

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 effective 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