U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
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Protecting the Food Supply

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FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA's New Food Bioterrorism Regulation: Establishment and Maintenance of Records

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) directs the Secretary of Health and Human Services to issue final regulations that establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms, restaurants and certain others) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records that must be kept by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. This regulation implements the recordkeeping authority in the Bioterrorism Act.

Who must establish and maintain records? Domestic persons that manufacture, process, pack, transport, distribute, receive, hold or import food; foreign persons that transport food in the U.S.; and persons who *place food directly in contact* with its finished container. For these regulations, the term *persons* includes individuals, partnerships, corporations, and associations.

How is food defined for purposes of this regulation? "Food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act. Section 201(f) which defines "food" as "(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." Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

Who is excluded entirely or in part from these regulations?

Excluded Entirely

Farms
Foreign persons, except for foreign persons who transport food in the U.S.
Restaurants are excluded entirely. A combination restaurant/retail facility is excluded entirely *if* sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.
Persons performing covered activities with food *to the extent* that the food is 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
Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food packaging (the outer packaging of food that bears the label and does not contact the food), except for those persons who also engage in a covered activity with respect to food (see below)

Excluded From The Requirement To Establish And Maintain Records *But Not The Record Availability Requirements For Existing Records*
Fishing vessels not engaged in processing
Retail food establishments that employ 10 or fewer full-time equivalent employees
Nonprofit food establishments
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to the record availability requirements with respect to its packaging (the outer packaging of food that bears the label and does not contact the food)
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts the food
Persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food, except for those persons who place food directly in contact with its finished container

Additional Partial Exclusions
Persons who distribute food directly to consumers (the term *consumers* does not include businesses) are excluded from the requirement to establish and maintain records to identify the immediate subsequent recipients
Persons who operate retail food establishments that distribute food to persons who are not consumers must establish and maintain records to identify the immediate subsequent recipients only to the extent the information is reasonably available

What records must be established and maintained by non-transporters of food? For non-transporters, i.e., persons who own food or who hold, manufacture, process, pack, import, receive, or distribute food for purposes other than transportation, the records have to:

1. Identify the immediate non-transporter previous *sources*, whether foreign or domestic.

of all foods received, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety (e.g., Brand X Cheddar Cheese, not just cheese; romaine lettuce, not just lettuce); date received; quantity and type of packaging (e.g., 12 oz. bottles); and identify the immediate transporter previous sources including the name, address, telephone number--and, if available, fax number and e-mail address. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.*

2. Identify the immediate non-transporter subsequent *recipients* of all foods released, including the name of the firm; address; telephone number; fax number and e-mail address, if available; type of food, including brand name and specific variety; date released; quantity and type of packaging; and identify the immediate transporter subsequent recipients, including the name, address, telephone number--and, if available, fax number and e-mail address. *Persons who manufacture, process or pack food also must include lot or code number or other identifier if the information exists.* The records must include information that is reasonably available to identify the specific source of each ingredient that was used to make every lot of finished product.

What records must be established and maintained by transporters of food?

The term *transporters* includes persons who have possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. The term *transporters* also includes foreign persons that transport food in the U.S., regardless of whether the foreign persons have possession, custody, or control of food for the sole purpose of transporting it. For transporters, records have to include names of the transporter's immediate previous source and transporter's 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 food was transported, and transfer point(s) through which the shipment moved.

Do transporters have alternative methods of meeting the requirements of the rule? Persons who have possession, custody, or control of food in the U.S. for the sole purpose of transporting the food, or foreign persons who transport food in the United States, *regardless* of whether they have possession, custody, or control of the food for the sole purpose of transporting that food, have five alternative methods, depending on the mode of transportation, of meeting the requirements of the final rule.

Alternative Methods for Food Transporters
1. Establishing and maintaining the records described above
2. Establishing and maintaining specified information that is in the records required of roadway interstate transporters by the Department of Transportation's Federal Motor Carrier Safety Administration contained in 49 CFR 373.101 and 373.103 as of December 9, 2004.
3. Establishing and maintaining specified information that is in the records required of rail and water interstate transporters by the Department of Transportation's Surface Transportation Board contained in 49 CFR 1035.1 and 1035.2 as of December 9, 2004.
4. Establishing and maintaining specified information that is in the records required of international air transporters by the Warsaw Convention
5. Entering into an agreement with a non-transporter immediate previous source or immediate subsequent recipient (if located in the United States) to establish, maintain, or

establish and maintain the required records in options 1, 2, 3 or 4.

How must the records be maintained? FDA is specifying the information a covered entity must keep but not specifying the form in which the records must be maintained. The records may be kept in any format, paper or electronic, provided they contain all the required information.

Can existing records be used to satisfy the requirements of these regulations? The regulations do not require duplication of existing records, *if* these records contain all the required information.

How long must the records be retained? The rule requires records to be created when food is received, released or transported except to the extent the information is contained in existing records. The period for which the records must be retained depends on the perishability of the food:

Type of food	Record retention period for non-transporters	Record retention period for transporters or persons keeping records on their behalf
Food having significant risk of spoilage, loss of value, or loss of palatability within 60 days	6 months	6 months
Food having significant risk of spoilage, loss of value, or loss of palatability occurring after a minimum of 60 days but within 6 months	1 year	1 year
Food having significant risk of spoilage, loss of value, or loss of palatability occurring no sooner than 6 months	2 years	1 year
Animal food including pet food	1 year	1 year

Where must the records be retained? At the establishment where the activities covered in the records occurred (onsite) or at a reasonably accessible location.

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 or other information to which FDA has access must be available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records requested may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such an article of food that are maintained by, or on behalf of, an entity subject to the recordkeeping regulation, and at any location.

What records are excluded from these regulations? Recipes, financial data, pricing data, personnel data, research data and sales data are excluded from these requirements. A recipe is defined as the formula, including ingredients, quantities and instructions necessary to

manufacture a food product. Therefore, records relating only to the ingredients of a food product and not the other two components of a recipe are *not* excluded.

What procedures does FDA intend to follow before requesting access to records?

FDA has issued draft guidance for industry and FDA staff regarding records access which details the internal procedures the agency intends to follow (see Draft Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002). FDA is seeking comment on this guidance and will take the comments into account when it finalizes the guidance.

How does FDA intend to make a request to access or copy records under the Bioterrorism Act? Under the draft guidance, once FDA makes the necessary determination following the specified procedures, an investigator or other FDA personnel, upon presentation of credentials, will submit a written notice, FDA 482 - Notice of Inspection, to the owner, operator, or agent in charge, and inform that person of the records requested and FDA's legal authority to obtain these records. FDA may request additional records related to the implicated food article at a later time under the same authority.

How will FDA maintain the confidentiality of any protected information in records it obtains? Information obtained under the records access provisions of sections 414(a) and 704 (a) may include, but is not limited to, a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and Freedom of Information Act, (5 U.S.C. 552) and the agency's information disclosure regulations at 21 CFR Parts 20 and 21 govern the agency's disclosure of information to the public. FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information.

What will happen if the required records are not established and maintained? The Bioterrorism Act makes failure to establish and maintain the required records or failure to make them available to FDA a prohibited act. The Federal government can bring a civil action in Federal court to enjoin persons who commit a prohibited act; the Federal government also can bring a criminal action in Federal court to prosecute persons who commit a prohibited act.

When is compliance with the recordkeeping regulation required? All businesses covered by this rule, must comply within 12 months from December 9, 2004, *except* small and very small businesses. Small businesses (11-499 full-time equivalent employees (FTEs)) must comply within 18 months from this date, and very small businesses (10 or fewer FTEs) have to comply within 24 months from this date. The term, *full-time equivalent employees* or *FTEs,* means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

For further information: For more details and information on the specific requirements of this final rule, please refer to the final rule itself. The final rule is available at http://www.cfsan.fda.gov/~lrd/fr04d09a.html.

FDA/Center for Food Safety & Applied Nutrition
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