

Legal Concerns in Food Production & Traceability

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- **Food Safety Modernization Act (FSMA):** Enacted in 2011, the FSMA represents a paradigm shift in US food safety regulation, emphasizing prevention over reaction to foodborne illness outbreaks. One of the central provisions of the FSMA is the establishment of enhanced traceback capabilities throughout the food supply chain. Under FSMA, certain facilities are required to develop and implement food safety plans, including provisions for traceability and recordkeeping.
- **Recordkeeping Requirements:** Both the FDA and USDA require recordkeeping obligations on food manufacturers, processors, distributors, and retailers. These requirements encompass various aspects of the production, processing, distribution, and sale of food products, including information on suppliers, recipients, dates of receipt and distribution, lot or batch numbers, and other critical data points. Comprehensive recordkeeping is essential for conducting effective traceback investigations in the event of a food safety incident.
- **Hazard Analysis and Critical Control Points (HACCP):** HACCP is a systematic approach to identifying, evaluating, and controlling food safety hazards. While not explicitly focused on traceback, HACCP principles emphasize the importance of maintaining detailed records and documentation throughout the food production process. Compliance with HACCP standards is mandatory for food establishments under FDA jurisdiction, further contributing to traceability efforts.

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- **FINAL RULE ON TRACEABILITY** (November 12, 2022)

- <https://www.federalregister.gov/documents/2022/11/21/2022-24417/requirements-for-additional-traceability-records-for-certain-foods>

- **FOOD TRACEABILITY LIST:**

- <https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>

- **Recordkeeping:** The compliance date for all persons subject to the recordkeeping requirements is Tuesday, **January 20, 2026.**

Lot Codes

- **21 CFR S 1.1320 When must I assign traceability lot codes to foods on the Food Traceability List?**
- (a) You must assign a traceability lot code when you do any of the following: Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel; perform the first land-based receiving of a food obtained from a fishing vessel; or transform a food.
- (b) Except as otherwise specified in this subpart, you must not establish a new traceability lot code when you conduct other activities (e.g., shipping) for a food on the Food Traceability List.

21 CFR § 1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?

- **§ 1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?**
- (a) Except as specified in paragraph (c) of this section, for each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack, you must maintain records containing the following information and linking this information to the traceability lot:
 - 1) The commodity and, if applicable, variety of the food received;
 - (2) The date you received the food;
 - (3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
 - (4) The location description for the farm where the food was harvested;
 - (5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;
 - (6) For aquacultured food, the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;
 - (7) The business name and phone number for the harvester of the food;
 - (8) The date of harvesting;
 - (9) The location description for where the food was cooled (if applicable);
 - (10) The date of cooling (if applicable);
 - 11) The traceability lot code you assigned;
 - (12) The product description of the packed food;
 - 13) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - 14) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
 - (15) The date of initial packing; and
 - (16) The reference document type and reference document number.

§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?

- **§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?**
- (a) Except as specified in paragraphs (b) and (c) of this section, for each traceability lot of a food on the Food Traceability List you receive, you must maintain records containing the following information and linking this information to the traceability lot:
 - (1) The traceability lot code for the food;
 - (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - (3) The product description for the food;
 - (4) The location description for the immediate previous source (other than a transporter) for the food;
 - (5) The location description for where the food was received;
 - (6) The date you received the food;
 - (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
 - (8) The reference document type and reference document number.
- If it comes from an exempt supplier, then assign the traceability code as described in the regulation.

21 CFR § 1.1350 What records must I keep when I transform a food on the Food Traceability List?

- (a) Except as specified in paragraphs (b) and (c) of this section, for each new traceability lot of food you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot:
 - (1) For the food on the Food Traceability List used in transformation (if applicable), the following information:(i) The traceability lot code for the food;(ii) The product description for the food to which the traceability lot code applies; and(iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.
 - (2) For the food produced through transformation, the following information:(i) The new traceability lot code for the food;(ii) The location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;(iii) The date transformation was completed;(iv) The product description for the food;(v) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and(vi) The reference document type and reference document number for the transformation event.
- (b) For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b)
- (c) Paragraphs (a) and (b) of this section do not apply to retail food establishments and restaurants with respect to foods they do not ship (e.g., foods they sell or send directly to consumers).

Modifiers & Waivers from requirements

- Modifier may be requested from the FDA through a petition.
- Waiver- submit a written request to FDA:
 - § 1.1420 What process applies to a request for a waiver for an individual entity?
 - (a) After considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision.

consequences

- **Ability to conduct effective recalls (prevent food borne illnesses and death + prevent blanket recalls)**

if you do not have sufficient information to target certain crops grown in certain region, then you would recall everything.

- **Enforcement by the FDA**
- **Product Liability & recall Insurance**
- **Lawsuits from buyers/sellers**
- **Lawsuits from consumers**

Discussion and Q &A