FDA News

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FDA Issues Final Two Proposed Food Safety Regulations

FDA today announced publication of the final two food safety proposed regulations required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("The Act"), which gave FDA new authority to protect the nation's food supply.

The proposals are two of four proposed regulations that the Act calls upon FDA to develop regarding food safety. These two proposals deal with establishing and maintaining records among food firms, and the administrative detention of foods that may pose a risk to public health. The other two proposals, concerning the registration of food facilities and prior notice of imported foods, were published in January 2003.

"Improving FDA's food safety inspection, detention and monitoring capabilities is a top priority of the Department. We have taken strong steps to enhance FDA's ability to make our food supply safer, said Secretary of Health and Human Services Tommy G. Thompson. "This FDA effort is the latest in a series of measures to build stronger safeguards for the American people."

"These proposed regulations measures will further bolster FDA ability to protect the more than 400,000 domestic and foreign facilities that deal with food within our country," said FDA Commissioner Dr. Mark B. McClellan, M.D., PhD. "Thanks to the efforts of Senators Gregg and Kennedy, and Representatives Tauzin and Dingell, the Bioterrorism Act gives FDA this important new authority."

The recordkeeping proposal is designed to help FDA track foods implicated in future emergencies, such as terrorism-related contamination. Under the proposed rule, manufacturers, processors, packers, distributors, receivers, holders and importers of food would be required to keep records identifying the immediate source from which they received the food, as well as, the immediate subsequent recipient, to whom they sent it. This requirement would apply to almost all foreign and domestic food sources and almost all recipients of food destined for consumption in the United States. It would assist FDA in addressing credible threats of serious adverse health consequences or death to humans or animals.

To minimize the economic burden on food companies affected by the proposal, FDA's proposals would allow companies to keep the required information in any form that they prefer. Records may be kept in any format, paper or electronic, provided they contain all the required information. The proposed rule also states that existing records can be used to satisfy the requirements of the regulations if these records contain all the required information.

For persons other than transporters the proposed rule would require the records to contain the following information for each article of food:

- The firm's name, and the responsible individual representative of the firm that was the immediate previous source or the immediate subsequent recipient of the food
- The address, telephone and fax numbers, and e-mail address of that person, if available
- The type of food, including brand name and specific variety

- The date received or released
- Lot number or other identifier number, if available
- The quantity and type of packaging
- The name, address, telephone number -- and, if available, fax number and e-mail address -- of the transporter who transported the food

With respect to the immediate previous source, the specific source of each ingredient that was used to make every lot of finished food product would have to be identified if this information is reasonably available. What is reasonably available may vary from case to case.

If an article of food is reasonably believed to be adulterated and presenting a threat of serious adverse health consequence or death to humans or animals firms would be required to provide these and other records to FDA within four hours during certain business hours, or eight hours at other times.

Transporters (e.g., trucking companies, private delivery carriers, railroads and airlines) would also be required to keep similar documentation-including information about all the means of transportation used.

The proposed rule would require records to be established at the time the covered activity occurs. FDA is proposing that required records for perishable foods not intended for processing into non-perishable foods, and required records for animal food including pet food, be retained for one year from the date they were created. Records for all other foods would have to be retained for two years after the date they were created.

Farms, restaurants, (including all operations that prepare food for, or serve food directly to consumers), fishing vessels not engaged in processing, and firms regulated exclusively by the U.S. Department of Agriculture, would be exempted from the new recordkeeping requirements. With some exceptions, foreign facilities would be excluded if their food products undergo further manufacturing/processing, including packaging, by another facility outside the United States.

Retail food operations would be exempted from maintaining records on immediate subsequent recipients of foods sold directly to consumers.

This proposed regulation provides that a final rule would become effective six months from the date of publication of the final rule in the *Federal Register*. For small businesses (fewer than 500 but more than ten full-time equivalent employees) a final regulation would become effective 12 months from that date, and for very small businesses (ten or fewer full-time equivalent employees), the effective date would be 18 months from publication of the final regulation.

FDA intends to publish a final rule no later than December 12, 2003, in accordance with the deadline set forth in the Act. Given this statutory deadline, FDA will not be able to extend the comment period on this proposed rule.

The other proposed regulation on administrative detention implements FDA's new authority to detain any article of food for which there is credible evidence that the article poses a threat of serious adverse health consequences or death.

The administrative detention authority granted to FDA under the Act is self-executing and currently in effect, and provides an added measure to ensure the safety of the nation's food supply. As required by the Act, FDA is issuing this proposed rule that includes expedited procedures for instituting certain enforcement actions against perishable foods. The proposed rule also includes procedures describing how FDA will detain an article of food and the process for appealing a detention order.

Specifically, the proposed rule would require a detention order to be approved by the FDA District Director of the district where the detained article of food is located or a more senior official. A copy of the detention order would be given to the owner, operator, and/or agent in charge of the place where the article of food is located, and to the owner of the food if different than those listed above. If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also would have to provide a copy of the detention order to the shipper of record.

The detention order would provide the following information:

- The detention order number
- The hour and date of the order
- The identification of the detained article of food
- The detention period
- A statement that the food identified in the order is detained for the period shown
- A brief, general statement of the reasons for the detention
- And the address and location where the article of food is to be detained and the appropriate storage and transportation conditions.

The proposed rule would require a detained article of food to be held in a secure location, as determined by FDA. Detained food may not be delivered to another entity, such as its importer, owner, or consignee. Detained food also may not be transferred from the place where it has been ordered detained, or from the place to which it has been removed, until FDA releases the article or the detention period expires. The detention may not exceed 30 days. Violation of a detention order is a prohibited act.

Any person who is entitled to claim the detained article of food may appeal the detention order. For perishable food, the proposed rule would require an appeal to be filed within two calendar days of receipt of the detention order. For non-perishable food, a notice of intent to appeal would have to be filed within four calendar days, and the appeal would have to be filed within ten calendar days of receipt of a detention order. FDA is required to issue a decision within five calendar days after an appeal is filed, after providing an opportunity for an informal hearing. The decision rendered on appeal is considered final agency action that may be challenged in court.

The definition of food used in the proposed rule references the definition of food in section 201(f) of the Federal Food, Drug, and Cosmetic Act and would include food intended for consumption both in the U.S. and elsewhere. Food under the exclusive jurisdiction of USDA (i.e., meat products, poultry products and egg products) is not be covered by the administrative detention proposed regulation.

A comment period of 60 days will be provided on these proposals. Written comments can be submitted to FDA at: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments can also be submitted electronically through www.fda.gov/dockets/ecomments. It is important to include docket number 02N-0277 for the recordkeeping proposal and docket number 02N-0275 for the administrative detention proposal when providing comments. These proposals can also be accessed electronically at the FDA web page on the Bioterrorism Act.

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Fact Sheet: Administrative Detention
Federal Register: Administrative Detention
Fact Sheet: Establishment and Maintenance of Records
Federal Register: Establishment and Maintenance of Records
