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MEMORANDUM

December 7, 2004

BY ELECTRONIC MAIL

FROM: Olsson, Frank and Weeda, P.C.

RE: FDA Final Rule – Establishment, Maintenance, and Availability of Records
Under § 306 of the Bioterrorism Act

The Food and Drug Administration (FDA) has issued a final rule implementing section 306 (establishment, maintenance, and availability of records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). 69 Fed. Reg. _____ (December 9, 2004). This is the last of four rulemakings implementing the Bioterrorism Act.¹

FDA also has issued a fact sheet on the final rule and a draft guidance document regarding how the agency intends to exercise its authority to access the required records (copies attached). In addition, FDA has published a notice announcing that it will hold four public meetings around the country in January and February 2005 to discuss the final rule. Copies of the final rule, fact sheet, draft guidance, and notice of public meeting are available on FDA's website at: <http://www.cfsan.fda.gov/~news/whatsnew.html>. FDA plans additional outreach activities, which will be announced on FDA's website (<http://www.fda.gov/oc/bioterrorism/bioact.html>).

The final rule requires that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States (and foreign persons that transport food in the United States), unless they qualify for an exclusion, must establish and maintain records sufficient to identify the immediate previous sources and immediate subsequent recipients of such food. The final rule also requires that these records be made

¹ FDA has issued interim final rules implementing §§ 305 (registration of food facilities) and 307 (prior notice of food imports) of the Bioterrorism Act, and expects to issue final rules by June 2005.

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available to FDA for inspection and copying when the agency 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.

The purpose of the rule is to give FDA the information it needs to conduct an efficient and effective tracing investigation in the event of a food emergency. For example, if FDA determines that an outbreak of foodborne illness was caused by a particular ingredient in a food, the rule enables FDA to trace back to the source of the contaminated ingredient and trace forward to other recipients of that ingredient.

This memorandum summarizes the final rule.

Summary of the Final Rule

The key features of the final rule are:

Scope

- The final rule applies to the following:
 - Domestic persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States, unless they qualify for exclusion; and
 - Foreign persons who transport food in the United States, unless they qualify for exclusion.

Exclusions

- The following are excluded from all requirements of the final rule, including both recordkeeping and records access requirements:
 - Farms;
 - Restaurants;
 - Foreign persons, except for foreign persons who transport food in the United States;
 - Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food within the exclusive jurisdiction of the U.S. Department of Agriculture;
 - Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption; and
 - Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food packaging (*i.e.*, the outer packaging of food that does not contact the food, and therefore is not a food contact substance).

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- Persons who distribute food directly to consumers are not required to maintain records of the immediate subsequent recipients of such food (*i.e.*, the consumers to whom they sell food).
- The following are exempt from the final rule's recordkeeping requirements, but are subject to its records access requirements²:
 - Retail food establishments that employ 10 or fewer full-time equivalent employees;
 - Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances;
 - Fishing vessels that do not engage in processing; and
 - Nonprofit food establishments.

Required Records

- "Nontransporters" (*i.e.*, persons who own food, or hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation) must maintain the following records for food that they receive:
 - Records sufficient to identify the nontransporter immediate previous source, domestic or foreign, and the transporter immediate previous source of the food including name of firm, address, telephone number, and (if available) fax number and E-mail address;
 - An adequate description of the type of food, including brand name and specific variety;
 - The date the food was received;
 - For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent such information exists); and
 - The quantity of food and how it is packaged.
- "Nontransporters" must maintain the following records for food that they release:
 - Records sufficient to identify the nontransporter immediate subsequent recipient, domestic or foreign, and the transporter immediate subsequent recipient of the food,

² While not clear, if a person is subject to records access but is not subject to the rule's recordkeeping requirements, FDA would seek access to records of the type that are likely to contain information about immediate previous sources and immediate subsequent recipients. The FD&C Act limits the records that FDA may have access to.

- including name of firm, address, telephone number, and (if available) fax number and E-mail address;
 - An adequate description of the type of food, including brand name and specific variety;
 - The date the food was released;
 - For persons who manufacture, process, or pack food, the lot or code number or other identifier (to the extent such information exists);
 - The quantity of food and how it is packaged; and
 - Information “reasonably available” that identifies the specific source of each ingredient to each lot of finished product.
- “Transporters” (*i.e.*, persons who have possession, custody, or control of food in the United States for the sole purpose of transporting such food) must maintain records for each food they transport in the United States, using one of five recordkeeping alternatives.

Records Access

- Records must be made available to FDA for inspection and copying “as soon as possible” but not more than 24 hours after receiving an official request from FDA.
- FDA intends to exercise its new records access authority when it has “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals,” and the records are needed in making such a determination.

Compliance Dates

- For very small businesses (having 10 or fewer full-time equivalent employees), 24 months after publication of the final rule, (*i.e.*, December 9, 2006).
- For small businesses (having more than 10, but fewer than 500 full-time equivalent employees), 18 months after publication of the final rule, (*i.e.*, June 9, 2006).
- For all other businesses, 12 months after publication of the final rule, (*i.e.*, December 9, 2005).

Major Changes From the Proposed Rule

This final rule differs from the proposed rule published by FDA in May 2003 in several ways. The principal changes include the following:

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- The final rule does not apply to foreign persons, except foreign persons who transport food in the United States.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the final rule's records access requirements with respect to the packaging of such food (*i.e.*, the outer packaging that does not contact the food).
- The requirement to maintain the name of a responsible individual has been deleted from the recordkeeping requirements.
- The requirement to maintain an article of food's lot or code number has been deleted, except for persons who manufacture, process, or pack food. It is no longer required for distributors, transporters, or retailers.
- The timeframe in which records must be made available to FDA upon request has been extended to a maximum of 24 hours after receiving an official request.
- The compliance date for the final rule has been extended to 12 months after publication of the final rule (18 months for small businesses, and 24 months for very small businesses).

Who Is Subject to the Final Rule?

The final rule applies to the following:

- Domestic persons that manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States, unless they qualify for exclusion. The definition of "person" includes an individual, partnership, corporation, or association. The United States includes any State or Territory, the District of Columbia, and Puerto Rico. It is not necessary that the food be intended for consumption in the United States. The final rule applies to foods intended for export from the United States.
- Foreign persons that transport food in the United States, unless they qualify for exclusion.

The final rule defines "food" as it is defined in Section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(f)). This is a very broad definition that includes, for example: shell eggs; raw agricultural commodities for use as food; animal feed, including pet food; food and feed ingredients and additives; dietary supplements and dietary ingredients; beverages, including alcoholic beverages and bottled water; live food animals; and substances that migrate into

food from the container or other articles that contact food. Although the definition of “food” includes food contact substances, persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances are not subject to the rule’s recordkeeping requirements; they are subject to its records access requirements.

Persons subject to the rule must retain the required records even if the food does not enter interstate commerce. However, the recordkeeping requirements do not apply to food samples used for quality assurance, research, or analysis purposes only and not for human or animal consumption. Food samples are considered to be for quality assurance, research, or analysis when they are in small quantities and the entire sample is used up by the analysis, destroyed after analysis, or destroyed within a reasonable time after analysis. Evidence that a sample is for quality assurance, research, or analysis purposes only might include markings on the food and shipping documents.

Who Is Excluded from the Final Rule?

The final rule provides for both total and partial exclusions. The following are excluded from all requirements, both the recordkeeping and records access requirements, of the final rule:

- Farms

The final rule defines a “farm” as “a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both.” Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. In addition, certain activities, such as applying pesticides to crops or transporting crops from the field, are considered part of growing and harvesting.

The definition of “farm” includes: (1) facilities that pack or hold food (*e.g.*, sorting, grading, wrapping, or boxing of harvested crops for the sole purpose of transporting it off the farm; placing stickers on produce), provided that all such food is grown, raised or consumed on that farm or another farm under the same ownership; and (2) facilities that manufactures/process food (*e.g.*, waxing, milling, grinding), provided that all food used in such activities is consumed on that farm or another farm under the same ownership. However, a facility that grows crops and/or raises animals and manufacture/processes food that is sold for consumption off the facility does not qualify for this exclusion.

A facility that packs crops grown at another location owned by someone else would therefore lose its exclusion from the recordkeeping and records access requirements, and would have to develop and maintain required records.

- Restaurants

The final rule defines “restaurant” as “a facility that prepares and sells food directly to consumers for immediate consumption.” Food is “for immediate consumption” when it is capable of being eaten immediately with no further preparation. Examples of “restaurants” include cafeterias, lunchrooms, cafes, fast food establishments, food stands, taverns, bars, catering facilities, and hospital kitchens.³ The term “restaurant” also encompasses pet shelters, kennels, and other facilities that provide food directly to animals. It does not include facilities that provide food to interstate conveyances (*e.g.*, airplanes, passenger trains, cruise ships), central kitchens, or similar facilities that do not prepare and serve food directly to consumers.

A combination restaurant/retail facility (*e.g.*, a restaurant with a gift shop) is also excluded from the final rule, provided its sales of food it prepares and sells to consumers for immediate consumption make up more than 90 percent of its total food sales. Thus, a bakery, deli, or confectioner qualifies as a restaurant if sales of food it prepares and sells to consumers for immediate consumption account for more than 90 percent of its total food sales.

- 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 (USDA) are excluded with respect to such food while it is under the exclusive jurisdiction of USDA. However, persons who manufacture, process, pack, transport, distribute, receive, hold, or import food that is jointly regulated by FDA and USDA (*e.g.*, TV dinners containing both meat and non-meat components) are required to keep records with regard to food regulated by FDA.
- Foreign persons, except foreign persons that transport food in the United States.⁴
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption.

³ Although not specifically mentioned by FDA in the preamble to the final rule, school cafeterias appear to qualify for this exclusion.

⁴ A foreign person that conducts other covered activities in the United States (*e.g.*, a subsidiary of a foreign corporation that manufactures, processes, packs, distributes, receives, holds, or imports food in the U.S.) is subject to the final rule.

- Persons who receive or hold food on behalf of specific individual consumers and who are not parties to the transaction and who are not in the business of distributing food. The exclusion would apply to a hotel concierge, a reception desk in an apartment building, or an office complex that receives bottled water.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food packaging only (and do not engage in any covered activities with respect to food). “Packaging” is defined as the outer packaging of food that bears the label and does not contact the food; it does not include food contact substances.

The following are excluded from certain, but not all, requirements of the final rule:

- Persons who distribute food directly to consumers are excluded from the requirement to maintain records identifying the immediate subsequent recipients of such food. This exclusion applies to retailers, direct marketers of food products, and any other persons who distribute food directly to consumers. The term “consumers” does not include businesses. Thus, a retailer that sells food to both consumers and businesses (*e.g.*, a warehouse club or “cash-and-carry” operation) is not required to maintain records of immediate subsequent recipients for its sales of food products to consumers. This exclusion applies also to sales of bagged feed, pet food, and feed ingredients/additives directly to consumers for their own animals, unless the feed is for animals that will be sold as human food. If the feed will be fed to food-producing animals, the purchaser is considered to be a business, not a consumer.
- Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in the final rule. However, they are only required to maintain records of immediate subsequent recipients that are not consumers to the extent such information is “reasonably available.” A “retail food establishment” is defined as “an establishment that sells food products directly to consumers as its primary function.” An establishment’s primary function is to sell food directly to consumers if the annual monetary value of sales of food directly to consumers exceeds the annual monetary value of sales of food to all other buyers. A retail food establishment may engage in manufacturing/processing, packing, or holding food as long as its primary function is selling food directly to consumers. The term “consumers” does not include businesses. Thus, for example, a warehouse club or “cash-and-carry” store that sells food products directly to consumers as its primary function is required to maintain records of immediate subsequent recipients for its sales of

food products to businesses only to the extent that such information is reasonably available (*e.g.*, when the purchaser has an existing commercial account to which food purchases are charged in an identifiable manner). The retail food establishment is not expected to ask each purchaser whether they are a consumer or business.

- Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from the recordkeeping requirements of the final rule, but are subject to its records access requirements. This exclusion is based on the number of full-time equivalent employees at each retail food establishment, not at the entire company (which may own many retail stores). The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees by the number of hours of work in one year -- 2,080 hours.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the records access requirements of the final rule with respect to such food's packaging. However, they are not required to keep records of immediate previous sources or immediate subsequent recipients of such packaging. "Packaging" is defined as the outer packaging of food that bears the label and does not contact the food; it does not include food contact substances.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import finished containers that directly contact food are not subject to the final rule's recordkeeping requirements, but are subject to its records access requirements, with respect to such containers. However, persons who place food directly in contact with its finished container are subject to all the requirements of the final rule with respect to the finished container.
- Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances (as distinct from "packaging") other than the finished container that directly contacts food are not subject to the final rule's recordkeeping requirements, but are subject to its records access requirements.
- Fishing vessels that do not engage in processing are excluded from the recordkeeping requirements of the final rule, but are subject to the records access requirements. Practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel are not considered "processing." If the fishing vessel is exempt from Hazard Analysis Critical

Control Point regulations under 21 C.F.R. Part 123, it is exempt from the recordkeeping requirements of this final rule.

- Nonprofit food establishments that are tax-exempt under § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to consumers or otherwise provide food or meals for consumption by humans or animals (*e.g.*, food banks, soup kitchens, food delivery services) are excluded from the recordkeeping requirements, but are subject to the records access requirements.⁵

If an entity conducts both exempt and non-exempt activities at the same location, the entity is required to keep records only with respect to its non-exempt activities. For example, if a farm grows tomatoes and processes the tomatoes into tomato paste for sale off of the farm, then it is required to maintain records of the immediate previous sources of all ingredients used in the tomato paste (other than the tomatoes themselves) and records of the immediate subsequent recipients of the finished tomato paste product.

What Records Must Be Maintained?

Nontransporters

“Nontransporters” (*i.e.*, persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation) are required to maintain the following records:⁶

- Records sufficient to identify the nontransporter immediate previous source (*i.e.*, the last nontransporter to have the food previously), domestic or foreign, and the transporter of all foods received, including the following items of information:

⁵ In addition, FDA considers nonprofit food establishments to be “consumers” for purposes of this final rule. Therefore, grocery stores, caterers, and others that give charitable donations of food to a food bank or other nonprofit food establishment are not required to keep records of the immediate subsequent recipients of such food. A reclamation center owned by a grocery store will be considered part of the grocery store that owns it.

⁶ A person who owns food, or who manufactures, processes, packs, holds, receives, distributes, or imports food for purposes other than transportation is considered a nontransporter, even if such person also transports food. For example, a manufacturer or distributor that delivers food in its own trucks is considered a nontransporter and is only subject to the recordkeeping requirements applicable to nontransporters.

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- The name of the firm, address, telephone number, and (if available) fax number and E-mail address of the nontransporter immediate previous source, whether domestic or foreign;
 - An adequate description of the type of food, including brand name and specific variety (*e.g.*, brand X cheddar cheese, not just cheese; romaine lettuce, not just lettuce);
 - The date the food was received;
 - For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent such information exists);
 - The quantity of food and how it is packaged (*e.g.*, 25 lb carton, 1 tank load); and
 - The name of the firm, address, telephone number, and (if available) fax number and E-mail address of the transporter immediate previous source (*i.e.*, the transporter who transported the food to the nontransporter).
- Records sufficient to identify the nontransporter immediate subsequent recipient (*i.e.*, the nontransporter that acquired the food from you) and the transporter of all food released, including the following items of information:
 - The name of the firm, address, telephone number, and (if available) fax number and E-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;
 - An adequate description of the type of food, including brand name and specific variety;
 - The date the food was released;
 - For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent such information exists);
 - The quantity of food and how it is packaged;
 - The name of the firm, address, telephone number, and (if available) fax number and E-mail address of the transporter immediate subsequent recipient (*i.e.*, the transporter who transported the food from the nontransporter); and
 - Information “reasonably available to identify the specific source of each ingredient used to make every lot of finished product.”

As noted above, the requirement to retain lot numbers only applies to persons who manufacture, process, or pack food.⁷ Moreover, manufacturers, processors, and packers are required to retain lot numbers only if these already exist for the food products they send or receive.

⁷ Persons who hold or transport food are not required to maintain lot numbers. “The final rule does not require warehouse distribution facilities to track lot/code number or other identifiers.” 69 Fed. Reg. at _____. Although warehouses may engage in re-packing of food, we were advised by

The requirement to retain information that matches the specific source of each ingredient to a specific lot of finished product only applies if this information is “reasonably available.” What is “reasonably available” will depend on the particular circumstances. FDA is aware that some food processors commonly commingle ingredients, such as flour, from a number of suppliers, making it difficult or impossible to identify a specific source of ingredients to a specific lot of finished product. FDA does not intend to require that processors reconfigure their operations or use dedicated storage facilities. FDA officials have acknowledged that, in some cases, processors may be able to do no more than narrow down the number of potential sources and may not be able to identify one specific source.

Transporters

“Transporters” (*i.e.*, persons who have possession, custody, or control of food in the United States for the sole purpose of transporting the food) are required to maintain records for each food they transport in the United States, using one of the following five alternatives:⁸

1. Establishing and maintaining the following information:
 - Names of the transporter’s immediate previous source and immediate subsequent recipient;
 - Origin and destination points;
 - Date shipment received and date released;
 - Number of packages;
 - Description of freight;
 - Route of movement during the time the transporter transported the food; and
 - Transfer points through which shipment moved.
2. Establishing and maintaining records containing the following information currently required by the Department of Transportation’s Federal Motor Carrier Safety Administration of roadway interstate transporters (49 C.F.R. §§ 373.101 and 373.103) as of December 9, 2004:

FDA officials during a briefing about the final rule that distributors and warehouses that re-pack food are not required to maintain lot numbers. Direct store delivery (DSD) vendors also are not required to track lot numbers.

⁸ “Transporter” also includes a foreign person that transports food in the United States, regardless of whether the foreign person has possession, custody, or control of that food for the sole purpose of transporting it. Truck terminals and similar facilities that are part of the transportation process and merely provide a location for trucks to transfer possession, custody, or control to another entity are not subject to the rule’s recordkeeping requirements (unless possession, custody, or control of food is transferred to the terminal).

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- Names of consignor and consignee;
 - Origin and destination points;
 - Date of shipment;
 - Number of packages;
 - Description of freight;
 - Route of movement and name of each carrier participating in the transportation; and
 - Transfer points through which shipment moved.
3. Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 C.F.R. §§ 1035.1 and 1035.2) as of December 9, 2004:
- Date received;
 - Received from;
 - Consigned to;
 - Destination;
 - State of;
 - County of;
 - Route;
 - Delivering carrier;
 - Car initial;
 - Car no.;
 - Trailer initials/number;
 - Container initials/number;
 - Number of packages; and
 - Description of articles.
4. Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:
- Shipper's name and address;
 - Consignee's name and address;
 - Customs reference/status;
 - Airport of departure and destination;
 - First carrier; and
 - Description of goods.

5. Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain the information in 1, 2, 3, or 4 above. The agreement must contain the following elements:
 - The effective date;
 - Printed names and signatures of authorized officials;
 - Description of the records to be established and/or maintained;
 - Provision for the records to be maintained in compliance with this final rule (if the agreement includes maintenance of the records);
 - Acknowledgement that the nontransporter assumes legal responsibility for establishing and/or maintaining the records; and
 - Provision that, if the agreement is terminated in writing by either party, responsibility for compliance with the final rule reverts to the transporter as of the date of termination.

What Records Are Excluded?

The final rule specifically excludes the following records from its recordkeeping provisions: recipes for food, financial data, pricing data, personnel data, research data, and sales data (other than shipment data regarding sales). A “recipe” is defined as “the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product.” Because a recipe must include all three elements, a list of ingredients without quantity information and manufacturing instructions is not a recipe. Therefore, FDA has access to records regarding the ingredients used in a food product under this final rule. This includes ingredients that are not required to be declared on the label, such as incidental additives, and ingredient that may be declared using a generic term, such as spices and flavorings.

FDA notes that several statutes and the agency’s information disclosure regulations (21 C.F.R. Parts 20 and 21) govern FDA’s ability to disclose information to the public and protect trade secret and confidential information. Moreover, FDA is planning to reemphasize in instructions to agency personnel the importance of protecting trade secret and confidential information against unauthorized disclosure.

Where and In What Form Must the Records Be Maintained?

The final rule permits records to be kept in any format, provided such records contain all required information. A firm’s existing records, such as purchase orders, bills of lading, and shipping documents, may be used to satisfy this new recordkeeping requirement. The required information may be maintained in paper or electronic records. Electronic records maintained to

comply with this rule are exempt from compliance with 21 C.F.R. Part 11; however, records kept for other purposes but also used to comply with this rule, are not exempt from Part 11. FDA's intent is to have as little impact as possible on current recordkeeping practices. FDA has decided not to provide a model form that can be used to record all required information. There is no obligation to create a new record or compilation of records to house the required information, and it is not necessary to maintain all of the required information in one set of records. Abbreviations and codes may be used in required records, provided they can be readily deciphered for FDA upon request.

The final rule requires records to be kept at the establishment where the covered activities described in such records occurred (*i.e.*, onsite) or at a reasonably accessible location. Records may be stored offsite, provided they can be retrieved and made available to FDA within the timeframe specified for records access (*i.e.*, not more than 24 hours after receiving an official request)

Intra-company transfers of food are not subject to additional recordkeeping requirements. A company is required to maintain records of foods it receives and records of foods it releases; it is not required to maintain records regarding internal transfers of food under this final rule.⁹

What Is the Record Retention Period?

Required records must be created at the time the transporter or nontransporter receives food and releases food, except to the extent the required information is already contained in existing records. The record retention period depends on the perishability of the food. Records must be retained for the following periods:

- For nontransporters:
 - 6 months after the date the nontransporter receives/releases the food, for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the food is received/released;
 - 1 year after the date the nontransporter receives/releases the food, for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the food is received/released;
 - 1 year after the date the nontransporter receives/releases the food for animal food, including pet food; and

⁹ "Once the vertically integrated company receives the food and keeps information on its immediate previous sources, that vertically integrated company does not need to keep additional records until it releases the food to another person." 69 Fed. Reg. at _____.

- 2 years after the date the nontransporter receives/releases the food, for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date the food is received/released (including foods preserved by freezing, dehydration, or being placed in a hermetically sealed container).
- For transporters (or nontransporters who maintain records on behalf of a transporter):
 - 6 months after the date the transporter receives/releases the food for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives/releases such food; and
 - 1 year after the date the transporter receives/releases the food for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the transporter receives/releases the food.

These record retention requirements are consistent with the definitions for perishable, semi-perishable, and long shelf-life foods used by the National Institute of Standards and Technology (NIST).

Relationship to Other Recordkeeping Requirements

The recordkeeping requirements contained in this final rule are in addition to any other applicable recordkeeping requirements under other statutes or regulations, such as those applicable to juice, seafood, low acid canned foods, infant formula, bottled water, color additives, animal feed, and medicated animal feed.

What Are the Compliance Dates for The Final Rule?

All persons, except small businesses and very small businesses, must comply 12 months after publication of this final rule (*i.e.*, December 9, 2005). Small businesses (those with more than 10 but fewer than 500 full-time equivalent employees) have 18 months to comply (*i.e.*, June 9, 2006), and very small businesses (those with 10 or fewer full-time equivalent employees) have 24 months to comply (*i.e.*, December 9, 2006). The size of a business is determined by using the total number of full-time equivalent employees in the entire business, not each individual location.

A person subject to the final rule is not required to maintain records of immediate previous sources for food that is received by that person before the compliance date. Likewise, a person is not required to maintain records of immediate subsequent recipients for food that is released by that person before the compliance date.

When Must These Records Be Made Available to FDA?

The required records must be made available to FDA for inspection and copying (or other means of reproduction) 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.”¹⁰ The records access provisions of the Bioterrorism Act are self-executing, so the requirement to make these records available to FDA once the recordkeeping requirements become effective is already in effect and does not require implementing regulations.

Records must be made available to FDA “as soon as possible, not to exceed 24 hours from the time of receipt of the official request.” If records are maintained offsite, they must be retrieved and provided onsite within this time period. The request for records is to be made by an officer or employee duly designated by the Secretary of Health and Human Services who will present appropriate credentials and a written notice (Form FDA 482 – Notice of Inspection) to the owner, operator, or agent in charge.

FDA has published a draft guidance document available at (<http://www.cfsan.fda.gov/~news/whatsnew.html>) regarding the circumstances in which FDA may request access to records and the procedure FDA intends to follow in doing so. According to the draft guidance, FDA intends to exercise records access authority “whenever the statutory criteria are satisfied, whether or not terrorism is known or suspected.” Thus, FDA will seek records access when: (1) FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals; and (2) the records are needed in making such a determination. FDA will not invoke this new records access authority during inspections unless these criteria are met. The scope of a record request will depend upon the particular circumstances. FDA intends to request access to records at reasonable times, within reasonable limits, and in a reasonable manner. Comments on the draft guidance must be submitted no later than **January 23, 2005**.

What Records Must Be Made Available to FDA?

The final rule gives FDA access to “any records and other information accessible to FDA under section 414 or 704(a) of the act.”

¹⁰ The standard of “serious adverse health consequences or death” is the same standard that FDA uses for Class I recalls. See 21 C.F.R. § 7.3(m)(1).

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Consequences of Failure to Comply

The failure to establish and maintain records required by the final rule, or refusal to permit access to or verification or copying of such records, is a prohibited act under Section 301 of the FD&C Act (21 U.S.C. § 331).

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We trust this information is useful. If you have any questions about the final rule, please contact Bob Hahn at (202) 518-6388 or at rhahn@ofwlaw.com.

OFW:jdm
Attachments