

following records for all food you release:

(1) The name of the firm and responsible individual, address, phone 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 the food was released;

(4) 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 ct. bunches, 25 lb carton, 12 oz bottle); and

(6) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the transporters who transported the food from you.

(b) [Reserved]

Requirements to Establish and Maintain Records to Trace the Transportation of All Food

§ 1.351 Who is required to establish and maintain records for tracing the transportation of all food?

If you are a domestic person and you are a transporter of food, you are required to establish and maintain records containing information not only about your transportation activities but also about the person from whom you received the food (the transporter's immediate previous source) and the person to whom you delivered it (the transporter's immediate subsequent recipient), as specified in § 1.352.

§ 1.352 What information is required in the transportation records?

(a) You must establish and maintain the following records for each food you transport:

(1) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately before you, and the date you received it from that person;

(2) The name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately after you, and the date you delivered it to that person;

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

(4) 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 ct. bunches, 25 lb carton, 12 oz bottle);

(6) Identification of each and every mode of transportation (e.g., company truck, private carrier, rail, air, etc.), and the individual responsible, from the time you first received the food until the time you delivered it.

(b) [Reserved]

General Requirements

§ 1.360 What are the record retention requirements?

(a) You must create the required records at the time the activity occurs.

(b) You must retain for 1 year after the date the records were created all required records for perishable foods not intended for processing into nonperishable foods.

(c) You must retain for 2 years after the date the records were created all required records for all other foods, except animal foods.

(d) You must retain for 1 year after the date the records were created all required records for animal food, including pet food.

(e) You must 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.

(f) The maintenance of electronic records is acceptable.

§ 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 must be readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m., 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. If records and other information are stored offsite, the records must be retrieved and provided onsite within the specified time period. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA?

(a) The failure to establish or maintain records as required by section 414(b) of the act or the refusal 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).

(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.

Effective Dates

§ 1.368 What are the compliance dates for this subpart?

(a) The regulations in this subpart shall be effective 6 months after the date of publication of the final rule in the **Federal Register**. However, this subpart is not binding on small and very small businesses until the dates listed in paragraphs (a)(1) and (a)(2) of this section.

(1) The regulations in this subpart are binding 12 months after the date of publication of the final rule in the **Federal Register**, for small businesses employing fewer than 500 but more than 10 full-time equivalent employees.

(2) The regulations are binding 18 months after the date of publication of the final rule in the **Federal Register**, for very small businesses that employ 10 or fewer full-time equivalent employees.

(b) [Reserved]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

4. Section 11.1 is amended to add paragraph (f) to read as follows:

§ 11.1 Scope.

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(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of Part 1, Subpart J of this chapter but that are also required under other applicable statutory provisions or regulations remain subject to this part.