

2. What are the record availability requirements? (Proposed § 1.361)

Proposed § 1.361 states that 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 accessible to FDA under section 414 or 704(a) of the act must be readily available for inspection and photocopying or other means of reproduction. Although the statutory requirements in section 414 and amended section 704(a) of the act regarding records access are self-executing and are currently in effect, FDA is issuing regulations to further refine some aspects of the food records access requirements. Because section 306 of the Bioterrorism Act includes two records inspection authorities, one of which, section 704(a), cross refers to records described in section 414, we request comment on the interconnection between the records access provisions in sections 414 and 704(a) of the act.

Proposed § 1.361 would require records to be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m. (local standard time), Monday through Friday, or within 8 hours of a request if made at any other time, by an officer or employee duly designated by the Secretary who presents appropriate credentials and a written notice. In the event of a threat of serious adverse health consequences or death to humans or animals, FDA believes these time limits are necessary to effectively and efficiently perform a tracing investigation.

The most common problem encountered by the FDA in a tracing investigation has been a lack of ready access to records. Records are often stored offsite or are stored in a database where the records are difficult to retrieve. In FDA's experience, rarely do firms make records available within 24 hours. The usual timeline is 2 to 3 days. This delay severely reduces the speed at which FDA can perform a traceback. If every firm were to take 2 days to give FDA the needed records, even with a short traceback (e.g., 3 firms), it could take FDA up to 2 weeks to trace the product to its source, taking into account time for record review and travel to the firms. This time may be increased if the records are incomplete and FDA has to wait for missing records to be retrieved. This possible delay would be a substantial concern if FDA were attempting to remove adulterated food that presents a threat of serious

adverse health consequences or death to humans or animals from commerce.

Proposed § 1.361 would also require that if you store the records required by these regulations offsite, you must be able to retrieve and provide the records onsite within the specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location.

3. What records are excluded from this subpart? (Proposed § 1.362)

Proposed § 1.362 would exclude from the proposed regulations recipes for food as defined in proposed § 1.328, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales). These exclusions are consistent with the express language in the Bioterrorism Act.

4. What are the consequences of failing to establish or maintain records or make them available to FDA? (Proposed § 1.363)

Consistent with the express language in the Bioterrorism Act, proposed § 1.363 states (a) the failure to establish or maintain records as required under section 414(b) of the act or to refuse to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act (21 U.S.C. 331) and (b) the failure to make records or other information available to FDA as required by section 414 or 704(a) of the act is a prohibited act under section 301 of the act (21 U.S.C. 331).

5. What are the compliance dates for this subpart? (Proposed 1.368)

Under sections 414 and 704(a) of the act, FDA may have access to and copy all records and other information related to an article of food if the Secretary has a reasonable belief that the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The basic requirement that access to records and other information be given under these circumstances is currently in effect and does not require implementing regulations. FDA has chosen to further define access requirements in regulations, but can use its inspectional authority prior to the effective date of these regulations.

FDA carefully considered the size of a business when developing these proposed regulations. FDA found that most products and ingredients pass through at least one small business when moving through the distribution process (see Initial Regulatory Flexibility Analysis discussion in

section III.B. of this document). If FDA were to exempt small businesses from these regulations or to permit shorter record retention times for them, the effectiveness of the regulations would be severely compromised due to the breaks in the recordkeeping chain during tracing investigations. Thus, FDA cannot propose totally exempting any business based on size from these requirements. However, FDA does propose to provide small and very small businesses additional time to come into compliance with these regulations.

Thus, proposed § 1.368(a) would require that firms that do not qualify as small businesses be in full compliance with these regulations within 6 months after the publishing date of the final rule. Proposed § 1.368(a)(1) would require that small businesses employing fewer than 500 but more than 10 full-time equivalent employees be in full compliance with these regulations within 12 months after the publishing date of the final rule. Proposed § 1.368(a)(2) would require that very small businesses, defined as those employing 10 or fewer full-time equivalent employees, be in full compliance with these regulations within 18 months after the publishing date of the final rule.

III. Analysis of Economic Impact

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

Need for the regulations: The purpose of these proposed regulations is to enable FDA to respond to, and help contain, adulterated food that presents a threat of serious adverse health consequences or death to humans or