What you need to know about the Food Traceability Rule: Recordkeeping Information for Produce Farms

FDA | U.S. FOOD & DRUG ADMINISTRATION

Background

The Food and Drug Administration has issued a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule requires these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods.

The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. The Food Traceability Rule was issued in accordance with the FDA Food Safety Modernization Act (FSMA).

Important elements of the Food Traceability Rule are described below.

Definitions

Critical Tracking Event (CTE): an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

Key Data Element (KDE): information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart.

Traceability lot: a batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

Traceability lot code: a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Traceability lot code source: the place where a food was assigned a traceability lot code.

Traceability lot code source reference: an alternative method for providing FDA with access to the location description for the traceability lot code source as required under the final rule. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

Key Data Element Requirements

The Critical Tracking Events that are most likely to be relevant to produce farms include: Harvesting, Cooling, Initial Packing and Shipping. For each Critical Tracking Event a covered entity performs, they must maintain (and in some cases, send) specific Key Data Elements as listed below:

Harvesting KDEs:

For each produce commodity on the Food Traceability List that you harvest, you must maintain records containing the following harvesting KDEs:

1. Location description for the immediate subsequent recipient (other than a transporter) of the food
2. Commodity and, if applicable, variety of the food
3. Quantity and unit of measure of the food
4. Location description for the farm where the food was harvested
5. Name of the field or other growing area from which the produce was harvested (must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as field or other growing area name
6. Date of harvesting
7. Reference document type and reference document number

For each produce commodity on the Food Traceability List that you harvest, you must provide (in electronic, paper, or other written form) the following information to the initial packer:

1. Your business name
2. Your phone number
3. Harvest KDEs listed above (except the reference document type and number)

Cooling (before initial packing) KDEs:

For each produce commodity on the Food Traceability List that you cool before it is initially packed, you must maintain records containing the following cooling KDEs:

1. Location description for the immediate subsequent recipient (other than a transporter) of the food
2. Commodity and, if applicable, variety of the food
3. Quantity and unit of measure of the food
4. Location description for where you cooled the food
5. Date of cooling
6. Location description for the farm where the food was harvested
7. Reference document type and reference document number

For each produce commodity on the Food Traceability List that you cool before it is initially packed, you must provide (in electronic, paper, or other written form) the following information to the initial packer:

1. Cooling KDEs listed above (except the reference document type and number)

Initial Packing KDEs:

For each traceability lot of a raw agricultural commodity on the Food Traceability List that you initially pack, you must maintain records containing the following Initial Packing KDEs, and linking these KDEs to the traceability lot:

1. Commodity and, if applicable, variety of the food received
2. Date you received the food
3. Quantity and unit of measure of the food received
4. Location description for the farm where the food was harvested
5. Name of the field or other growing area from which the produce was harvested (must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as field or other growing area name
6. Business name and phone number for the harvester of the food
7. Date of harvesting
8. Location description for where the food was cooled (if applicable)
9. Date of cooling (if applicable)
10. The traceability lot code you assigned
11. Product description of the packed food
12. Quantity and unit of measure of the packed food
13. 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
14. Date of initial packing
15. Reference document type and reference document number

Note that additional Initial Packing KDEs must be kept for sprouts (except soil- or substrate-grown sprouts harvested without their roots). See 21 CFR 1.1330(b).

Note that if you are the initial packer of a raw agricultural commodity on the Food Traceability List that you receive from an exempt entity, you are only required to maintain a reduced set of Initial Packing KDEs. See 21 CFR 1.1330(c).

Shipping KDEs:

For each traceability lot of packed produce that you ship (if the produce is on the Food Traceability List)[1], you must maintain records containing the following Shipping KDEs, and linking these KDEs to the traceability lot:

1. Traceability lot code for the food
2. Quantity and unit of measure of the food
3. Product description for the food
4. Location description for the immediate subsequent recipient (other than a transporter) of the food
5. Location description for the location from which you shipped the food
6. Date you shipped the food
7. Location description for the traceability lot code source, or the traceability lot code source reference
8. Reference document type and reference document number

For each traceability lot that you ship, you must provide the following information (in electronic, paper, or other written form) to the immediate subsequent recipient (other than a transporter):

1. Shipping KDEs listed above (except the reference document type and number)

Traceability Plan:

All entities covered by the rule must maintain a traceability plan. For produce farms, your traceability plan must include the following:

1. A description of the procedures you use to maintain the records required by the Food Traceability Rule, including the format and location of the records.
2. A description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold.
3. A description of how you assign traceability lot codes, if applicable.
4. A point of contact that can answer questions about your traceability plan and records.
5. A farm map showing where you grow produce (can be digital or hand drawn)
   - Farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area
6. You must update your traceability plan as needed to ensure that it reflects your current practices, and the old plan must be kept a minimum of 2 years after an update.

FAQs

Does FDA require a specific application or technology for keeping records?

No. In accordance with FSMA 204(d)(1)(C), the final rule does not prescribe specific technologies for the maintenance of records. Records must be kept as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Records must be legible and stored to prevent deterioration or loss. Electronic records may include valid, working electronic links to the information required to be maintained under the final rule. You must make all required records available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request.

In certain situations, such as when necessary to help prevent or mitigate a foodborne illness outbreak or other threat to public health, FDA may request that records be provided in an electronic sortable spreadsheet. Note that certain smaller farms are exempt from this requirement.

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[1] Shipping KDEs do not apply to the shipment of a food that occurs before the food is initially packed.

How long must I keep the records required by the rule?

Unless otherwise stated, records containing the information required under the final rule must be maintained for 2 years from the date you created or obtained the records.

When do I need to comply with the Food Traceability Rule?

The compliance date for all covered entities is January 20, 2026.

For additional questions

The Technical Assistance Network (TAN) is a central source of information for questions related to the Food Safety Modernization Act (FSMA) rules, programs, and implementation strategies.

Submit Your Question Electronically:

Please submit your question to the TAN for assistance.

Mail Your Question

If you prefer to mail in your question, please send it to the address below:

> Food and Drug Administration
> 5001 Campus Drive
> Wiley Building, HFS-009
> Attn: FSMA Outreach
> College Park, MD 20740

How TAN Works

Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. FDA will respond to inquiries received as soon as possible. However, response times may vary, due to complexity of question and the volume of inquiries we receive. Once a question is submitted, the inquirer will receive notification of receipt and a case number to be referenced in future correspondence.