

(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in §1.352(a), (b), (c), or (d). The agreement must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) Description of the records to be established and/or maintained;

(4) Provision for the records to be maintained in compliance with §1.360, if the agreement provides for maintenance of records;

(5) Provision for the records to be available to FDA as required by §1.361, if the agreement provides for maintenance of records;

(6) Acknowledgement that the nontransporter assumes legal responsibility under §1.363 for establishing and/or maintaining the records as required by this subpart; and

(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

GENERAL REQUIREMENTS

§1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs

only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§1.361 What are the record availability requirements?

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 and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made