requirement to provide this emergency contact information with the records being kept will not be useful. The stated purpose of having such a contact name is to obtain help in accessing the records. However, to find that information, FDA would have already obtained the records without this emergency contact information.

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

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

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

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

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

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

2. The FD&C Act

There were no comments on this issue.

3. Domestic Person

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

4. Farm

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

Some comments believe that the proposed definition of ''farm'' should be modified to include certain of the activities defined as manufacturing/ processing, regardless of whether the foods that are the focus of these activities

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

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

FDA considers several of the activities identified in the comments to be ''packing or holding,'' including sorting, grading, wrapping, and boxing harvested food for the sole purpose of transporting this food off the farm. FDA also considers placing stickers on produce grown or consumed on a farm to be part of ''packing.'' FDA notes that the definition of ''farm'' includes facilities that pack or hold food, provided all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. Thus, a farm that performs these packing and holding activities will not

necessarily cease to be a farm and therefore cease to be exempt from these regulations. Similarly, FDA considers several of the activities identified in the comment (waxing, milling, and grinding) to be manufacturing/processing. A farm that performs these activities will not necessarily cease to be a farm because the definition of ''farm'' includes facilities that manufacture/process food, provided that all food used in these activities is consumed on that farm or another farm under the same ownership.

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

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

so long as all of the involved produce is grown or consumed on the farm or a farm under the same ownership. Accordingly, a farm that simply places a raw agricultural commodity into containers, such as placing berries in clamshells, is not ''manufacturing/processing.''

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

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

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

5. Food

FDA received a number of comments regarding using the definition of ''food'' in section 201(f) of the FD&C Act, which includes food contact substances within its scope. These comments are addressed in section III.D.10, entitled ''Food Contact Materials.'' For the reasons stated therein, FDA has

decided to retain the definition of food as proposed; however, the final rule exempts persons who manufacture, pack, transport, distribute, receive, hold, or import food contact substances, other than the finished container that directly contacts the food, from all requirements of subpart J of this final rule, except §§ 1.361 and 1.363. Further, persons who place food directly in contact with its finished container are subject to all of the requirements of subpart J as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of subpart J as to the finished container, except §§ 1.361 and 1.363 (regarding access to existing records).

6. Foreign Facility

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

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

7. Manufacturing/Processing

There were no comments on this issue.

8. Nontransporter

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

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

whether that person has possession, custody, or control of the food for the sole purpose of transporting that food.

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

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

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

9. Nontransporter Immediate Previous Source

There were no comments on this issue.

10. Nontransporter Immediate Subsequent Recipient

There were no comments on this issue.

11. Perishable Food

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

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

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

One comment states that FDA should harmonize the Bioterrorism regulations with the other current regulatory provisions such as the Perishable

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

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

One comment states that the ''perishable food'' definition is confusing because the definition begins by stating that perishable foods are foods that

are ''not heat-treated, not frozen and not otherwise preserved * * * '' Confusion arises because pasteurized milk is heat treated, and FDA's qualification of the three criteria is somewhat awkward and combined with an extensive use of negatives.

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

having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

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

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

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

12. Pet Food

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

13. Recipe

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

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

comments state that FDA is exceeding its statutory authority under the Bioterrorism Act.

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

Another comment similarly states that many products will be affected by the proposed definition, and ingredients and quantities must be protected. Many products are unique and were expensive to develop. Reverse engineering as well as trial and error can lead to duplication of products that can have very serious consequences for companies. FDA must find a solution to this

challenge so as to not impede its investigations and at the same time protect the recipes of the involved companies.

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

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

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

that there are in effect effective procedures to prevent the unauthorized disclosure of [such information]'' (21 U.S.C. 414(c)). FDA is planning to reemphasize in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained. Therefore, FDA disagrees that a manufacturer would be harmed by disclosing ingredient information to FDA.

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

(Comment 75) A comment states that FDA's procedures for the exercise of its records access authority should embody recognition of the special status of confidential ingredients, as follows: First, FDA should provide that it will not routinely seek access to records that would require the disclosure of confidential ingredient information; second, if FDA concludes that it needs access to information about ingredients, it should present a written explanation to the custodian of the records that sets forth the basis for the agency's conclusion; and third, FDA should seek records access in an orderly manner, beginning with ingredients other than flavors and spices. The comment states that it will not be possible for FDA to assess simultaneously each ingredient in a product as the potential source of the problem that is being investigated.

Given that flavor and spice information is highly confidential and that the low levels of use of those ingredients make it unlikely that one of them will be the source of the problem investigated, it is reasonable to provide that requesting information on flavors and spices will occur only as a ''last resort.'' Finally, FDA should provide for special procedures to ensure that, when flavor and spice information is obtained, it is properly protected from disclosure, whether advertently or otherwise. The comment urges FDA to implement a system to adequately safeguard against the inadvertent release of proprietary and confidential information. Among other things, such information should be shared within FDA only to the limited extent necessary to conduct the particular investigation that resulted in the disclosure. The comment asserts that highly proprietary information about product formulas should not be widely distributed within the agency, and all persons who are made privy to the information should be reminded explicitly of the confidential nature of the information. Moreover, the comment states that FDA should amend its public information regulations to provide expressly that information obtained under the records access authority is exempt from disclosure under one or more of the exemptions under the Freedom of Information Act (FOIA) (5 U.S.C. 552).

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

14. Restaurant

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

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

The comments view their industry as similar to a large restaurant or hotel kitchen, which produces a wide variety of meals within a matter of hours. The comments state that inflight catering is not regulated under the same rules as a food processing plant because the same rules would not fit the inflight catering industry. Food in a processing plant may be prepared weeks to a year

before consumption. The comments state that the only difference between the catering and the restaurant service is that the catering meals are generally consumed 1 to 4 hours after departing from the kitchen rather than immediately consumed, as in the restaurant industry.

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

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

The comments further state that the airline catering industry currently must be in compliance with many Government regulatory agencies (FDA, Federal Aviation Administration (FAA), USDA, Environmental Protection Agency, Transportation Security Administration (TSA)), and that they have strict specifications for products and vendors, whereas most food service operations do not. The comments also note that they currently employ security companies to monitor their staff, the food processes in which they prepare meals, the equipment the food items are loaded into, and the process of how it gets on board the aircraft. They also state that their customers have always expected traceability of all products used on their flights as part of their food safety and hygiene audits to resolve flight passenger complaints, food poisoning reports, and for other purposes, but not to the extent that is required by the proposed rule.

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

(Response) For the reasons stated in response to comment 76 of this document, FDA continues to believe that facilities that provide food to interstate conveyances should not be covered by the restaurant exclusion because they do not provide food directly to consumers for immediate

consumption. However, these final regulations state that duplication of existing records is not required if those records contain all of the information required by subpart J of this final rule. Therefore, if a covered person keeps records of all of the information as required by subpart J in order to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. As the comment notes, the airline catering industry currently has the capability to trace all food products on their flights. These regulations do not dictate the format or system in which the required records are maintained. The airline catering industry can use existing tracing mechanisms to comply with these regulations to the extent those mechanisms contain the required information.

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

with other ingredients from different sources and fruit or chips, and then loaded onto numerous flights. This level of batch control would make the production of these sandwiches and meals cost prohibitive.

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

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

would have that information reasonably available at the time records are created to identify the immediate previous sources of the food.

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

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

15. Retail Facility

As explained in response to comment 40 of this document, for purposes of § 1.327(e) of this final rule, ''retail food establishment'' is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food

products to all other buyers. A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations. In addition, retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from the requirements in subpart J of this final rule, except §§ 1.361 and 1.363. (See response to comment 38 of the document for a further discussion of FDA's rationale underlying this exclusion.)

16. Transporter

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

17. Transporter's Immediate Previous Source

There were no comments on this definition.

18. Transporter's Immediate Subsequent Recipient

There were no comments on this definition.

19. You

There were no comments on this definition.

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

There were no comments on this issue.

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

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

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

(Response) FDA based the requirements of the final rule on what records are needed by the Secretary for inspection to help the Secretary identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals. Section 1.330 of subpart J of this final rule states that duplication of existing records is not required if those records contain all of the information required by subpart J. If a person keeps records of all of the information as required by subpart J to comply with other

Federal, State, or local regulations (including those of TSA or FAA), or for any other reason, then those records may be used to meet these requirements. In addition, where a person currently has existing records that contain some, but not all, of the required information, only records for the nonexisting information needs to be created.

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

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

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

(Response) As explained in the proposed rule (68 FR 25188), FDA has been involved in traceback investigations where not all necessary records were

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

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

(Response) FDA agrees in part with the comments. The final rule has been revised from the proposal. The final rule provides five alternatives for transporters to meet their obligation to establish and maintain records. First, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(a) of this final rule. Second, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(b) of this final rule, which are included within the current requirements for roadway interstate transporters under FMCSA regulations as of the date of publication of this final rule (49 CFR 373.101 and 373.103). Third, transporters can meet

the requirements of this final rule by keeping the records listed in § 1.352(c) of this final rule, which are included within the current requirements for rail and water interstate transporters under STB regulations as of the date of publication of this final rule (49 CFR 1035.1 and 1035.2). Fourth, transporters can meet the requirements of this final rule by keeping the records listed in § 1.352(d) of this final rule, which are included with the current requirements for international air transporters under the Warsaw Convention. Fifth, transporters can meet the requirements of this final rule by entering into an agreement with a nontransporter immediate previous source in the United States or a nontransporter immediate subsequent recipient in the United States to keep records for them. Such agreements must contain the elements specified in § 1.352(e) of this final rule. Failure by the immediate previous source or immediate subsequent recipient who enters into an agreement under § 1.352(c) of this final rule to keep such records is a prohibited act under § 1.363 of this final rule.

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

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

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

Data on the volume of foods that move in intrastate commerce are maintained by individual state Departments of Agriculture and by DOT. For example, from CA, LA, TX alone, DOT reports over 12 percent of intrastate truck tonnage is FDA-regulated products. Past traceback investigations provide examples of the need to regulate intrastate transport. For example, in 2003,

there were two produce-associated outbreaks that occurred in CA from intrastate shipments. There were also two *Salmonella enteritidis* outbreaks in WI associated with intrastate shipments of eggs. Other foods, such as pasteurized milk, nearly all raw products, seafood, and sprouts, may be shipped either intrastate or interstate depending on the production or processing site.

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

The NC green onion traceback investigation in 2003, which was part of the largest Hepatitis A outbreak that has ever occurred in the United States, is another example of the importance of intrastate records. There, the amount of time spent on the traceback within that State was twice as long as the other three tracebacks done in other states because the distributor in NC did not have records. Traceback from the TN outbreak took over a month, the GA traceback took a month, and Pennsylvania (PA) traceback took a week. Because

we had no intrastate records in the NC outbreak, the traceback was determined to be inconclusive after two months, which meant that we would not have been able to identify the farms involved if it had not been for the other outbreaks.

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

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

- An intrastate sandwich/snack food company that sells to retail outlets for consumption had an outbreak of *Listeriosis* or *Salmonellosis* that was traced back to the sandwiches. The product was completely distributed using the company trucks within the state. FDA was unable to determine which sandwiches caused the outbreak. The sandwiches were delivered to retail customers, and it was impossible to track which sandwiches went to which

retailer. The transporter did not track which product was delivered to which location. In this case, the firm had to recall all of its products.

- Retail stores regularly purchase food, especially locally grown produce, from ''truck farmers.'' These farm trucks travel from store to store within a state, sometimes selling an entire truckload to a store, other times a portion. There is no manifest or record other than a bill of sale—e.g., 200 cantaloupes from Farmer Brown. If the contamination occurred on the truck, FDA would not have a record from the truck of all other delivery sites.

- Several days into the investigation of a Hepatitis A outbreak from chicken salad in one city, FDA learned that the chicken was ''cubed'' at another facility in another city within the state, and transported to the ''manufacturing facility.'' The source of the outbreak was the site where the chicken was ''cubed'' by an ill employee; however, there were no records to indicate when the cubed product was shipped or received by the salad manufacturing facility.

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

a requirement would be unreasonably onerous, particularly if the company's system is designed to make certain that the company can provide all of this information to the agency within the specified time. The respondent asks the agency to clarify in the final rule that it is not necessary to develop one transportation record that contains all of the information in a single form.

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

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

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

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

(Response) FDA is not able to determine what records currently exist throughout the entire food industry that satisfy these regulations due to the diversity and complexity of the food industry and the various existing Federal, State, and local regulations that require recordkeeping, as well as varying business practices. The person subject to these regulations is responsible for ensuring that it keeps all applicable records and that those records are available to FDA under the record availability requirements in § 1.361 of this final rule. FDA points out that the earliest compliance date of this final rule is [*insert date 12 months after date of publication in the* **Federal Register**], and that many persons are not required to comply with this final rule for up to 2 years after publication. Therefore, FDA believes that it has provided sufficient time for persons to determine what, if any, additional information must be kept to comply with these provisions well ahead of the compliance date of this final rule.

(Comment 86) A few comments note that most food companies currently maintain the chain of distribution information that FDA proposed, but the diversity and complexity of the food industry means that the information is maintained in many different ways and formats, ranging from computerized records systems to file folders of paper records. The comments state that it

should be of no concern to FDA and, therefore, not the subject of the regulations to prescribe any specific manner or form of maintaining the information.

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

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

1. General Comments

(Comment 87) Several comments state that the information required by the recordkeeping regulations exceeds the information required by the Bioterrorism Act, thereby exceeding FDA's statutory authority. Some of these comments state that according to the Bioterrorism Act, the regulations need to provide that those persons subject to the recordkeeping requirement maintain the ''one-up and one-back'' information in a records maintenance system in which the information is reasonably accessible to FDA upon request. The comments ask that FDA consider the diversity and complexity of the food

industry and allow for more flexibility. They contend that the name and address of the person from whom an article of food was received or to whom it was shipped and a description of the article of food should be sufficient. The comments further suggest that not all companies require or need the same type of identification as other members in the food chain, e.g., lot numbers and identity preserved ingredients. They request that, because of this diversity in the supply chain, the agency not define rigid identification requirements. The comments contend that this flexibility is in keeping with the intent of the Bioterrorism Act and will avoid dramatic changes to what are currently efficient and effective business practices.

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

Information such as the specific name of the food will allow FDA to limit its investigation to the implicated food. For example, if FDA has a reasonable belief that a shipment of cheddar cheese is contaminated, traceback or trace forward would be better facilitated if the records contained the identifier ''cheddar.'' This would help FDA narrow its investigation and increase the speed of the trace. The information would also help the involved firm limit the scope of any recall, should it be necessary. However, FDA does recognize the diversity of the food chain and has allowed for flexibility in the final rule.

For example, the requirement to record lot/code number or other identifier applies only to persons who manufacture, process, or pack food and only to the extent that information exists. Also, the final rule allows covered persons to use existing abbreviations or codes currently used to identify the food. However, if these abbreviations and/or codes are used, they must be readily deciphered for FDA upon request so that an ''adequate description'' of the food is recorded.

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

(Response) FDA does not agree that much of the information required under this recordkeeping rule is already required under the registration interim final rule. Information required under the registration interim final rule pertains to the facility itself, including information about the general food product categories that the facility manufactures/processes, packs, or holds. Information that this final rule mandates be established and maintained in records is information pertaining to food that will assist FDA in identifying the immediate previous sources and the immediate subsequent recipients of all food that is received and released by a person. In addition, to complete the tracing investigation, the identity of the transporters who transported the

food to and from the sources and recipients is required, which is not covered by the facility registration. Moreover, the scope of section 305 of the Bioterrorism Act (registration) is not as broad as section 306 of the Bioterrorism Act (establishment and maintenance of records). Specifically, registration applies only to facilities that manufacture, process, pack, or hold food for consumption for humans or animals in the United States. Recordkeeping applies to these facilities, as well as those who transport, distribute, receive, or import food. Recordkeeping also applies to all food regardless of whether it will be consumed in the United States or exported.

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

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

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

rule only requires nontransporters to establish and maintain records of the transporter that took the food from them. The transporters are required to keep records that identify intermediate transporters.

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

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

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

(Response) There is no requirement for a person that manufactures or processes food to know the ultimate destination of its product. A person

subject to subpart J of this final rule is only required to establish and maintain records to identify the transporter and nontransporter immediate previous sources and transporter and nontransporter immediate subsequent recipients of food. Further, FDA notes that it has excluded all foreign persons, except foreign persons who transport food in the United States, from all of the regulations in subpart J.

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

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

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

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

would support including a requirement that products received be directly associated with products that are shipped.

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

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

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

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

(Comment 94) A few comments state that they are not able to provide information that ties the specific source of each ingredient to a lot of the finished product. Several comments agreed with FDA's decision to require

identification of the specific source of an ingredient in a finished product only when the information is ''reasonably available.'' Some comments request that the agency make clear in the final rule that, in many instances, it will be impossible to identify the specific source of a material that is held in bulk and that multiple sourcing information in recordkeeping is to be anticipated for raw materials that are held in bulk form.

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

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

released and only if this information is reasonably available. With respect to the comment that companies should only be required to produce records during a crisis, the agency notes that FDA will request access to the records under section 306 of the Bioterrorism Act only when it has reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

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

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

(Comment 96) A few comments request that the agency treat processing aids and incidental additives as it does commingled ingredients. The comments state that they are able to identify the source(s) in use in a facility

when specific food products were produced, but are not able to identify the source of the processing aid or incidental additive used to produce a specific lot of food.

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

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

(Response) What is ''reasonably available'' is going to depend on the particular circumstances. To illustrate this point in the proposed rule, FDA used a hypothetical case of a cookie maker. (See 68 FR 25188 at 25197.) A company that bakes cookies may source flour from five different companies rather than depend on a single company as its supplier. The flour from the five companies may be stored in one common silo before being used in the manufacture of the cookies. In this scenario, the manufacturer could identify, depending on the date the flour was received from each company and placed in the silo and when the silo was emptied, the various companies that were the sources of the flour. Under this situation, the information is not reasonably available to determine a single source of the flour used in a particular lot of

cookies. The information reasonably available to the manufacturer would be the identity of all of the potential sources of the flour for each finished lot of cookies. However, if the manufacturer had dedicated silos for each supplier of flour, then the information would be reasonably available to the manufacturer to specify the specific source of the flour for each finished product. If we determine that additional guidance is needed, FDA will consider issuing guidance in the future to explain this requirement further. Again, FDA notes that this requirement now appears in § 1.345(b) of this final rule and has been deleted from § 1.337(a) of this final rule.

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

(Response) Manufacturers of packaging (the outer packaging of food that bears the label and does not contact the food) are excluded from all requirements of subpart J of this final rule unless such persons also manufacture, process, pack, transport, distribute, receive, hold or import food in the United States, in which case they are subject to §§ 1.361 and 1.363 of this final rule as to the food's packaging. Manufacturers of food contact substances, whether or not the substances are the finished container that

directly contacts the food, are excluded from all of the requirements of subpart J, except §§ 1.361 and 1.363 of this final rule. Therefore, such manufacturers are not required to know which lot of the input materials is in an individual roll of finished product.

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

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

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

(Response) Bottled water is within the definition of food as defined in § 1.328 of this final rule. If water is obtained from a public water system, then

the public water system is the immediate previous source. If ground water is used, then the location where the water was extracted should be provided.

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

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

3. Requirement to Record Responsible Individual

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

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

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

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

4. Adequate Description of Type of Food

(Comment 104) One comment notes that ''specific variety'' is not appropriate for many food ingredients and should be changed to ''common name.''

(Response) FDA is requiring an adequate description of the type of food received or released to include brand name where applicable and specific

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

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

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

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

(Response) It is not clear from the comment what the ''customer's description'' entails; however, FDA is requiring an adequate description of the type of food to be able to narrow the scope of the implicated food in the event

of a public health emergency. For this reason, each entity within the chain of distribution of the food must establish and maintain records that adequately describe the type of food received and released so that FDA can identify the immediate previous sources and immediate subsequent recipients of food to address credible threats of serious adverse consequences or death to humans or animals. It is the responsibility of the covered entity to revise its recordkeeping system so that it establishes and maintains records containing all required information. In the previous example, the warehouse may need to require its customers to provide it with a more detailed description when food is delivered or released than it currently receives.

5. Date Food Received or Released

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

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

6. Lot or Code Number/Other Identifier

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

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

code number or other identifier throughout the entire food chain, but that the current technology has not made such tracking cost efficient.

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

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

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

(Response) The final rule does not require warehouse distribution facilities to track lot/code number or other identifiers in these final regulations.

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

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

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

Several comments note that protecting public health does not necessitate the maintenance of records in every step of the distribution process. The comments state that the current recall system is the most efficient and practical way to identify and remove product from distribution. These comments state that consumers typically return all products in a recall with no regard to the

lot code, and that this is the most appropriate response in the event of a terrorist attack. In these comments' opinion, complex lot numbers may slow or substantially limit the recall of contaminated food. Additionally, requiring distributors to compromise the integrity of food packaging to determine lot codes defeats the purpose of the proposal. Some comments state that this requirement represents a disproportionate burden to packaged food distributors.

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

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

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

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

numbers, or other identifiers to identify specific lots of products. In this case, the regulations do not specify that these sectors start using such identifiers. The identifiers are required only to the extent that they already exist.

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

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

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

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

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

7. Quantity and How the Food is Packaged

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

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

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

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

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

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

the transporter that delivered the product, especially if multiple transporters may have been involved. The comments state that such information would be available from the shipper that arranged the transport. One comment states that it is not usual business practice for distributors to keep records about the transporter who delivers food.

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

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

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

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

(Comment 120) A number of comments noted that many ''nontransporters'' own trucks or other vehicles and transport food or feed as an incidental part

of their operations. They express concern that they would be required to keep two sets of records, one as a nontransporter, and the other as a transporter. One comment recommends that the final rule be applicable to both private and ''for-hire'' transporters.

(Response) ''Transporter'' is defined in § 1.328 of this final rule to mean a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that person has possession, custody, or control of that food for the sole purpose of transporting that food. If a person is considered a nontransporter under the rule, then the person is not subject to the transporter provisions when transporting food, but must comply with the requirements applicable to nontransporters. The final rule applies to transporters regardless of their status as private or for-hire. For example, if a U.S. manufacturer hires a company to deliver its food, the delivery company is subject to the transporter provisions whether or not it is private or for-hire.

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

(Comment 121) A number of comments note that the specific records being required of transporters are duplicative of the information being required of

the immediate prior sources and the immediate subsequent recipients with respect to each other and that such redundancy is unnecessary because the agency could get the information from either or both of the immediate prior sources or immediate subsequent recipients.

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

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

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

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

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

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

(Comment 124) A number of comments state that the transporter has no access to detailed information about the shipment and is dependent on the information listed on the bill of lading provided by the shipper. Therefore, the information required of transporters should be limited to the information on the bill of lading. One comment states that a bulk shipper, for example, has a 5,000 gal shipment of orange juice and has access to only this

information, and detailed descriptive information such as brand names, specific variety, and package types are not applicable to bulk loads. Several comments state that transporters are frequently provided with preloaded and/or sealed vehicles for transport, and the transporter does not have knowledge of the contents other than what is on the bill of lading prepared by the shipper. They argue that they cannot access the sealed cargo to obtain specific information to confirm or supplement the bill of lading information. Similarly, other comments advise that they cannot verify bill of lading information for food contained in shrink-wrapped pallets. These comments believe that the carriers responsibility should be limited to the description provided by the shipper.

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

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

(Response) The final rule provides five alternatives for transporters to meet their obligation to establish and maintain records. Failure by the immediate previous source or immediate subsequent recipient who enters into an

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

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

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

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

* * * In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, *transports*, distributes, holds, or imports foods, the inspection shall extend to all records or other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals * * *. (Emphasis added.)

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

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

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

(Comment 128) Some comments state that requiring brand name descriptions raises cargo security concerns because having more detailed

descriptions on paperwork will increase the risk of theft and make it easier for bioterrorists to target certain shipments.

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

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

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

solely on whether a food has a shelflife of 7 days, does not appear to utilize sound risk management principles.

(Response) FDA agrees in part with these comments and has revised the record retention requirements in the final rule. FDA used similar criteria as the NIST definitions for perishable, semiperishable and long shelf-life food. The record retention requirements in § 1.360(b) of this final rule now require record retention of: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydration, or being placed in a hermetically sealed container.

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

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food

for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

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

(Response) FDA agrees with this comment and has revised the final rule accordingly. Section 1.360(f) of the final rule requires transporters, or nontransporters retaining records on behalf of a transporter, to retain records for 6 months for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received or released and 1 year for any food having a significant risk of spoilage, loss of value, or loss of palatability only after a minimum of 60 days after the date the food is received or released.

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

(Response) As stated previously in response to comment 129 of this document, FDA has considered various options and has chosen to require record retention based on criteria similar to the NIST definitions for perishable, semi-perishable and long shelf-life food. FDA is convinced such an approach

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

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

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

(Response) As previously noted in response to comment number 129, FDA has considered various options and has chosen to require record retention based on criteria similar to the NIST definitions for perishable, semiperishable and long shelf-life food. FDA is convinced such an approach is the most

efficient and effective because the food industry already is familiar with classification of foods into these three categories due to existing regulations and practices; and it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods.

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

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

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

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

than 6 months, respectively. Several comments suggest the record retention time should be 6 months for perishable food; 12 months for semiperishable food and 18 months (or product shelflife plus 12 months or 24 months, whichever is greater) for long shelflife food.

(Response) FDA agrees with this comment. FDA has concluded that this objective can be achieved by inserting language directly in § 1.360(b) of this final rule using similar criteria as the NIST definitions for perishable, semi-perishable and long shelf-life food. Therefore, FDA has changed the record retention requirements in § 1.360(b) of this final rule to require record retention by nontransporters for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food; and (3) 2 years for food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

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

FDA chose this approach because: (1) The food industry already is familiar with classification of foods into these three categories due to existing

regulations and practices and (2) it will mitigate the problem raised by some comments of inadequate infrastructure for long term storage of records for the shorter shelf life foods. FDA believes that a tracing investigation involving food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days will not be compromised by providing for the reduced record retention of 6 months because most of these tracebacks are initiated within 6 months of the outbreak.

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

(Response) FDA does not agree with the comment's suggestion, as this will not ensure that FDA has access to the requisite records at the time of a traceback investigation. Often, a traceback begins after consumers become sickened or die. In the comment's example, if the wine was adulterated and presented a threat of serious adverse health consequences or death to humans, FDA may not know this until the wine has been consumed, i.e., after the product was released by the manufacturer into commerce and consumers became seriously ill. If the record retention period began at the time of production, but the wine was aged at the manufacturer's facility 2 years before distribution into commerce, the record retention period would have expired

before the wine entered commerce. In the final rule, FDA retains the requirement that records required under subpart J must be established at the time food is received or released and maintained from that time until the end of the time period specified in § 1.360 of this final rule.

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

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

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

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

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

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

For the final rule, FDA has changed the record retention requirements in § 1.360(b) to require record retention by nontransporters for: (1) 6 months for food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days after the date you receive or release the food; (2) 1 year

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

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

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

In addition, FDA has excluded the distribution of food directly to consumers from the requirement to keep records of immediate subsequent recipients of food because FDA can obtain information from consumers and notify them when necessary. Often, consumer illness is the first common

indicator that food may be adulterated and present a threat of serious adverse health consequences or death. Requiring retailers to retain records for only weeks or months would greatly impede FDA's ability to conduct a rapid and effective traceback. FDA has selected those timeframes for record retention based on the amount of time perishable and nonperishable food may remain in commerce, and thus, may be the subject of a traceback investigation. FDA further notes its understanding that many retailers currently maintain records for 2 years.

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

(Comment 139) A few comments state that the requirement to maintain records for 2 years is very burdensome for those who obtain a variety of fresh produce from a large number of small farmers and commingle lots of produce for distribution.

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

(Comment 140) A few comments state that, for alcoholic beverages and distilled spirits, retention of records for a period of only 2 years would be inadequate to trace a matured product back to the source. They suggest that

FDA should rely on alcoholic beverage importers' and producers' own existing record systems to facilitate tracebacks.

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

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

records that contain part of the required information to be maintained in different locations.

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

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

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

(Comment 142) Some comments state that the proposed time is reasonable for record production if the requested records are onsite and of recent transactions (i.e., within the last 3 months). One comment urges the agency to clarify that, although companies must make the records available within 4

hours, the agency does not expect companies to link the sources of each ingredient with every finished lot of product within that timeframe. Another comment states that, within the 4-hour proposed time, a firm will not be able to make records available that are stored offsite and currently are subject to contracts that allow the vendors to deliver records on the next business day. The comment recommends that FDA consider the possibility of allowing records stored offsite to be produced at locations more convenient than the manufacturing facility, such as FDA offices, headquarters, or other locations mutually agreed upon to expedite record examination.

Some comments also state that the cost of renegotiating record storage contracts would cost thousands of dollars, more than the $151 per firm cost that FDA estimated. They recommend that FDA allow companies to provide records ''within a reasonable period of time'' or that the final rule give companies 24 hours to make records available to FDA from the time of receipt of FDA's official request. Several comments state that the proposed time does not reasonably reflect the following: The scope of requested records; the accessibility, degree of compatibility and number of recordkeeping systems involved; the limitations on record maintenance of some systems; the limited physical access to nonelectronic records; and the presence or absence of a quality assurance system. Comments further state that, with millions of foods transported annually, many firms utilize various data systems and have implemented records maintenance procedures to meet their specific company needs. Compliance with this new rule requires establishing new protocols and developing new database systems, which would require a substantial capital investment.

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

(Response) FDA agrees with these comments in part and has amended the proposed records availability requirements in this final rule. Section 1.361(a) of this final rule states: ''* * * Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of an official request * * *.'' FDA notes that, although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.'' (Comment 143) Other comments suggest that records be available within 12 hours regardless of what time of day the FDA request is made or the next business day, in the event the next day falls on a weekend or a holiday. Some suggest a timeframe within 24 hours if the request is made during a working week and within 72 hours if a request is made during a weekend.

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

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

(Comment 144) Several comments urge FDA to reconsider its proposed definition of work hours (8 a.m. to 6 p.m.). The comments state that in most ports of entry, the hours of operation of the trade community are established to mirror the hours of the commercial operations of CBP. If FDA requests records outside of those hours of operation, FDA could encounter difficulty

in contacting the appropriate parties from whom to request records. Comments suggest that FDA use the phrase ''during times in which a firm is operating'' or ''during a firm's normal business hours.''

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

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

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

(Comment 146) Many foreign governments express concern that FDA does not have authority regarding recordkeeping and record access when a firm is located in a foreign country. One foreign government urges FDA to recognize the role of another competent authority with respect to records access as provided for under the World Trade Organization Agreement on Sanitary and

Phytosanitary Measures. Foreign governments request that FDA operate under agreements with these governments so that FDA will convey its request to the competent authority in that country. The competent authority can then carry out investigations on behalf of FDA and provide FDA with any resulting relevant information.

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

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

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

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

(Response) FDA has considered this and other comments and has changed the record availability requirement from the proposed rule. Under this final regulation, records shall be made available as soon as possible, but not to exceed 24 hours after FDA has made the request. In the circumstances in which FDA would access the records, it is critical for FDA to move as quickly as

possible to trace backwards to identify the source of any such adulteration and trace forward from that source to remove all similarly adulterated food from commerce to protect the public health. FDA notes that, although the rule sets an outer limit of 24 hours to provide records, it requires that records be provided ''as soon as possible.''

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

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

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

Comments recommend that FDA establish procedural safeguards to protect manufacturers and their customers by providing the affected company with a reasonable written notice that explains how the ''reasonable belief'' standard is being met and identifies the type of records being requested. According to comments, this would inform the affected company which records are being sought and the legal basis for the request. Several comments also request that FDA develop procedures requiring that the written notice be examined and

approved by the District Director in whose district the implicated food is located, or by any FDA official senior to such District Director. They urge FDA to develop guidelines to define ''reasonable belief'' and base a decision to access records on laboratory analyses confirming adulteration and/or on an affidavit sworn under penalty of perjury.

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

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

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

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

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

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

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

(Comment 153) Several comments express concern that information that FDA would view, copy, or otherwise access could contain confidential information, such as confidential commercial or trade secret information. Two comments ask FDA to permit a person subject to the requirements of section 414 of the FD&C Act to redact what they consider to be nonpublic information from records properly sought by FDA. One comment asks FDA to permit a person to create a separate document containing only that information FDA is entitled to inspect. Examples of confidential information that comments

have described include formulas, recipes, information about their businesses, where the product was purchased or sold, product development information, and location and business operations of farms.

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

(Response) FDA understands the comments' concerns about protecting the confidentiality of nonpublic information. If a person wishes to create separate records that do not contain certain confidential information, the person may do so, as long as the records are created at the time the food is received or released and the records contain the information required by the regulations. In addition, section 306 of the Bioterrorism Act excludes many types of confidential data from the record requirements: Recipes for food (see § 1.328 for the definition of recipe), financial data, pricing data, personnel data, research data, and sales data (other than shipment data regarding sales). Section 306 of the Bioterrorism Act, however, does not allow other types of confidential data to be withheld from FDA even if they are confidential. The laws governing FDA's activities, however, require it to protect certain trade secret and confidential information. See responses to comments 74 and 154 of this document.

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

that information can be redacted, the information and records may not have been provided ''as soon as possible.''

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

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

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

(Response) As discussed in response to comment 74, several statutes and the agency's information disclosure regulations at parts 20 and 21 govern the

agency's ability to disclose information to the public, including information obtained under section 306 of the Bioterrorism Act. For example, section 301 of the FD&C Act prohibits any person from using

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

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

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

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

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

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

information from the public in certain circumstances (5 U.S.C. 552(b)(6) and (b)(7)).

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

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

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

(Response) FDA is authorized to share certain nonpublic information with others. For example, FDA may share confidential commercial information with a sister agency within the Department of Health and Human Services, a State government agency official whom FDA has commissioned to act on its behalf under section 702 of the FD&C Act (21 U.S.C. 372) (§ 20.84), its contractors (§ 20.90), other Federal government agencies (§ 20.85), or foreign government agencies (§ 20.89). Procedural and other safeguards must be followed for FDA to share nonpublic information with other persons. For FDA to share confidential commercial information with CBP under § 20.85, CBP must sign

a written agreement that it will not further disclose the information except with FDA's written permission.

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

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

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

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

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

(Comment 159) Three comments state that imposition of criminal liability would be inappropriate and excessive if they performed to the best of their abilities. The comments state that taking time beyond 4 hours to locate,

compile, and provide records on a detained article's manufacture should not be viewed as a prohibited act.

(Response) As noted previously, FDA has changed the proposed times in § 1.361 of this final rule for responding to a request for access to records to a requirement that all records be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request. Failure to establish or maintain records or refusal to permit access to or verification or copying of any record is a prohibited act under section 301 of the FD&C Act.

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

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

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

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

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

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

(Response) FDA has carefully considered these comments and agrees that businesses should be given additional time to comply in view of the programming, training, and business practice adjustments that will be needed. Section 1.368 of the final rule requires large businesses (500 or more full-time equivalent employees) to be in compliance within [*insert date 12 months after date of publication of publication in the* **Federal Register**]. Small businesses (those with fewer than 500, but more than 10 full-time equivalent employees) must be in compliance within [*insert date 18 months after date of publication of publication in the* **Federal Register**], and very small businesses that employ 10 or fewer full-time equivalent employees must be in compliance within

[*insert date 24 months after date of publication of publication in the* **Federal Register**]. 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 [*insert date 18 months after date of publication in the* **Federal Register**].

(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.