

Food and Drug Administration, HHS

§ 1.352

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

REQUIREMENTS FOR NONTRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS TO IDENTIFY THE NONTRANSPORTER AND TRANSPORTER IMMEDIATE SUBSEQUENT RECIPIENTS OF FOOD

§ 1.345 What information must non-transporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

REQUIREMENTS FOR TRANSPORTERS TO ESTABLISH AND MAINTAIN RECORDS

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement and name of each carrier participating in the transportation; and

(7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:

(1) Date received;

(2) Received from;

(3) Consigned to;

(4) Destination;

(5) State of;

(6) County of;

(7) Route;

(8) Delivering carrier;

(9) Car initial;

(10) Car no;

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- (11) Trailer initials/number;
- (12) Container initials/number;
- (13) No. packages; and
- (14) Description of articles; or
- (d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:
 - (1) Shipper's name and address;
 - (2) Consignee's name and address;
 - (3) Customs reference/status;
 - (4) Airport of departure and destination;
 - (5) First carrier; and
 - (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 in-

formation 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.