,390,000
1.337, 1.345, and 1.352 (redesign)	150,358	1	150,358	29.084	$70,409,000	4,373,000
Total						7,763,000

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 26.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Section	No. of Record Keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (additional records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	70,767	1	70,767	4.790	339,000
Total					5,359,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions of this final rule have been submitted to OMB for review.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Analysis of Environmental Impact

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

X. Federalism

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

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Eastern Research Group, Small Business Model, 2003.

2. Estrin, A., Memo to Docket Summarizing Conversations Held Between May 15, 2003, and August 7, 2003, With Experts Jack Guzewich and Sarah Pichette; Also a Description of Data Obtained From FDA's Outbreak Investigations, February 6, 2004.

3. Mead, P.S., L. Slutaker, V. Dietz, et al., ''Food-Related Illness and Death in the United States,'' *Emerging Infectious Diseases*, Center for Disease Control and Prevention (CDC), vol. 5, no. 5, September-October 1999.

4. Finger, Anne L., Senior Editor, ''Primary Care: Where Do You Stand on the Pay Scale?'' Medical Economics, (*http://www.memag.com/*), March 19, 2001.

5. Healthcare Cost and Utilization Project, Nation Inpatient Sample (NIS)—2001, Washington, DC, Agency for Healthcare Research and Quality, 2003.

6. FDA/CFSAN Bad Bug Book, accessed at *http://www.cfsan.fda.gov/~mow/intro.html* on May 3. 2004.

7. National Center for Infectious Diseases, Infectious Disease Information, CDC, accessed at *http://www.cdc.gov/ncidod/diseases/index.htm* on May 3, 2004.

8. ''Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act,'' Research Triangle Institute (RTI), vol. II, Final Report, September 1988.

9. ''Modeling the Effects of Food Handling Practices on the Incidence of Foodborne Illness,'' Final Report Contract No. 223–01–2466, Task Order 1, With FDA Performed by RTI International, April 2003.

10. Brevard, Theresa A., et al, ''Acute Occupational Disinfectant-Related Illness Among Youth, 1993–1998,'' Environmental Health Perspectives, vol. 111, no. 13, 2003.

11. ''Surveillance for Acute Insecticide-Related Illness Associated with Mosquito-Control Efforts—Nine States, 1999–2002,'' Morbidity and Mortality Weekly Report, vol. 52, no. 27, pp. 629–634, July 11, 2003.

12. Kaplan, et al., ''The Quality of Well-Being Scale: Rationale for a Single Quality of Life Index,'' *Quality of Life Assessment: Key Issues in the 1990s*, ed. Stuart R. Walker and Rachel M. Rosser, 1993.

13. Garber, A.M. and C.E. Phelps, Economic Foundations of Cost-Effectiveness Analysis,'' Journal of Health Economics, vol. 16, pp. 1–31, 1997.

14. U.S. Census Bureau, USA Statistics in Brief, *http://www.census.gov/statab/www/*

part3.html#income, accessed on November 29, 2004.

15. Viscusi, W., Joseph E. Kip and Aldy, ''The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World,'' February 2003, NBER Working Paper No. W9487, accessed at *http://ssrn.com/abstract=379270* on May 3, 2004.

16. National Restaurant Association, 2004 Restaurant Industry Forecast, 2004.

17. U.S. Census, American FactFinder, 1997 Economic Census, accessed at (*http://factfinder.census.gov/servlet/DatasetMainPageServlet?_program=ECN&_lang=en&_t=*) on March 31, 2004.

18. U.S. Department of Transportation, available at *http://www.transtats.bts.gov*, accessed on April 6, 2004.

19. Hennessy, T.W., C.W. Hedberg, L. Slutsker, et al., ''A National Outbreak of *Salmonella Enteriditis* Infections from Ice Cream,'' *New England Journal of Medicine*, vol. 334, pp. 1281–1286, 1996.

20. Lee, Judy O., E-Mail Correspondence, October 27, 2004 at 1:33 p.m.

21. United States Census Bureau, 2000 County Business Patterns, available at *http://www.census.gov/epcd/cbp/view/cbpview.html*, accessed on March 30, 2004.

22. United States Census Bureau, 1999 Nonemployer Statistics, available at *http://www.census.gov/epcd/nonemployer/index.html*, accessed on March 30, 2004.

23. Economic Data Resources, Estimates of Commercial Motor Vehicles Using the Southwest Border Crossings, Under the Auspices of the International Association of Chiefs of Police for U.S. Department of Transportation, September 20, 2000.

24. Direct Sales World, Facts and Figures and Comment of the World of Direct Sales, accessed at *http://www.nmworld.com/pages/Countries/USA/index.html* on July 10, 2003.

25. Direct Selling Association, Direct Selling By the Numbers, accessed at *http://www.dsa.org/research/numbers.htm#DISTTYPE* on July 10, 2003.

26. University of Pennsylvania Center Rate Schedule, Internet address: *http://www.archives.upenn.edu/urc/rates04.html* accessed on September 15, 2003.

27. United States Census Bureau, 2002 NAICS Definitions accessed at *http://www.census.gov/epcd/naics02/def/ND488510.HTM* on September 15, 2003.

28. United States Small Business Administration, Small Business Size Regulations, 13 CFR 121.201, available at *http://www.sba.gov/size/indextableofsize.html*, accessed on February 27, 2004.

29. Memorandum on the Number of Restaurants Selling Retail Food, dated December 15, 2003.

List of Subjects

21 CFR Part 1

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

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 11 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

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

■ 2. New subpart J (§§ 1.326 through 1.368) is added to part 1 to read as follows:

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

Sec.
1.326 Who is subject to this subpart?
1.327 Who is excluded from all or part of the regulations in this subpart?
1.328 What definitions apply to this subpart?
1.329 Do other statutory provisions and regulations apply?
1.330 Can existing records satisfy the requirements of this subpart?

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

Requirements for Transporters to Establish and Maintain Records

1.352 What information must transporters establish and maintain?

General Requirements

1.360 What are the record retention requirements?
1.361 What are the record availability requirements?
1.362 What records are excluded from this subpart?
1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

Compliance Dates

1.368 What are the compliance dates for this subpart?

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, ''processing'' means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. 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.

(1) 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.

(2) 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.

(3) 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.

(4) A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. 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.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) 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) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart 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 this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) 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 this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

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

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term ''farm'' includes:

(1) 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; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

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

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nonprofit food establishment 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)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging 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 act (21 U.S.C. 348(h)(6)).

Person includes individual, partnership, corporation, and association.

Recipe means 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.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means 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 foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this 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 information required by this 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.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

§ 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

§ 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

Requirements for Transporters to Establish and Maintain Records

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following

records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement and name of each carrier participating in the transportation; and

(7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:

(1) Date received;

(2) Received from;

(3) Consigned to;

(4) Destination;

(5) State of;

(6) County of;

(7) Route;

(8) Delivering carrier;

(9) Car initial;

(10) Car no;

(11) Trailer initials/number;

(12) Container initials/number;

(13) No. packages; and

(14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:

(1) Shipper's name and address;

(2) Consignee's name and address;

(3) Customs reference/status;

(4) Airport of departure and destination;

(5) First carrier; and

(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in § 1.352(a), (b), (c), or (d). The agreement must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) Description of the records to be established and/or maintained;

(4) Provision for the records to be maintained in compliance with § 1.360, if the agreement provides for maintenance of records;

(5) Provision for the records to be available to FDA as required by § 1.361, if the agreement provides for maintenance of records;

(6) Acknowledgement that the nontransporter assumes legal responsibility under § 1.363 for establishing and/or maintaining the records as required by this subpart; and

(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

§ 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) 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 having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) 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.

(d) 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.

(e) 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.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records 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. If you are a transporter, or nontransporter retaining records on behalf of a transporter, 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 after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.361 What are the record availability requirements?

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, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(c) to establish, maintain, or establish and maintain, records required under § 1.352(a) or (b), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the act and this regulation is a prohibited act under section 301 of the act.

Compliance Dates

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2004, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (f) to read as follows:

§ 11.1 Scope

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: November 30, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Dated: December 2, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 04–26929 Filed 12–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N–0277]

Final Regulation Implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—Establishment and Maintenance of Records for Foods; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; public meeting on final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of domestic public meetings to discuss the final regulation implementing section 306 (Maintenance and Inspection of Records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), which is publishing in this issue of **Federal Register**. The purpose of these public meetings is to provide information on the rule to the public and to provide the public an opportunity to ask questions of clarification.

DATES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1584, FAX: 301–436–2605, e-mail: *marion.allen@fda.hhs.gov*, for general questions only about the meeting.

SUPPLEMENTARY INFORMATION:

I. Background

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act (Public Law 107–188), which was signed into law on June 12, 2002.

In this issue of the **Federal Register**, FDA is publishing the final rule implementing section 306 of the Bioterrorism Act and a draft guidance on records access under the Bioterrorism Act. During the public meetings, FDA will explain this rule and the draft guidance and answer questions of clarification.

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

II. Final Rule and Draft Guidance

Section 306 of the Bioterrorism Act directs the Secretary of Health and Human Services (the Secretary) to issue final regulations that 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 must be kept by these regulations are those that are 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, in order to address credible threats of serious adverse health consequences or death to humans or animals. This regulation implements the recordkeeping authority in the Bioterrorism Act.

In addition, the Bioterrorism Act provides records inspection authority to FDA such that if 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, and the records are necessary to assist FDA in making such a determination, persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food must provide access to records.

III. Registration for the Public Meetings

Please submit your registration information (including name, title, firm name, address, telephone number, e-