

records to trace the transportation of all food, (4) record retention requirements, (5) record availability requirements, and (6) compliance dates. Following is an overview of the proposed regulations, which is intended to highlight the content of certain sections and request comment on those sections specifically, including comment on whether certain requirements should be included in the final regulations.

Proposed requirements to establish and maintain records to identify the nontransporter and transporter immediate previous sources of all food (§ 1.337) would require specific persons ("you") to establish and maintain records that identify the sources of all food you receive. The information that we propose as necessary to identify the nontransporter immediate previous sources includes: (1) The name, address, and phone number of the nontransporter immediate previous source; (2) the type of food received; (3) the date you received the food; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) the name, address, and phone number of the transporters who transported the food to you.

Proposed requirements to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients of all food (§ 1.345) would require that you keep records that identify the nontransporter recipients of all food you release. The information that we propose as necessary to identify the nontransporter immediate subsequent recipients is similar to that required to identify the nontransporter immediate previous sources.

Proposed requirements to establish and maintain records to trace the transportation of all food (§§ 1.351 and 1.352) would require that you keep records that trace the transportation process of all food you transport. The information that we propose as necessary to trace the transportation process includes: (1) The name, address, and phone number of the person who had the food immediately before you (the transporter's immediate previous source), and the date you received it from that person; (2) the name, address, and phone number of the person who had the food immediately after you (the transporter's immediate subsequent recipient), and the date you delivered it to that person; (3) the type of food transported; (4) the lot number or other identifier of the food if available; (5) the quantity; and (6) identification of each and every mode of transportation used (e.g., company truck, private carrier, rail, air, etc.) from the time you first

received the food until the time you delivered it.

Proposed record retention requirements (§ 1.360) would require records for perishable foods not intended to be processed into nonperishable foods to be retained for 1 year after the date the records were created. FDA seeks comment on whether a person subject to these proposed regulations always or usually knows at the time perishable food is released whether or not it is intended to be processed into nonperishable food. For all other food, you would be required to retain the records for 2 years after the date the records were created. You would be required to retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. The maintenance of electronic records would be acceptable. FDA is proposing to exempt electronic records established or maintained to satisfy the requirements of this subpart from the requirement to comply with part 11—Electronic Records; Electronic Signatures (21 CFR part 11) and proposing to amend part 11 to reflect this exemption.

Proposed records availability requirements (§ 1.361) would require that records be made available within 4 hours of an FDA 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.

In § 1.368, the agency is proposing that firms be in full compliance with these regulations within 6 months of publishing the final regulations. However, these proposed requirements would not be effective for small businesses (those employing fewer than 500 but more than 10 full-time equivalent employees) until 12 months after publishing the final regulations. Very small businesses that employ 10 or fewer full-time equivalent employees would have 18 months to comply.

The Bioterrorism Act directs the Secretary to take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary under the new regulations. FDA is planning to reemphasize in instructions to FDA personnel the importance of current protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information that is obtained.

Section 306 of the Bioterrorism Act expressly states that FDA has authority

to require recordkeeping as to "food, including its packaging." FDA interprets this section as authority to require persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records to allow for the identification of the immediate previous sources and immediate subsequent recipients of food packaging as well. FDA interprets packaging in section 306 of the Bioterrorism Act to mean the outer packaging of food that bears the label. FDA is not interpreting packaging to include food contact substances, which are included in the definition of "food." Outer packaging would include, for example, the outer cardboard cereal box that bears the label of the cereal, but would not include the inner lining that holds the cereal. Outer packaging would also not include the outer shipping box in which the cereal boxes are shipped.

FDA has tentatively concluded that the risk to human and animal health from contamination of outer food packaging is relatively small compared to the risk from contamination of the immediate packaging that comes in direct contact with food. Therefore, FDA is proposing not to require covered persons to keep records regarding outer food packaging. However, the agency also recognizes that there may be instances where it may be necessary for FDA to be able to investigate agents that could lace outer packaging and could thereby contaminate a food for which the immediate food contact packaging may not provide an adequate barrier. In addition, outer packaging could be intentionally diverted and used to package food that has been tampered with. FDA seeks comment on whether the level of risk to human and animal health from potential contamination of outer packaging is high enough to warrant inclusion of outer packaging in the final regulations.

In addition to the above, we seek comment on all other provisions in the proposed regulations, such as the proposed definitions and exclusions. We also invite comment on whether the final rule should include additional provisions, such as a model form that can be used to record all the required information.

II. Description of the Proposed Regulations

A. General Provisions

1. Who is subject to this subpart? (Proposed § 1.326)

Proposed § 1.326(a) describes the scope of the rule. As required by the Bioterrorism Act, proposed § 1.326(a) would require domestic persons who