



U.S. Food and Drug Administration



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## FDA News

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### **FDA Issues Final Rule on the Establishment and Maintenance of Records to Enhance the Security of the U.S. Food Supply Under the Bioterrorism Act** ***FDA also issues draft guidance regarding records access***

The U.S. Food and Drug Administration (FDA) today issued final regulations on the establishment and maintenance of records to protect the U.S. human food and animal feed supply in the event of credible threats of serious adverse health consequences or death to humans or animals. FDA also issued draft guidance to FDA staff and industry, which details the internal procedures the agency will follow before requesting access to records.

"Publication of this recordkeeping rule represents a milestone in U.S. food safety and security," said Secretary of Health and Human Services, Tommy G. Thompson. "There is more work to do yet, but our nation is now more prepared than ever before to protect the public against threats to the food supply."

This final regulation implements section 306 of the Bioterrorism Act, which directs the HHS Secretary to issue regulations requiring persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. These records identify the immediate previous source of all food received, as well as, the immediate subsequent recipient of all food released.

"These records will be crucial for FDA to deal effectively with food-related emergencies, such as deliberate contamination of food by terrorists," said Dr. Lester M. Crawford, Acting FDA Commissioner. "The ability to trace back will enable us to get to the source of contamination. The records also enable FDA to trace forward to remove adulterated food that poses a significant health threat in the food supply."

The final regulation is the fourth regulation designed to increase the safety and security of the U.S. human and animal food supply under the authority of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (the Bioterrorism Act).

The record retention period for human foods ranges from six months to two years depending on the shelf life of the food. Records for animal food, including pet food, must be retained for one year. The maximum record retention requirement for transporters of all types of food is one year.

Records must be retained at the establishment where the activities covered in the records occurred or at a reasonable accessible location. To minimize the burden on food companies affected by the final rule, companies may keep the required information in any format, paper or electronic. All businesses covered by this rule must comply within 12 months from the date the rule is published in the Federal Register, 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.

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 copying as soon as possible, not to exceed 24 hours from time of receipt of the official request. The records access authority applies both to records required to be established and maintained by the final rule, or any other records a covered entity may keep to comply with federal, state, or local law or as a matter of business practice.

The Bioterrorism Act allows FDA to bring a civil action in federal court to enjoin the persons who fail to comply with this rule. FDA also can seek criminal actions in federal court to prosecute persons who fail to establish and maintain records, as required by the final rule.

FDA has already issued three other final regulations under the Bioterrorism Act, which are in effect. They cover:

- Registration foreign and domestic food facilities;
- Prior notice of food shipments imported or offered for import into the U.S.; and
- Administrative detention, so that food products that might pose a threat of serious adverse health consequences or death may be detained.

FDA will be holding seven public meetings in January and February 2005 to explain the requirements of the final rule to interested parties and answer questions.

Registration is on a first-come, first served basis. Additional information on how to register for one of the public meetings or information about all four rules designed to protect the U.S. food supply is available at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

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