Food Traceability Rule Documentation Guide

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GROW WITH SCIENCE.

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Purpose of this document

The purpose of this document is to provide Western Growers members who are subject to FSMA 204 with a manual to properly maintain and comply with the documentation requirements established in the Food Traceability Rule.

Summary and Main Concepts of FSMA 204

On November 15, 2022, The United States Food and Drug Administration (FDA) announced the final rule for Food Traceability. The Traceability Rule fulfills the mandate outlined in Section 204 of the Food Safety Modernization Act (FSMA) requiring FDA to develop a system for enhanced traceability of certain foods through the supply chain. The rule establishes additional record-keeping requirements for foods that are included in the traceability list.

Produce Items in the Food Traceability List (FTL)

The requirements of the Traceability Rule are limited to persons who manufacture, process, pack or hold foods on the FTL and to foods that contain listed foods as ingredients, provided the listed food that is used as an ingredient remains in the same form on which it appears on the list. If an entity handles FTL foods as well as non-FTL foods, the traceability record-keeping obligations only apply to the FTL foods, making it important to understand which foods are covered and which are not.

Produce items in the Food Traceability List include:

- Cucumbers (fresh)
- Leafy greens (fresh)
- Melons (fresh)
- Sprouts (fresh)
- Tropical tree fruits (fresh)
- Vegetables other than leafy greens (fresh cut)
- Herbs (fresh)
- Leafy greens (fresh cut)
- Peppers (fresh)
- Tomatoes (fresh)
- Fruits (fresh cut)

Critical Tracking Events (CTEs)

As part of the Food Traceability Rule, the FDA requires that those who manufacture, process, pack or hold food on the FTL to maintain key data elements (KDEs), which are specific data records pertaining to critical tracking events (CTEs).

The main CTEs in FSMA 204 are the following:

- Harvesting
- Initial packing
- Shipping
- Cooling before initial packing
- Transforming
- Receiving

Key Data Elements for Critical Tracking Events

Western Growers has developed an in-depth guide titled "Guidance for Compliance with the FDA Traceability Rule," to assist and give examples of the records for KDEs that need to be maintained for different *critical tracking events.*

A summary of the KDEs for each critical tracking event is found later in this document.

Traceability Lot Codes (TLC) and Traceability Lot Code Sources: [FDA Resource](#)

Traceability Lot Code: A *traceability lot code* means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source (defined below). Industry currently refers to this as a 'lot' or 'lot code.'

Produce operations must assign a traceability lot code when they:

- Initially pack a raw agricultural commodity (RAC)
- Transform a food
- Receive a food on the FTL from an exempt entity

Traceability Lot Code Source: A *traceability lot code source* refers to the physical location where a food was assigned a traceability lot code. In certain situations, the Food Traceability Rule requires documentation of either the *location description for the traceability lot code source (i.e., the place where food was assigned a traceability lot code), or the traceability lot code source reference* (e.g., the FDA food facility registration number or a web address).

Compliance Date

The compliance date for all persons subject to the Food Traceability Rule record-keeping requirements is Tuesday, January 20, 2026.

Checking for Exemptions to the Rule

Follow the exemptions to the Food Traceability Rule established in section § 1.1360.

Documentation Requirements

Records Maintenance

24-hour record availability

The rule also requires covered persons keep all required records for at least two years and provide them to the FDA within 24 hours of an FDA request (or within some reasonable time to which the FDA has agreed). Under certain circumstances, the FDA may request that covered persons provide certain CTEs and KDEs in the form of an electronic sortable spreadsheet.

English Translation

To be provided to FDA upon FDA request when records are in a language other than English.

Record retention time

Two years from the date you created or obtained the records.

Traceability Plan: FDA Rule

Those who are subject to the Food Traceability Rule must establish and maintain a traceability plan. The traceability plan should be updated as needed to ensure the information provided reflects current practices. You must retain all previous traceability plans for two years.

The traceability plan must include the following:

- A description of the procedures you use to maintain the records you are required to keep under the rule, including the format and location of these records.
- A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack or hold.
- A description of how you assign traceability lot codes to foods on the Food Traceability List.
- A statement identifying a point of contact for questions regarding your traceability plan and records.
- If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods. The 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.

Examples of Traceability Plans:

- Western Growers Traceability Plan Template for Growers
- FDA traceability Plan for Farms

NOTE: Farms that do not engage in other activities, such as harvesting, cooling or initial packing are nonetheless required to maintain a traceability plan.

Key Data Elements (KDEs) for Critical Tracking Events (CTEs)

Harvesting: FDA Rule

Records: Records for all KDEs below must be maintained, along with the harvester's business name and phone number for all raw agricultural commodities in the FTL.

Provide these records to the initial packer either directly from the harvester or throughout the supply chain. Refence document type and document do not need to be passed forward.

*The reference document type and reference document number are not required to be provided to the next recipient.

Key Data Elements that must be maintained:

KDE	Comment
The location description for the immediate subsequent recipient (other than a transporter) of the food	Generally, the initial packer location or cooling facility, if separate from the packer location
The commodity and, if applicable, variety of the food	Describe the commodity; be consistent throughout your records.
The quantity and unit of measure of the food	Depending on how the product is harvested, i.e., could be bins or cases if the product is field-packed
The location description for the farm where the food was harvested	Farm location description includes the business name, physical address or GIS coordinates, city, state, zip, country and phone number
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	Be consistent with the name of the field assigned in the grower's traceability plan.
The date of harvesting	PTI recommends that if harvesting over multiple days, record the final day of harvest.
The reference document type and reference document number*	Document may include but is not limited to purchase orders, sales order, production order, etc.

*The reference document type and reference document number are not required to be provided to the subsequent recipient.

Cooling (Before Initial Packing): [FDA Rule](#)

Records: Records for all KDEs below must be maintained by the cooler for all raw agricultural commodities in the FTL that you cool before it is initially packed.

Provide these records to: the initial packer

KDE	Comment
The location description for the immediate subsequent recipient (other than a transporter) of the food	The location of the initial packer. If cooling in the same location as the packer, record the cooling location.
The commodity and, if applicable, variety of the food	Should be the same as captured in harvest and should stay consistent throughout the process.
The quantity and unit of measure of the food	Could be cases or bins
The location description for where you cooled the food	Record the cooling location, which could be the same as the initial packer
The date of cooling	Record date; if multiple days use the final date before the product went to packing.
The location description for the farm where the food was harvested	Farm location description includes the business name, physical address or GIS coordinates, city, state, zip, country and phone number
The reference document type and reference document number*	Document may include but is not limited to purchase orders, sales orders, production orders, etc.

*The reference document type and reference document number are not required to be provided to the subsequent recipient.

Records: For each traceability lot of a raw agricultural commodity on the Food Traceability List you initially pack, you must maintain records containing the following information and linking this information to the traceability lot.

Provide these records to: The KDEs below should be maintained and must be linked to the traceability lot code assigned by the initial packer. Keep these records; no need to provide to subsequent recipient.

KDE	Comment
The commodity and, if applicable, variety of the food	Should be the same as captured in harvest and should stay consistent throughout the process.
The date you received the food	Record the receiving date.
The quantity and unit of measure of the food received	Similar to cooling, most likely will be bins.
The location description for the farm where the food was harvested	Farm location description includes the business name, physical address or GIS coordinates, city, state, zip, country and phone number.
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	Be consistent with the traceability plan (name of the field) assigned in the grower's traceability plan. You can also use other coding schemes.
The business name and phone number for the harvester of the food	Be consistent throughout your records.
The date of harvesting	Use same date as in the harvesting KDEs
The location description for where the food was cooled (if applicable)	Use the same location as the cooling KDEs
The date of cooling (if applicable)	Use the same date as the cooling KDEs
The traceability lot code you assigned	Assign a traceability lot code. See FDAs guide. Also PTIs guide.
The product description of the packed food	Product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
The quantity and unit of measure of the packed food	This is usually the numbers of cases packed
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	Use information from the traceability lot code source. Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The date of initial packing	PTI: If packing spans more than one day, use the last day of packing.
The reference document type and reference document number	Relevant documents include but are not limited to: Purchase order, Bill of Lading, work order, etc.

If the food you are packing is received from a person to whom the Traceability Food Rule does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

KDE	Comment
The commodity and, if applicable, variety of the food received	Should be the same as captured in harvest and should stay consistent throughout the process.
The date you received the food	Record the receiving date
The quantity and unit of measure of the food received	Similar to cooling, most likely will be bins.
The location description for the person from whom you received the food	Location description includes the business name, physical address or GIS coordinates, city, state, zip, country and phone number
The traceability lot code you assigned	Assign a traceability lot code. See FDAs guide. Also PTIs guide.
The product description of the packed food	Product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
The quantity and unit of measure of the packed food	This is usually the number of cases packed
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.	Use information from the traceability lot code source. Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The date of initial packing	PTI: If packing spans more than one day, use the last day of packing.
The reference document type and reference document number	Relevant documents include but are not limited to: Purchase Order, Bill of Lading, work order, etc.

Shipping: FDA Rule

Records: For each traceability lot of a food on the Food Traceability List you ship, you must maintain records containing the following information and linking this information to the traceability lot. *NOTE: This section does not apply to the shipment of a food that occurs before the food is initially packed.*

Provide these records to: All KDEs except the reference document type, and reference document number must be provided to the immediate subsequent recipient (electronic, paper or written form).

KDE	Comment
The traceability lot code for the food	See FDAs guide. Also PTIs guide.
The quantity and unit of measure of the food	This will be the cases that are being shipped.
The product description for the food	Product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
The location description for the immediate subsequent recipient (other than a transporter) of the food	Ship-to-location, physical location where the product is being shipped to: Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The location description for the location from which you shipped the food	Ship-from-location, physical location where product is being shipped from: Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The date you shipped the food	Date when product leaves the physical location from which it is shipped
The location description for the traceability lot code source or the traceability lot code source reference	Use information from the traceability lot code source from initial packing or transformation. Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The reference document type and reference document number*	Could be the packing list, bill of lading, invoice, etc. Make sure this is being tracked in the sortable spreadsheet.

The reference document type and reference document number are not required to be provided to the subsequent recipient.

Records: 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.

Provide these records to: The KDEs below should be maintained and must be linked to the traceability lot code assigned by the initial packer. Keep these records; no need to provide to subsequent recipient.

KDE	Comment
The traceability lot code for the food	The traceability lot code assigned to the product you are receiving
The quantity and unit of measure of the food	Number of cases received
The product description for the food	Product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
The location description for the immediate previous source (other than a transporter) for the food	Physical location from where the product was received; Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The location description for where the food was received	Physical location where product is being received. Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The date you received the food	Date when product got to the physical location where it was received
The location description for the traceability lot code source or the traceability lot code source reference	Use information from the traceability lot code source from initial packing or transformation. Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The reference document type and reference document number	Could be the packing list, bill of lading, invoice, etc. Make sure this is being tracked in the sortable spreadsheet.

If the food you are packing is received from a person to whom the traceability Food Rule does not apply, you must maintain records containing the following information and linking this information to the traceability lot. *NOTE: This section does not apply to receipt of a food that occurs before the food is initially packed.*

KDE	Comment
The traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to retail food establishments or restaurants)	If not assigned. Assign a traceability lot code. See FDAs guide. Also PTIs guide.
The quantity and unit of measure of the food	Number of cases received
The product description for the food	Product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
The location description for the immediate previous source (other than a transporter) for the food	Physical location from where the product was received; Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The location description for where the food was received (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference	Physical location where product is being received. Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The date you received the food	Date when product got to the physical location, where it was received
The reference document type and reference document number	Could be the packing list, bill of lading, invoice, etc. Make sure this is being tracked in the sortable spreadsheet.

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Transformation of Food: FDA Rule

Records: 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), reference the following information:

KDE	Comment
The traceability lot code for the food	The traceability lot code assigned to the product you are using
The product description for the food to which the traceability lot code applies	Product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
For each traceability lot used, the quantity and unit of measure of the food used from that lot	Could be cases, bins, pallets, etc.

2. For the food produced through transformation, reference the following information:

KDE	Comment
The new traceability lot code for the food	Assign a traceability lot code. See FDAs guide. Also PTIs guide.
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	Information includes business name, phone number, physical location address or GIS coordinates, city, state and zip code.
The date transformation was completed	Date on which the transformation was completed
The product description for the food	This should be for the case. It should include product name (including, if applicable, the brand name, commodity and variety), packaging size, packaging style
The quantity and unit of measure of the food	Normally number of cases
The reference document type and reference document number for the transformation event	Could be the packing list, bill of lading, invoice, etc. Make sure this is being tracked in the sortable spreadsheet.

Sortable Spreadsheet

During an investigation, the FDA will ask for a sortable spreadsheet for location, date ranges, products, traceability, descriptions, etc.

The FDA has outlined in its sortable spreadsheet template that each column within a spreadsheet represents a key data element (KDE), and that different tables within the spreadsheet represent a different critical tracking event (CTE).

Below is a list of resources for developing and maintaining a sortable spreadsheet:

- From the FDA: a complete list of KDEs required in sortable spreadsheets is available here.
- Sortable spreadsheet template from the FDA

The Produce Traceability Initiative has developed a few templates for different operations, which can be found below:

- Harvester/Cooler/Initial Packer/Transformer
- Receiver
- Shipper
- Final Distributor
- Retail Store
- Foodservice Operation/Restaurant

Summary of documentation requirements for example entities

Documentation Needed			
Entity Type	**Grower only**	**Entities that grow, harvest, cool and initially pack covered foods**	**Those that only repack or transform**

Documentation
 	
(Keep all records for two years)
	• Traceability Plan	• Traceability Plan
		• KDEs for all CTEs that are part of their operation
		  - Harvesting KDEs
		  - Cooling KDEs
		  - Initial Packing KDEs
		  - Shipping KDEs
		• Sortable spreadsheet
			• Traceability Plan
			• KDEs for all CTEs that are part of their operation
			  - Receiving KDEs
			  - Transformation KDEs
			  - Shipping KDEs
			• Sortable spreadsheet

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Additional Resources

[PTI: Produce Traceability initiative](#)
- [Implementation guide](#)
- [Lot code source and reference guide](#)
- Templates – [Within the resource page](#)
- [Best practices for formatting case labels](#)
- [Guides and examples](#)

Food and Drug Administration
- [Main Webpage – FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods](#)
- [Main Webpage – Frequently Asked Questions (FAQ)](#)
- [Small Entity Compliance Guide](#)
- [FDA Webinar on Traceability Rule](#)

KDEs/ CTEs/ Food Traceability List/ Lot Codes
- [Critical Tracking Events and Key Data Elements at Different Stages](#)
- [Food Traceability List](#)
- [Traceability Lot Code Information](#)
- [Traceability Plan Example for Farms](#)
- [Sortable Spreadsheet with CTE and KDEs](#)

Exemptions
- [Chart Summarizing Exemptions Relevant to Produce Farms](#)
- [Interactive Tool for Exemptions](#)

Examples
- [Supply Chain Example for Sprouts](#)
- [Supply Chain Example for Cucumbers (Video)](#)

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