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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. 02N–0277]

RIN 0910–AC39

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations that would require the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. In addition, these requirements apply to certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The proposed regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and are necessary to properly address credible threats of serious adverse health consequences or death to humans and animals. FDA expects that the requirements the agency is proposing in these regulations, if finalized as proposed, would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

DATES: Submit written or electronic comments by July 8, 2003. Written comments on the information collection provisions should be submitted by June 9, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

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

SUPPLEMENTARY INFORMATION:

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I. Background and Legal Authority

A. Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The events of September 11, 2001, reinforced the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (''the Bioterrorism Act'') (Public Law 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 306 (21 U.S.C. 335a), which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 414, Maintenance and Inspection of Records (21 U.S.C. 350(c)). Section 414(b) of the act provides, in part, that the Secretary of Health and Human Services (the Secretary), may by regulation establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. In section 306(d) of the Bioterrorism Act, Congress directed the Secretary to issue proposed and final regulations establishing recordkeeping requirements under section 414(b) of the act no later than 18 months after enactment of the Bioterrorism Act, that is, by December 12, 2003.

In addition, the Bioterrorism Act adds a new section 414(a) to the act that

provides records inspection authority to FDA. Section 414(a) of the act provides that when the Secretary has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons who manufacture, process, pack, distribute, receive, hold, or import food must provide access to records related to the food that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Section 306 of the Bioterrorism Act also amends section 704(a) of the act (21 U.S.C. 374(a)) to specifically authorize FDA inspections of all records and other information described in section 414 of the act, when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. Also, section 301 of the act (21 U.S.C. 331) is amended to make it a prohibited act to refuse to permit access to, or copying of, any record as required by section 414 or 704(a) of the act; or to fail to establish or maintain any record as required by section 414(b) of the act or to refuse to permit access to or verification or copying of any such required record; or for any person to use to his own advantage, or to reveal, other than to the Secretary or officers or employees of the Department of Health and Human Services, or to the courts when relevant in any judicial proceeding under this act, any information acquired under authority of section 414 of the act.

In addition to section 306 of the Bioterrorism Act, which amends the act as described above, FDA is relying on sections 701(a) of the act (21 U.S.C. 371(a)) in issuing this proposed rule. Section 701(a) of the act authorizes the agency to issue regulations for the efficient enforcement of the act.

B. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to the members of the public interested in food issues outlining the four provisions in Title III of the Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them. In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, to solicit stakeholder comments. In response to these solicitations, FDA received a number of comments regarding section 306 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we received so far with the comments we receive during the public comment period on this proposed rule in developing the final rule. Some of the significant comments FDA received on or before August 30, 2002, include:

- The regulations should be performance-based. There is no need to specify the form or manner in which the information must be kept by a person subject to the regulations;
- The regulations should provide flexibility for using existing recordkeeping systems;
- The regulations should give businesses the flexibility they need to store records in the manner they find most efficient;
- The regulations should divide food products into two categories, perishable and nonperishable, and establish separate recordkeeping requirements for each;
- The regulations should not have a 2-year time period for maintenance of records for fresh fruits and vegetables;
- The regulations should not require retailers to maintain records to identify which consumers bought specific food products;
- The regulations should make clear that the transporter of the food and its packaging between sources and recipients should not be considered the ''immediate previous source'' or the ''immediate subsequent recipient'' under the Bioterrorism Act;
- The regulations should make the actual physical location of the food the key to identifying the source and recipient, which may differ from ownership (i.e., corporate headquarters);
- The regulations should exclude as farms those engaged in shellfish growing and harvesting in the farm exemption;
- The regulations should define the exemption for restaurants as businesses that prepare food at the same location where such food is sold to individual consumers, and where such food may be eaten;
- The regulations should provide a phase-in period of at least 6 months to allow all businesses to make any needed adjustments to their current practices before implementation of new regulations;
- Although the regulations must take size of business into account, the regulations should not have a general exemption for small businesses;
- The regulations should allow for phasing-in of the requirements based on the size of regulated companies.

C. Highlights of the Proposed Rule

This proposal is just one of several rulemaking activities currently underway as part of the overall implementation of Title III of the Bioterrorism Act that enhance FDA's ability effectively and efficiently to respond to bioterrorist threats and other food-related emergencies in a way that promotes and protects the public health. Our intent in developing these proposed regulations is to provide the proper balance between ensuring that FDA has information it needs to complete a tracing investigation and ensuring adequate and reasonable flexibility for industry to comply with these requirements.

Section 414(b) of the act, as added by section 306(a) of the Bioterrorism Act, provides that the Secretary ''may'' by regulation establish recordkeeping requirements. Section 306(d) of the Bioterrorism Act, however, provides that the Secretary ''shall'' issue proposed and final regulations no later than 18 months from the date of enactment. FDA believes that Congress has directed the agency to exercise the authority in section 414(b). However, the agency recognizes that the use of the term ''may'' in one section of the statute and ''shall'' in another section creates an ambiguity. We request comments on our interpretation that we are required by section 306(d) of the Bioterrorism Act to exercise the authority in section 414(b) of the act.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (NAFTA). For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. FDA has endeavored to make the establishment and maintenance of records process as simple as possible for both domestic and foreign facilities.

FDA is proposing to describe the specific information a covered entity must keep, but not specify the form or type of system in which those records must be maintained. Some of the key provisions we are proposing include: (1) Requirements to establish and maintain records to identify the immediate previous source of all food, (2) requirements to establish and maintain records to identify the immediate subsequent recipient of all food, (3) requirements to establish and maintain

records to trace the transportation of all food, (4) record retention requirements, (5) record availability requirements, and (6) compliance dates. Following is an overview of the proposed regulations, which is intended to highlight the content of certain sections and request comment on those sections specifically, including comment on whether certain requirements should be included in the final regulations.

Proposed requirements to establish and maintain records to identify the nontransporter and transporter immediate previous sources of all food (§ 1.337) would require specific persons (''you'') to establish and maintain records that identify the sources of all food you receive. The information that we propose as necessary to identify the nontransporter immediate previous sources includes: (1) The name, address, and phone number of the nontransporter immediate previous source; (2) the type of food received; (3) the date you received the food; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) the name, address, and phone number of the transporters who transported the food to you.

Proposed requirements to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients of all food (§ 1.345) would require that you keep records that identify the nontransporter recipients of all food you release. The information that we propose as necessary to identify the nontransporter immediate subsequent recipients is similar to that required to identify the nontransporter immediate previous sources.

Proposed requirements to establish and maintain records to trace the transportation of all food (§§ 1.351 and 1.352) would require that you keep records that trace the transportation process of all food you transport. The information that we propose as necessary to trace the transportation process includes: (1) The name, address, and phone number of the person who had the food immediately before you (the transporter's immediate previous source), and the date you received it from that person; (2) the name, address, and phone number of the person who had the food immediately after you (the transporter's immediate subsequent recipient), and the date you delivered it to that person; (3) the type of food transported; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) identification of each and every mode of transportation used (e.g., company truck, private carrier, rail, air, etc.) from the time you first received the food until the time you delivered it.

Proposed record retention requirements (§ 1.360) would require records for perishable foods not intended to be processed into nonperishable foods to be retained for 1 year after the date the records were created. FDA seeks comment on whether a person subject to these proposed regulations always or usually knows at the time perishable food is released whether or not it is intended to be processed into nonperishable food. For all other food, you would be required to retain the records for 2 years after the date the records were created. You would be required to retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. The maintenance of electronic records would be acceptable. FDA is proposing to exempt electronic records established or maintained to satisfy the requirements of this subpart from the requirement to comply with part 11—Electronic Records; Electronic Signatures (21 CFR part 11) and proposing to amend part 11 to reflect this exemption.

Proposed records availability requirements (§ 1.361) would require that records be made available within 4 hours of an FDA request if the request is made between 8 a.m. and 6 p.m., local standard time, Monday through Friday, or within 8 hours of a request if made at any other time.

In § 1.368, the agency is proposing that firms be in full compliance with these regulations within 6 months of publishing the final regulations. However, these proposed requirements would not be effective for small businesses (those employing fewer than 500 but more than 10 full-time equivalent employees) until 12 months after publishing the final regulations. Very small businesses that employ 10 or fewer full-time equivalent employees would have 18 months to comply.

The Bioterrorism Act directs the Secretary to take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary under the new regulations. 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.

Section 306 of the Bioterrorism Act expressly states that FDA has authority to require recordkeeping as to ''food, including its packaging.'' FDA interprets this section as authority to require persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records to allow for the identification of the immediate previous sources and immediate subsequent recipients of food packaging as well. FDA interprets packaging in section 306 of the Bioterrorism Act to mean the outer packaging of food that bears the label. FDA is not interpreting packaging to include food contact substances, which are included in the definition of ''food.'' Outer packaging would include, for example, the outer cardboard cereal box that bears the label of the cereal, but would not include the inner lining that holds the cereal. Outer packaging would also not include the outer shipping box in which the cereal boxes are shipped.

FDA has tentatively concluded that the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food. Therefore, FDA is proposing not to require covered persons to keep records regarding outer food packaging. However, the agency also recognizes that there may be instances where it may be necessary for FDA to be able to investigate agents that could lace outer packaging and could thereby contaminate a food for which the immediate food contact packaging may not provide an adequate barrier. In addition, outer packaging could be intentionally diverted and used to package food that has been tampered with. FDA seeks comment on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulations.

In addition to the above, we seek comment on all other provisions in the proposed regulations, such as the proposed definitions and exclusions. We also invite comment on whether the final rule should include additional provisions, such as a model form that can be used to record all the required information.

II. Description of the Proposed Regulations

A. General Provisions

1. Who is subject to this subpart? (Proposed § 1.326)

Proposed § 1.326(a) describes the scope of the rule. As required by the Bioterrorism Act, proposed § 1.326(a) would require domestic persons who

manufacture, process, pack, transport, distribute, receive, hold or import food intended for human or animal consumption in the United States to comply with the regulations in this subpart, unless you qualify for one of the exclusions proposed in § 1.327. In addition, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to these regulations, unless you qualify for one of the exclusions proposed in § 1.327.

However, even if you qualify for one of the exclusions proposed in § 1.327, if you conduct more than one type of activity at a location, and some of that activity is not exempt, you would be required to keep records with respect to the statutorily covered activities. For example, in addition to selling food to consumers, a retail facility may have an onsite restaurant or counter that prepares food it sells to consumers. The restaurant activity is exempt from all of the regulations in this subpart; however, the retail activities are covered by § 1.336. Similarly, a retail facility may sell both food and nonfood products, and may even sell primarily nonfood products. Regardless of what proportion of the retail facility sells nonfood products, these proposed regulations would require the retail facility to keep records of the immediate previous source for all food it receives that is not exempted by an exclusion. The regulations do not apply to the nonfood products the retail facility receives.

Proposed § 1.326(b) would require compliance by persons who engage either in interstate or in intrastate activities involving food. The Bioterrorism Act does not limit the establishment and maintenance of records requirement only to persons directly engaged in interstate commerce. To the contrary, the Bioterrorism Act provides FDA with the authority to require the establishment and maintenance of records by all ''persons'' who engage in specified activities involving food. Therefore, FDA tentatively concludes that the statute allows FDA to require domestic persons to keep records, whether or not they engage in interstate commerce. Because a bioterrorist threat involving food or other food-related emergency would have the same effect on the public health regardless of whether the food had originated from an out of state source, FDA is proposing in § 1.326(b) that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food be subject to these regulations, whether or not they directly engage in interstate activities involving food. Nonetheless, because FDA recognizes that this is an important and controversial issue, the agency is seeking comment on whether its tentative conclusion that it has authority to require recordkeeping by persons engaged in only intrastate commerce is correct. FDA also seeks comment on how many intrastate persons are not covered by one of the exemptions from the recordkeeping requirement (e.g., the farm or retail exemption) and we invite recommendations on what screening questions the agency could ask to enable a person to easily determine whether the person is engaged in interstate or intrastate commerce.

Proposed § 1.326(a) would also require compliance by foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States unless the facilities qualify for an exclusion under proposed § 1.327(f). FDA is proposing that the foreign facilities that are required to register under section 305 of the Bioterrorism Act also be required to establish and maintain records under section 306 of the Bioterrorism Act. (The foreign facilities that would be excluded from both the proposed registration and recordkeeping requirements are described in the discussion of proposed § 1.327(f).) FDA believes if these foreign firms were not required to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, trace back of food products from outside the United States would be severely compromised. FDA believes that this approach provides the most efficient and effective strategy for obtaining needed information on food from foreign countries. FDA plans to take the appropriate steps and work closely with foreign governments to obtain access to the needed records if a threat of serious adverse health consequences or death to humans or animals from adulterated food necessitates inspection of records in foreign countries.

The provisions of this proposed rule apply to records of both human food and animal food. FDA believes that some recordkeeping requirements are necessary for food intended for food-producing animals, as well as for certain food for nonfood-producing animals (e.g., pet dogs and cats, horses, and zoo and circus animals). We define food for nonfood-producing animals as pet food. FDA believes, however, that the consequences of a potential terrorist attack or food-related emergency are greater for human food than for animal food. FDA also believes that the consequences of a potential terrorist attack or food-related emergency are greater for food for food-producing animals than for pet food. FDA addressed certain animal food risks in our regulation for animal proteins prohibited in ruminant feed (21 CFR 589.2000), also referred to as the bovine spongiform encephalopathy (BSE) rule.

Although FDA acknowledges that the risk to humans from an attack on the animal food supply is lower than the risk to humans from an attack on the human food supply, there is some risk to both humans and animals from an attack on the animal food supply. Contaminated animal food can be a link to human foodborne illness. (Ref. 32). People could be at risk through direct contact with animal food or through unintentional cross-contamination of cooking surfaces or utensils. Animals may also become infected and serve as a reservoir for exposing other animals and humans. For example, in 1996, an organochlorine pesticide was intentionally introduced into an ingredient used in animal food, including pet food. In 2002, dog chew treats were contaminated with Salmonella and became a vehicle to transmit Salmonella into homes. As a consequence, many pet owners became ill and one person died.

We propose that (1) All entities that manufacture, process, pack, transport, distribute, receive, hold, or import food for food-producing animals must keep records under this proposed rule; and that (2) those entities that manufacture, process, pack, transport, distribute, receive, hold, or import pet food that must keep records under the BSE rule also keep records under this rule. Because of the concern that some pet food is diverted for use for food-producing animals, the BSE rule recordkeeping requirements apply to pet food. We believe this proposal to require recordkeeping under the Bioterrorism Act by pet food entities covered by the BSE rule will provide important safeguards needed to limit the impact of contamination of pet food while minimizing additional costs to industry.

As discussed below, we are proposing to exempt pet food entities that are not subject to the recordkeeping requirements of the BSE rule from the recordkeeping requirements of this proposed rule. We propose that all entities involved in animal food, including the pet food entities exempt from the recordkeeping requirements, remain subject to the proposed records access and availability requirements.

FDA is interested in comments on whether or not the proposal provides adequate tools to trace animal food affected by a terrorist attack or other food related emergency and whether an

alternative approach should be used. Specifically, FDA is soliciting comments on the following questions: (1) Should we exempt all types of animal food entities from all or part of this proposed rule? (2) Should we exempt all pet food entities from all or part of this proposed rule? (3) Should we treat pet food the same as other types of animal food by requiring all pet food entities to meet the recordkeeping requirements under this regulation, not just those subject to the BSE rule? (4) Should we use criteria other than the scope of the BSE rule to determine which pet food entities should be exempt? If so, what should those criteria be?

2. Who is excluded from all or part of the regulations in this subpart? (Proposed § 1.327)

Proposed § 1.327(a) codifies the exemption for farms. This exemption is consistent with and required by the express language of the Bioterrorism Act.

Proposed § 1.327(b) codifies the exemption for restaurants. This exemption is consistent with and required by the express language of the Bioterrorism Act.

Proposed § 1.327(c) would exclude certain fishing vessels from all of the regulations in this subpart, except §§ 1.361 and 1.363. These vessels include those that not only harvest and transport fish, but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. The Bioterrorism Act is silent with respect to exempting fishing vessels in section 306, the ''Maintenance and Inspection of Records for Foods'' provision, although the ''Registration of Food Facilities'' provision, section 305, expressly exempts fishing vessels, except such vessels engaged in processing as defined in § 123.3(k) (21 CFR 123.3(k)).

FDA has tentatively concluded that the records of fishing vessels as defined in § 123.3(k), like those of farms, are not a necessary component of an effective traceback investigation. Nevertheless, because the records of ''fishing vessels otherwise engaged in processing fish, which for purposes of this subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding'' are necessary to an effective traceback investigation, these would still be subject to all of the regulations in this subpart.

Proposed § 1.327(d)(1) would exclude retail facilities from the regulations in § 1.345 of this subpart. This limited exclusion is only from the requirement to establish and maintain records of the immediate subsequent recipients of food when the food is sold directly to consumers. The Bioterrorism Act expressly states that the Secretary may require the establishment and maintenance of records by persons who ''distribute'' food, and therefore retail facilities could be subject to all other regulations in this subpart if FDA required it. FDA has tentatively concluded that to require retail facilities to keep records of each individual recipient consumer would be too burdensome and not necessary in order to address credible threats of serious adverse health consequences or death to humans or animals.

Proposed § 1.327(d)(2) would exclude retail facilities, such as roadside stands, located in the same general physical location as farms, as defined in proposed § 1.328, that sell unprocessed food grown or raised on those farms directly to consumers. This exclusion only applies to those retail facilities that employ 10 or fewer full-time equivalent employees, which is consistent with the way FDA is proposing to define very small businesses in proposed § 1.368(a)(2). This exclusion applies only to unprocessed food, including fresh fruits and vegetables and other raw agricultural commodities for use as food, such as honeycomb. The exclusion also applies to fish raised on farms. Unprocessed food grown or raised on locations other than farms, or on farms not located in the same general physical location, are not excluded.

This exclusion does not apply to processed food, even if it is sold directly to consumers from a retail facility in the same general location as a farm, unless all of the ingredients in that processed food were grown or raised on that farm. Processed foods include, for example, baked goods, jams, jellies, and maple syrup. Retail facilities would be required to establish and maintain records of the immediate previous sources under proposed § 1.337 for processed food sold directly to consumers if any of the ingredients of that processed food were not grown on that farm.

FDA believes that the burden placed on these retail facilities to establish and maintain records for unprocessed food grown or raised on a nearby farm and sold directly to consumers would likely outweigh the risk to the public health that follows from this proposed exclusion. FDA has tentatively concluded that such records are not needed in order to address credible threats of serious adverse health consequences or death to humans or animals. FDA believes it is necessary to narrow this exemption only to those retail facilities that remain close to the source farm in order to not compromise FDA's ability to trace adulterated food that has been transported over a distance greater than the same general physical location. The agency solicits comments on this proposed exemption.

FDA also is proposing in § 1.327(e) to exempt from all of the regulations in this subpart persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is regulated exclusively by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). This section complies with section 306(d)(2) of the Bioterrorism Act, which states that section 306 should not be construed to authorize FDA to promulgate regulations for records governing foods within the exclusive jurisdiction of USDA. It also complies with section 315 of the Bioterrorism Act, which states that nothing in Title III of the Bioterrorism Act, or an amendment made by Title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services under applicable statutes and regulations.

This exemption is for food within the exclusive jurisdiction of the USDA. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is jointly regulated by FDA and USDA would be required to keep records with regard to the food regulated by FDA. An example of food that is jointly regulated by FDA and USDA is frozen T.V. dinners containing both meat and fish.

Proposed § 1.327(f) would exclude foreign facilities that are also excluded from the requirement to register under section 305 of the Bioterrorism Act. As discussed previously in this document, FDA believes that requiring foreign facilities that must register to also establish and maintain records would be the most efficient and effective way to obtain information on food from foreign countries. Therefore, foreign facilities would not be required to establish and maintain records ''if food from these facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States.'' In other words, foreign facilities involved in the initial stages of manufacturing/

processing food are not required to establish and maintain records if another facility further manufactures/processes or packs the food produced at that facility outside the United States.

This exclusion would not apply to facilities if the ''further manufacturing/processing'' at the subsequent facility is of a de minimis nature, such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. In that case, both the facility conducting the de minimis activity and the facility immediately prior to it would be required to register and, therefore, would also be subject to these regulations. FDA seeks comment on the requirement for facilities conducting de minimis activities to keep records. The following are examples of which foreign facilities would be subject to, or excluded from, these regulations based on the activities they perform. As stated previously, the foreign facilities that are subject to these regulations are the same facilities that would be required to register under section 305 of the Bioterrorism Act.

- A foreign facility would be subject to these regulations if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.
- A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be subject to these regulations, unless the further manufacturing/processing entails adding labeling or other de minimis activity. If the further manufacturing/processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility immediately prior to it would be subject to these regulations.
- The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be subject to these regulations, even if the food subsequently is held or stored at a different facility outside of the United States.
- Facilities located outside the United States that take possession, custody, or control of finished foods for holding, packing, and/or storage prior to export to the United States are subject to these regulations.

Proposed § 1.327(g) provides that persons who manufacture, process, pack, transport, distribute, receive, hold, or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (21 CFR 589.2000) would be excluded from the recordkeeping requirements of this proposed rule. However, these entities, like all entities involved in animal food, remain subject to the proposed records access and availability requirements in proposed § 1.361 and § 1.363.

3. What definitions apply to this subpart? (Proposed § 1.328)

Proposed § 1.328 states that the definitions of terms in section 201 of the act (21 U.S.C. 321) apply to such terms when used in this subpart. Section 201 of the act defines various terms that appear throughout the act, including ''food'' (see section 201(f) of the act). The definitions of such terms apply when we use those terms in these regulations. In addition, proposed § 1.328 defines specific additional terms used in the proposed rule.

Proposed § 1.328 defines ''act'' as the Federal Food, Drug, and Cosmetic Act.

FDA is proposing in § 1.328 to define ''domestic person'' consistent with the definition of ''State'' in section 201(a)(1) of the act. That is, FDA is proposing to define a domestic person as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

FDA is proposing in § 1.328 to define a ''foreign facility'' as a facility other than a domestic person that manufactures, processes, packs, or holds food for consumption in the United States.

Proposed § 1.328 defines ''farm'' as a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. A farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens. The term ''farm'' includes: (a) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and (b) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. ''Farm'' includes such facilities because they are activities incidental to farming that most farms engage in (e.g., holding and packing of harvested crops). Facilities that engage in manufacturing/processing, packing, or holding of food that is not described in the definition of ''farm'' are subject to these regulations because such activities are not activities that most farms engage in and are thus not included in the definition of ''farm.'' Some examples of farms include: Apple orchards, hog farms, dairy farms, feedlots, and aquaculture facilities.

Persons that engage in more than one type of activity may meet the definition of farm as to some of those activities while not meeting the definition of farm as to other activities. Persons that grow crops and raise animals and also manufacture/process food that is sold for consumption off the premises are not farms for purposes of this subpart and are not exempt. For example, a person who grows oranges and manufactures/processes them into orange juice for sale to a distributor would need to keep records under this subpart of both the immediate previous sources and the immediate subsequent recipients of the orange juice. However, establishing and maintaining records of the immediate previous sources would only be required when persons manufacture/process food from ingredients obtained from other sources than that farm.

Similarly, persons who manufacture/process food from ingredients obtained from other sources only meet the definition of farm if all the food used in such activities is consumed on that farm or another farm under the same ownership. If a person combines oranges grown on his farm with oranges obtained from another source, processes them into orange juice on his premises, and consumes all of the orange juice on those premises, he would not need to keep records regarding those oranges. However, if the person sells that orange juice at a roadside stand directly to consumers, that roadside stand would not meet the definition of farm but would fall within the partial retail exclusion provided in proposed § 1.344. Retailers need only keep records identifying the immediate previous source.

Proposed § 1.328 defines ''food'' as having the meaning given in section 201(f) of the act, which is: ''(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.'' FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods;

snack foods; candy; and canned foods. ''Substances that migrate into food from food packaging'' include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food.

The provisions of this proposed rule apply to records of both nontransporters and transporters. Section 414(b) of the act provides that FDA may require recordkeeping with regard to records that are needed for inspection to allow the agency to identify the immediate previous sources and the immediate subsequent recipients of food. The proposed rule establishes two sets of immediate previous sources and immediate subsequent recipients, one for nontransporters and one for transporters. For nontransporters, the proposed rule defines immediate previous source as the nontransporter from which the company received the food. The immediate subsequent recipient for nontransporters is the nontransporter to which the company sent the food. The definition of nontransporter immediate previous source and immediate subsequent recipient describes them as persons who own food or who hold, process, pack, import, receive, or distribute food for purposes other than transportation. Nontransporters are also expected to keep records of the transporters that they receive food from and send food with. Nontransporters will thus be required to keep records on both transporters and nontransporters for both previous sources and subsequent recipients.

With respect to transporters (persons who have possession, custody, or control of food for the sole purpose of transporting it), the proposed rule provides for the company to establish and maintain records about its own transportation activities and the person from whom it received the food and the person to whom the food is delivered. The person from whom the food is received by the transporter is the immediate previous source. This could be a nontransporter as described previously or another transporter. The person to whom the food is delivered by the transporter is the immediate subsequent recipient. This person could be another transporter or a nontransporter. These records allow FDA to follow the chain of custody of the food through each transportation step, which may include a variety of forms of transportation (e.g., plane, train, and truck).

Because it is critically important for FDA to have the ability to trace back and trace forward quickly in the event of a terrorist event or other food-related emergency, FDA has defined for nontransporters the immediate previous source and immediate subsequent recipient as the previous nontransporter or next nontransporter. This will allow FDA in most cases to efficiently and effectively determine where the food was contaminated and to locate where the contaminated food was sent. However, the contamination could occur during the transportation process as well. The records of transporters will ensure that FDA has the potential in all cases to determine the source of contamination and trace the food back and forward through the transportation chain. FDA recognizes that requiring nontransporters to keep records on both previous and subsequent transporters and nontransporters is potentially burdensome. FDA is mandating this in order to facilitate the efficient investigation of food related emergencies (records on nontransporters) and to increase the likelihood of a successful traceback by ensuring all those who handle the food are examined (records on transporters).

We also recognize that there could be other interpretations of the statute. The statute could be read to provide that at every step of the movement of the food, the immediate previous source is the person who had the food before they delivered it to the next person. That next person would be the immediate subsequent recipient. Under that reading, if company A processes the food and sends it to company B via several modes of transportation, the chain of custody would be as follows: (1) Company A; (2) Red Truck Co.; (3) train; (4) Blue Truck Co.; and (5) company B. In this scenario, the immediate subsequent recipient for company A is Red Truck Co. The immediate previous source for Red Truck Co. is company A and the immediate subsequent recipient is the train. The immediate previous source for the train is Red Truck Co. and the immediate subsequent recipient is Blue Truck Co. The immediate previous source for Blue Truck Co. is the train and the immediate subsequent recipient is company B. If it is discovered at company B that the food is contaminated, since company B only has records to identify Blue Truck Co. as its immediate previous source, FDA would have to trace back from company B to Blue Truck Co. and from there to the train, then to Red Truck Co., until FDA finally arrives at company A, the source of the contamination. This type of tracing would not allow the agency to efficiently and effectively trace back from company B to company A or get to company A quickly to trace forward other food sent out by company A.

We are requesting comments on whether the approach with two sets of immediate previous sources and immediate subsequent recipients in this proposed rule is a reasonable interpretation of the statute. We also request comments on whether all transporters, including small independent transporters, have the capability to maintain records for the 1 and 2 year record retention periods. FDA also requests comment on the extent to which the recordkeeping burden on nontransporters (previous and subsequent transporters and nontransporters) creates new burdens for firms. We are also interested in suggestions for alternative recordkeeping arrangements that would allow for the complete and efficient investigation of food-related emergencies. In addition, we request comments on whether an approach different from the proposed rule that would require or create incentives for nontransporters to obtain and keep records on all the transporters that transport food between the nontransporters, by obtaining the records from the transporters, would be a reasonable interpretation of the statute.

Proposed § 1.328 defines ''manufacturing/processing'' as making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Some examples of manufacturing/processing include, but are not limited to, cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. FDA is defining ''manufacturing'' and ''processing'' together because the meanings of the terms overlap. For example, combining two materials into a finished product, such as macaroni and cheese, could be considered ''manufacturing,'' ''processing,'' or both. Since both manufacturers and processors are subject to these regulations, FDA does not believe it is necessary to distinguish between manufacturing and processing in the proposed rule.

Proposed § 1.328 defines ''nontransporter'' as a person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Proposed § 1.328 defines the ''nontransporter immediate previous source'' as a nontransporter who last had an article of food before transferring it to another nontransporter. Nontransporter immediate previous source includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity. Government entities include school systems, public hospitals, prisons, commissaries, etc.

Proposed § 1.328 defines ''nontransporter immediate subsequent recipient'' as a nontransporter who acquires an article of food from another nontransporter. Nontransporter immediate subsequent recipient also includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed §§ 1.337(a)(1) and 1.345(a)(1) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source and nontransporter immediate subsequent recipient, respectively, whether domestic or foreign. We propose these requirements to mean the address and information of the specific location of where the statutorily covered activity occurred, and not that of a corporate headquarters at another location than where the activities took place. For example, a food product may be processed at a manufacturing plant, shipped to a packing facility, and then transported to a retail store all owned by the same corporation. The proposed requirements would apply to each individual location that received or released the food, even if each facility is owned by the same corporation. This would mean that firms would need to establish and maintain records accessible at each specific plant, packing facility, and retail store. FDA's intention is that these requirements identify the physical location of the food at each step of the way as it travels through the chain of distribution, from the farm or sea to the consumer. FDA requests information on whether this requirement to keep records on intra-corporate transfers will impose new burdens upon firms or whether firms keep these records currently.

Proposed § 1.328 defines ''perishable food'' as food that is 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.

The ''perishable food'' definition has been modeled after the current Regulatory Procedures Manual definition of ''perishable commodity'' for purposes of this proposal. Examples include, but are not limited to, fluid milk (but not ultrapasteurized), live fish, lobster, crab, other crustaceans, shellfish, fresh fruits and vegetables. The agency is seeking comment on whether we have best defined ''perishable food'' for purposes of these regulations.

In addition, FDA is defining ''perishable foods'' for the purposes of establishing a shorter record retention time for those foods as opposed to nonperishable foods. FDA seeks comments on the proposed definition of perishable foods and whether the agency should use that definition as the basis for establishing record retention times.

Proposed § 1.328 defines ''pet food'' as food for nonfood-producing animals. Nonfood-producing animals include household pets, such as dogs and cats, and also include other nonfood-producing animals such as horses and circus and zoo animals.

Section 306 of the Bioterrorism Act does not extend to recipes. Proposed § 1.328 defines ''recipe'' as the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food. If finalized as proposed, FDA would have access to the records containing the ingredients used in a food product, but would not have access to the quantities of the ingredients used to make a product. The act currently requires manufacturers to disclose to the public the ingredients they use on the labels of their food products. It is critical to a tracing investigation that the ingredients and the sources of the ingredients are identified.

Proposed § 1.328 defines ''restaurant'' as a facility that prepares and sells food directly to consumers for immediate consumption. As with farms, persons who engage in more than one type of activity may meet the definition of restaurant as to some of those activities while not meeting the definition of restaurant as to other activities. Those persons would be required to keep records as to those activities covered by this subsection that do not meet the definition of restaurant.

Some examples of restaurants as defined in the proposed regulations include: Cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens.

Due to possible ambiguity in the term ''catering facilities,'' FDA states in the proposed restaurant definition that facilities that provide food to interstate conveyances, such as airplanes, passenger trains, and cruise ships, rather than directly to consumers, are not restaurants. Facilities that provide food to interstate conveyances are not considered restaurants because they do not serve food directly to consumers for immediate consumption. For example, a facility that provides sandwiches to a passenger train for eventual sale to passengers would not be considered a restaurant. However, the snack bar on the train that sells the sandwiches to consumers would be considered a restaurant. FDA has historically inspected these facilities that provide food to interstate conveyances and considers them processors, rather than restaurants.

Because the proposed regulations also apply to persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for animal consumption in the United States, by analogy, the term ''restaurant'' also includes pet shelters, kennels, and veterinary facilities in which food is provided to animals.

Proposed § 1.328 defines ''retail facility'' as a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries. The limited exclusion from establishing and maintaining records of the immediate subsequent recipient applies only to food sold directly to consumers. A facility that sells food to wholesalers and/or other retailers, in addition to consumers, would have to keep records of the immediate subsequent recipients because wholesalers and retailers are not considered consumers for purposes of these proposed regulations.

Proposed § 1.328 defines ''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.

Proposed § 1.328 defines ''transporter's immediate previous source'' as the person from whom a transporter receives food. This source can be either another transporter or a nontransporter. The transporter's immediate previous source includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed § 1.328 defines ''transporter's immediate subsequent recipient'' as the person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter. A transporter's immediate subsequent recipient includes, but is not limited to, an individual, a partnership, a corporation, a cooperative, an association, or a government entity.

Proposed § 1.328 defines ''you'' as a person or facility subject to this subpart under § 1.326. FDA is proposing to use ''you'' throughout the proposed rule for easier readability.

4. Do other statutory provisions and regulations apply? (Proposed § 1.329)

Proposed § 1.329 would require that in addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods. Regulations in this subpart are in addition to existing recordkeeping regulations, such as the regulations for low acid canned foods, juice, infant formula, color additives, bottled water, animal feed, and medicated animal feed. (See 21 CFR 113.100(d); 21 CFR 120.12; 21 CFR 106.100(g); 21 CFR 80.39; 21 CFR 129.35; § 589.2000; and 21 CFR 225.102 & 225.110, respectively).

5. Can existing records satisfy the requirements of this subpart? (Proposed § 1.330)

Proposed § 1.330 states that the regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a person subject to the regulations keeps records of all of the information as required by this subpart in compliance with other Federal, State, or local regulations, or for any other reason, e.g., as a result of its own business practices, then those records may be used to meet these requirements. Such records may include, but are not limited to, purchase orders, bills of lading, invoices and shipping documents. Some current FDA regulations require records, including those for low acid canned foods, juice, infant formula, color additives, bottled water, animal feed, and medicated animal feed. (See 21 CFR 113.100(d); 21 CFR 120.12; 21 CFR 106.100(g); 21 CFR 80.39; 21 CFR 129.35; 21 CFR 589.2000; and 21 CFR 225.102 & 225.110, respectively). However, none of the existing FDA regulations are sufficient alone to meet the requirements we are proposing in these regulations. A person who has been complying with these regulations only would have to add records addressing the new elements. The burden is on the person subject to these regulations to ensure it keeps all applicable records. Our intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these proposed regulations. We are proposing the specific information a covered person must keep, but we will not specify the form or type of system in which those records must be maintained.

B. Establishment and Maintenance of Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

What information is required in the records established and maintained to identify the nontransporter and transporter immediate previous source? (Proposed § 1.337)

The Bioterrorism Act authorizes FDA to require by regulation the establishment and maintenance of records ''needed'' by the Secretary for inspection to allow the Secretary to ''identify'' the immediate previous sources of food. Based on FDA's interpretation of this statutory authority and what is ''needed'' to ''identify'' the immediate previous source, proposed § 1.337(a) would require that you establish and maintain records for all food as follows:

- Proposed § 1.337(a)(1) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;
- Proposed § 1.337(a)(2) would require an adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- Proposed § 1.337(a)(3) would require the date you received the food;
- Proposed § 1.337(a)(4) would require the lot or code number or other identifier of the food (to the extent this information exists);
- Proposed § 1.337(a)(5) would require the quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and
- Proposed § 1.337(a)(6) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food to you.

Proposed § 1.337(a) would require that you include information reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products. If FDA cannot immediately narrow the trace back to a specific source, tracing becomes much more difficult, there is an increased risk to consumers, and some food sources are unfairly implicated. FDA believes this is a necessary and beneficial requirement for consumers, and will help conserve FDA's limited resources, by focusing our investigation only on those entities who handled the at-risk food. FDA's investigation of the unaffected sources is time consuming and may have a negative business impact on the incorrectly implicated sources. These sources should not be penalized by exposure to unwarranted scrutiny and perhaps unwarranted adverse publicity because of inadequate recordkeeping by others in the distribution chain. In addition, in a recall situation, a business could limit the economic impact by being able to limit its recall to only a specific group of products instead of having to conduct a broader recall. What is reasonably available may vary from case to case.

FDA recognizes that the food industry often relies on multiple sources of ingredients to make food products, and that it is common practice to commingle ingredients from different sources prior to incorporating them into a finished product. For example, some food processors commonly store raw materials like corn syrup and flour in tanks and silos. In some instances, these tanks and silos are not dedicated by suppliers, but are topped off as supplies run low, resulting in routine commingling of raw ingredients from a number of suppliers. Moreover, it is FDA's understanding that flour or grain silo crowns do not uniformly dissipate, resulting in uneven distribution of ingredients. FDA acknowledges that changing this longstanding system to require dedicated supplier storage to facilitate source specific recordkeeping would involve significant financial costs.

It is not FDA's intent to require the reconfiguration of each manufacturing plant. These proposed regulations, however, would require you to capture the information that is reasonably available to you to connect finished products with the immediate previous source of each of the food products used to make that finished product. FDA understands that in some multiple sourcing contexts this information only may allow for a reduction in the number of potential sources for a specific food product, but may not necessarily

identify one specific source of the food product.

For example, 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 prior to 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. In this case, the information reasonably available to you would be the identity of all of the potential sources of the flour for each finished lot of cookies.

Conversely, if the manufacturer did have 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.

Proposed § 1.337(a)(4) would require maintenance of the lot or code number or other identifier of the food (to the extent this information exists) to allow FDA the capability to limit its investigation to the implicated food. For instance, if a company repeatedly and consistently orders a particular food from a supplier, and the threat is associated with a single shipment or some shipments but not others, it is important to have the capability to isolate the shipment or shipments in question from others. This would be more cost effective and less burdensome to FDA. In addition, if the threat affects the transporter, identifying information such as lot numbers or other identifiers would facilitate the location and isolation of the conveyance that may have become contaminated by the implicated food. This cannot readily be done without information that specifically identifies the food.

Proposed § 1.337(a)(5) would require you to record the quantity of the food and how it is packaged to assist FDA in identifying the implicated food and also allow FDA to determine the scope of the threat. With this information contained in the records, FDA would be able to determine the quantity of the potentially adulterated food that is in the stream of commerce, i.e., whether it is one crate or 1,000 crates of tomatoes. In addition, as part of a tracing investigation, FDA would be able to identify at each location whether all of the potentially adulterated food has been accounted for or whether any part of a shipment had been diverted. Both the immediate previous source and immediate subsequent recipient would be required to keep records of the quantity of food received or released to allow FDA to determine that the quantity of food sent was the quantity received. This would ensure that FDA is best able to protect public health by being able to identify and locate adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

Proposed § 1.337(a)(6) would require you to keep in your records information to identify the transporter who transported the food to you. This requirement to identify the transporter is in addition to proposed § 1.337(a)(1), which requires you to keep in your records information that identifies the nontransporter immediate previous source.

C. Establishment and Maintenance of Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

What information is required in the records established and maintained to identify the nontransporter and transporter immediate subsequent recipient? (Proposed § 1.345)

The Bioterrorism Act authorizes FDA to require by regulation the establishment and maintenance of records ''needed'' by the Secretary for inspection to allow the Secretary to ''identify'' the immediate subsequent recipient of food. Based on FDA's interpretation of this statutory authority and what is ''needed'' to ''identify'' the immediate subsequent recipient, proposed § 1.345(a) would require that you establish and maintain records for all food you release that identifies information that is substantially similar to that discussed in the requirements to identify the nontransporter immediate previous source.

D. Requirements to Establish and Maintain Records to Trace the Transportation of All Food

1. Who is required to establish and maintain records for tracing the transportation of all food? (Proposed § 1.351)

The Bioterrorism Act expressly states persons who transport food are subject to these regulations. Proposed § 1.351 would require you, if you are a domestic person, to establish and maintain records for tracing those immediately before (transporter's immediate previous source) and immediately after you (transporter's immediate subsequent recipient) in the transportation process if you transport food.

2. What information is required in the transportation records? (Proposed § 1.352)

Proposed § 1.352(a) would require that you establish and maintain the following records for each food you transport:

- Proposed § 1.352(a)(1) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had possession, custody, or control of the food immediately before you, and the date you received it from that person;
- Proposed § 1.352(a)(2) would require the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had possession, custody, or control of the food immediately after you, and the date you delivered it to that person;
- Proposed § 1.352(a)(3) would require an adequate description of the type of food, including brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);
- Proposed § 1.352(a)(4) would require the lot or code number or other identifier of the food (to the extent this information exists);
- Proposed § 1.352(a)(5) would require the quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and
- Proposed § 1.352(a)(6) would require the identification of each and every mode of transportation (e.g., company truck, private carrier, rail, air, etc.), and the individual responsible, from the time you first received the food until the time you delivered it.

The proposed requirements are intended to provide the necessary information to allow FDA to trace the transportation of all food. In proposed § 1.352(a)(1) and (a)(2), the required information would consist of whoever had the food before you and after you. This person could be either a nontransporter or another transporter. In a multiple transporter situation, you may be receiving the food from another transporter and/or delivering it to another transporter. The proposed requirements in § 1.352(a)(1) and (a)(2) are intended to capture this information regardless of whether you receive food from a nontransporter or another transporter, or deliver it to a nontransporter or another transporter. You would only be responsible for maintaining a record of the required information with respect to the person

from whom you received the food from and the person to whom you gave it. You would not be required to maintain records of transactions to which you were not a party.

Proposed § 1.352(a)(6) would require transportation companies that use several modes of transportation within their company to record when the food was put on which kind of vehicle and who was responsible for it during that leg of the trip. For example, Yellow Transportation Co. may use two different Yellow trucks and a Yellow plane. This section would require Yellow Transportation Co. to keep records of each and every mode of transportation and the individual responsible, from the time the food was first received until the time it was delivered. The ''individual responsible'' should be the person within the transportation company who is responsible for that vehicle and the food being transported. FDA seeks comments on whether ''individual responsible'' should be the operator of the conveyance or whether it can be someone within the corporation who has overall responsibility for the vehicle and the food being transported. FDA understands that it is common practice for one transportation company to use several different modes of transportation within that company throughout its possession and control over the food. The food is potentially subject to tampering at each phase of the transportation process. If the transportation company responsible for the food does not have complete records identifying the mode of transportation and who was responsible for the food throughout the entire time that company had possession and control over the food, the tracing chain is broken and it becomes more difficult and time consuming to determine if that shipment of food has been diverted or tampered with. FDA believes this detailed information regarding the food transportation would be necessary to expedite the tracing investigation in situations when FDA has a reasonable belief that food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

E. General Requirements

1. What are the record retention requirements? (Proposed § 1.360)

Proposed § 1.360(a) states the records required by these regulations are to be created at the time the statutorily covered activities take place. Proposed § 1.360(b) would require records for perishable foods not intended to be processed into nonperishable foods to be retained for 1 year after the date the records were created. Although perishable foods have a relatively short shelf life, FDA is proposing a 1 year record retention period for these foods. In some situations, the health hazard may not be immediately apparent but may emerge months after the food has been consumed. In other situations, the harm may have been caused by novel contaminants or novel vehicles for known contaminants, and it may take months to identify the sources of contamination. As an example, in 1995, there was an investigation of an outbreak of cyclosporiasis. At the time, FDA did not know that Cyclospora could contaminate raspberries. An investigation concluded that water was the likely vehicle. In 1996, there were numerous additional cyclosporiasis outbreaks in the United States and the link was made to raspberries from Guatemala. Fresh raspberries had been served at the site of the 1995 outbreak and then, a year later, FDA needed to determine their source. The distributor had no records to facilitate the traceback.

The proposed 1-year period would not apply to perishable foods that are intended for processing into nonperishable foods, e.g., jams and jellies made from fruits. In those instances, the longer record retention period of 2 years is needed to ensure the recordkeeping chain for finished food products made using perishable foods is available during tracing investigations. If you are uncertain whether a perishable food is destined or intended for processing into a nonperishable food, the 2-year record retention period applies. FDA seeks comment on the impact of this provision.

Proposed § 1.360(c) would require that you retain records for all foods (except animal foods as discussed below) not covered by proposed § 1.360(b) for 2 years after the date the records were created. This proposed requirement is consistent with the authority given in the Bioterrorism Act. Based on information provided to FDA by the food industry, the minimum time for processed food products to clear the food production and distribution/retail system is 3 years. In addition, the average distribution time between harvesting and final retail sale of frozen fruits and vegetables is approximately 3 to 24 months. These are average times, and individual products may be in commerce for a longer period. FDA believes that allowing anything less than a 2-year record retention period for nonperishable food, as well as perishable foods intended to be processed into nonperishable food, would severely compromise a tracing investigation.

Proposed § 1.360(d) would require that you retain records required by these regulations for animal food, including pet food, for 1 year after the date the records are created. Food for food-producing animals tends to have a faster turnover rate than many kinds of human food. In addition, since pet foods are typically the sole source of food for pets, such foods tend not to be stored as long as many human foods. Therefore we propose that records for all animal food, including pet food, be retained for only one year after the date the records are created. This is consistent with the BSE rule.

Proposed § 1.360(e) would require that you retain all records required by these regulations at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. We recognize that there may be more records than available storage space at the location where the covered activities occur. We are therefore proposing that records may be stored offsite, provided you can comply with the record availability requirements in proposed § 1.361.

Proposed § 1.360(f) provides that the maintenance of electronic records is acceptable. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA issued regulations at part 11 that provide criteria for acceptance by FDA of electronic records under certain circumstances. To minimize the burden of this proposed rule, FDA proposes to exempt electronic records established or maintained to satisfy the requirements of this subpart from the requirement to comply with part 11. FDA believes that a requirement that records kept under this subpart comply with part 11 would hinder the ability of persons subject to these regulations to utilize existing systems and records to satisfy the requirements of these proposed regulations as contemplated in proposed § 1.330. If the agency decided to require all electronic records to satisfy part 11 before they could satisfy these proposed recordkeeping requirements, large numbers of already existing electronic records and recordkeeping systems would have to be recreated and redesigned. This provision would require that records kept for some other statutory or regulatory purpose, but which also may be used to meet the requirements of this subpart, must comply with part 11 as required.

2. What are the record availability requirements? (Proposed § 1.361)

Proposed § 1.361 states 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 or other information accessible to FDA under section 414 or 704(a) of the act must be readily available for inspection and photocopying or other means of reproduction. Although the statutory requirements in section 414 and amended section 704(a) of the act regarding records access are self-executing and are currently in effect, FDA is issuing regulations to further refine some aspects of the food records access requirements. Because section 306 of the Bioterrorism Act includes two records inspection authorities, one of which, section 704(a), cross refers to records described in section 414, we request comment on the interconnection between the records access provisions in sections 414 and 704(a) of the act.

Proposed § 1.361 would require records to be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m. (local standard time), Monday through Friday, or within 8 hours of a request if made at any other time, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice. In the event of a threat of serious adverse health consequences or death to humans or animals, FDA believes these time limits are necessary to effectively and efficiently perform a tracing investigation.

The most common problem encountered by the FDA in a tracing investigation has been a lack of ready access to records. Records are often stored offsite or are stored in a database where the records are difficult to retrieve. In FDA's experience, rarely do firms make records available within 24 hours. The usual timeline is 2 to 3 days. This delay severely reduces the speed at which FDA can perform a traceback. If every firm were to take 2 days to give FDA the needed records, even with a short traceback (e.g., 3 firms), it could take FDA up to 2 weeks to trace the product to its source, taking into account time for record review and travel to the firms. This time may be increased if the records are incomplete and FDA has to wait for missing records to be retrieved. This possible delay would be a substantial concern if FDA were attempting to remove adulterated food that presents a threat of serious adverse health consequences or death to humans or animals from commerce.

Proposed § 1.361 would also require that if you store the records required by these regulations offsite, you must be able to retrieve and provide the records onsite within the specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location.

3. What records are excluded from this subpart? (Proposed § 1.362)

Proposed § 1.362 would exclude from the proposed regulations recipes for food as defined in proposed § 1.328, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales). These exclusions are consistent with the express language in the Bioterrorism Act.

4. What are the consequences of failing to establish or maintain records or make them available to FDA? (Proposed § 1.363)

Consistent with the express language in the Bioterrorism Act, proposed § 1.363 states (a) the failure to establish or maintain records as required under section 414(b) of the act or to refuse to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act (21 U.S.C. 331) and (b) the failure to make records or other information available to FDA as required by section 414 or 704(a) of the act is a prohibited act under section 301 of the act (21 U.S.C. 331).

5. What are the compliance dates for this subpart? (Proposed 1.368)

Under sections 414 and 704(a) of the act, FDA may have access to and copy all records and other information related to an article of food if the Secretary has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The basic requirement that access to records and other information be given under these circumstances is currently in effect and does not require implementing regulations. FDA has chosen to further define access requirements in regulations, but can use its inspectional authority prior to the effective date of these regulations.

FDA carefully considered the size of a business when developing these proposed regulations. FDA found that most products and ingredients pass through at least one small business when moving through the distribution process (see Initial Regulatory Flexibility Analysis discussion in section III.B. of this document). If FDA were to exempt small businesses from these regulations or to permit shorter record retention times for them, the effectiveness of the regulations would be severely compromised due to the breaks in the recordkeeping chain during tracing investigations. Thus, FDA cannot propose totally exempting any business based on size from these requirements. However, FDA does propose to provide small and very small businesses additional time to come into compliance with these regulations.

Thus, proposed § 1.368(a) would require that firms that do not qualify as small businesses be in full compliance with these regulations within 6 months after the publishing date of the final rule. Proposed § 1.368(a)(1) would require that small businesses employing fewer than 500 but more than 10 full-time equivalent employees be in full compliance with these regulations within 12 months after the publishing date of the final rule. Proposed § 1.368(a)(2) would require that very small businesses, defined as those employing 10 or fewer full-time equivalent employees, be in full compliance with these regulations within 18 months after the publishing date of the final rule.

III. Analysis of Economic Impact

A. Benefit-Cost Analysis

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

Need for the regulations: The purpose of these proposed regulations is to enable FDA to respond to, and help contain, adulterated food that presents a threat of serious adverse health consequences or death to humans or

animals. The benefits of these proposed regulations would be realized by accomplishing this purpose.

Reason for the regulations: FDA is proposing several regulations that will work in harmony to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or plant—particularly if the plant is considered negligent—would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of food-borne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to the private efforts to protect against deliberate contamination at the plant level, there are external effects associated with privately produced protection. The most important external effect of protection against deliberate contamination is information. Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food producers and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system would probably be prohibitive for any single firm or third party organization.

We estimate that an effective system of information would require several hundred thousand participants to gather information and provide it to a central system. The private transaction costs to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. No single organization could capture additional revenue sufficient to cover the cost. Also, because the provision of information by some participants makes it available for all, there would be a tendency for establishments to try to be free riders in the information system. But the more information and participation in the system, the more effective it is.

Another way of looking at the problem of participation is in terms of marginal private benefits and marginal social benefits. By gathering and providing the information used in a food safety system, an individual establishment receives additional private benefits from enhancing the safety of its own food. In addition, participating in the system increases the effectiveness of the entire information system. In other words, the system works better the more establishments participate in it. The individual establishment does not capture this additional social benefit. The marginal private benefit (enhanced safety for individual establishments) is less than the marginal social benefit (the marginal private benefit plus the increased effectiveness of the entire information system). The difference between private and social benefit reduces the incentive for establishments to participate in a voluntary private system.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have an integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: The need to keep product and ingredient distribution records. However, as stated above, FDA is proposing several regulations to address these needs so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the regulations in place, the agency would have the additional tools necessary to help deter and respond to deliberate threats to the nation's food supply as well as to other food safety problems.

Baseline: FDA considers the baseline for this analysis the current state of the world, and we assume this baseline has zero costs and benefits. We also consider having no new recordkeeping requirements as option 1 in our analysis. Section 414(b) of the act, as added by section 306(a) of the Bioterrorism Act, provides that the Secretary ''may'' by regulation establish recordkeeping requirements. Section 306(d) of the Bioterrorism Act, however, provides that the Secretary ''shall'' issue proposed and final regulations no later than 18 months from the date of enactment. FDA believes that Congress has directed the agency to exercise the authority in section 414(b) of the act, so the current state of the world as considered in option 1 is not legally viable. The agency recognizes, however, that the use of the term ''may'' in one section of the statute and ''shall'' in another section creates an ambiguity. We request comments on our interpretation that we are required by section 306(d) of the Bioterrorism Act to exercise the authority in section 414(b) of the act. However, the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity costs of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. Option 1 will serve as the baseline against which other options will be measured for assessing costs and benefits.

Options: The following section analyzes regulatory options that address the need for the recordkeeping regulation:

1. No recordkeeping requirements. Take no new regulatory action.

2. Require all persons that manufacture, process, pack, hold, receive, distribute, transport, or import food destined for consumption or use in the United States to establish and maintain records identifying the immediate previous source and the immediate subsequent recipient of the food, and its outer packaging. Also require all persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging destined for use in the United States to establish and maintain records identifying the immediate previous source and the immediate subsequent recipient of that outer food packaging. The records requirements apply to both foreign and domestic persons. For domestic persons, this includes those who engage in the specified food-related activity whether or not those activities occur solely intrastate. Persons engaging in more than one type of activity, some of which is covered by this proposed

regulation, would be required to keep records pertaining to the covered activity even if they are not required to keep records relating to exempt activity. Records must include information reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product. Required times for record-retention would be 1 year for perishables destined for final consumption in their perishable state, and 2 years for all other foods or food packaging. Upon a written request, records must be made available to FDA in 4 hours, if the request is made during the normal business hours of 8 a.m. to 6 p.m., or 8 hours otherwise.

3. Require all elements of option 2, except exclude persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging.

4. Require all components of option 3 but do not require persons that are required to establish and maintain records on food to establish and maintain records on the food's outer packaging.

5. Require all components of option 4, but change the required time for responding to an FDA records request to 24 hours.

6. Require all components of option 4, but exempt intrastate businesses.

7. Require all components of option 4, but exempt persons who operate farms, and persons who operate restaurants, who also perform a covered activity.

8. Require all components of option 4, but change the record retention requirement to 1 year for all products.

9. Require all components of option 4, but change the record retention requirement to 2 years for all products.

10. The proposed rule. Require all components of option 4, but only cover foreign facilities also covered by the proposed registration regulation published at 68 FR 5377 (February 3, 2003).

11. Require all components of option 4, but only cover foreign facilities that are the final holder of the product before export to the United States.

12. Require all components of option 4 but cover only domestic persons.

13. Require all components of option 4, but the required information would include the records necessary for facilities to be able to link specific raw ingredients to specific outgoing finished products for all raw ingredients and all products. This option is to analyze the costs and benefits of requiring records that link specific raw ingredients to specific finished products, including ingredients from different sources that are currently commingled before being incorporated into finished products.

In order to clearly identify the marginal cost of each provision specified in the codified, most options represent only one modification of a provision in another option. Option 4 is appropriate to use for comparison with the other options, since it differs by only one provision from almost all other options considered. As the Analysis of Economic Impact section will reflect, FDA has examined the economic implications of this proposed rule by analyzing several regulatory options that address the need for the recordkeeping regulation. FDA is proposing option 10. FDA believes that this option would require creation and maintenance of the records needed to address credible threats of serious adverse health consequences or death to humans or animals while providing adequate flexibility and minimizing industry burden. FDA requests comments on other viable options not considered by this analysis. Note that additional options designed to lower the regulatory burden on small businesses are considered in the initial regulatory flexibility analysis below.

Cost assumptions: The total cost of each of these options will depend on the number of facilities affected and the extra burden these options place on facilities. For all options, FDA would only specify the information a covered entity must keep, but not specify the form or type of system in which those records must be maintained; we expect that for all options, if possible, firms will choose to collect the additional information not currently included in their existing records. Furthermore, FDA assumes that firms will choose to comply with any new requirements by modifying shipping or purchase records such as Bills of Lading, Invoices, or Purchase Orders. In its cost computations, FDA does not take into account other Federal, State, or local regulations that require similar recordkeeping practices for small sectors of the food economy (e.g., ''the BSE rule'', § 589.2000) because of the relatively large amount of uncertainty in our knowledge of existing State and local recordkeeping requirements, and because the effect on the cost computations from their inclusion is likely to be very small. For this reason the analysis does not distinguish among entities that may be covered by the recordkeeping requirements in ''the BSE rule'' which may result in a small overstatement of the costs of the proposed rule. The following discussion of facility counts and per facility costs is not tied to any specific option, but describes the data and assumptions we use to analyze the cost of each option.

Number of facilities and number of firms affected: FDA assumes that for the options that do not consider exemptions, approximately 1,230,000 facilities owned by approximately 960,000 firms would be covered. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food or food packaging, and foreign facilities performing any of these activities on food or food packaging destined for consumption or use in the United States. Table 1 contains a summary and breakdown of this estimate.

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
Domestic				
Manufacturers	43,376	1.17	36,948	3111–3119, 3121
Wholesalers/Warehouses	95,745	1.24	76,952	4224, 4225, 4228, 49312, 49313
Packaging[1]	73,813	1.07	69,266	32221, 32222, 326111, 326112, 326130, 326140, 326150, 326160, 3272, 331315, 331316, 332431, 332439, 42261, 323110, 323111, 323112, 323113, 323114, 323115

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS—Continued

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
Transporters/Packers	16,773	1.11	15,171	481112, 481212, 483111, 483113, 483211, 4841, 48422, 48423, 488320, 488510, 488991
Retail Grocery and Specialty Food	207,657	1.35	153,277	44511, 445220, 445230, 44529, 445310, 446191,
Convenience Stores	128,985	1.87	68,866	44512, 447110
Mixed-Type Facilities that Have Farms	30,497	1.25	24,397	—
Importers	5,036–32,768	1.25	4,029–26,214	—
Total Domestic	601,883–629,615		448,905–471,090	
Foreign				
Final Holders	77,427	1.25	61,942	
Manufacturers	125,450	1.17	106,858	
Other Facility Types	457,836	1.25	366,269	—
Total Foreign	660,713		535,068	

[1] Includes both outer packaging and food contact substances.

Data sources for the number of facilities and firms affected: Except for the firm-to-facility adjustments explained below, the unit of observation for all data used for this analysis is the number of establishments performing a particular activity. To estimate the number of establishments, FDA uses several sources: The 2000 County Business Patterns (Ref. 1) and the 1999 Nonemployer Statistics from the U.S. Census Bureau (Ref. 2), the FDA Field Accomplishments and Compliance Tracking System (FACTS), the FDA Operational and Administrative System for Import Support (OASIS), and the 1997 National Agricultural Statistics Service (NASS) Survey (Ref. 3). All datasets used in this analysis were the latest available as of the time of writing.

The Census Bureau creates the 2000 County Business Patterns (CBP) by analyzing data from the Business Register, the Census Bureau's file of all known single and multiestablishment companies with at least one employee. Data for single-location firms are obtained from the Economic Censuses, the Annual Survey of Manufacturers, Current Business Surveys, and administrative records from the U.S. Internal Revenue Service, Social Security Administration, and the Bureau of Labor Statistics.

Facilities not included in the CBP are counted in the Nonemployer Statistics, also from the Census Bureau. Nonemployer businesses are companies with no paid employees. The Census Bureau primarily obtains data about nonemployer businesses from business income tax returns filed with the Internal Revenue Service.

The FDA FACTS tracking system is an online database designed to monitor compliance related information for each facility that is regulated by FDA. The database contains an updated list of regulated facilities. FACTS and the Census Bureau use different categories for facilities, making a direct comparison of FACTS with the CBP and Nonemployer Statistics difficult. In our estimates, FACTS facility counts are the primary source of data on importers and foreign facilities, and interstate manufacturers, wholesalers, and warehouses.

Manufacturing, warehouses, wholesalers, and packaging facilities: The primary source for the total (both intrastate and interstate) number of manufacturers, warehouses, wholesalers, and packaging facilities is the 2000 CBP and 1999 Nonemployer Statistics for the NAICS codes identified in table 1 of this document. The NAICS codes identify industry groups and subgroups. Often the data are more aggregated in the 1999 Nonemployer Statistics than in the CBP; when the nonemployer statistics only exist for an aggregated NAICS code, we adjust the total number of facilities identified in the aggregated nonemployer category by the ratio of CBP counts in the relevant subcategory and aggregated category. For example, the 1999 Nonemployer Statistics identified 4,700 facilities under code 4931, but does not break the total down further. Our adjustment changes the 4,700 facilities to 964 [4,700 x (1,461/7,123)] facilities in subcategories 49312 and 49313. The sum of the number of facilities under the codes 49312 and 49313 in the CBP is 1,461, and 7,123 is the number of facilities under the aggregated code 4931 in the CBP.

The term ''packaging'' described by the data used in this analysis varies from FDA's interpretation of ''packaging'' in section 306 of the Bioterrorism Act because it is broader and includes food contact substances, which fall within the act's definition of food. In this economic analysis, we use the term ''manufacturer and distributor'' of outer packaging to refer to all persons who manufacture, process, pack, hold, receive, distribute, transport, or import ''packaging'' as that term is used in the Bioterrorism Act. FDA was unable to find any data that discriminated between outer packaging manufacturers and distributors and those that manufacture or distribute materials that FDA currently regulates as food contact substances, including plastic beverage bottles and inner cereal box liners. The data used for the analyses include the number of manufacturers and distributors of the following types of packaging: Paperboard containers, paper

bags and treated paper, plastic bags, bottles, laminated plastics and other plastic materials, polystyrene and urethane foam products, glass products, and metal and aluminum can, sheet, plate, and products. Furthermore, printing services and label producers are included such as lithographic, gravure, flexographic, screen, digital, and quick printing services.

Transporters and packers: Although the CBP and Nonemployer statistics distinguish passenger and nonpassenger transport, they do not separately identify establishments engaged in the transport of food. Based on a comment received through our preliminary outreach activities, FDA assumes that 20 percent of the specialized freight transport industry is engaged in food transport. FDA requests comments on this assumption. The largest category in transport and packing is trucking.

Mixed-type facilities that engage in farming: Firms engaged in covered activities would be required to keep records on these activities as discussed above, even if those firms were mixed-type facilities that engage in farming. Covered activities conducted on mixed-type facilities that engage in farming potentially comprise a large percentage of the activity conducted at these facilities. For example, manufacturing or processing for farms includes canning, freezing, cooking, pasteurization, homogenization, irradiation, milling, grinding, chopping, slicing, cutting, coloring, waxing, shelling of nuts, peeling, labeling, and packaging. Facilities with farms will be considered mixed-type facilities if they alter the general state of the commodity, use any ingredients obtained from another source, and then sell or transfer the product for final use offsite.

To estimate the number of mixed-type facilities that engage in farming that would be affected by this rule, FDA uses the 1997 USDA NASS Census of Agriculture and data obtained from various county level Cooperative Extension Service (CES) offices. The Census of Agriculture provides the total number of farms producing specific commodities. To estimate the number of farms that are part of mixed-type facilities, FDA used a sample of counties with information from their respective CES offices. CES offices from Clay County, Kansas; Monterey, Sonoma, Marin, and San Diego counties in California; Jackson County, Wisconsin; Gillespie and San Saba counties in Texas; Carol County, Maryland; and Berks County, Pennsylvania provide data on the percentage of farms producing specific commodities that could be considered mixed-type facilities (Ref. 4). Table 2 presents the estimated number of mixed-type facilities that engage in farming by type of farm. While some of the facilities described in table 2 may qualify as roadside stands for some of the products that are sold from these facilities (and would not be subject to recordkeeping requirements for those products), we were not able to distinguish between facilities that would qualify as roadside stands and mixed-type facilities that engage in farming. The numbers of mixed-type facilities that engage in farming listed in table 2 may be overstated to the extent that they qualify as roadside stands. The estimated total is 30,497. FDA requests comments on the methods used to estimate the numbers of mixed-type facilities that engage in farming and for identifying the number roadside stand facilities.

TABLE 2.—MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Facilities that Engage in Farming
Pig Farms (Feed Mixing)	46,353	1.5%	695
Cattle (Feed Mixing)	785,672	1%	7,857
Poultry (Feed Mixing)	36,944	1%	369
Other Animal Production (Feed Mixing)	110,580	1%	1,106
Dairy	86,022	1.1%	903
Grain, Rice, and Beans	462,877	1%	4,629
Apples	10,872	1.5%	163
Oranges	9,321	1.5%	140
Peaches	14,459	1.5%	217
Cherries	8,423	1.5%	126
Pears	8,062	1.5%	121
Other Fruit	29,413	1.5%	441
Nuts	14,500	2%	290
Berries	6,807	1.5%	102
Grapes	11,043	10.5%	1,160
Olives	1,363	3.5%	48
Vegetables and Melons	31,030	0.5%	155
Organic vegetables	6,206	50%	3,103

TABLE 2.—MIXED-TYPE FACILITIES THAT ENGAGE IN FARMING—Continued

Commodity	Total No. of Farms	Percent Mixed-Type	No. of Mixed-Type Facilities that Engage in Farming
Honey	7,688	50%	3,844
Syrup	4,850	100%	4,850
Herbs	1,776	10%	178
Total			30,497

Importers: FDA bases the number of importers on a database collected from shipment records that list all companies that were listed as importers or consignees for a covered product in 2001. These data were collected through FDA's OASIS system, which is an automated system for processing and making admissibility determinations for shipments of FDA-regulated products seeking to enter U.S. domestic commerce. Many of these facilities are of a type that would already be counted in the FDA FACTS or CBP (or nonemployer statistics) data. In order to avoid double counting, FDA assumes the following: (1) Any facility that identifies itself through its name as being a facility type covered by the CBP will already be counted in the CBP; (2) any facility that is a consignee only will already be counted in the CBP since its main business is not simply importing; (3) any facility self-identified as an importer only is not in the CBP; and (4) all other facilities will be considered in an uncertain range of facilities affected. Since it is uncertain whether these facilities would already be counted in the CBP, we will use a uniform distribution to assign a probability of double counting in all of our cost estimates. For example, if the uniform distribution generates a probability of 0.5, then we will assume that half of these unclassified facilities are already in the CBP. A uniform distribution implies that any probability from zero to 100 is equally likely. FDA requests comments on these assumptions.

Foreign establishments: FDA estimated the number of foreign manufacturing establishments that will be affected by the regulation from a count of foreign manufacturers identified in the OASIS system. We were unable to find reliable data on the number of foreign nonmanufacturing establishments and made the following assumptions to estimate their numbers: For the final holders of the article before the food or food packaging is imported into the United States, we assumed the same number of facilities as on the domestic side of the importation process, for a total of approximately 77,000 foreign final holders. For other firm types, we assumed that the ratio of foreign to domestic facilities of other types is approximately equal to the ratio of foreign to domestic manufacturers. We also assumed that the facility to firm ratio is the same for both foreign and domestic establishments. We request comments on the assumptions used to arrive at these estimates, as well as on reliable sources of data that would improve these estimates.

Firm adjustment: Even though recordkeeping requirements apply to each facility within a firm, some of the overall burden will be estimated at a firm level in order to better capture the true burden of the regulation. In order to estimate the number of firms affected, we used the 1999 Statistics of U.S. Businesses, also from the U.S. Census Bureau (Ref. 5). This dataset is based on the CBP and Nonemployer Statistics, but calculates both the number of establishments and the number of firms for each NAICS code. The Census Bureau has not updated this dataset for the latest 2000 CBP, so we use the 1999 ratio of establishments to firms to adjust the 2000 CBP and 1999 nonemployer establishment count numbers to firm numbers.

Costs per facility or per firm: Some costs of the regulatory options apply to firms, while other costs apply to individual facilities. FDA assumes that the costs to facilities are the same for transfers within firms as for transfers between firms. We request comments on this assumption. Costs fall into several broad categories:

Additional record information: Any possible new regulation may require more information on the input, output, or source ingredients than is kept in existing food facility records. A limited amount of new information could be accommodated by a simple redesign of existing records, whereas requiring more new information may require a completely new design and collection. The extreme version of this requirement is explored under option 13: requiring all raw ingredients to be connected through records to all final products would cause a substantial change in recordkeeping and other business practices for many commingled commodities.

Information Collection and Maintenance: The burden of maintaining extra information is a direct function of the amount of information required by this proposed regulation that is not normally collected by industry. This burden estimate will be substantially correlated with the redesign burden described previously.

Storage time: A longer storage time may place more of a burden on industry, but will also increase the probability of having records available should an outbreak occur. The major determinant of the impact on costs of storage time requirements is whether the proposed storage times will be longer than normal industry practices. FDA believes that the storage times proposed in option 2 are within normal industry practices. Requiring longer retention times than those proposed in option 2 for records on perishable foods might impose an additional burden. This issue is discussed in more detail below and in options 2, 8, and 9.

Records access time: As in storage time, the major determinant of the impact of any required response time for records access is what firms would reasonably be able to achieve in an emergency situation with current business practices.

Data sources and cost estimates common to options:

Labor costs: For all labor costs, FDA used a wage rate for an administrative worker of $25.10 from the Bureau of Labor Statistics occupational wage rates for the year 2000 (Ref. 6), doubled to include overhead costs. We assume that all labor for all options is by administrative workers. FDA lacks wage data specific to each of the foreign countries that export to the United States, so we used the wage rate for an administrative worker in the United States for the foreign wage rate. We

assume that the nature of the worker and the worker's wage would be about the same in foreign countries as in the United States. In open markets where trade takes place, real wage rates tend to be equal for similar work and productivity across countries.

Learning costs: Foreign and domestic facilities will incur administrative costs in order to learn how to comply with any new regulation. Because most of the facilities covered by the proposed registration rule would be covered by this proposed rule, the administrative costs will be shared between the registration and recordkeeping rules. Those establishments covered by both regulations will probably search for information on both regulations at the same time and find information in the same places. Therefore, the learning cost estimates presented here probably overestimate the costs actually incurred by firms covered by both rules since there is the potential for double counting. The potential for double counting occurs in estimates of costs for firms covered by both rules. These include domestic manufacturers, wholesalers, warehouses, mixed-type facilities that engage in farming, foreign final holders, foreign manufacturers, and importers in any of these categories.

Facilities will become aware of these requirements through normal business activities: Reading trade press, reading industry news, FDA outreach, or conversation with other business operators. Because facility operators or owners must be aware of the requirement to change their activity, we assume that becoming aware of the regulations will occur as part of normal business practice and so have no economic costs for the facility. There may be costs incurred, however, by FDA or trade organizations to undertake the outreach.

Once the owner or operator of the facility becomes aware of the regulations, he or she will need to research the requirements of the regulation, which will require searching for a copy of the requirements and reading and understanding them. Owners or operators may search for a copy of these requirements on the Internet or at a library. FDA received comments indicating that many businesses might not have access to the Internet. Searching costs will be higher for facilities that do not have access to the Internet and have to write to FDA or find other sources of information. In the United States, 59.1 percent of the population accessed the Internet at least once in the 3 months prior to being surveyed (Ref. 7). A Small Business Administration (SBA) report cites two studies that report 40 and 47 percent of small businesses had Internet access in 1998 (Ref. 8). An updated report from Dunn and Bradstreet in 2002 reports that 71 percent of small businesses have Internet access (Ref. 9). Therefore, FDA assumes that 71 percent of domestic facilities will search for the requirements for both regulations electronically. FDA estimates it will take domestic facilities with Internet access 1 hour to search for the requirements, and domestic facilities without Internet access 2 hours to search for the requirements. FDA requests comments on these assumptions.

FDA expects foreign establishments to go through the same searching, reading, and comprehending steps as domestic establishments. Costs for searching, reading, and comprehending the regulation requirements will be higher for some foreign establishments than for domestic establishments due to distance and language differences. Costs for searching, reading, and comprehending for some foreign establishments may be so high that, rather than become informed about the requirements before shipping, they learn about the requirements after shipments to the United States have been made. Costs for searching, reading, and comprehending for foreign facilities will vary depending on: (1) Whether the worker researching the regulatory requirements or the person who manufactures, processes, packs, transports, distributes, receives, holds, or imports food or food packaging can read and write in English; and (2) the level of Internet access available in exporting countries.

The percent of foreign facilities with Internet access will be lower than in the United States. Although 71 percent of the small businesses in the United States have Internet access, only 3 percent of the population of China, the country that has the largest number of manufacturers that export to the United States, has access to the Internet (Ref. 7). To get an idea of how many facilities that export to the United States have access to the Internet, FDA looked at Internet access for the 26 countries that represent 80 percent of the manufacturers that export to the United States (OASIS) and the percent of the population that has access to the Internet worldwide for the remaining 20 percent. A weighted average of these 26 countries by the number of manufacturers suggests that 26 percent of the population that exports to the United States has Internet access. Because businesses are more likely to have Internet access than individuals, FDA adjusts the percent of the populations of other countries with Internet access upward by the percent difference in Internet access between individuals and small businesses in the United States. Seventy one percent of small businesses in the United States have Internet access versus 59 percent of the population, or the percent of businesses with Internet access represents a 20 percent increase over the population. Applying this adjustment to Internet access in foreign countries increases the percent of businesses with Internet access from 26 percent to 31 percent. FDA therefore assumes that 31 percent of foreign manufacturers would be able to research the new requirements electronically. Regardless of whether the cost of obtaining Internet access is borne by the facility, or by a third party, for ease of computation FDA estimates the cost per facility. FDA expects that, due to the overall lower level of Internet access in foreign countries, it will be more difficult for foreign facilities without Internet access at their place of business than it will be for domestic facilities to access the Internet elsewhere. FDA assumes it would take foreign facility operators that do not have access to the Internet 5 additional hours to search for the recordkeeping requirements. FDA requests comments on these assumptions.

In addition to search costs, there are costs for reading and comprehending the regulation requirements. Reading costs depend on the length of the document that describes the requirements and the reading speed of the user. Costs for comprehending the regulation requirements are linked to the reading speed of the user. For purposes of simplicity FDA assumes that, on average, the user comprehends the requirements described in the regulation after one reading. FDA requests comments on this assumption.

The online speed-reading training course, TurboRead Speed Reading (Ref. 10), estimates that the average reading speeds for the vast majority of the worlds' readers is between 200 and 250 words per minute. Dividing the approximate length of the current proposal (approximately 44,450 words) by an average speed of 225 words per minute yields an estimate of the time required to read the regulation of about 3 hours and 18 minutes. Because the length of the document may change and the approximate nature of the calculation, FDA rounds up to the nearest half-hour to 3 1/2 hours for the time required for reading and comprehending the requirements of this rule for all English reading users. FDA requests comments on this assumption.

Users who have limited ability to read English may take longer to read and comprehend the requirements. Comments suggest that many foreign manufacturers are limited in their ability to read and write English. Estimates of the number of people outside of countries where English is the primary language who are able to speak English fluently vary widely, ranging from 300 million to 750 million (Ref. 11). To estimate the number of English speakers outside of the United States, FDA adds the number of English speakers in countries where English is the primary language, excluding the United States (151 million), the number of English speakers in countries where English is a secondary language (300 million), and the midpoint (525 million) of the range of the estimate of the number of speakers of English as a foreign language. FDA then divides this total number of English speakers by 5.9 billion—the world population minus the U.S. population (Ref. 11) to tentatively conclude that 16 percent of foreign manufacturers read and write English well enough to research the recordkeeping requirement directly. FDA requests comments on this calculation. Facilities without the capacity to read and write English would have to hire a translator to aid them in comprehending the regulatory requirements. Alternatively, trade groups, distributors, or the government may provide translation services. Regardless of whether the translation is paid for directly by the registrant or a third party, for ease of computation we assume there is a cost for translation for 84 percent of foreign facilities. FDA assumes it would take foreign facility operators who do not understand English 5 additional hours to read and comprehend the recordkeeping requirements. FDA requests comments on these assumptions.

Table 3 summarizes these cost estimates, which do not differ across any of the options that do not grant exemptions. These include costs for searching, reading, and comprehending the requirements of the rule for English and non-English speaking users, and for users with and without Internet access.

TABLE 3.—LEARNING COSTS

	Firm Count	Cost (at labor rate of $25.10)	Average Learning Costs per Firm
Domestic			
Manufacturers	43,376	$5,215,000	$120
Wholesalers/Warehouses	95,745	$11,511,000	$120
Packaging[1]	73,813	$8,875,000	$120
Transporter/Packer	16,773	$2,017,000	$120
Retail Grocery and Specialty Food	207,657	$24,966,000	$120
Convenience Stores	128,985	$15,508,000	$120
Mixed-Type Facilities that Engage in Farming	30,497	$3,667,000	$120
Importer	5,036	$605,000	$120
Total Domestic	601,883	$72,364,000	$120
Foreign			
Final Holders	77,427	$23,613,000	$305
Manufacturers	125,450	$38,258,000	$305
Other Facility Types	457,836	$139,624,000	$305
Total Foreign	660,713	$201,495,000	$305

[1] Includes both outer packaging material and food contact substances.

New and closing facilities: In future years new businesses will open and existing businesses will close. Since the total number of firms in the food industry remains stable from year to year, we assume that the rate at which new firms enter the industry is the same as the rate at which existing firms leave the industry. The Small Business Administration estimates that in 2000 approximately 10 percent of all businesses were new businesses and 10 percent of all businesses closed (Ref. 31). FDA estimates that new businesses will also have to incur learning costs.

New information collection costs: These costs include the burden of redesigning records to accommodate new information specified in possible options, and the burden of collecting and maintaining that new information within the recordkeeping system.

Records redesign: In order to estimate the cost of adding additional information to a firm's records, we used the Label Cost Model developed for FDA by RTI International (Ref. 13). We modified this model to estimate the graphic design and printing cost for adding information onto existing records such as Bills of Lading, Invoices, and Purchase Orders. We also used the model to estimate the cost of designing an entirely new input-to-output ingredient record for part of option 13.

Based on a sample of bills of lading collected through FDA's early outreach efforts and through the Web sites of companies and trade associations, FDA assumes that firms already collect most

of the information necessary to comply with options 2–12. Bills of lading, purchase orders, or invoices typically have the full address of all parties, the transaction date, and descriptions of the relevant food articles. Based on the samples, FDA assumes that firms will have to add a limited amount of new information to their standard documents. This new information principally depends on how the precise definition of ''description of the food article'' developed in these regulations differs from that commonly used by industry under its current recordkeeping practices. In some of the sample bills of lading the description of the food article being transported did not have the precision required under these proposed regulations. In addition, some bills of lading did not have a design that would allow for the identification of other entities in custody, or control of the transported food articles, or an official spot to record the mode of transportation.

The FDA Labeling Cost Model was designed to estimate the costs of designing and printing new food labels, but many of the design issues should be similar when designing and printing a new food product record. For example, both a label and a document designer must make similar decisions regarding wording and spacing, and both activities should include administrative activity, graphic design, and printing. The model also includes cost categories, such as analytical testing and focus groups that we do not use, since they are not relevant for document redesign. FDA does acknowledge that these estimates are only approximations; we believe the values this model generates are reasonable, and request comments on all assumptions. For the purposes of the analysis of options 2–12, FDA assumes a limited information, one-color redesign of a paper document. For the purposes of option 13, FDA assumes an additional full design of a new paper document.

The model also includes an estimate of central tendency, and a low and a high estimate for each cost category included in the document redesign cost. For each component of cost in this model, FDA's contractor, RTI International, received a range of estimates from food companies. The lowest of these estimates is considered the limit of the low range, and the highest of the estimates is considered the limit of the high range. The low and high range of total cost is calculated by adding together all of the low and high range estimates of each component cost, so the low and high range estimates of this model are unlikely. The estimated cost of a limited information redesign in year 1 is $1,309, with an uncertainty range of between $897 and $2,299. The estimated cost of a full information redesign in year 1 is $6,193, with an uncertainty range of between $4,653 and $11,198. The label cost model estimates an approximately 10 percent efficiency savings in redesign costs incurred by very small firms in year 2.

The cost of redesigning product records will not be borne by all firms. For each step in the chain of custody, copies of the same bills of lading or invoices probably will be used for records of the immediate previous source, records of the immediate subsequent recipient, and transportation records. Consider the following example of a long chain of custody for a food product: (1) Farmer, (2) transporter, (3) bulk collection (e.g. grain silo), (4) transporter, (5) processor, (6) transporter, (7) warehouse, (8) transporter, and (9) retailer. The number of entities in this series is clearly limited by the total number of transporters in the country, so FDA assumes that all transporting firms have to redesign their records. This supply chain should generate four sets of bills of lading and four sets of invoices for all products. Similarly, a six-step supply chain should generate three separate sets of records. Since farmers are exempt under this proposed regulation, the number of records possibly containing new information is roughly equal to the number of facilities in the supply chain, but FDA assumes a substantial number of nontransporters will depend on storing only the redesigned bill of lading to comply with the regulation. Assuming an equal probability of a firm using the bill of lading or redesigning its own documents, FDA assumes that half of the nontransporting firms will incur redesign costs.

We modify this estimate for convenience stores. Individual convenience stores have a small sales volume and—according to a comment received during FDA's early outreach efforts—only 11.4 percent of their average total sales are for food products. In addition, the majority of convenience stores are locally owned franchises of large corporations, and these stores may have access to the parent corporation to assist in redesign. FDA therefore assumes that 90 percent of convenience stores will rely on other parties for records redesign. The total costs for other firm types may also be an overestimate; FDA expects that trade groups may assist in the needed redesign of existing records, further lowering the burden, but we do not estimate the cost savings for this activity.

In addition, we make a further adjustment for foreign facilities: According to comments received, firms exporting from the European Union (EU) are already subject to similar recordkeeping requirements under EU regulation 178/2002. Article 18: *Traceability* of the EU regulation states: * * *

(1) The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

(2) Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures, which allow for this information to be made available to the competent authorities on demand.

(3) Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand * * *. (Ref. 14).

Because of these regulations, FDA assumes that the firms from EU member states (31.9 percent of all foreign firms that export to the United States) will already be subject to recordkeeping requirements similar to the requirements of this proposed rule. Therefore these foreign firms would not have to redesign their records and would not incur a redesign burden.

Additional records maintenance: FDA expects that personnel at most facilities will incur a burden in order to collect and maintain a limited amount of additional information. However, as in the redesign section previously discussed in this document, FDA assumes that one set of records can serve as source, transportation, and recipient records, so the estimated burden of collecting and maintaining the additional information will be shared among more than one facility.

FDA does not have a direct estimate of this recordkeeping burden; we rely on a previous analysis of Juice Hazard Analysis and Critical Control Point (HACCP) recordkeeping (Ref. 15) because that analysis also dealt with the costs of additional recordkeeping. In that analysis an estimate of 3 minutes per hour is made of the burden that would be incurred by some food

processing facilities for the additional monitoring of critical control points and keeping HACCP system records that would be required. In this proposed rule the additional monitoring activities required would be negligible since records will likely only need to be modified. Furthermore, compared to the Juice HACCP requirements, there would be less additional information that would need to be maintained in this proposed rule. If the weekly burden for additional monitoring and recordkeeping required for Juice HACCP compliance is 120 minutes (assuming 3 minutes per hour of additional monitoring and recordkeeping for 8 hours a day and 5 days a week) a burden estimate of about 6 minutes per day or 30 minutes per week seems reasonable for this proposed rule. We request comments on this assumption. FDA treats foreign facilities already subject to a similar recordkeeping regulation as already in compliance, and assumes that the burden of additional records maintenance will be shared among an average of two covered entities, including transporters, for an average of 15 minutes per week per facility or 13 hours per year per facility.

Grocery stores, convenience stores, and packaging producers and distributors may have different additional records maintenance burdens. Since, under the proposed rule, grocery stores only have to maintain immediate previous source records, their additional burden may be lower but they also receive many shipment records they would need to maintain. In a comment FDA received during our early outreach efforts, a large retail grocery chain estimated that they received approximately 300 purchase orders per store per year, or approximately 6 purchase orders per week per store. A purchase order could contain many invoices and may be more of a burden to maintain, so FDA considers the estimated additional burden of 15 minutes per week reasonable for grocery stores. We request comments on the assumptions used to derive this estimate.

Convenience stores have a lower records maintenance burden than grocery stores. According to comments received during our early outreach efforts, approximately 50–70 percent of grocery store stock keeping units (SKUs) are food products, while only 11.4 percent of the sales of convenience stores are from food products. SKUs and sales are not equivalent measures of size, but this comparison is a reasonable basis to lower the estimated additional burden for convenience stores relative to grocery stores. Dividing the grocery store burden by the ratio of the percent of food sales for convenience stores and grocery stores (assumed to be 60 percent, or an average between 50 percent and 70 percent of SKU totals) yields an additional records maintenance burden of approximately 2.5 hours per year for convenience stores. We request comments on the assumptions used to derive this estimate.

Finally, the data sources do not distinguish between facilities that produce packaging for food and packaging for other products. Although we assume that all packaging facilities potentially could be producing or handling food packaging, not all of their output would be dedicated in this way. We assume that, for the average packaging facility, 50 percent of the output is for food packaging and that an information collection burden of 50 percent would be required of packaging facilities. We request comments on this assumption.

Storage costs: Although FDA does not believe the marginal burden of storing records to the specified times in any of the options is zero, evidence on record storage times suggests that the burden would be minimal. Since FDA was unable to gather any evidence suggesting the size of this extra burden, however small, and since the specified storage time requirement in these options is well within industry norms, we estimate the cost for extra storage time to be zero.

Many comments received in response to FDA's early outreach supported requirements of either 1 year for perishable products or 2 years for nonperishable products, stating that the maximum allowable 2-year requirement was both reasonable and necessary. In addition, a survey of dietary supplement manufacturing practices conducted by FDA's contractor, RTI International, asked a representative sample of dietary supplement manufacturers how long they kept records of shipped ingredients (Ref. 16). The facilities had a choice of two response types: Keeping records a certain amount of time past the date of expiration, and keeping records a certain amount of time past the manufacturing date. The survey did not distinguish between perishable and nonperishable ingredients. Because of nonresponse weighting, stratification, and deductive disclosure problems, FDA's contractor, RTI International, did not report confidence intervals for these estimates, but the mean number of years that firms kept data records was 2.31 years for facilities that reported retention from the date of the expiration of the ingredient, and 4.57 years for facilities that reported retention from the date of product manufacture. The lowest mean response from any facility category was 1.94 years from the expiration date of the ingredient, which is still probably more than 2 years from the delivery date.

Access costs: For purposes of evaluating the marginal cost of the record access time provision, FDA considered two possible requirements: The combination of 4 hours during normal business hours and 8 hours at other times, or 1-day regardless of when the request was made. Accessing records in a shorter time period than what industry is currently capable of will impose a burden on firms and facilities, and the shorter the required response time the larger the burden. The cost of records access response fall into two categories: Costs that would be incurred only in the event that FDA requests records under this authority, and costs that would be incurred to plan for records access and to change business practices to allow for a rapid response. The latter costs would be incurred regardless of whether or not FDA ever requested records under this authority.

For the first cost, FDA expects that in the event of a records request under this authority, any access requirements less than the current average access time of 2–3 days would impose a burden on businesses involved in providing those records. All other things equal, a 4-hour or 8-hour requirement would probably impose a greater burden than the 1-day requirement. However, we cannot quantify the probability of this burden for the same reason as the lack of quantification in the benefits section: It is impossible to predict when FDA will have to invoke this authority in response to an adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

For the second cost, FDA assumes that a 1-day records access time requirement is approximately the shortest possible response time that would not compel some firms to change their business practices. The costs for a 1-day records access requirement are considered in option 5. We assume that the 4-hour or 8-hour response time required in all options except option 5 is more likely to compel business practice changes and preemptive emergency planning than is the 1-day response requirement. A 1-day response time is possible with the types of recordkeeping systems currently in use, including automated recordkeeping technology, and offsite storage and paper retrieval. While the average access

time for FDA traceback investigations is 2–3 days, we believe the same information could be provided in one day with the types of recordkeeping systems currently in use. Therefore, the difference between the cost of a 2–3 day response time and a 1-day response time is assumed to be negligible. However, the shorter access time requirements of 4 hours or 8 hours would likely impose a new burden on a number of firms.

FDA assumes that regardless of whether or not the firms maintain records electronically, every firm would probably have to devise a predetermined compliance strategy to deal with the situation where FDA requested records under this authority. Furthermore, a comprehensive response plan may allow firms to maintain their current business practices, such as maintaining paper records or maintaining records offsite, and still comply with a request, so it may be the lowest cost solution. Therefore, as a first estimate of the potential impact of this proposed rule, FDA assumes a burden for each firm of devising a response plan that could accommodate a 4-hour or 8-hour access time for an FDA record request. Since European firms are required to supply their tracing records on demand to the appropriate authorities, FDA assumes that they already have in place a plan that would accommodate a 4-hour or 8-hours records required response time. (Ref. 14).

In the analysis of previous regulations, we estimated a related planning cost for food firms. In the juice HACCP rule, (Ref. 15), we estimated a 60-hour labor burden per firm of developing a HACCP plan. Developing a HACCP plan is very complicated and includes the establishment of: (1) Critical control points and critical limits for every hazard identified, (2) protocols on how to manage deviations from these limits, and (3) procedures for verifying and validating all aspects of the plan. By contrast, developing a records access plan requires: (1) Evaluating current recordkeeping practices including records maintenances and records storage practices, which we assume would take on average about 3 hours; and (2) identifying and planning for any changes in recordkeeping practices that would be required, which we assume would also take on average about 3 hours. FDA considers the planning needed to deal with a possible records request under this authority much less complicated than what would be needed in a HACCP plan. If developing a HACCP plan takes 60 hours, then 6 hours of administrative labor per firm (lowered to 3 hours per convenience store firm) is a reasonable estimate of the burden imposed from this planning requirement, which is far more simple than a HACCP plan. We request comments on this assumption. FDA estimates that new businesses will also have to incur records access costs.

FDA requests comments regarding how many firms may need to adopt a new records retention strategy under both the 4-hour or 8-hour, and 1-day records access time requirements, and the additional time and capital needed to comply with these requirements. We plan to conduct further research on all of these burden estimates before publishing the final rule, and expect that the estimates could change.

Option 2: Comprehensive foreign and domestic coverage with 4-hour and 8-hour records access times and 1 and 2 year records retention times.

FDA assumes that facilities currently collect and keep records with most of the information required by this option in their normal business activities. FDA assumes that learning and redesign costs will be incurred per firm, and that the additional records maintenance costs will be incurred per facility. For all options the learning costs are explained in the general cost section above.

Redesign Costs, option 2. Table 4 of this document presents the average redesign cost calculations. For the purposes of presentation, Table 4 only includes calculations for the mean number of exclusive importers affected. FDA assumes that large and small firms incur all redesign costs in the first year following the final rule, while very small firms will incur all redesign costs in the second year following the final rule. The label cost model estimated planning efficiencies of 10 percent for redesign processes further than 1 year in the future, and this savings is included in the categorical totals in table 4.

TABLE 4.—REDESIGN COSTS, OPTION 2

	Firm Count	Middle Estimate	Low Estimate	High Estimate	Average Middle Cost per Firm
Domestic					
Manufacturers	18,474	$22,488,000	$15,402,000	$39,497,000	$1,217
Wholesalers/Warehouses	38,476	$46,601,000	$31,916,000	$81,845,000	$1,211
Packaging[1]	34,633	$42,092,000	$28,827,000	$73,926,000	$1,215
Transporters/Packers	15,171	$18,243,000	$12,494,000	$32,040,000	$1,203
Retail Grocery and Specialty Food	76,639	$92,308,000	$63,220,000	$162,122,000	$1,204
Convenience Stores	6,887	$8,415,000	$5,763,000	$14,779,000	$1,222
Mixed-Type Facilities that Engage in Farming	12,199	$14,786,000	$10,127,000	$25,969,000	$1,212
Importers	7,561	$9,165,000	$6,277,000	$16,096,000	$1,212
Total Domestic	210,038	$254,098,000	$174,026,000	$446,274,000	$1,210
Foreign					
Final Holders	21,091	$25,565,000	$17,509,000	$44,900,000	$1,212
Manufacturers	36,385	$44,103,000	$30,205,000	$77,459,000	$1,212

TABLE 4.—REDESIGN COSTS, OPTION 2—Continued

	Firm Count	Middle Estimate	Low Estimate	High Estimate	Average Middle Cost per Firm
Other Facility Types	124,714	$151,170,000	$103,532,000	$265,500,000	$1,212
Total Foreign	182,191	$220,838,000	$151,246,000	$387,859,000	$1,212

[1] Includes both outer packaging and food contact substances.

Additional records maintenance: Table 5 of this document presents the calculations for additional records maintenance costs. Based on the previous discussion, the annual burden per facility that is assumed in the computation of the cost of additional records maintenance is: 13 hours for most facilities, 2.5 hours for convenience stores, and 6.5 hours for packaging facilities. A $25.10 hourly wage is also assumed in the computation. For example, the additional records maintenance costs for manufacturers reported in the top row of Table 5 is calculated by multiplying the number of facilities (43,376) by the number of hours required (13) and the hourly wage ($25.10).

In Table 5, variation in the number of importers reflects the range of uncertainty in the data on the number of these facilities. Additional records maintenance costs are assumed to be incurred by facility. The estimated average cost per firm for additional records maintenance is also reported in table 5 and is computed using the facilities-to-firm adjustment factor reported in table 1. FDA assumes that facilities will begin to incur the additional records maintenance burden in the second year following the enactment of the final rule. There is considerable nonquantified uncertainty surrounding these estimates; FDA requests comments.

TABLE 5.—ADDITIONAL RECORDS MAINTENANCE COSTS, OPTION 2

	Facility Count	Cost	Average Cost per Firm
Manufacturers	43,376	$14,154,000	$383
Wholesalers/Warehouses	95,745	$31,242,000	$406
Packaging[1]	73,813	$12,043,000	$174
Transporters/Packers	16,773	$5,473,000	$361
Retail Grocery and Specialty Food	207,657	$67,759,000	$442
Convenience Stores	128,985	$8,094,000	$118
Mixed-Type Facilities that Engage in Farming	30,497	$9,951,000	$408
Importers	5,036	$1,643,000	$408
Total Domestic	601,883	$150,359,000	$335
Foreign			
Final Holders	52,728	$17,205,000	$278
Manufacturers	85,431	$27,876,000	$261
Other Facility Types	311,786	$101,736,000	$278
Total Foreign	449,945	$146,817,000	$274

[1] Includes both outer packaging and food contact substances.

Access costs: For the purposes of this analysis, as mentioned above, FDA assumes that the 4-hour or 8-hour records access times in option 2 imply extra planning and may imply a change in record retention practices for many firms. FDA has little information on the possible impact of this requirement, and requests comments. As previously discussed, the computation of the access costs reported in Table 6 of this document assumes a 6-hour burden per firm for developing an access plan and a $25.10 hourly wage. FDA assumes that all access planning costs will be incurred in the first year following the final rule for large and small firms, and in the second year following the final rule for very small firms. Table 6 presents the calculations.

TABLE 6.—ACCESS COSTS OPTION 2

	Firm Count	Cost	Average Cost per Firm
Domestic			
Manufacturers	36,948	$5,564,000	$151
Wholesalers/Warehouses	76,952	$11,589,000	$151
Packaging[1]	69,266	$10,431,000	$151
Transporters/Packers	15,171	$2,285,000	$151
Retail Grocery and Specialty Food	153,277	$23,084,000	$151
Convenience Stores	68,866	$5,186,000	$75
Mixed-Type Facilities that Engage in Farming	24,397	$3,674,000	$151
Importers	4,029	$607,000	$151
Total Domestic	448,905	$62,420,000	$139
Foreign			
Final Holders	42,182	$6,353,000	$151
Manufacturers	72,770	$10,959,000	$151
Other Facility Types	249,429	$37,564,000	$151
Total Foreign	364,381	$54,876,000	$151

[1] Includes both outer packaging and food contact substances.

Total quantified costs for option 2. Table 7 of this document presents the total quantifiable startup and recurring costs for option 2, and a range of uncertainty based on the uncertain number of exclusive importers and the range of uncertainty in design costs. We calculated the range of uncertainty using the 5th and 95th percentiles of the range of costs, with a uniform distribution of importers and a separate triangular distribution of redesign costs for each facility category and size. Both distributions represent the most amount of information implied by the known characteristics of the uncertain ranges. This procedure allows each component of cost uncertainty to vary independently, but this range cannot be interpreted in probabilistic terms.

Table 7 of this document presents the range of undiscounted annual costs of future compliance for option 2. Costs incurred in year 1 are learning costs for all existing firms, redesign costs for large and small firms, and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. The cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate. Table 8 presents the discounted annual costs incurred in future years and the present value of total costs incurred for option 2. The computations are made using the mean costs, and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms ($341,669,000 reported in Table 7), they are reported in discounted terms for each year in Table 8 to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol ''.'' is meant to convey the continuation of the series depicted in the cells that precede it from above. FDA acknowledges considerable nonquantifiable uncertainty in the estimates presented in Table 7 and requests comments.

TABLE 7.—TOTAL ANNUAL COSTS, OPTION 2

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$412,474,000	$389,256,000	$432,307,000	$415
Year 2	$737,595,000	$665,189,000	$816,183,000	$741
Year 3 and later years	$341,669,000	$327,575,000	$355,445,000	$343

TABLE 8.—DISCOUNTED ANNUAL COSTS, OPTION 2

Year 1	$412,474,000
Year 2	$689,341,000
Year 3	$298,427,000
Year 4	$278,904,000
Year 5	$260,658,000
Year 6	$243,605,000
:[1]	:
:	:
Year 15	$132,505,000
:	:
:	:
Year 30	$48,026,000
:	:
:	:
Present Value	$5,663,484,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 3: Require all elements of option 2 (comprehensive coverage, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except persons who manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging are excluded.

FDA identifies the option excluding outer packaging facilities separately because the fundamental risk to the public from contaminated packaging is probably different from the risk associated with contaminated food, including inner materials that are food contact substances.

FDA was unable to find any data that discriminated between outer packaging manufacturers and distributors and those that manufacture or distribute materials that FDA currently regulates as food contact substances, including plastic beverage bottles and inner cereal box liners. The possibility exists that some of these data describe manufacturers and distributors of outer packaging materials only, and the remainder describe manufacturers and distributors of both outer packaging materials and food contact substances. To distinguish between manufacturers and distributors of outer packaging materials and food contact substances, we assume that the data is distributed uniformly over the interval between 0 and 1, and each packaging facility has an equal probability (0.5) of being either one or both types of facilities. Based on this distributional assumption, the expected number of manufacturers and distributors of outer packaging materials exclusive of food contact substances is 36,906.5 (or 73,813 divided by 2). We request comments on this distributional assumption.

The range and discounted costs for option 3 are estimated to be the same as for option 4, as explained in the following paragraphs, and are reported in tables 9 and 10. The discount computations are made using mean costs. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $334,682,000 reported in table 9), they are reported in discounted terms for each year in table 10. As previously discussed, costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

Option 4: Require all components of option 3 (no outer packagers, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but do not require persons that are required to establish and maintain records on food to establish and maintain records on the food's outer packaging.

FDA is unable to distinguish between the costs incurred when these persons are required to keep records on the food's outer packaging and when they are not required to keep such records. Persons required to establish and maintain records on foods will also keep records on the food contact substances they use because these substances meet the definition of food. Moreover, we believe that a large portion of outer packaging materials used by persons required to establish records is shipped to that person along with food contact substances. Consequently, persons keeping records on food contact substances are also likely to keep records on the food's outer packaging under current recordkeeping practices. As a result, the cost savings from exempting recordkeeping on outer packaging are assumed to be negligible and the costs of this option are assumed to be the same as option 3. We request comments on this assumption.

Tables 9 and 10 present the range and discounted cost estimates for options 3 and 4.

TABLE 9: TOTAL ANNUAL COSTS, OPTIONS 3 AND 4

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$400,491,000	$318,274,000	$404,529,000	$417
Year 2	$711,860,000	$566,254,000	$738,803,000	$741
Year 3 and later years	$334,682,000	$279,074,000	$334,079,000	$348

TABLE 10.—DISCOUNTED ANNUAL COSTS OF OPTIONS 3 AND 4

Year 1	$400,491,000
Year 2	$665,290,000
Year 3	$292,324,000
Year 4	$273,200,000
Year 5	$255,327,000
Year 6	$238,624,000
:[1]	:
:	:
Year 15	$129,795,000
:	:
:	:
Year 30	$47,044,000
:	:
:	:
Present Value as of Year 1	$5,534,165,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 5: Require all components of option 4, but change the required records access time to 24 hours.

All costs for this option will be identical to those for option 4 except for the access costs for records detailed in that section. As mentioned previously, FDA believes that 24 hours is the least amount of time allowable that would not cause any firms to need to plan for a rapid response or change their business practices. While the average access time for FDA traceback investigations is 2–3 days, we believe the same information could be provided in 1 day with the types of recordkeeping systems currently in use, including automated recordkeeping technology, and offsite storage and paper retrieval. Therefore, the difference between the cost of a 2–3 day response time and a 1-day response time is assumed to be negligible. However, the shorter response time requirements of 4 hours or 8 hours would likely impose a new burden on a number of firms. Therefore, we assume that the difference between 4 or 8 hours and 24 hours is the difference between having to preplan a response and being able to react with normal personnel in an emergency capacity. In order to estimate this cost difference, FDA assumes that no firm would incur extra planning costs detailed in option 2, and requests comments on this assumption. The marginal cost savings of extending the records access time requirement is approximately $715,355,000.

Table 11 of this document presents the range of undiscounted costs of future compliance and Table 12 of this document presents the discounted annual costs incurred in all future years and the present value of total costs incurred for option 5. In addition, Table 12 reports the marginal savings of option 5 with respect to option 4 as well as the discounted annual costs and the present value of total costs. The marginal savings of option 5 with respect to option 4 reflect the cost savings realized from relaxing the records access requirements from 4 and 8 hours in option 4 to 24 hours in option 5. As discussed earlier in this document, discounted computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 11.—TOTAL ANNUAL COSTS, OPTION 5

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$338,594,000	$288,569,000	$387,887,000	$387
Year 2	$567,921,000	$481,993,000	$659,106,000	$649
Year 3 and later years	$295,813,000	$258,715,000	$326,509,000	$338

TABLE 12.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 5

	Discounted Annual Costs of Option 5	Marginal Savings of Option 5 With Respect to Option 4
Year 1	$338,594,000	$61,897,000
Year 2	$530,767,000	$134,523,000
Year 3	$258,375,000	$33,949,000
Year 4	$241,472,000	$31,728,000
Year 5	$225,675,000	$29,652,000
Year 6	$210,911,000	$27,713,000
:[1]	:	:
:	:	:

TABLE 12.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 5—Continued

	Discounted Annual Costs of Option 5	Marginal Savings of Option 5 With Respect to Option 4
Year 15	$114,722,000	$15,073,000
:	:	:
:	:	:
Year 30	$41,580,000	$5,464,000
:	:	:
:	:	:
Present Value	$4,818,810,000	$715,355,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 6: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except intrastate facilities are excluded.

In the datasets used for this analysis, it is difficult to distinguish between interstate and intrastate facilities. In order to be considered only engaged in intrastate commerce, a food or food packaging facility must obtain all its ingredients and sell its entire product within a single state. Since all food and food ingredients are regulated in a similar manner, even one ingredient in a food not obtained from within a particular state would make the food facility involved in interstate commerce. None of these datasets distinguishes facilities based on interstate or intrastate commerce. It is reasonable to assume, however, that intrastate facilities will be very small and are unlikely to be retailers or transporters.

The FACTS database of currently regulated facilities contains 71,781 facilities possibly engaged in manufacturing, warehousing, and wholesale marketing of foods. Since the FACTS database gives a count of facilities that FDA inspects, this would estimate the total number of manufacturing, warehousing, and wholesale marketing facilities that are engaged in interstate commerce. The count of covered facilities of these types obtained from the CBP and non-employer statistics and presented in table 1, is 139,121 and includes both intrastate and interstate facilities. We estimate the number of intrastate facilities engaged in manufacturing, warehousing, and wholesale marketing by subtracting the number of facilities in FACTS from the number of corresponding facilities reported in table 1. The FACTS database does not track food packaging producers and distributors, so we assume that the ratio of intrastate to total packaging facilities is the same as that of the facility types (48.3 percent) that are tracked by FACTS. This estimate may underestimate the intrastate facilities by the number of mixed-type facilities that engage in farming and other facility types engaged in only intrastate commerce. For the firm estimates, we assume one firm per facility for the facilities not counted in the FACTS data; intrastate firms are likely to be very small, and the average number of facilities to firms for small firms in the Census datasets is almost exactly 1.

Table 13 of this document presents the effects of excluding these intrastate firms on the number of facilities affected, and Tables 14 and 15 of this document present the range of undiscounted costs and the discounted annual costs, present value of total costs, and marginal savings of option 6 with respect to option 4.

TABLE 13.—NUMBER OF FACILITIES AND FIRMS AFFECTED, OPTION 6

Type	Facility Estimate	Firm Estimate
Manufacturers	34,437	28,009
Wholesalers/Warehouses	37,434	30,189
Packaging[1]	17,840	16,741
Transporters/Packers	16,773	15,171
Retail Grocery and Specialty Food	207,657	153,277
Convenience Stores	128,985	68,866
Mixed-Type Facilities that Engage in Farming	30,497	24,397
Importers	18,902	15,122
Total Domestic	492,525	351,772
Foreign		

TABLE 13.—NUMBER OF FACILITIES AND FIRMS AFFECTED, OPTION 6—Continued

Type	Facility Estimate	Firm Estimate
Final Holders	77,427	61,942
Manufacturers	125,450	107,222
Other Facility Types	423,348	338,678
Total Foreign	626,225	507,842

[1] Includes both outer packaging and food contact substances.

TABLE 14.—TOTAL ANNUAL COSTS, OPTION 6

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$376,263,000	$358,454,000	$397,619,000	$424
Year 2	$648,418,000	$583,071,000	$720,849,000	$731
Year 3 and later years	$307,485,000	$286,089,000	$317,845,000	$347

TABLE 15.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 6

	Discounted Annual Costs of Option 6	Marginal Savings of Option 6 With Respect to Option 4
Year 1	$376,263,000	$24,228,000
Year 2	$605,998,000	$59,292,000
Year 3	$268,569,000	$23,755,000
Year 4	$250,999,000	$22,201,000
Year 5	$234,579,000	$20,748,000
Year 6	$219,233,000	$19,391,000
:[1]	:	:
:	:	:
Year 15	$119,248,000	$10,547,000
:	:	:
:	:	:
Year 30	$43,221,000	$3,823,000
:	:	:
:	:	:
Present Value as of Year 1	$5,087,535,000	$446,630,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 7: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except persons who operate mixed-type facilities that engage in farming are excluded.

This option would exempt from recordkeeping requirements all persons who operate mixed-type facilities that engage in farming. The total number of mixed-type facilities that would be exempt under this option is estimated to be 30,497, and the estimated numbers of such facilities by commodity type are reported in table 2. Tables 16 and 17 of this document summarize the estimated range and impact of this exemption on total costs and marginal savings into the future.

TABLE 16.—TOTAL ANNUAL COSTS, OPTION 7

	Mean	Low	High	Average Cost per Firm
Year 1	$379,977,000	$354,015,000	$406,264,000	$406
Year 2	$689,275,000	$619,484,000	$771,484,000	$736
Year 3 and later years	$322,701,000	$309,635,000	$337,022,000	$345

TABLE 17.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS OF OPTION 7

	Discounted Annual Costs of Option 7	Marginal Savings of Option 7 With Respect to Option 4
Year 1	$379,977,000	$20,514,000
Year 2	$644,182,000	$21,108,000
Year 3	$281,860,000	$10,464,000
Year 4	$263,420,000	$9,780,000
Year 5	$246,187,000	$9,140,000
Year 6	$230,081,000	$8,543,000
:[1]	:	:
:	:	:
Year 15	$125,149,000	$4,646,000
:	:	:
:	:	:
Year 30	$45,360,000	$1,684,000
:	:	:
:	:	:
Present Value	$5,332,584,000	$201,581,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

We believe that there is an even smaller number of mixed-type facilities that have restaurants. We have assumed that the costs and marginal savings for these facilities would be negligible. We invite comment and information relating to this assumption.

Options 8 and 9: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but change required records-retention times for perishables and all other foods to 1 year (option 8), and 2 years (option 9).

FDA believes that the 1-year record retention requirement for perishable foods not intended for processing into nonperishable foods and the 2-year record retention requirement for all other food products is well within industry norms (see the discussion of evidence supporting provided in a previous section of this document). We do not have enough information to quantify any marginal change in the cost of record storage under a universal 1-year required storage time (option 8) or a universal 2-year required storage time (option 9). All other things equal, FDA assumes that option 8 would be less costly than option 4, which in turn would be less costly than option 9. Because evidence suggests that most firms keep records for 2 years or more, FDA also believes that the marginal difference in storage costs between all of these options is smaller than the marginal difference in cost between other options we consider in this analysis. Therefore, while there may be a benefit from simplifying requirements by requiring the same storage time for both perishable and nonperishable foods, because the increased benefit is negligible, we assume that the marginal cost is zero for both options 8 and 9. We explicitly specify these options principally to request comments, including specific examples where required record retention times may have a large impact on cost.

Option 10: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) but cover only those foreign facilities also covered by FDA's proposed registration regulation published at 68 FR 5378, February 3, 2003.

The proposed registration regulation (68 FR 5378, February 3, 2003) would require certain foreign facilities that manufacture, process, pack, and hold food for consumption in the United States to register. Therefore, a useful alternative to explore may be to cover the same facilities in both regulations. This exclusion implies that these

regulations would not cover most of the category ''Other Facility Types'' in the last row of Table 1 of this document. Only facilities that do de minimis processing or packaging of food, such as affixing a label, are included in this option from the category of ''Other Facility Types''. Because the minimal degree of processing that de minimis processing facilities perform, they are not included in the OASIS count of foreign manufacturers.

We assume that domestic packers and repackers are the domestic counterpart to foreign de minimis food processing facilities. This seems reasonable since the amount of processing performed by packers and repackers is minimal. To estimate the number of foreign packers and repackers, FDA takes the number of packers and repackers in the FACTS database, 6,204, and adjusts it by the ratio of foreign manufacturers in OASIS to the number of domestic manufacturers in FACTS. This adjustment of 3.64 (125,450 foreign facilities divided by 34,437 domestic facilities), estimates the total number of foreign packers and repackers (or foreign de minimis processing facilities) as 22,600. The facilities-to-firms adjustment factor of 1.25, used to compute the number of firms in the ''Other Facility Types'' category, indicated that 18,080 firms were included in the foreign de minimis category. Table 18 reports the numbers of facilities and firms that were used in the cost estimates. FDA requests comments on these estimates.

TABLE 18.—NUMBER OF FACILITIES AND FIRMS AFFECTED. OPTION 10

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate
Domestic			
Manufacturers	43,376	1.17	36,948
Wholesalers/Warehouses	95,745	1.24	76,952
Packaging[1]	36,907	1.07	34,633
Transporters/Packers	16,773	1.11	15,171
Retail Grocery and Specialty Food	207,657	1.35	153,277
Convenience Stores	128,985	1.87	68,866
Mixed-Type Facilities that Engage in Farming	30,497	1.25	24,397
Importers	18,902	1.25	15,122
Total Domestic	578,842		425,366
Foreign			
Final Holders	77,427	1.25	61,942
De minimus Processors/Packagers	22,600	1.25	18,080
Manufacturers	125,450	1.17	106,858
Other Facility Types	0	0	0
Total Foreign	225,477		186,879

[1] Includes both outer packaging and food contact substances.

Since ''Other Facility Types'' is such a large and uncertain category, the exclusion of most of the category has a significant impact on all cost estimates.

The estimated ranges of the costs for learning, records access planning, additional records maintenance, and records redesign, as well as the total for this option are reported in table 19. The costs reported in the table are identified by the applicable Code of Federal Regulations (CFR) section and are expressed in present value terms to account for the fact that some costs are one-time costs while others are recurring costs. The cost estimate that is greater than 95 percent of all other estimates generated by the model is reported as the high value. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low value.

TABLE 19.—COST DESCRIPTION IN PRESENT VALUE TERMS: OPTION 10

21 CFR Section	Mean	Low	High
1.337, 1.345, and 1.352, (Learning)	$138,357,000	$134,017,000	$142,346,000
1.337, 1.345, and 1.352, (Redesign)	$381,292,000	$326,799,000	$430,439,000
1.361 (Access Planning)	$78,834,000	$73,176,000	$84,179,000

TABLE 19.—COST DESCRIPTION IN PRESENT VALUE TERMS: OPTION 10—Continued

21 CFR Section	Mean	Low	High
1.337, 1.345, and 1.352 (Additional Records Maintenance)	$2,952,309,000	$2,817,570,000	$3,070,891,000
1.337, 1.345, and 1.352, (Learning for New Firms)	$13,836,000	$13,310,000	$14,328,000
1.361 (Access Preparation for New Firms)	$7,883,000	$7,318,000	$8,418,000
Total[1]	$3,660,808,000	$3,478,944,000	$3,833,452,000

[1] The totals reported at the bottom of each column differ slightly from the results that would be obtained by adding together all of the cells in the column. This is because the computation of the totals reported here is made assuming a joint distribution of the cost components, as described elsewhere in the analysis, rather then by adding together the individually computed component costs.

The annual range and discounted costs for option 10 as well as the marginal savings of option 10 with respect to option 4 are detailed in tables 20 and 21 of this document. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 20.—TOTAL ANNUAL COSTS, OPTION 10

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$234,425,000	$215,030,000	$252,196,000	$383
Year 2	$507,230,000	$459,345,000	$550,801,000	$828
Year 3 and later years	$221,130,000	$212,313,000	$229,680,000	$361

TABLE 21.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 10

	Discounted Annual Costs: Option 10	Marginal Savings of Option 10 With Respect to Option 4
Year 1	$234,425,000	$166,066,000
Year 2	$474,047,000	$191,243,000
Year 3	$193,144,000	$99,180,000
Year 4	$180,508,000	$92,692,000
Year 5	$168,699,000	$86,628,000
Year 6	$157,663,000	$80,961,000
:[1]	:	:
:	:	:
Year 15	$85,758,000	$44,037,000
:	:	:
:	:	:
Year 30	$31,083,000	$15,961,000
:	:	:
:	:	:
Present Value as of Year 1	$3,660,808,000	$1,873,357,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 11: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except foreign coverage includes only facilities that are the final holders of the product before export to the United States.

We estimate that there would be approximately 62,000 foreign facilities covered under this option. We assumed that the number of foreign final holding facilities is equivalent to the number of domestic importers. Since foreign manufacturing facilities and foreign de minimus processors/packagers would be excluded from recordkeeping requirements, the coverage under this option is more limited than the coverage under option 10. The rationale for specifying this option is that final holders may be the most accessible foreign facilities in the event of an FDA traceback investigation. In addition, foreign final holders may be particularly at risk at this level in the food chain if the food is clearly identified as destined for consumption in the United States.

Tables 22 and 23 of this document present the cost estimates for option 11. As previously discussed, discount computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $182,429,000 reported in Table 22 of this document), they are reported in discounted terms for each year in Table 23 of this document to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol ''.'' is meant to convey the continuation of the series depicted in the cells that precede it from above. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 22.—TOTAL ANNUAL COSTS, OPTION 11

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$172,973,000	$156,033,000	$190,831,000	$355
Year 2	$413,484,000	$369,335,000	$458,871,000	$849
Year 3 and later years	$182,429,000	$174,474,000	$190,610,000	$374

TABLE 23.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 11

	Discounted Annual Costs: Option 11	Marginal Savings of Option 11 With Respect to Option 4
Year 1	$172,973,000	$227,518,000
Year 2	$386,434,000	$278,856,000
Year 3	$159,341,000	$132,983,000
Year 4	$148,916,000	$124,284,000
Year 5	$139,174,000	$116,153,000
Year 6	$130,069,000	$108,555,000
:[1]	:	:
:	:	:
Year 15	$70,749,000	$59,046,000
:	:	:
:	:	:
Year 30	$25,643,000	$21,401,000
:	:	:
:	:	:
Present Value as of Year 1	$2,995,041,000	$2,539,124,000

[1] Each cell that contains only the symbol ''.'' is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 12: Require all components of option 4 (no outer packagers, no recordkeeping on outer packaging, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products) except all foreign food facilities are excluded.

This option excludes all foreign firms from recordkeeping requirements and has even less coverage than under option 11. Tables 24 and 25 of this document present the cost estimates. As previously discussed, discount computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $162,228,000 reported in Table 24), they are reported in discounted terms for each year in Table 25 of this document. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 24.—TOTAL ANNUAL COSTS, OPTION 12

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$139,947,000	$125,857,000	$152,775,000	$329
Year 2	$376,310,000	$334,230,000	$421,832,000	$885
Year 3 and later years	$162,228,000	$155,337,000	$169,446,000	$381

TABLE 25.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 12

	Discounted Annual Costs: Option 12	Marginal Savings of Option 12 With Respect to Option 4
Year 1	$139,947,000	$260,544,000
Year 2	$351,692,000	$313,598,000
Year 3	$141,696,000	$150,628,000
Year 4	$132,426,000	$140,774,000
Year 5	$123,763,000	$131,564,000
Year 6	$115,666,000	$122,958,000
:[1]	:	:
:	:	:
Year 15	$62,915,000	$66,880,000
:	:	:
:	:	:
Year 30	$22,803,000	$24,241,000
:	:	:
:	:	:
Present Value as of Year 1	$2,657,566,000	$2,876,599,000

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Option 13: Facilities must be able to tie specific input ingredients to specific products.

Most comments FDA received during its early outreach efforts for this proposed rule stated that tying specific raw input ingredients to specific finished products would significantly increase the burden on industry, which would translate into large social costs. Some comments suggested that some facilities have systems in place that can link each lot of raw ingredient to each lot of finished product, but such systems are rare for bulk agricultural commodities. For example, it is common practice in handling agricultural commodities to commingle raw ingredients from several suppliers in a large silo or storage tank. While this business practice would not be required to change under options 2–12, option 13 would add the significant new burden of requiring firms that traditionally commingle raw ingredients from several suppliers to redesign a production or storage strategy that would allow them

to identify more precisely the source of all the food products.

Most agricultural crops are traded as bulk commodities; bulk trading operates on the premise that crops produced by different farmers are sufficiently similar to be traded at a common price and with a common grading specification. For various reasons, some firms have put in place identity preservation systems, which they use to track individual lots of products throughout production and distribution. These identity preservations systems exist for organic products, kosher products, and some specialty versions of bulk products. FDA estimated the potential impact of this option by reviewing studies of current identity preservation systems. We assume that the identity preservation systems put in place for specialty versions of traditionally commingled products closely resembles what would be required to comply with the input-to-output requirement of this option. The study we rely on for our estimates (Ref. 17) is for corn and soybeans, the largest crops by value in the United States, but the issues should be similar for other types of bulk products.

The cost of identity preservation consists of: (1) The cost of segregating crops to prevent commingling, and (2) the cost of tracking ingredients. First, commodity suppliers should incur an increase in cost due to their inability to mix commodities in bulk. The Bender et al (Ref. 16) study estimates costs based on responses to a small survey of specialty elevators, grain firms, seed companies, and brokers. On average, 35 percent of the volume handled by these firms is specialty product, so they have ample experience in identifying cost differences, including storage, handling and segregation, risk management, transportation, analysis and testing, and marketing costs. Of the 84 survey responses, 55 estimated the cost of segregating and handling specialty crops. FDA used the overall average across facility types to estimate an average cost premium to be applied to each preprocessed commodity: $0.17 per bushel for corn and $0.48 per bushel for soybeans. The original estimate included a premium paid to farmers, but we subtracted this amount out of the total. Since option 13 would only require the identification of a particular immediate previous source, in this case a farm, we assume no new farming activity would have to take place. At an average price of $1.81 per bushel for corn and $4.60 per bushel for soybeans in 1999 (Ref. 18), the premium estimated for corn is 9.4 percent and for soybeans is 10.4 percent. Due to the small sample, standard errors were not reported in this study, but considerable nonquantified uncertainty exists around these estimates. These estimates may be an overestimate of premiums if economies of scale are possible in identity preservations systems. These estimates may be an underestimate if the reason these specialty product systems exist is that it is easier to preserve identities for corn and soybeans than for other products.

Table 26 of this document presents the calculations of the cost based on these segregation premiums. We apply the premium to the 1999 farm value of commodities, not to the retail values as retail prices include many other aspects of branding and bringing the product to market. These are also the latest data available, and since agricultural prices have been fairly stable, we do not adjust these dollar amounts to 2002. The estimated corn premium from the studies is used for all other bulk grain products, and the estimated soybean premium is also used for nuts, sugarcane and beets, sunflowers, and flaxseeds. Milk is assumed to have a lower cost increase; most milk production is local and already includes a tracking system to allow for the use of expiration dates for the final product. Vegetables destined for final consumption in an unaltered state, vegetables used for production, and eggs are also assumed to have a lower cost of tracking since current commingling practices for these products are limited. The table includes nuts, but we were unable to find a satisfactory price estimate. FDA requests comments on these assumptions.

TABLE 26.—COMMINGLING COSTS BASED ON SPECIALTY PREMIUMS, OPTION 13

Food Type	Count	Unit	$ Farm gate	Premium %	Premium $
Corn (for grain)	9,430,612,000	bushels	$17,103,991,000	9.4%	$1,603,204,000
Soybeans	2,653,758,000	bushels	$12,205,352,000	10.4%	$1,273,804,000
Milk	162,716,000,000	pounds	$23,400,050,000	5.0%	$1,170,003,000
Wheat	2,299,010,000	bushels	$5,593,989,000	9.4%	$524,340,000
Fruits	31,152,000	tons	$9,345,600,000	5.0%	$467,280,000
Fresh Vegetables	22,484,150	tons	$7,610,780,000	5.0%	$380,539,000
Eggs	82,715,000,000	eggs	$4,321,859,000	5.0%	$216,093,000
Sugar beets	33,420,000	tons	$1,242,898,000	10.4%	$129,714,000
Rice	20,602,700,000	pounds	$1,231,207,000	9.4%	$115,404,000
Peanuts	3,829,490,000	pounds	$971,608,000	10.4%	$101,401,000
Sugarcane	35,299,000	tons	$941,791,000	10.4%	$98,290,000
Sorghum	595,166,000	bushels	$937,406,000	9.4%	$87,866,000
Prod. Vegetables	15,476,230	tons	$1,660,051,000	5.0%	$83,003,000
Barley	280,292,000	bushels	$597,038,000	9.4%	$55,962,000
Sunflower	4,341,862,000	pounds	$339,993,000	10.4%	$35,483,000

TABLE 26.—COMMINGLING COSTS BASED ON SPECIALTY PREMIUMS, OPTION 13—Continued

Food Type	Count	Unit	$ Farm gate	Premium %	Premium $
Oats	146,193,000	bushels	$175,172,000	9.4%	$16,419,000
Honey	205,250,000	pounds	$126,075,000	5.0%	$6,304,000
Flaxseed	7,864,000	bushels	$30,098,000	10.4%	$3,141,000
Rye	11,038,000	bushels	$25,084,000	9.4%	$2,351,000
Nuts	1,295,700,000	pounds	$0	5.0%	$0
Total			$87,860,042,000		$6,370,601,000

As the second component of cost, FDA assumes that manufacturers using bulk production processes would have to adopt a new tracking system for their input ingredients. Having identity-preserved input ingredients delivered from their suppliers would help in this task, but the disruption to production practices could be substantial. FDA does not have an estimate of the percentage of producers that may be affected by this option, or the amount of change in production practices that would have to take place, but we assume that a useful lower bound of the increase in production cost would be the increase in information design and collection costs that manufacturers would face in this system.

For redesign costs, FDA used the Labeling Cost Model, assuming a full new document design as opposed to simple addition of information. FDA also assumed a doubling of information collection burden for manufacturers when compared to other options; they would have to track three sets of records (input sources, output sources, and input to output tracking) instead of two, but could not share the information collection burden with others in the production chain for these manufacturing records. As in the other options, we assumed the design costs would be incurred at the firm level and the additional records maintenance costs would be incurred at the facility level. FDA considers these design and records maintenance costs a probable underestimate of the total cost of disruption in manufacturing possible under this option, since it does not consider production process changes or additional tracking costs required in the post-production distribution chain. Table 26 of this document summarizes the redesign and additional records maintenance burden calculations unique to option 13.

TABLE 27.—ADDITIONAL REDESIGN AND RECORDS MAINTENANCE COSTS, OPTION 13.

	Count	Medium	Low	High
Redesign				
Domestic Manufacturing Firms	36,948	$228,816,000	$171,917,000	$413,738,000
Foreign Manufacturing Firms	72,770	$450,666,000	$338,600,000	$814,880,000
Total	109,718	$679,482,000	$510,517,000	$1,228,618,000
Additional Records Maintenance				
Domestic Manufacturing Facilities	43,376	$14,154,000		
Foreign Manufacturing Facilities	85,431	$27,876,000		
Total	128,807	$42,030,000		

Tables 28 and 29 of this document present the estimated range and impact of option 13 on total costs into the future. As the tables indicate, option 13 is much costlier than any of the other regulatory options. The numbers in parentheses in the right hand column of Table 29 reflect a negative marginal cost savings of option 13 with respect to option 4. As previously discussed, discount computations are made using mean costs and assume no increase in real labor cost and a 7 percent real discount rate. Although the recurring costs reported for year 3 and later years are the same in nominal terms (i.e., $6,743,086,000 reported in Table 28), they are reported in discounted terms for each year in Table 29 to account for the fact that a dollar in 5 years, for example, is worth less than a dollar today. Each cell that contains only the symbol ''.'' is meant to convey the continuation of the series depicted in the cells that precede it from above. Costs incurred in year 1 are learning costs for all firms and redesign and access planning costs for large and small firms. Costs incurred in year 2 are redesign and access planning costs for very small firms. Recurring costs are the additional records maintenance costs incurred by all firms, and learning costs and records access costs for new firms. The mean, low, and high cost estimates presented here characterize the known and quantifiable uncertainties as they are defined previously. The cost estimate that is greater than 5 percent of all other estimates generated by the model is reported as the low cost estimate. That cost estimate that is greater than 95 percent of all other estimates generated in the model is reported as the high cost estimate.

TABLE 28.—ANNUAL TOTAL COSTS, OPTION 13

	Mean	Low	High	Average Mean Cost per Firm
Year 1	$442,970,000	$405,800,000	$484,402,000	$445
Year 2	$2,692,790,000	$2,504,068,000	$2,921,375,000	$2,706
Year 3 and later years	$6,743,086,000	$6,702,239,000	$6,726,422,000	$6,748

TABLE 29.—DISCOUNTED ANNUAL COSTS, PRESENT VALUE, AND MARGINAL SAVINGS: OPTION 13 (NUMBERS IN PARENTHESES ARE NEGATIVE)

	Discounted Annual Costs: Option 13	Marginal Savings of Option 13 With Respect to Option 4
Year 1	$442,970,000	($183,745,000)
Year 2	$2,516,626,000	($1,901,433,000)
Year 3	$5,889,672,000	($5,630,368,000)
Year 4	$5,504,367,000	($5,262,026,000)
Year 5	$5,144,268,000	($4,917,781,000)
Year 6	$4,807,727,000	($4,596,057,000)
:[1]	:	:
:	:	:
Year 15	$2,615,085,000	($2,499,951,000)
:	:	:
:	:	:
Year 30	$947,827,000	($906,097,000)
:	:	:
:	:	:
Present Value as of Year 1	$92,987,447,000	($88,149,370,000)

[1] Each cell that contains only the symbol ":" is meant to convey the continuation of the series depicted in the cells that precede it from above.

Marginal analysis: As a way of comparing the options, Table 30 of this document presents the present values of total costs and the marginal savings of each option compared with option 4. Option 4 was chosen for comparison since it differs by only one provision from almost all the other options considered in the analysis. The marginal savings for all options, except options 2 and 13, are either zero or positive reflecting either a lower total cost or equivalent total cost compared with option 4.

Since option 3 and options 5–12 involve a single modification of the requirements in option 4, the marginal savings expressed for each of those options reflects the cost savings from removing that requirement. Furthermore, while option 2 differs from option 4 by two provisions, rather than one provision (option 4 does not require persons that manufacture, process, pack, hold, receive, distribute, transport, or import outer food packaging to keep records and does not require persons that are required to keep records on foods to keep records on the food's outer packaging), the costs computed for both options are equivalent. As a result, there is no loss in meaning by comparing the costs of all options to option 4 in Table 30. Consequently, for option 10, the marginal savings in present value terms from relaxing the comprehensive foreign coverage requirement in option 4 to the reduced level of coverage specified by the registration rule is $1,873,357,000 as reported in the following table.

TABLE 30.—PRESENT VALUE AND MARGINAL SAVINGS WITH RESPECT TO OPTION 4

Option	Present Value of Total Cost	Marginal Savings With Respect to Option 4	Description of Option Requirements
2	$5,663,484,000	($129,319,000)[1]	Comprehensive coverage, 4 or 8 hour records-access requirement, 1 and 2-year records-retention requirement

TABLE 30.—PRESENT VALUE AND MARGINAL SAVINGS WITH RESPECT TO OPTION 4—Continued

Option	Present Value of Total Cost	Marginal Savings With Respect to Option 4	Description of Option Requirements
3	$5,534,165,000	$0	Exclude outer packagers
4	$5,534,165,000	$0	Exclude outer packagers and recordkeeping on outer packaging
5	$4,818,810,000	$715,355,000	Same as option 4 except records-access requirement is relaxed to 24 hours
6	$5,087,535,000	$446,630,000	Same as option 4 except intrastate facilities are excluded
7	$5,332,584,000	$201,581,000	Same as option 4 except mixed-type facilities that engage in farming are excluded
8	$5,534,165,000	$0	Same as option 4 except universal records retention of 1 year
9	$5,534,165,000	$0	Same as option 4 except universal records retention of 2 years
10	$3,660,808,000	$1,873,357,000	Proposed. Same as option 4 but limit foreign coverage to be the same as registration.
11	$2,995,041,000	$2,539,124,000	Same as option 4 but limit foreign coverage to the final holders prior to export.
12	$2,657,566,000	$2,876,599,000	Same as option 4 except all foreign facilities are excluded.
13	$93,137,167,000	($87,603,002,000)[1]	Comprehensive coverage. Precise input to output recordkeeping requirement.

[1] Numbers in parentheses are negative.

Sensitivity of cost estimates to assumptions: For all the options, FDA attempted to quantify the uncertainty associated with redesign costs and the number firms and facilities exclusively dedicated to imports, but we had no basis for assigning distributions to other uncertain components. By far the largest source of uncertainty is the premium on products that would be subject to new identity preservation under option 13. FDA also tested the sensitivity of other sources of uncertainty under option 10, in order for the reader to compare various sources of uncertainty and submit comments regarding our assumptions. Although the dollar sensitivities to the assumptions specified in Table 31 of this document should be similar across the options, many of the percentage sensitivities would—because of different base costs—differ under other options. FDA believes that the ranking of the costs of these options is not affected by any uncertainty in our estimates.

There is significant uncertainty in the estimate of the number of mixed-type facilities that engage in farming. Based on research described earlier, our estimate of the number of mixed-type facilities that engage in farming that would be covered by this proposed rule is 30,497. To determine the sensitivity of the cost estimates to changes in the numbers of mixed-type facilities that engage in farming, a sensitivity analysis was performed in which the number of these types of facilities was increased by 10 percent.

Table 31 of this document presents the results of the sensitivity analyses that we conducted. For option 13, Table 31 reports the effect of an increase in crop premium for identity preservation of 1 percent for all crops. For option 10, Table 31 reports the effect of a 10 percent increase in the estimate of the number of mixed-type facilities that engage in farming, and 10 percent cost increases for each component cost on the mean first-year total cost estimates. For redesign costs, we assumed a 10 percent increase in the medium cost estimate.

Finally, to be consistent with the analysis conducted for the Registration proposed rule, a sensitivity analysis was conducted that accounted for the possibility that a number of foreign firms would cease to export to the United States because of the burden imposed by these regulations. This is particularly relevant when considering the burden imposed on foreign firms by the Registration proposed rule. In the analysis of the registration proposed rule, it was estimated that approximately 16 percent of small manufacturers and processors (defined in that analysis as those exporting 10 or fewer line items to the United States) would cease exporting to the United States because of the increase in costs due to that proposed rule. Consistent with the analysis of the Registration proposed rule, we analyzed the cost sensitivity of a 16 percent reduction in the number of foreign firms. FDA requests comments on other desired sensitivity analyses.

TABLE 31.—SENSITIVITY ANALYSIS

Test	Option	Effect on Present Value Mean Cost ($)	Percent Effect
10% increase in records maintenance	10	$276,513,000	7.02%
10% increase mixed-type facilities that engage in farming	10	$17,061,000	0.46%
10% decrease in percent European	10	$33,529,000	0.91%
10% increase in redesign	10	$38,006,000	1.03%
10% increase in learning	10	$32,185,000	0.87%
10% increase in access	10	$18,873,000	0.51%
16% decrease in number of foreign firms	10	($138,484,000)[1]	(3.93%)[1]
1% increase in identity preservation premium	13	$490,117,000	0.52%

[1] Numbers in parentheses are negative.

Benefits: These options would improve FDA's ability to address adulterated food and food packaging that presents a threat of serious adverse health consequences or death to humans and animals. FDA is unable to quantify the benefits of these regulations, though we consider them substantial. While the probability of a deliberate contamination of the food supply may be low, the potential cost of a deliberate contamination of the food supply may be high. Below we present some examples to demonstrate what such a contamination may look like. Without having any hypothesis on the likelihood of a deliberate contamination, it is impossible to quantitatively measure the benefits of the reduced impact due to each of these regulatory options.

Further hindering any quantification of benefits is the interactive effect of other regulations that are being developed to implement Title III of the Bioterrorism Act of 2002. The registration (section 305 of the Bioterrorism Act) and recordkeeping regulations would work cooperatively to identify and track possible sources of an outbreak. The prior notice for imported shipments (section 307 of the Bioterrorism Act) would allow the agency time to identify possible sources of risk from adulterated food and its packaging that presents a threat of serious adverse health consequences or death to humans and animals, which could then be investigated with the aid of the new registration and recordkeeping regulations.

To understand possible costs of an intentional attack on the food supply, we examine five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. It is possible that an intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens would be much larger. Also, intentional attacks may be fundamentally more difficult to trace than natural outbreaks due to deliberate obfuscation of the source and possible multiple contamination events of different food types and food facilities. We then examine mechanisms through which each regulatory option discussed in this analysis may act and analyze how each of the options affects the mechanisms.

TABLE 32.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and Year	Vehicle	Confirmed or Reported Cases	Estimated Number of Cases	Total Illness Cost (dollars)
Salmonella enteritidis	Minnesota 1994	Ice cream	150 cases; 30 hospitalized	29,100 in MN; 224,00 nationwide	3,187,744,000 to 5,629,792,000
Shigella sonnei	Michigan 1988	Tofu salad	3,175 cases	Not available	45,183,000 to 79,797,000
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalized	Not available	10,687,000 to 18,875,000
Shigella dysentreriae type 2	Texas 1996	Muffins and doughnuts	12 cases; 4 hospitalized	All cases identified	83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalized	Not available	3,941,000

Salmonella enteritidis in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with *Salmonella enteritidis*. The source of the contamination appeared to be pasteurized premix that had been contaminated during transport in tanker trailers that carried nonpasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream processed during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 19).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause 1 to 3 days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as cases that require a trip to a physician, account for 8 percent of the cases. These cases typically have a duration of 2 to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over 1 percent of cases develop short-term reactive arthritis and 2 percent of cases develop chronic, reactive arthritis.

FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Table 32 of this document provides a summary of these estimates. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. FDA uses the value placed by consumers on the risks to life found in current economic literature (See Refs. 20, 21, 22, and 23). In addition, FDA presents two estimates of values of pain and suffering associated with arithritis, one based on physician estimates (Ref. 24) and another based on a regression analysis approach (Ref. 25). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

TABLE 33.—THE COST OF A TYPICAL CASE OF SALMONELLOSIS

Severity	Case Breakdown (percent)	Total QALDs Lost per Illness	Health Loss (dollars) per Case (Discounted)	Medical Costs (dollars) per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7	1.05	660	0	599
Moderate	8.1	3.68	2,310	283	209
Severe	1.2	9.99	6,266	9,250	188
Arthritis					
Regression approach					
Short-term	1.26	5.41	3,391	100	44
Long-term	2.40	2,613.12	452,554	7,322	11,048
Direct survey approach					
Short-term	1.26	10.81	6,778	100	87
Long-term	2.40	5,223.15	904,573	7,322	21,906
Death	0.04		5,000,000		2,143
Total expected loss per case					
Regression approach					14,231
Direct survey approach					25,133

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival (Ref. 26). Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of *Salmonella* typhimirium occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying *Salmonella* typhimirium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 27).

The 751 people affected primarily were identified through passive surveillance; thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost

of known cases for the outbreak of $10,687,000 to $18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician. Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 28).

To estimate the cost of this outbreak, FDA assumed that the eight cases requiring consultation with a doctor, but not requiring hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $83,000 for illnesses associated with the event.

TABLE 34.—SUMMARY OF COSTS FOR CASES OF SHIGELLOSIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	0	0	0
Moderate	8	2,593	21,000
Severe	4	15,516	62,000
Grand total			83,000

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 29). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 30).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref. 30). We estimated the cost of a mild case of cyclosporiasis as two and a half times higher than the cost of a mild case of gastroenteritis from salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak (Ref. 29). No deaths were confirmed.

TABLE 35.—SUMMARY OF COSTS FOR CASES OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case (dollars)	Total cost (dollars)
Mild	879	1,650	1,450,000
Moderate	586	3,748	2,196,000
Severe	19	15,516	295,000
Grand total			$3,941,000

Mechanisms: The new recordkeeping provisions we describe in the options section would not only help FDA determine the cause of a particular outbreak by tracing the source, they would also reduce further adverse health effects by enabling FDA to trace forward to locate adulterated food and its packaging that presents a threat of serious adverse health consequences or death to humans and animals. We expect that, working in concert with other regulations, having complete records identifying all links in the chain of custody for a particular product will allow FDA to more efficiently deploy its compliance and regulatory resources in an event of an outbreak. Having complete records increases the probabilities of FDA being able to trace back to the source of an outbreak and of FDA being able to trace forward to locate adulterated food and its packaging. FDA conducts approximately 20 emergency traceback investigations per year. Although no investigation has been completely halted by a lack of adequate records in the past several years, inadequate records have hindered investigations. For example, FDA attempted to conduct approximately 38 tracebacks in a Cyclospora outbreak in 1997. Of those, we were able to complete 33, and the majority of failures were due to the lack of available records. More commonly, incomplete records severely impede the ability of FDA to conduct effective investigations.

Faster required record access times may allow FDA to more rapidly identify the source of an outbreak and limit its effects. Over the past several years of FDA traceback investigations, the normal response time between a request for data and the receipt of the records from the firm is 2–3 days. The response times in these options would greatly speed up the traceback process, which would be critical in limiting a deliberate or accidental major outbreak.

Comparison of benefits under each option: Because we cannot quantify these benefits, we cannot differentiate the benefits of each option in dollar terms. Instead, we explore how effectively each of the two mechanisms, trace back and response, would operate under each of the options. The extent of coverage by each option is one criterion that we use to evaluate the effectiveness of each mechanism since the extent of coverage may influence the effectiveness of both trace-back and response times. Tables 36 and 37 of this document present the numbers of firms covered under each option, and the reduction in the numbers of firms covered under each option when compared to those covered under option 4. As in the costs section, option 4 was chosen for comparison purposes for the sake of consistency. Foreign and domestic coverage are presented separately in Tables 36 and 37 of this document since there may be reason to weigh the benefits from the inclusion of each category differently. Table 38 of this document provides a summary of the expected effects.

TABLE 36.—NUMBER OF FIRMS COVERED BY OPTION

Option	Domestic	Foreign	Total
2	459,998	535,432	995,431
3	425,365	449,676	875,041
4	425,365	449,676	875,041
5	425,365	449,676	875,041
6	351,772	449,676	801,448
7	400,968	449,676	850,644
8	425,365	449,676	875,041
9	425,365	449,676	875,041
10	425,365	186,879	612,245
11	425,365	61,942	487,307
12	425,365	0	425,365
13	459,998	535,432	995,431

TABLE 37.—MARGINAL REDUCTION IN THE NUMBERS OF FIRMS COVERED WITH RESPECT TO OPTION 4

Option	Domestic	Foreign	Total
2	(34,633)[1]	(85,756)[1]	(120,389)[1]
3	0	0	0
4	0	0	0
5	0	0	0
6	73,594	0	73,594
7	24,397	0	24,397
8	0	0	0
9	0	0	0
10	0	262,797	262,797
11	0	387,735	387,735
12	0	449,676	449,676
13	(34,633)[1]	(85,756)[1]	(120,389)[1]

[1] Numbers in parentheses are negative.

Evaluating the benefits by option using two mechanisms: (1) Complete records (which increase the probability of a thorough trace-back investigation), and (2) faster records access times (which may allow for more rapid identification of the source of an outbreak and limit its effects).

Option 1, no action: No impact.

Option 2, comprehensive coverage, 4 or 8 hour records access, 1 and 2 year records retention for perishables and all other products: This option contains no exemptions, so it has the largest coverage of any of the options we consider and ranks high with regard to improving the ability to perform a thorough trace-back investigation. However, option 13 requires even greater additional record information collection, which would aid in trace-back investigations. So, based on mechanism 1, this option has the second highest benefits. With regard to the speed criterion—this option also has the quickest response time specified in any of the options. It is ranked second in overall benefits behind option 13.

Option 3, same as option 2 except outer-packaging manufacturers and distributors are excluded: The exclusion of outer food packagers from recordkeeping requirements reduces the coverage and the potential to perform a thorough trace-back investigation compared with option 2. It is also unclear what the relative risk of outer food packaging is compared with the risk of the food itself (including food contact substances), but FDA assumes that the potential harm through packaging adulteration, although serious, is lower than the potential harm through adulteration of food. This would tend to mitigate the consequences on potential trace-back capability from excluding these facilities. This option also scores relatively well if rated by the speed criterion since the records-access time is the same as in option 2. The exclusion of outer packaging manufacturers and distributors will not reduce benefits by much compared with option 2—especially because the risk of contamination through outer packaging is likely to be small.

Option 4, same as option 3 except recordkeeping on outer-packaging is excluded: The reduction in benefits from not requiring recordkeeping on outer food packaging is assumed to be negligible compared with option 3. Therefore, the benefits from this option are about the same as option 3 using both the complete records criterion and the speed criterion.

Option 5, same as option 4 except records access requirement is relaxed to 24 hours: This option does not differ much from option 4 by this ranking criterion, since it has the same domestic and foreign coverage and record scope requirements. However, this option scores relatively low by the speed criterion, since all other options would require a much faster response time for records access.

Option 6, same as option 4 except intrastate facilities are excluded: This option has lower benefits than many other options since it exempts the largest number of domestic facilities of any option. The relative ranking of options that offer exemptions will be affected by the total number of facilities exempted and the breadth of the supply chain these facilities cross. This intrastate exclusion would affect many different facility types throughout the supply chain, including approximately 91,383 domestic manufacturers, wholesalers, and warehouses. In addition, many facilities involved only in intrastate commerce handle food products that eventually will be introduced into interstate commerce farther along the supply chain. While intrastate facilities are likely to be small, if they are participants in the chain of custody of the food that causes a major outbreak, their exclusion could disrupt FDA's ability to identify the source of an outbreak and limit its effects. The overall ranking of this option is behind option 10.

Option 7, same as option 4 except mixed-type facilities that engage in farming are excluded: There are fewer exempted facilities in this option, owned by approximately 24,397 domestic firms, than in option 6. Furthermore, these exempt firms are mixed-type facilities that engage in farming and would be closer to the beginning of the chain of custody for food products. FDA considers this option to have lower benefits than option 5, since fewer facilities would be required to keep records that may be needed for a traceback investigation, but higher benefits than options 6 and 10–12, since fewer facilities would be exempt and especially since these facilities are closer to the beginning of the supply chain.

Option 8, same as option 4 except there is a universal records-retention requirement of 1 year for perishables and all other products: All other things being equal, the shorter the retention time for records, the more likely that those records would be missing when needed for a trace-back investigation. Most nonperishable products and perishable products that are processed into finished food products may be in the supply chain for longer than a year, but it is very likely that the effects of a contamination of nonperishable goods would be seen within a year of being introduced in the market. FDA considers this option to have higher benefits than options 6 and 7, and higher benefits than the other exemptions offered in options 10–12. Option 8 is ranked lower than option 9 because of the nonzero probability that a nonperishable food is adulterated and that adulteration is not discovered until more than a year after the event.

Option 9, same as option 4 except there is a universal records-retention requirement of 2 years for perishables and all other products: Once again, all other things being equal, the longer the record retention the better, so this option probably has more benefits than option 2. While option 9 has the benefit of simplicity in that there is only one retention requirement for all records, in practical terms the danger from a perishable good will be known soon after that good is consumed. Consequently, keeping records longer than one year for perishable goods that are consumed in an unaltered state would most likely exceed the time period of many tracing investigations. Therefore, based on the ability to conduct a thorough investigation, FDA ranks the benefits of this option as roughly equal to option 4, especially since the longer records-retention requirement should not affect the speed of an investigation.

Option 10, same as option 4 except that foreign coverage is the same as for the registration proposed rule: The proposed option would generate more benefits than other options that exempt foreign facilities. Since the foreign coverage is progressively lower for options 10, 11, and 12, the benefits also decrease for those options accordingly. However, the benefit from improved recordkeeping practices by a given set of facilities also depends on the amount of food produced by those facilities. Because imported food accounts for a small percentage of total domestic food consumption, the average amount of domestically consumed food from foreign facilities is smaller than that from domestic facilities. Under this option, the reduction in the number of foreign facilities that are covered is proportionally greater than the reduction in the amount of food covered. As a result, the incremental reduction in potential costs caused by the exemption of foreign facilities should be larger than the incremental reduction in benefits. The exemption of foreign facilities under this option

would likely hamper trace-back capability by less than an exemption of the same number of domestic facilities.

Moreover, option 10 has the added benefit of simplicity in that the foreign coverage would be the same as that covered under the registration rule. This parallel coverage to the registration rule would make monitoring both recordkeeping and registration practices less costly.

Option 11, same as option 4 except that foreign coverage includes only the final holders before export: In addition to the exemptions in option 10, this option exempts an additional single category in the middle of the foreign supply chain and with a large number of facilities. Consequently, the benefits under this option are lower than under option 10 by both the speed criterion and the thorough investigation criterion. However, as we explained in the discussion of option 10, the proportionally smaller importance of imported foods in the domestic food supply implies that the exemption should have relatively little effect on benefits.

Option 12, same as option 4 except that all foreign facilities are excluded: This option exempts all foreign suppliers from record-keeping requirements. When compared to options 10 and 11, the number of foreign firms covered under this option is the lowest. As such, the benefits of this option, when compared to the other two, are the lowest as well using both the speed criterion and the ability to conduct a thorough investigation.

Option 13, comprehensive coverage that requires facilities to be able to tie specific input ingredients to specific products: This option generates the highest benefits. A complete list of the specific source of all ingredients would be available for all processed and raw foods, greatly aiding traceback and trace forward investigations. In addtion, of all the options, this would allow investigators to most quickly identify candidate traceback facilities, since it would allow FDA to effectively narrow our search to specific entities.

Table 38 of this document presents the overall ranking of each option based on the previous summary. Option 13, requiring input ingredients to be connected to output ingredients through records, has the highest absolute benefits, followed by option 2. The lowest ranked option in terms of absolute benefits is the baseline, option 1, and the lowest benefits of the possible interventions would be the proposed rule with a complete foreign facility exemption, due to the large number of foreign facilities where adulteration might occur. FDA requests comments on this ranking.

TABLE 38.—RANKING OF EFFECTIVENESS OF EACH MECHANISM UNDER EACH OPTION

Option:	Benefit 1	Benefit 2	Overall Ranking
1) No action	13	13	13
2) 4 or 8 hour records access	2	2	2
3) Outer packaging exemption	3	3	3
4) Exclude recordkeeping on outer packaging	3	3	3
5) 24-hour records access	7	9	8
6) Intrastate exemption	10	10	10
7) Mixed-type facilities that engage in farming	5	5	5
8) 1-year record retention	7	7	7
9) 2-year record retention	6	6	6
10) Proposed. Same foreign coverage as Registration	8	8	8
11) Cover only final foreign holders	11	11	11
12) Exempt all foreign suppliers	12	12	12
13) Input to output requirement	1	1	1

B. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

Impact per firm: We define small as employing fewer than 500 full-time-equivalent workers. The SBA uses several criteria for identifying a small firm based on its NAICS code, but having less than 500 employees is the most common SBA small definition in the food industry (Ref. 31). We also consider two definitions of very small: Less than 20 employees and less than 10 employees. The great majority of firms are considered small when classified by any of these definitions. Table 39 presents the percent of firms in each of these categories. Not included in this table are farm numbers. We calculated farm percentages using the Agricultural census through the NASS, but the Agricultural census only classifies farm size by sales and acreage, not by the number of employees (Ref. 19). Fifty percent of farms have less than $10,000 in annual sales. Neither SBA definitions nor employee data exist for exclusive food importers; we assume that the percentage of small firms in this category is similar to the percentage in other food categories. We do not include foreign firms in this analysis because the Regulatory Flexibility Act does not

apply to foreign entities. It is clear from Table 39 of this document that any provision in this regulation that takes the size of the facility into account would cover a significant percent of food businesses.

TABLE 39.—PERCENTAGE OF SMALL AND VERY SMALL FIRMS

Type	< 500 Employees	< 20 Employees	< 10 Employees
Manufacturers	98.0%	85.3%	77.0%
Wholesalers/Warehouses	99.3%	89.4%	82.2%
Packaging[1]	98.6%	87.0%	78.7%
Transporter/Packers	99.5%	94.8%	89.5%
Grocery and other Retail	99.7%	93.9%	87.8%
Convenience Stores	99.6%	88.9%	73.1%
Mixed-Type Facilities that Have Farms	—	—	—
Importers	—	—	—

[1] Includes both outer packaging and food contact substances.

In Tables 40 and 41 of this document, FDA presents the average and maximum possible burden placed on each small and very small firm following the adoption of the final rule. We explain these costs in detail in the preliminary regulatory impact analysis. Costs fall into four categories: learning about the regulation, redesigning records to accommodate new information, collecting and maintaining new information, and planning for a rapid response in the event of a records request from FDA under this authority. The average mean startup costs reported in the table are approximately $888, and the average mean recurring costs reported in the table are approximately $222. Based on our assumptions, average maximum startup costs are approximately $2569 and the average maximum recurring costs reported in the table are $521. We also acknowledge considerable nonquantifiable uncertainty in these estimates, so the true burden of the regulation on small businesses could be higher or lower.

The estimated burden on convenience stores is lower since: (1) We assume that most convenience stores will depend on either a corporate parent or other facility in the supply chain for document redesign, and (2) only a small percentage of convenience stores sales (11.4 percent according to a comment received through FDA's early outreach) is for food products, so the volume of food products for which they would have to collect information and prepare access is relatively small. Transporters and Packing firm costs are larger since we assume that transporting firms would not be able to share records redesign costs with firms up or down the supply chain. We also assumed that packaging producers and distributors would have to maintain relatively less additional information since not all of their products will be used to pack food. In subsequent years, all firms will only incur the additional records maintenance burden.

TABLE 40.—AVERAGE STARTUP AND RECURRING COSTS PER FIRM

Cost	Transporter/ Packer	Convenience Store	Packaging[1]	Other
Startup				
Learning	$120	$120	$120	$120
Redesign	$1,211	$121	$606	$606
Access Preparation	$151	$75	$151	$151
Total Startup	$1,482	$317	$876	$876
Recurring				
Additional Records Maintenance	$326	$63	$163	$326

[1] Includes both outer packaging and food contact substances.

The maximum first year costs per firm are calculated using the following assumptions: First, a firm may not have Internet access, so it may have a 5 1/2 hour learning burden. Next, a firm may incur the largest value in the distribution of redesign costs, and may not be able to share the redesign burden with other facilities. Finally, the firm may not receive records with any additional information previously collected that is required in this proposed rule. Thus they may incur the entire burden of additional records maintenance. We assume access preparation costs do not vary.

TABLE 41.—MAXIMUM STARTUP AND RECURRING COSTS PER FIRM

Cost	Transporter/ Packer	Convenience Store	Packaging[1]	Other
Startup				
Learning	$138	$138	$138	$138
Redesign	$2,299	$2,299	$2,299	$2,299
Access Preparation	$151	$75	$151	$151
Total Startup	$2,588	$2,512	$2,588	$2,588
Recurring				
Additional Records Maintenance	$653	$126	$653	$653

[1] Includes both outer packaging and food contact substances.

In order to get a rough estimate of the impact of higher recordkeeping costs on small businesses, we ran the small business simulation model that was developed by FDA's contractor, RTI International (Ref. 31), for the candy and ready-to-eat food sectors. In the simulation, we used the high annual costs of the second year per-firm recordkeeping costs (about $850) to see the impact on revenues and cash flow. The results from the simulation indicate that when firm size (by number of employees) is assumed to be normally distributed, the recordkeeping costs in the second year would result in pre-tax costs being greater than cash flow for 0.1 percent of firms with fewer than 20 employees in the candy industry. For the ready-to-eat sector, the results indicate that the high second year per-firm recordkeeping costs would not result in pre-tax costs being greater than cash flow for any firms.

Additional flexibility considered: Agencies can consider three basic small business regulatory options: First, if the implementing statute allows, an agency could exempt small businesses from all regulatory requirements. In addition, an agency could modify the regulatory requirements for small businesses, including offering an exemption from part of the regulation. Finally, an agency could specify a longer effective compliance date for small businesses. In this proposed rule, FDA considers each of these possibilities. We designed several provisions to lower the impact on small firms, some of which apply to small firms exclusively, and some of which apply to all firms.

First, FDA proposes a staggered effective compliance date for this regulation. The compliance dates are the following: 6 months for large firms, 12 months for small firms, defined as having less than 500 but more than 10 full-time equivalent employees, and 18 months for very small firms, defined as having 10 or fewer full-time equivalent employees. Only one of the cost estimates we explained in detail in the preliminary regulatory impact analysis directly depends on the compliance date; records redesign cost. We estimated using the FDA Label Cost Model that very small firms would save an average of 10 percent in their redesign costs by having longer than a year to comply. The medium 1-year redesign cost estimate is $1,309 per redesign. We assume this cost is shared between two firms, since a single set of records can serve as source, recipient, and transport records. The average redesign cost per firm is $655 for firm types other than transporters and convenience stores. The median 18-month redesign cost estimate is $1,190 per redesign, for an average cost of $595 per firm. The estimated medium redesign burden would drop by $60 per firm, or 8 percent of the estimated average first startup burden of the regulation. Also, present value considerations will result in reduced future cost estimates. Thus, the later compliance dates specified in the proposed rule will reduce the total cost for all small firms. FDA requests comments regarding these assumptions.

In addition, FDA is proposing to describe the specific information a covered entity must keep, but not specify the form or type of system in which those records must be maintained, which will allow firms to comply with the regulation in a manner that is cost effective. Mandated structural changes to records or required retention technology probably would not be the most cost effective solution for every firm, so not specifying the form or type of system in which the records must be maintained almost certainly would impose a smaller burden on industry, including small businesses. Comments to FDA's preliminary outreach generally agreed with this position. FDA believes that describing the specific information a covered entity must keep, but not specifying the form or type of system in which those records must be maintained is the most flexible means of proposing this regulation for all businesses. However, FDA also believes that each provision in this proposed rule is necessary to tracing investigations, so we do not propose any additional flexibility for small or very small businesses.

Finally, FDA is proposing several exemptions based on facility type. Since the majority of facilities of each type are small businesses, these exemptions will reduce the small business burden of this regulation. In the proposed rule, FDA exempts retail facilities from having to maintain records of final consumers who purchase retail food products. Requiring firms to collect and maintain consumer information would increase the burden on retail facilities by at least the amount of the current redesign burden and current additional records maintenance burden summarized in Table 40 of this document. Without this exemption, retail firms (including small retail firms) would have to design and maintain an entirely new recordkeeping system.

Most other small business exemptions are infeasible for this regulation because we believe records held by these businesses are an important link in the chain of custody for the food products. As shown in Table 39 of this document, a large percentage of the food industry would be exempt under any blanket small business exemption. Even nonemployee businesses (who have no paid employees, the smallest exemption possible) still constitute a substantial proportion of the food industry. Any type of exemption in the middle of the

supply chain very likely would make records unavailable and therefore would break the chain of custody of many products during tracing investigations.

The Bioterrorism Act exempts farms and restaurants. Because most farms and restaurants are small businesses, this exemption provides regulatory relief to small entities. In addition, in this proposed rule the term ''farm'' includes facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; ''farm'' also includes facilities that manufacture or process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. Most of these facilities are small entities. The statutory exemptions provide considerable relief to small entities without compromising the purpose of the recordkeeping regulation. FDA will continue to conduct research regarding possible further exemptions, and requests comments regarding possible exemptions that would provide additional relief for small businesses while still accomplishing the goals of the Bioterrorism Act.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112,300,000. FDA has determined that this proposed rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates are fulfilled in the Executive Order 12866 analysis, above. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future costs: The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after the proposed rule would become final. These costs would be incurred by domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food, and the foreign facilities that are subject to this proposed rule (foreign manufacturers, processors, packers, and holders of food that would be required to register).

Recurring costs from collecting new information would be incurred in each future year. The estimates of these costs were modeled using the previous analysis of the juice HAACP regulation as a frame of reference. An hourly burden of 30 minutes a week was used for the additional monitoring and recordkeeping that would be required from this proposed rule. This hourly burden estimate was modified for foreign facilities and convenience stores to allow for structural differences assumed in their operations. For a fuller illustration of the future costs of the proposed rule, see Table 20 of this document.

TABLE 42.—FUTURE COSTS

	Mean	Low	High
Year 3 and later years	$221,130,000	$212,313,000	$229,680,000

Particular regions, communities, or industrial sectors: The costs of the recordkeeping requirement will be shared among domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, and the foreign facilities that would be subject to this proposed rule (foreign holders, packers, manufacturers, and processors that would be required to register) as well as domestic consumers. The higher costs incurred by domestic and foreign suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Since consumer demand for food is highly inelastic almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental or deliberate contamination of food.

National productivity, economic growth, job creation, and full employment: Although this proposed regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports: This proposed rule would require additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs would increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of U.S. exports could reduce the quantity of U.S. exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the proposed rule (option 10, described above), the increases in the price of U.S. exports (and resulting decreases in quantity demanded) would be quite small.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that

this proposed rule, when final, will be a major rule for the purpose of congressional review.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information would have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping and Records Access Requirements for Food Facilities

Description: The Bioterrorism Act contains a provision authorizing the Secretary to develop regulations requiring food facilities that manufacture, process, pack, hold, receive, distribute, transport, or import food to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, animal food, or food ingredients. Records for nontransporters must include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and the way that it is packaged, and the receipt and shipping dates. Records for transporters must include similar information about the food or food packaging, sources, and recipients, identification of all modes of transportation, and responsible individuals, while the food or food packaging is in the custody of the transporter.

Description of Respondents: Facilities that manufacture, process, pack, hold, receive, distribute, transport, or import food are required to establish and maintain records, including facilities in both interstate and intrastate commerce. Foreign manufacturers, processors, packers, and holders of food that would be required to register are required to maintain records if they ship food to the United States.

Burden: FDA estimates that the paperwork burden of this rule will be incurred by the number and types of firms and facilities listed in Table 43 of this document. FDA assumes that, approximately 841,000 facilities owned by approximately 646,000 firms would be covered. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food, and the foreign facilities that manufacture, process, package, or hold food destined for consumption or use in the United States that would be required to register. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

TABLE 43.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Firm Estimate
Manufacturers	43,376	36,948
Wholesalers/Warehouses	95,745	76,952
Packaging[1]	36,907	34,633
Transporters/Packers	16,773	15,171
Retail Grocery and Specialty Food	207,657	153,277
Convenience Stores	128,985	68,866
Mixed-Type Facilities That Have Farms	30,497	24,397
Importers	18,902	15,122
Total Domestic	578,842	425,366
Final Holders	77,427	61,942
De minimus Processors/Packagers	22,600	18,080
Manufacturers	125,450	106,858
Other Facility Types		
Total Foreign	225,477	186,879

[1] Including outer packaging and food contact substances.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. The burden for § 1.361 is associated with planning for and executing an FDA request for records. Because it is difficult to estimate with any degree of precision the burden incurred from executing a records access request, we only compute the burden for firms to prepare for a potential records access request from FDA.

The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the proposed rule entitled ''Registration of Food Facilities'' (68 FR 5378, February 3, 2003). The learning burden presented in Table 44 of this document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following enactment of the final rule.

The records redesign burden presented in Table 44 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

The records access preparation burden presented in Table 44 of this document reflects the burden of preparing a plan for modifying current business practices in order to be able to respond to an FDA records request in the 4-hour or 8-hour required timeframe. The estimate of the records access planning burden is a one-time burden that would be incurred in the first and second years following enactment of the final rule. We assume that this burden will be incurred by each facility.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the proposed rule. The burden from this activity is reported in table 45 of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning and records access preparation in each subsequent year following enactment of the final rule. These burdens for new firms are reported in table 44 of this document.

TABLE 44.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—ONE-TIME BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352, (Learning)	804,319	1	804,319	6.853		5,512,000
1.337, 1.345, and 1.352, (Redesign)	278,858	1	278,858	29.607	$130,582,000	8,256,000
1.361 (Access Preparation)	552,630	1	552,630	5.626		3,109,000
Total						16,877,000

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 45.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (Additional Records Maintenance)	772,410	1	772,410	10.625	8,207,000
1.337, 1.345, and 1.352, (Learning for New Firms)	80,432	1	80,432	6.853	551,000
1.361 (Access Preparation for New Firms)	55,263	1	55,263	5.626	311,000
Total					9,069,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see **ADDRESSES**).

V. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the

heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, ''Implementation of the North American Free Trade Agreement'' (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended ''[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.'' In order to meet these objectives, section 306 of the act requires FDA to propose and issue final regulations requiring the establishment and maintenance of records within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. This expedited timeframe reflects the urgency of the U.S. Government's need to prepare to respond to bioterrorism and other food-related emergencies. Accordingly, FDA has concluded that the urgency of this matter is sufficient justification for shortening the public comment period for this proposal to 60 days, consistent with Executive Order 12889.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's December 12, 2003, deadline.

VIII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1 and 11 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart J is added to part 1 to read as follows:

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

Sec.

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

Requirements to Establish and Maintain Records to Trace the Transportation of All Food

General Requirements

Effective Dates

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

§ 1.326 Who is subject to this subpart?

(a) Domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for consumption in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. In addition, foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are subject to these regulations, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the regulations in this subpart;

(b) Restaurants are excluded from all of the regulations in this subpart;

(c) Fishing vessels including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel are excluded from all of the regulations in this subpart, except § 1.361 and § 1.363. However, those fishing vessels otherwise engaged in processing fish, which for purposes of this subsection means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding, are subject to all of the regulations in this subpart;

(d)(1) All retail facilities are excluded from § 1.345 of this subpart;

(2) Retail facilities that employ 10 or fewer full-time equivalent employees that:

(i) Are located in the same general physical location as a farm; and

(ii) Sell unprocessed food grown or raised on that farm or on another farm located in the same general physical location are excluded from all of the regulations in this subpart, except § 1.361 and § 1.363, with respect to that unprocessed food.

(e) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is within the exclusive jurisdiction of the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the regulations in this subpart with respect to that food.

(f) Foreign facilities are excluded from all the regulations in this subpart, if food from such facilities undergoes further manufacturing/processing (including packaging) by another foreign facility outside the United States. This exclusion does not apply to a foreign facility if the further manufacturing/processing (including packaging) conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import pet food who are not subject to the recordkeeping provisions of the animal proteins prohibited in ruminant feed regulation (§ 589.2000 of this chapter) are, with respect to pet food records, excluded from all the regulations in this subpart except for § 1.361 and § 1.363.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart.

In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Domestic person means any person located in any State or Territory of the

United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Farm means a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both. The term ''farm'' includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown or raised on that farm or is consumed on that farm; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to: Fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Foreign facility means a facility other than a domestic person that manufactures/processes, packs, or holds food for consumption in the United States.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples include, but are not limited to: Cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nontransporter means a person who owns food or who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had an article of food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires an article of food from another nontransporter.

Perishable food means food that is 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.

Pet food means food for nonfood-producing animals.

Recipe means the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. Restaurants include, but are not limited to, cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens. Facilities that provide food to interstate conveyances, rather than directly to consumers, are not restaurants.

Retail facility means a facility that sells food products directly to consumers only. The term includes, but is not limited to, grocery and convenience stores, vending machine locations, and commissaries.

Transporter means 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.

Transporter's immediate previous source means a person from whom a transporter received an article of food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered an article of food. This recipient can be either another transporter or a nontransporter.

You means a person or facility subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart 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.

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Source of All Food

§ 1.337 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate previous source?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive. Your records must include information reasonably available to you to identify the specific source of each ingredient that was used to make every lot of finished product.

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) The lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and

(6) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food to you.

Requirements to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipient of All Food

§ 1.345 What information is required in the records you must establish and maintain to identify the nontransporter and transporter immediate subsequent recipient?

(a) If you are a nontransporter, you must establish and maintain the

following records for all food you release:

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date the food was released;

(4) The lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle); and

(6) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food from you.

(b) [Reserved]

Requirements to Establish and Maintain Records to Trace the Transportation of All Food

§ 1.351 Who is required to establish and maintain records for tracing the transportation of all food?

If you are a domestic person and you are a transporter of food, you are required to establish and maintain records containing information not only about your transportation activities but also about the person from whom you received the food (the transporter's immediate previous source) and the person to whom you delivered it (the transporter's immediate subsequent recipient), as specified in § 1.352.

§ 1.352 What information is required in the transportation records?

(a) You must establish and maintain the following records for each food you transport:

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately before you, and the date you received it from that person;

(2) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately after you, and the date you delivered it to that person;

(3) An adequate description of the type of food, including brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(4) The lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle);

(6) Identification of each and every mode of transportation (e.g., company truck, private carrier, rail, air, etc.), and the individual responsible, from the time you first received the food until the time you delivered it.

(b) [Reserved]

General Requirements

§ 1.360 What are the record retention requirements?

(a) You must create the required records at the time the activity occurs.

(b) You must retain for 1 year after the date the records were created all required records for perishable foods not intended for processing into nonperishable foods.

(c) You must retain for 2 years after the date the records were created all required records for all other foods, except animal foods.

(d) You must retain for 1 year after the date the records were created all required records for animal food, including pet food.

(e) You must retain all records required by these regulations at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(f) The maintenance of electronic records is acceptable.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act must be readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within 8 hours of a request if made at any other time, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice. If records and other information are stored offsite, the records must be retrieved and provided onsite within the specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA?

(a) The failure to establish or maintain records as required by section 414(b) of the act or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act (21 U.S.C. 331).

(b) The failure to make records or other information available to FDA as required by section 414 or 704(a) of the act is a prohibited act under section 301 of the act.

Effective Dates

§ 1.368 What are the compliance dates for this subpart?

(a) The regulations in this subpart shall be effective 6 months after the date of publication of the final rule in the **Federal Register**. However, this subpart is not binding on small and very small businesses until the dates listed in paragraphs (a)(1) and (a)(2) of this section.

(1) The regulations in this subpart are binding 12 months after the date of publication of the final rule in the **Federal Register**, for small businesses employing fewer than 500 but more than 10 full-time equivalent employees.

(2) The regulations are binding 18 months after the date of publication of the final rule in the **Federal Register**, for very small businesses that employ 10 or fewer full-time equivalent employees.

(b) [Reserved]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

4. Section 11.1 is amended to add paragraph (f) to read as follows:

§ 11.1 Scope.

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of Part 1, Subpart J of this chapter but that are also required under other applicable statutory provisions or regulations remain subject to this part.

Dated: May 1, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: May 2, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

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