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

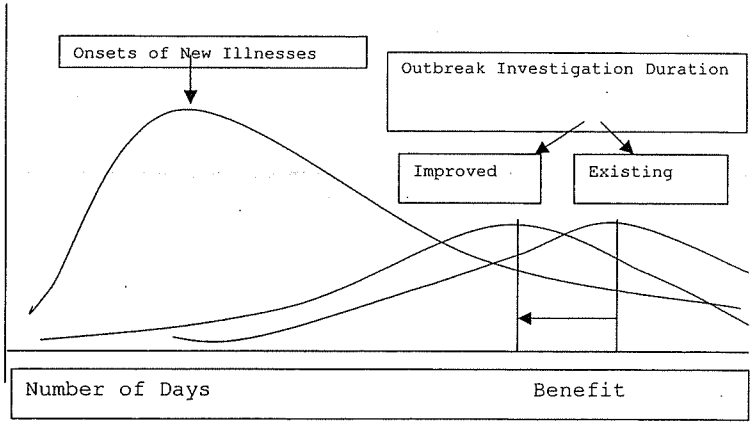
extensive protective efforts by businesses and consumers. Consumers might take costly preventive actions, such as throwing away food, stopping their consumption of the suspect food item, or visiting physicians or emergency rooms to determine if they have been exposed to some hazard. Producers and distributors 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:

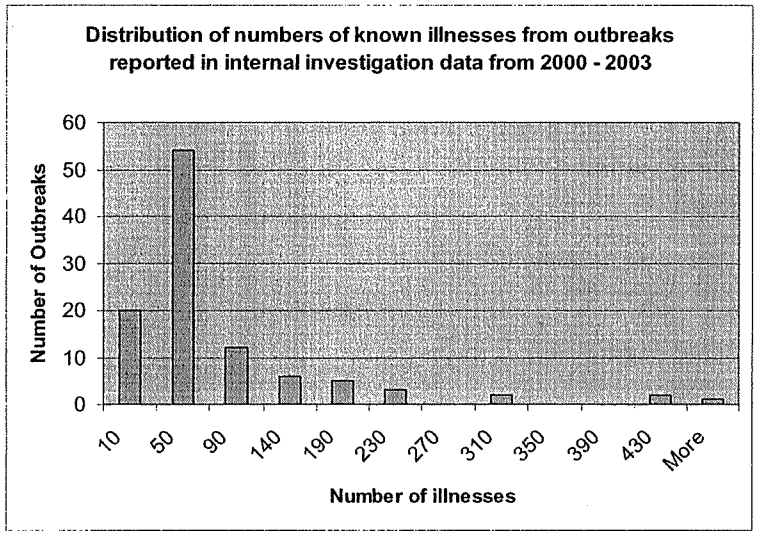
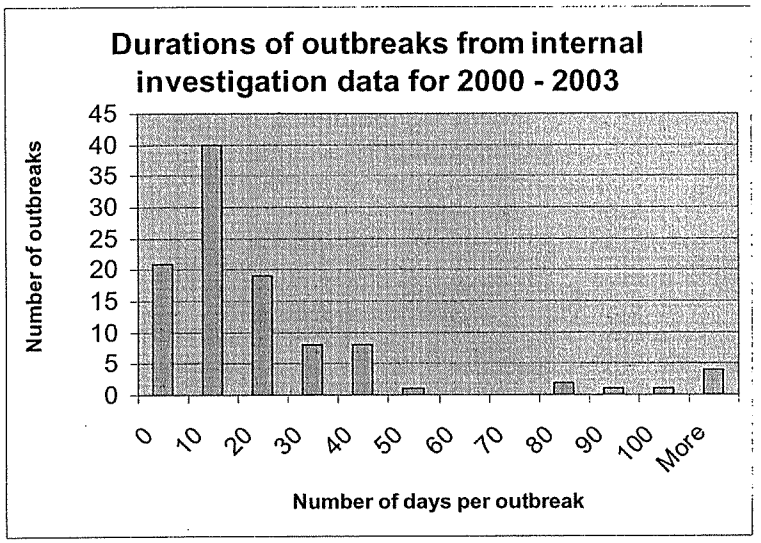
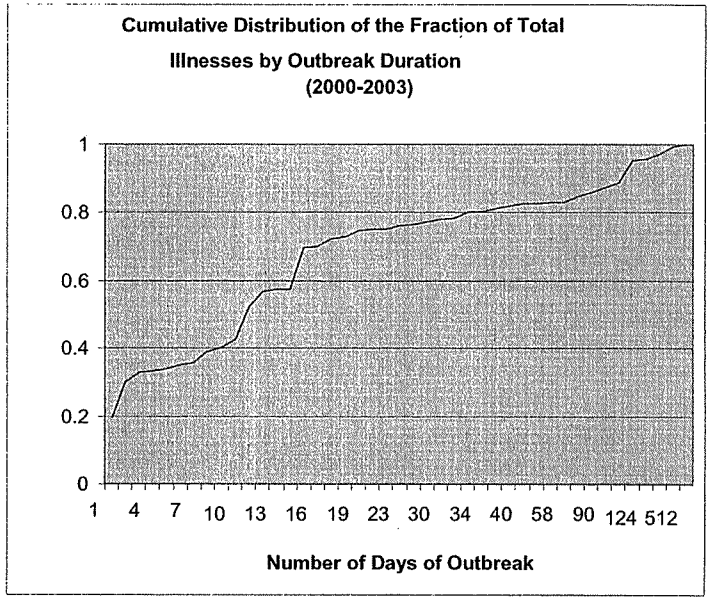


Chart 2:



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