

from whom you received the food from and the person to whom you gave it. You would not be required to maintain records of transactions to which you were not a party.

Proposed § 1.352(a)(6) would require transportation companies that use several modes of transportation within their company to record when the food was put on which kind of vehicle and who was responsible for it during that leg of the trip. For example, Yellow Transportation Co. may use two different Yellow trucks and a Yellow plane. This section would require Yellow Transportation Co. to keep records of each and every mode of transportation and the individual responsible, from the time the food was first received until the time it was delivered. The "individual responsible" should be the person within the transportation company who is responsible for that vehicle and the food being transported. FDA seeks comments on whether "individual responsible" should be the operator of the conveyance or whether it can be someone within the corporation who has overall responsibility for the vehicle and the food being transported. FDA understands that it is common practice for one transportation company to use several different modes of transportation within that company throughout its possession and control over the food. The food is potentially subject to tampering at each phase of the transportation process. If the transportation company responsible for the food does not have complete records identifying the mode of transportation and who was responsible for the food throughout the entire time that company had possession and control over the food, the tracing chain is broken and it becomes more difficult and time consuming to determine if that shipment of food has been diverted or tampered with. FDA believes this detailed information regarding the food transportation would be necessary to expedite the tracing investigation in situations when FDA has a reasonable belief that food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

E. General Requirements

1. What are the record retention requirements? (Proposed § 1.360)

Proposed § 1.360(a) states the records required by these regulations are to be created at the time the statutorily covered activities take place. Proposed § 1.360(b) 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. Although perishable foods have a relatively short shelf life, FDA is proposing a 1 year record retention period for these foods. In some situations, the health hazard may not be immediately apparent but may emerge months after the food has been consumed. In other situations, the harm may have been caused by novel contaminants or novel vehicles for known contaminants, and it may take months to identify the sources of contamination. As an example, in 1995, there was an investigation of an outbreak of cyclosporiasis. At the time, FDA did not know that *Cyclospora* could contaminate raspberries. An investigation concluded that water was the likely vehicle. In 1996, there were numerous additional cyclosporiasis outbreaks in the United States and the link was made to raspberries from Guatemala. Fresh raspberries had been served at the site of the 1995 outbreak and then, a year later, FDA needed to determine their source. The distributor had no records to facilitate the traceback.

The proposed 1-year period would not apply to perishable foods that are intended for processing into nonperishable foods, e.g., jams and jellies made from fruits. In those instances, the longer record retention period of 2 years is needed to ensure the recordkeeping chain for finished food products made using perishable foods is available during tracing investigations. If you are uncertain whether a perishable food is destined or intended for processing into a nonperishable food, the 2-year record retention period applies. FDA seeks comment on the impact of this provision.

Proposed § 1.360(c) would require that you retain records for all foods (except animal foods as discussed below) not covered by proposed § 1.360(b) for 2 years after the date the records were created. This proposed requirement is consistent with the authority given in the Bioterrorism Act. Based on information provided to FDA by the food industry, the minimum time for processed food products to clear the food production and distribution/retail system is 3 years. In addition, the average distribution time between harvesting and final retail sale of frozen fruits and vegetables is approximately 3 to 24 months. These are average times, and individual products may be in commerce for a longer period. FDA believes that allowing anything less than a 2-year record retention period for nonperishable food, as well as perishable foods intended to be

processed into nonperishable food, would severely compromise a tracing investigation.

Proposed § 1.360(d) would require that you retain records required by these regulations for animal food, including pet food, for 1 year after the date the records are created. Food for food-producing animals tends to have a faster turnover rate than many kinds of human food. In addition, since pet foods are typically the sole source of food for pets, such foods tend not to be stored as long as many human foods. Therefore we propose that records for all animal food, including pet food, be retained for only one year after the date the records are created. This is consistent with the BSE rule.

Proposed § 1.360(e) would require that you retain all records required by these regulations at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. We recognize that there may be more records than available storage space at the location where the covered activities occur. We are therefore proposing that records may be stored offsite, provided you can comply with the record availability requirements in proposed § 1.361.

Proposed § 1.360(f) provides that the maintenance of electronic records is acceptable. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA issued regulations at part 11 that provide criteria for acceptance by FDA of electronic records under certain circumstances. To minimize the burden of this proposed rule, FDA proposes to exempt electronic records established or maintained to satisfy the requirements of this subpart from the requirement to comply with part 11. FDA believes that a requirement that records kept under this subpart comply with part 11 would hinder the ability of persons subject to these regulations to utilize existing systems and records to satisfy the requirements of these proposed regulations as contemplated in proposed § 1.330. If the agency decided to require all electronic records to satisfy part 11 before they could satisfy these proposed recordkeeping requirements, large numbers of already existing electronic records and recordkeeping systems would have to be recreated and redesigned. This provision would require that records kept for some other statutory or regulatory purpose, but which also may be used to meet the requirements of this subpart, must comply with part 11 as required.