



WESTERN GROWERS GUIDANCE FOR COMPLIANCE WITH THE FDA TRACEABILITY RULE

August 15, 2023
Version 1

GROW WITH
SCIENCE.



DISCLAIMER

This document represents a high-level summary designed to assist members of Western Growers in familiarizing themselves with certain key components of FDA's Final Rule: Requirements for Additional Traceability Records for Certain Foods. Although this summary highlights certain current regulatory requirements, it is not intended to be and cannot serve as a substitute for careful review or application of the regulatory framework as it relates to each member's own products and operations, nor does adherence to the descriptions of regulatory requirements contained herein ensure compliance with applicable statutory and regulatory requirements. This guide does not constitute legal advice, nor does it create or imply the existence of an attorney-client relationship. The recommendations are not exhaustive and may not apply in every situation. Western Growers does not assume any responsibility for members' compliance with applicable laws and regulations and recommends that users consult with their own legal and technical advisers to ensure that their procedures and operations meet relevant federal, state, and local requirements.

This guide is designed to provide an overview of and practical guidance for compliance with the Food and Drug Administration's (FDA) final rule: Requirements for Additional Traceability Records for Certain Foods¹ ("the Traceability Rule" or "the rule"). Below you will find both an overview of the Traceability Rule and specific content aimed at addressing questions posed by WG members.

These topics include:

- 1) What foods are and are not covered by the rule.
- 2) How to determine what requirements apply to you.
- 3) Identifying your responsibilities and how they impact supply chain operations.
- 4) How data and information will move through the supply chain.
- 5) What sharing information and data with FDA may look like.

1. 21 CFR §§ 1.1300 - 1.1465.

OVERVIEW OF THE TRACEABILITY RULE

The Traceability Rule fulfills the mandate outlined in Section 204 of the FDA Food Safety Modernization Act (FSMA) requiring FDA to develop a system for enhanced traceability of certain foods through the supply chain. *The rule requires any person who manufacturers, processes, packs or holds food on the established Food Traceability List (FTL) at certain nodes in the supply chain (called Critical Tracking Events (CTEs)) to maintain and share with their supply chain partners certain data and information (called Key Data Elements (KDEs));* see Appendix B for a list of KDEs and their definitions). Specifically, the rule assigns recordkeeping responsibilities to the critical tracking events of harvesting, cooling, initial packing of raw agricultural commodities, first land-based receiving, receiving, transformation, and shipping.

Central to the rule's operation is the establishment of traceability lot codes which will follow a food item through the supply chain in order to connect the same traceability lot to the relevant KDEs at each step in the supply chain. Traceability lot codes can only be assigned at the initial packing, first land-based receiving,² and transformation CTEs.³ The relevant KDEs must be maintained by each entity for two years after creation and while the rule does not mandate the form in which the data is stored, it does require that in certain cases the data be provided to FDA in an electronic, sortable spreadsheet within 24 hours of request.

In addition to these requirements, covered entities must also maintain a traceability plan that outlines the details of the entity's traceability program. This traceability plan may be routinely requested during facility inspections, along with traceability records.

FOOD TRACEABILITY LIST

The requirements of the Traceability Rule are limited to persons who manufacture, process, pack, or hold foods on the FTL and to foods (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 (e.g., fresh). If an entity handles FTL foods as well as non-FTL foods, the traceability recordkeeping obligations only apply to the FTL foods, making it important to understand which foods are covered and which are not. The FTL was developed by FDA based on a risk-ranking model that evaluated the comparative food safety risks of various commodity-hazard pairs. A detailed copy of the FTL is available in Appendix A. Below is a summary of the notable foods that are and are NOT on the FTL.



2. "First-land based receiving" applies to seafood, it is not addressed in this guide
3. Traceability lot codes can also be assigned at the receiving CTE when the receiver is the first covered entity to handle the food.

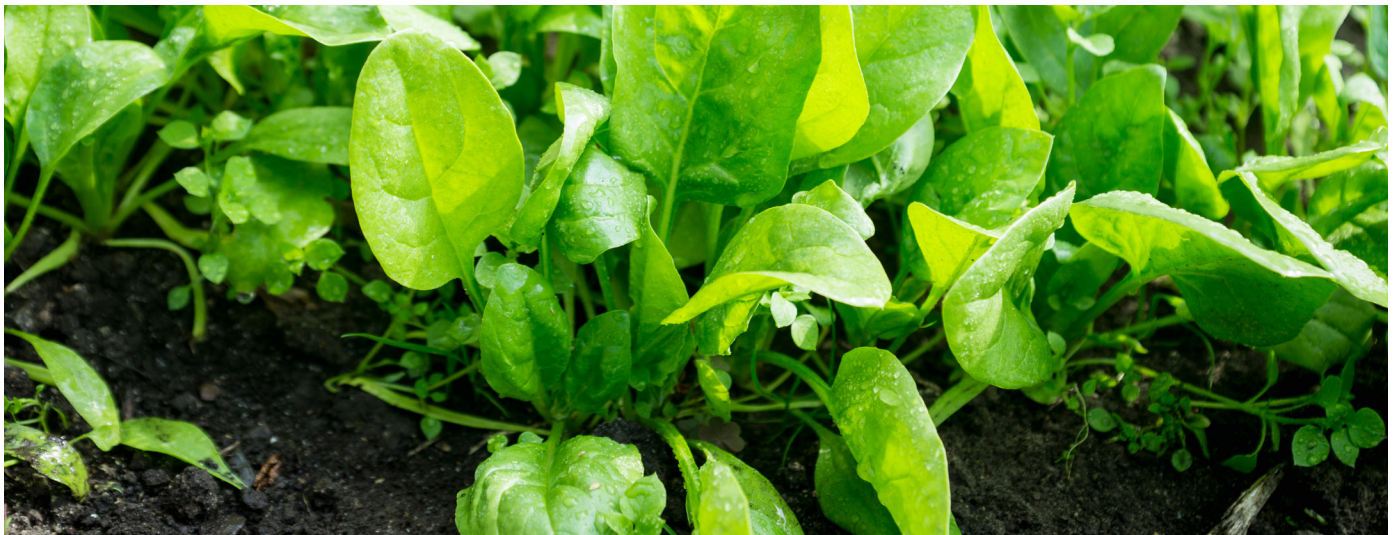
OVERVIEW OF THE TRACEABILITY RULE

Foods on the FTL and covered by the Traceability Rule

- Cheeses, other than hard cheeses
- Shell Eggs
- Nut Butters
- Fresh Cucumbers
- Fresh Herbs
- Fresh and Fresh-Cut Leafy Greens
- Fresh Melons
- Fresh Peppers
- Fresh Sprouts
- Fresh Tomatoes
- Fresh Tropical Tree Fruits
- Fresh-Cut Fruits and Vegetables
- Fresh, Smoked, and Frozen Finfish
- Fresh and Frozen Crustaceans
- Bivalve Molluscan Shellfish
- RTE Deli Salads

Examples of foods not on the FTL and not covered by the Traceability Rule

- Frozen, shelf-stable cheeses
- Frozen or dried versions of cucumbers, herbs, leafy greens, melons, peppers, sprouts, tomatoes, tree fruits, and cut fruits and vegetables
- Nut meals and powders
- Food that is produced and packaged on a farm when the packaging remains in place (21 CFR § 1.1305(c))
- Produce when a kill step has been applied (21 CFR § 1.1305(d))
- Produce that is identified as Rarely Consumed Raw in 21 C.F.R. § 112.2(a)(1)
- Foods that will be transformed or receive a kill step when there is a written agreement in place. (21 CFR § 1.1305(d))



FDA has indicated that it intends to review the FTL every five years subject to available resources. When new foods are added to the FTL, entities will have two years before the related recordkeeping requirements begin. When foods are removed from the FTL, the related recordkeeping obligations will terminate immediately.

Even though the FDA traceability requirements only apply to foods on the FTL, you may decide to apply the requirements to other foods that you handle. This may be because a customer asks you to treat all commodities the same or because you find it is easier within your own recordkeeping programs to do so. If you voluntarily choose to keep Traceability Rule records for foods NOT on the FTL, you will still not be subject to the rule requirements for these foods, and the FDA cannot enforce the rule with respect to those foods.

WHAT REQUIREMENTS APPLY TO ME?

Understanding what rules apply to a given entity is a two-part analysis. First, the rule provides numerous full and partial exemptions for entities and foods that meet certain characteristics. Second, after you determine whether or not you are exempt, you will determine your recordkeeping requirements based on whether your entity's operations meet the definition of each critical tracking event (keep in mind that more than one may apply). Once you have identified which CTEs you engage in, you will need to maintain the relevant KDEs for that CTE (and, in some cases, send information to the next party in the supply chain).



OVERVIEW OF THE TRACEABILITY RULE

EXEMPTIONS

Full exemptions to the Traceability Rule for **entities**:

- Farms (or the farm activities of farm mixed-type facilities) with respect to the produce they grow, when the farm is not subject to the Produce Safety Rule or farms with no more than \$25,000 in average annual produce sales as calculated under 21 CFR 112.⁴
- Other producers of RACs (other than produce or eggs) with an average annual monetary value of food sold during the previous 3-year period of no more than \$25,000, on a rolling basis, adjusted for inflation using 2020 as the baseline year for calculating the adjustment.⁵
- Transporters of food.⁶
- Nonprofit food establishments.⁷
- Persons who manufacture, process, pack, or hold food for personal consumption⁸.
- Certain persons who hold food on behalf of individual consumers (e.g., hotel desk concierge, reception desk staff in an apartment building, staff at an office complex).⁹
- Persons who manufacture, process, pack, or hold foods on the FTL during or after the time the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act, The Poultry Products Inspection Act, or the Egg Products Inspection Act.¹⁰
- Small retail food establishments and small restaurants with a rolling average annual monetary value of food sold or provided during the previous 3-years of no more than \$250,000.¹¹
- Shell egg producers with fewer than 3,000 laying hens at a farm, with respect to the shell eggs they produce at that farm.¹²

4. 4:21 CFR § 1.1305(a)(1).

7. 21 CFR § 1.1305(o).

10. 21 CFR § 1.1305(g).

5. 21 CFR § 1.1305(a)(3).

8. 21 CFR § 1.1305(p).

11. 21 CFR § 1.1305(i).

6. 21 CFR § 1.1305(n).

9. 21 CFR § 1.1305(q).

12. 21 CFR § 1.1305(a)(2).



OVERVIEW OF THE TRACEABILITY RULE

FULL EXEMPTIONS TO THE TRACEABILITY RULE FOR PRODUCE FOOD ITEMS:

- Produce that is identified as rarely consumed raw in 21 C.F.R. § 112.2(a)(1).¹³
- Food that is produced and packaged on a farm when 1) the packaging remains in place until the food reaches the consumer and 2) the packaging label includes the contact information for the producing farm.¹⁴
- Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., tomatoes that are canned), provided the conditions in Section 112.2(b) of the Produce Safety Rule are satisfied.¹⁵
- When it is known early in the supply chain that a food will be subject to a kill step (e.g., nut butter will be baked into a cookie) or be changed by another entity (other than by a restaurant, retail food establishment, or consumer) such that the food is no longer on the FTL (e.g., mango will be frozen), the food is exempt from traceability recordkeeping requirements provided there is a written agreement between the shipper and receiver stating that the receiver will apply a kill step or change the food such that it is no longer on the FTL.
- Foods designated for research or evaluation use provided that the food is not intended for retail sale or distribution to the public and is accompanied by the statement “food for research or evaluation use.”¹⁶

13. 21 CFR § 1.1305(e). The current exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

14. 21 CFR § 1.1305(c).

15. 21 CFR § 1.1305(d)(1). Note that the requirements of Section 112.2(b) of the Produce Safety Rule include requirements that farms disclose in documents accompanying the produce that the is “not processed to adequately reduce the presence of microorganisms of public health significance” and annually obtain written assurances from the relevant party in the supply chain that commercial processing will occur (21 CFR § 112.2(b)).

16. 21 CFR § 1.1305(r)

OVERVIEW OF THE TRACEABILITY RULE

FULL EXEMPTIONS TO THE TRACEABILITY RULE RELATED TO NON-PRODUCE FOOD ITEMS:

- Shell eggs from farms where all eggs produced receive a treatment in accordance with Section 118.1(a)(2) of the Shell Egg Rule.¹⁷
- Raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation program subject to the requirements of 21 C.F.R. § 1240.60 or covered by a final equivalence determination by FDA.¹⁸
- Commingled RACs other than produce, or those that will become commingled RACs provided there is a written agreement in place.¹⁹

In addition, there are the following partial exemptions, which apply if there is no written agreement in place: For FTL foods that undergo a kill step, the entity performing the kill step must maintain (1) records of the application of the kill step and (2) receiving records. Entities handling the food earlier in the supply chain must maintain the required records.

- For foods that are changed such that they are no longer on the FTL (e.g., freezing fresh spinach), the entity performing the change must maintain receiving records. Entities handling the food earlier in the supply chain must maintain the required records.

CTES AND KDES

The Traceability Rule assigns different entities slightly different responsibilities depending on whether they are engaged in harvesting, cooling, initial packing, first land-based receiving,² receiving, transforming, or shipping foods on the FTL. Below, each of these critical tracking events and their related requirements are explained. Keep in mind that it is possible to perform multiple CTE in your handling of a food. For example, an initial packer will be responsible for both initial packer and shipping KDEs.

Note that although “growing” is not a CTE, farms that do not engage in other activities such as harvesting, cooling, or initial packing are nonetheless required to maintain a traceability plan, as explained further below.

17. 21 CFR § 1.1305(d)(2).

18. 21 CFR § 1.1305(f)

19. 21 CFR § 1.1305(h).

OVERVIEW OF THE TRACEABILITY RULE

HARVESTING

- **Definition:** The activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food.
- **Example Operations:** Harvesting and stripping lettuce crops in a field; removing tomatoes from plants in a greenhouse, etc.
- **Records:** The relevant KDEs listed below must be maintained, and along with the harvester's business name and phone number, must be provided to the initial packer either directly from the harvester or through the supply chain. Note that the reference document type and number do not need to be passed forward.

Key Data Element	Example
Location Description for next recipient	ABC Packing House, 123 1st St., Produce City, CA, 99999
Commodity and variety (if applicable)	Tomatoes, Cherry
Quantity and Unit of Measure (UOM)	200 Cases
Location Description of Farm	XYZ Farms. 100 Farm Ave., Produce City, CA, 99999
Date of Harvesting	4/21/2023
Name of Growing Area	"Field 2," or GPS Coordinates, or other identifying name
Reference Document Type and Number	Packing Slip 123
Harvester Business Name and Phone Number	XYZ Farms. (123) 555-1234

OVERVIEW OF THE TRACEABILITY RULE

COOLING (BEFORE INITIAL PACKING)

- **Definition:** The active temperature reduction of a raw agricultural commodity.
- **Example Operations:** Pre-cooling activities occurring in packinghouses; standalone cooling operations.
- **Records:** The relevant KDEs listed below must be maintained by the cooler, and all KDEs except for the reference document type and number must be provided to the initial packer either directly or through the supply chain.

Key Data Element	Example
Location Description for next recipient	ABC Packing House, 123 1st St., Produce City, CA, 99999
Commodity and variety (if applicable)	Tomatoes, Cherry
Quantity and Unit of Measure	200 Cases
Location Description of where the food was cooled	AAA Cooling Services, 55 Freeze Ave., Produce City, CA, 99999
Date of Cooling	4/22/2023
Location Description for the farm where harvested	XYZ Farms. 100 Farm Ave., Produce City, CA, 99999
Reference Document Type and Number	Packing Slip 123



OVERVIEW OF THE TRACEABILITY RULE

INITIAL PACKING OF RAW AGRICULTURAL COMMODITIES²⁰

- **Definition:** The packing of a raw agricultural commodity, other than food obtained from a fishing vessel for the first time.
- **Example Operations:** Packing tomatoes into produce crates for transport to processor, packaging lettuce in bag to be sent to grocery stores, etc.
- **Records:** All of the relevant KDEs below must be maintained and must be linked to the traceability lot code assigned by the initial packer.²¹

Key Data Element	Example
Commodity and variety (if applicable)	Tomatoes, Cherry
Quantity and UOM of Packed Food	200 Cases
Date of Receipt	4/25/2023
Location Description for the farm where harvested	"Field 2," GPS Coordinates, other identifying name
Business Name and Phone Number of Harvester	XYZ Farms (123) 555-1234
Traceability Lot Code	TC0425231
Product Description of Packed Foods	20 ct. Cherry Tomatoes in Bag
Date of Initial Packing	4/26/2023
Location description of where the food was initially packed (i.e., the Traceability Lot Code Source or Traceability Lot Code Source Reference)	ABC Packing House, 123 1st St., Produce City, CA, 99999
Reference Document Type and Number	PO 456

20. Note that this guidance does not address recordkeeping for initial packers of sprouts"

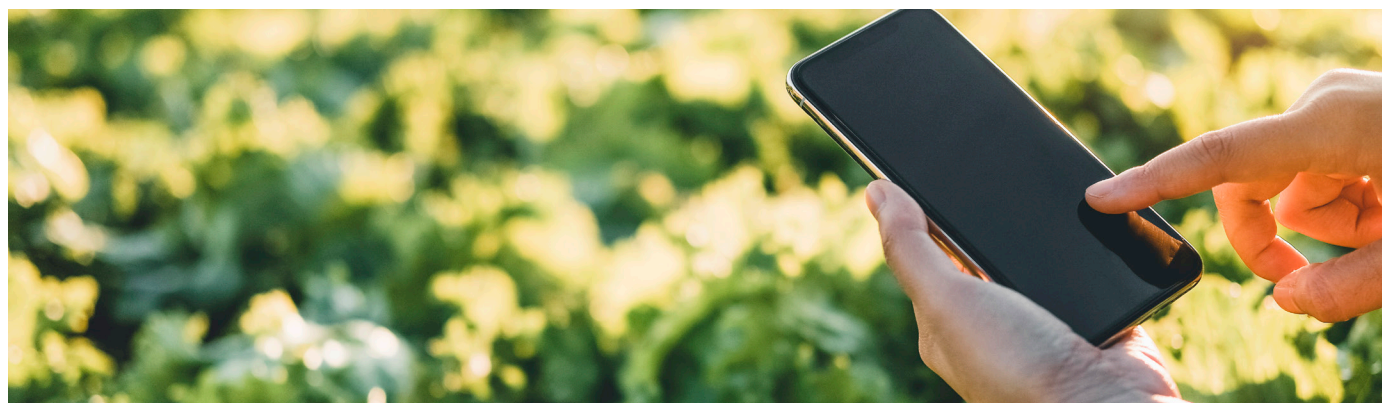
21. Note if you as the initial packer receive an FTL food from a person who is not covered by the Traceability Rule, you must maintain the following records: (1) the commodity and variety, if applicable, (2) the date of receipt, (3) the quantity and unit of measure of the food, (4) the location description for the person from whom you received the food, (5) the traceability lot code you assigned, (6) the product description of the packed food, (7) quantity and unit of measure of the packed food, (8) the location description of where the food was initially packed, (9) the date of packing, and (10) the reference document type and reference document number

OVERVIEW OF THE TRACEABILITY RULE

SHIPPING

- **Definition:** An event in a food's supply chain where it is transported from one physical address to another, including intracompany shipments. Shipping KDEs do not apply to the shipment of food that occurs before the food is initially packed.
- **Example Operations:** Farm that packs harvested produce and ships produce to food manufacturer; shipping food from processing plant to off-site warehouse, etc.
- **Records:** All of the relevant KDEs must be linked to the traceability lot code previously assigned and maintained by the shipper. All KDEs except the reference document type and reference document number must be provided to the immediate subsequent recipient.

Key Data Element	Example
Traceability Lot Code	TC0425231
Quantity and UOM	200 Cases
Product Description for Food	20 ct. Cherry Tomatoes in Bag
Location Description for next recipient	345 Grocery, 123 Store Lane, Produce City, CA 99999
Location Description where the food was Shipped	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA, 99999
Date food was Shipped	4/30/2023
Traceability Lot Code Source or Traceability Lot Code Source Reference	ABC Packing House, 123 1st St., Produce City, CA, 99999
Reference Document Type and Number	BOL 789



OVERVIEW OF THE TRACEABILITY RULE

RECEIVING

- **Definition:** An event in a food's supply chain when food is received by someone other than a consumer after being transported from one physical location to another, including intracompany shipments. Receiving KDE requirements do not apply to receipt of food that occurs before the food is initially packed.
- **Example Operations:** Food processor receiving produce from a farm, a warehouse receiving produce from an initial packer, a restaurant receiving produce from a distributor, etc
- **Records:** All of the relevant KDEs must be linked to the traceability lot code previously assigned. When food is received from a person who is exempt from the rule, the receiver must assign a traceability lot code if one has not already been assigned (does not apply to RFEs or restaurants) and maintain the receiving KDEs.

Key Data Element	Example
Traceability Lot Code	TC0425231
Quantity and Unit of Measure	200 Cases
Date of Receipt	4/25/2023
Product Description for Food	20 ct. Cherry Tomatoes in Bag
Location Description for Immediate Previous Source	ABC Fish Processor, 123 Ocean Road, Port City, ME, 99999
Location Description for where food is received	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA, 99999
Traceability Lot Code Source or Traceability Lot Code Source Reference	ABC Fish Processor, Port City, ME, 99999
Reference Document Type and Number	BOL 789

OVERVIEW OF THE TRACEABILITY RULE

TRANSFORMATION

- **Definition:** An event in a food's supply chain that involves manufacturing/processing a food or changing a food or its packaging when the food output is on the Food Traceability List. Transformation does not apply to retail food establishments and restaurants with respect to foods they do not ship.
- **Example Operations:** Turning fresh cucumbers into fresh-cut cucumbers, changing peanuts into peanut butter; mixing leafy greens into a bagged salad mix, etc.
- **Records:** All of the relevant KDEs must be linked to the traceability lot code assigned during the transformation. For raw agricultural commodities and sprouts that are not initially packed before transformation, the transformer also must maintain initial packer KDEs.

Key Data Element	Example
For FTL Foods Used as Ingredients	
Traceability Lot Code	TC0425231
Product Description for Food (ingredient)	20 ct. Cherry Tomatoes in Bag
Quantity and Unit of Measure (from this lot)	80 Cases
For new FTL Foods Produced	
New Traceability Lot Code	FF0429231
Traceability Lot Code Source or Traceability Lot Code Source Reference	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA, 99999
Date Transformation was Completed	4/29/2023
Product Description for Food	Cod and Vegetable Frozen Dinner
Quantity and Unit of Measure	100 boxes
Reference Document Type and Number	BOL 789

SUPPLY CHAIN OBLIGATIONS

Traceability Rule Scope

The Traceability Rule does not require end-to-end traceability or full visibility for each entity through the supply chain. Instead, the rule focuses on the use of traceability lot codes to recreate the path of a food in the event of a traceback investigation. Functionally, some entities, such as initial packers, will need to maintain information further than one step back in the supply chain. Additionally, the traceability lot code source needs to be maintained at every CTE that follows the traceability lot code assignment. This may mean that some entities further down the supply chain will have visibility into the initial packer, but not any intervening steps. *The obligations under the Traceability Rule are very narrowly tailored to the express KDEs required at each step. Also note that the Traceability Rule does not replace the one-up, one-back requirements outlined in the Bioterrorism Act.*

Oversight of Supply Chain Partners

FDA has articulated that it is the responsibility of any covered entity to ensure that the required records are being maintained, including records that can only be provided by a previous participant in the supply chain. While it is understood that entities will not always have visibility or influence over the operations of their supply chain partners, the agency encourages collaboration in the industry to educate and promote universal compliance. *Specifically, in FDA's training webinar on the Traceability Rule, the agency emphasized that importing entities are subject to the Traceability Rule and encouraged importers to work with their international counterparts to ensure they understand the requirements.*²² FDA has not provided practical guidance on how to encourage compliance among supply chain partners, but the possibilities include:

- Require suppliers to provide assurances of compliance in your supplier oversight activities.
- Structure payment terms such that invoices will only be paid if the relevant KDEs are included in the invoice.

In the event that a supplier is not compliant with the Traceability Rule, and you receive goods that should already have been assigned a traceability lot code, it would be appropriate to assign one yourself as if the previous entity was not covered by the rule.

22. FDA, Webinar on the Food Traceability Rule, FDA.gov (Dec. 7, 2022), <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/webinar-food-traceability-final-rule-12072022>.



TRACEABILITY PLAN

The Traceability Rule also requires all covered entities to maintain a traceability plan that acts as a roadmap for your program and where the different data elements can be found. The plan must include:

- Description of the procedures you use to maintain the required records, including the format and location of the records.
- Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack, or hold and how you assign traceability lot codes to foods on the FTL, if applicable.
- Description of how you assign traceability lot codes.
- Statement identifying a point of contact for questions regarding your traceability plan and records.
- If you grow a food on the FTL (other than eggs), a farm map showing the areas in which you grow such foods, including the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area. An example of a farm map is provided in Appendix D.

See Appendix C for an example of a traceability plan. The plan should be updated as needed to ensure it accurately reflects current practices and is compliant with the rule. Any outdated plans need to be retained for at least two years following the plan update.

HOW DOES INFORMATION MOVE BETWEEN CTES

The Traceability Rule does not mandate that KDEs are kept in a specific form as long as the information can be provided to FDA in a timely manner. An important aspect of the rule is that it requires certain KDEs to be shared with other members of the supply chain, which means covered entities need to ensure they have mechanisms in place to share information. *KDEs can be shared via paper forms that move with the product, electronic records sent between supply chain partners, or any other way feasible within the industry.* Much of the relevant information is likely already being passed along the supply chain in bills of lading, invoices, purchase orders, advance shipping notices, truck manifests, etc. Below are a couple of examples of how this information may travel.

RESPONSIBILITIES UNDER THE TRACEABILITY RULE

EXAMPLE: BILL OF LADING

OP-097G 11/11
Straight bill of lading—original—not negotiable

DATE: _____
 B/L NO.: _____

Date, Reference Doc. Type and Number

Place PRO label here.

SHIPPER NO. _____ TRAILER NO. _____
 SHIPPER NAME _____
 ADDRESS _____ **Location Description**

CITY _____ STATE _____ ZIP CODE _____
 ORIGIN CITY (IF DIFFERENT FROM ABOVE) _____ STATE _____ ZIP CODE _____

CONSIGNEE NAME AND ADDRESS _____

 DESTINATION CITY _____ STATE _____ ZIP CODE _____
 PHONE NO. _____

INVOICEE OR COD REMIT TO NAME (IF DIFFERENT FROM SHIPPER) _____
 ADDRESS _____

 CITY _____ STATE _____ ZIP CODE _____
 ATTN. _____

CUSTOMER NO. _____ STORE NO. _____ DEPT. _____
 P.O. NO. _____
 SPECIAL INSTRUCTIONS _____

COD FEE PREPAID COLLECT COD AMT \$ _____ CUSTOMER CHECK OK FOR COD AMOUNT? Yes No

NO. SHPNG UNITS	PKG TYPE	HM	DESCRIPTION OF ARTICLES, SPECIAL MARKS AND EXCEPTIONS	NMFC ITEM NO.	CLASS	WEIGHT (LB) SUBJ TO CORR	RATE	CHARGES CARRIER USE ONLY
Quantity and UOM			Product Description and could contain TLC, TLC Source, etc.					

EMERGENCY CONTACT
 Phone: _____ Name: _____ Contract #: _____

SHIPMENT CHARGES PREPAID UNLESS MARKED COLLECT: COLLECT TOTAL CHARGES \$ _____

NOTE (1) Where the rate depends on value, shippers must state specifically in writing the agreed or declared value of the commodity as follows: _____

NOTE (3) Products requiring special or additional care or attention in handling or stowing must be so marked and packaged as to ensure safe transportation with ordinary care. See Sec. 2(e) of NMFC Form 350.

RESPONSIBILITIES UNDER THE TRACEABILITY RULE

EXAMPLE: INVOICE

Location Description of Shipper

Street Address City, State

[Phone:] [Fax:]

[Email:]

Billed To:

Location Description of Receiver

Invoice Number: Doc. Type and No.

Invoice Date Ship Date

Due Date _____

Description	Price	Quantity	Total
Product Description including TCL & TLC Source		Quantity and UOM	

RESPONSIBILITIES UNDER THE TRACEABILITY RULE

EXAMPLE: ORIGINAL FORM SENT VIA EMAIL

(SHIPPING KDES PASSED TO NEXT RECEIVER)

SHIPMENT TRACEABILITY INFORMATION

Order No/ Pallet No./Ect.	Traceability Lot Code	Quality and Unit of Measure	Product Description for Food	Location Description for next description	Location Description where the food was shipped	Date food was Shipped	Traceability Lot Code Source or Traceability Lot Code Source Reference	Reference Document Type and Number
1	TC0425231	80 Cases	20 ct. Cherry Tomatoes in Bag	345 Grocery, 123 Store Lane, Produce City, CA 99999	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA 99999	4/30/2023	ABC Packing House, 123 1st St., Produce City, CA 99999	BOL 789
2	CC0423235	200 Pounds	Cucumbers in Tote	345 Grocery, 123 Store Lane, Produce City, CA 99999	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA 99999	4/30/2023	ABC Packing House, 123 1st St., Produce City, CA 99999	BOL 789
3	042524PINE	30 Cases	Fresh-cut Pineapple	345 Grocery, 123 Store Lane, Produce City, CA 99999	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA 99999	4/30/2023	ABC Packing House, 123 1st St., Produce City, CA 99999	Invoice 123

RESPONSIBILITIES UNDER THE TRACEABILITY RULE

FDA REQUESTS FOR DATA

The Traceability Rule requires that all records be made available to FDA within 24 hours of a request, unless FDA has agreed to another reasonable time in a given circumstance. This information can be requested during a routine inspection or as part of a traceback investigation, and must be provided in an electronic, sortable spreadsheet when necessary to support FDA's efforts to prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or to otherwise address a threat to the public health. This includes but is not limited to situations where FDA has a reasonable belief that a food presents a risk of serious adverse health consequence or death to humans or animals (SAHCODHA) hazard. This spreadsheet may include weblinks and may be required to be provided in English within a reasonable time if not maintained in English. These requests may be made by phone and can be made in writing upon request.

The records established and maintained under this rule must be maintained for two years from the date they were created. This information does not need to be stored on-site, and covered entities may enter into agreements with individuals or other firms to create and keep records required by FDA on their behalf.

In many cases, the electronic, sortable spreadsheet may be able to be pulled directly from an entity's ERP or other operational tracking system, but FDA does not mandate the form these records are stored or provided in. Below are examples of electronic sortable spreadsheets for different CTEs.

EXAMPLE 1 – HARVESTER

HARVEST ELECTRONIC, SORTABLE SHEET

Location Description for next recipient	Commodity and variety (if applicable)	Quality and Unit of Measure	Location Description of Farm	Date of Harvesting	Name of Growing Area	Reference Document Type and Number	Reference Document Type and Number	Business Name and Phone Number of Harvester
ABC Packing House, 123 1st St., Produce City, CA 99999	Tomatoes, Cheery	200 Cases	20 ct. Cherry Tomatoes in Bag	XYZ Farms, 100 Farm Ave., Produce City, CA 99999	4/35/2023	Field 2	Packing Slip 123	Bob's Harvesting (123) 555-1234
ABC Packing House, 123 1st St., Produce City, CA 99999	Cucumbers	500 Lbs	Cucumbers in Tote	Mr. Potato Farms, 555 Potato Road, Produce City, CA 99999	4/35/2023	123 Potato Rd.	Harvesting Plan	Bob's Harvesting (123) 555-1234
ABC Packing House, 123 1st St., Produce City, CA 99999	Tricolor Bell Peppers	100 Totes	Fresh-cut Pineapple	Mr. Pepper Farms, 777 Pepper St., Produce City, CA 99999	4/35/2023	36.7014631,-118.755997	Invoice 4019	Bob's Harvesting (123) 555-1234

RESPONSIBILITIES UNDER THE TRACEABILITY RULE

EXAMPLE 2 – RECEIVER²³

TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
UPC:456456456403. BIUB:12OCT2020	50 Cases	Charles Cheese Co. Brand Feta Cheese 10 X 3 2 oz Containers	Charles' Cheese Co	Distro Foodservice DC #45	9/23/2020	Ffrn:456456	PO111101
(01)11411411411404(10) FPP16-092220	100 Cases	Fresh Processor Brand, Cut Mangos, 12x1 Lb Bags	Fresh Processor Plant #16	Distro Foodservice DC #45	9/23/2020	11231 TLC Source, TLCville, MN, 55441	PO456213
(01)11411411411404(10) FPP16-092220	50 Cases	Fresh Processor Brand, Cut Cantaloupe 12x1 Lb Bags	Fresh Processor Plant #16	Distro Foodservice DC #45	9/23/2020	https://id.gs1.org/01/11411411411402/10/FPP16092420	BOL 11401
(01)11411411411404(10) FPP16-092220	100 Cases	Fresh Processor Brand, Garden Salad Kit, 10x12 Oz Bags	Fresh Processor Plant #16	Distro Foodservice DC #45	9/23/2020	https://id.gs1.org/01/11411411411401/10/FPP16092120	BOL 11401
(01)11411411411404(10) FPP16-092220	140 Cases	Freshfish Brand, Frozen Yellowfin Tuna Steaks, 25 Lb Case	FreshFish Importer Inc.	Distro Foodservice DC #45	9/23/2020	https://id.gs1.org/01/2232232232302/10/FP1202009-20	BOL 22302

EXAMPLE 3 – TRANSFORMER

TRANSFORMATION ELECTRONIC, SORTABLE SPREADSHEET

Traceability Lot Code	Product Description for Food (ingredient)	Quality and Unit of Measure (from this lot)	New Traceability Lot Code	Traceability Lot Code Source or Traceability Lot Code Source Reference	Date Transformation was Completed	Product Description for Food	Quantity and Unit of Measure	Reference Document Type and Number
TC0425231	20 ct. Cherry Tomatoes in Bag	80 Cases	2FF0429231	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA 99999	4/29/2023	Cod and Vegetable Frozen Dinner	100 boxes	BOL 789
COD1234	Frozen Cod Fillets	200 Pounds	FF0429231	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA 99999	4/29/2023	Cod and Vegetable Frozen Dinner	100 boxes	Invoice 179
PINE44551	Fresh-Cut Pineapple	30 Cases	A04300234	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA 99999	4/29/2023	Mixed Fruit Salad	200 boxes	OL 334

23. Example from FDA resource available at <https://www.fda.gov/media/163838/download> Presentation Slides - Webinar on the Food Traceability Final Rule (December 7, 2022) (fda.gov)

EXCEPTION TO THE ELECTRONIC, SORTABLE SPREADSHEET REQUIREMENT

There is a narrow exception to the requirement that data be provided to FDA in an electronic, sortable spreadsheet when requested. This exception is narrowly tailored to relieve the burden of producing an electronic, sortable spreadsheet and does not relieve those who qualify from providing this information to FDA in another form. This exception applies to three types of entities:

- Farms with a three-year rolling sales average of no more than \$250,000,
- Retail food establishments and restaurants with a three-year rolling sales average of no more than \$1 million, and
- Persons other than a farm, retail food establishment, or restaurant whose three-year rolling sales average is no more than \$1 million.

FREQUENTLY ASKED QUESTIONS

If all of the FTL foods produced on a farm are packaged on the farm, and the packaging remains in place until the food reaches the consumer such that it is exempt from the Traceability Rule under 21 CFR § 1.1305(c), does the farm need to maintain a traceability plan?

Under 21 CFR § 1.1315 a traceability plan is required for all entities that are subject to the requirements of the Traceability Rule. If an entity is fully exempt from the rule, then they are not required to maintain a traceability plan. When a farm is exempt because its produce is packed in the field and that packaging remains intact until purchased by a consumer under 21 CFR § 1.1305(c), the entity itself is still subject to the Traceability Rule. Specifically, this exemption still requires that the farm include its name, complete address, and phone number on the product label. Because this is only a partial exemption and one that applies to foods and not entities, the farm would still be required to maintain a traceability plan.

Do I need to maintain information electronically?

No, FDA explicitly did not mandate that traceability records be maintained in a specific format and covered entities are permitted to choose their preferred storage method. That said, the rule still requires traceability records to be provided in an electronic, sortable spreadsheet within 24 hours when it is necessary to address a threat to the public health. For this reason, you may decide it is worthwhile to store the information electronically, but this is not required.



RESPONSIBILITIES UNDER THE TRACEABILITY RULE

Where can I find the rule or learn more about the rule?

FDA has created numerous resources to help industry learn about the rule including:

- The final Traceability Rule:
[eCFR :: 21 CFR Part 1 Subpart S -- Additional Traceability Records for Certain Foods](#)
- FDA's Traceability Rule Website:
[FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods | FDA](#)
- FDA's tool for identifying relevant exemptions:
[Traceability Exemptions Flow Chart \(fda.gov\)](#)
- FDA's guide to CTEs and KDEs:
[Food Traceability Rule: Critical Tracking Events and Key Data Elements \(fda.gov\)](#)
- A produce supply chain example video:
[How the Food Traceability Rule works: Produce Supply Chain Example - YouTube](#)
- Frequently Asked Questions:
[Frequently Asked Questions: FSMA Food Traceability Rule | FDA](#)
- Initial webinar explaining the Traceability Rule:
[Webinar on the Food Traceability Final Rule - 12/07/2022 | FDA](#)

APPENDIX A – FOOD TRACEABILITY LIST AS OF NOVEMBER 21, 2023

Food Traceability List	Description
Cheeses, other than hard cheeses, specifically	
Cheese (made from pasteurized milk), fresh soft or soft unripened	Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna; does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Cheese (made from pasteurized milk), soft ripened or semi-soft	Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Cheese (made from unpasteurized milk), other than hard cheese ¹	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.
Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e).
Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.

1. "Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, colby cheese as defined in 21 CFR 133.118 and caciocavallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.

Key Data Element	Example
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.
Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Vegetables other than leafy greens (fresh-cut)	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Finfish (fresh and frozen), specifically:	
Finfish, histamine-producing species	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.
Finfish, species potentially contaminated with ciguatoxin	Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.
Finfish, species not associated with histamine or ciguatoxin	Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout. ² Siluriformes fish, such as catfish, are not included. ³
Smoked finfish (refrigerated and frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish. ⁴

2. For a more comprehensive list, see Chapter 3 of the Fish and Fishery Products Hazards and Controls Guidance at <https://www.fda.gov/media/80637/download>.

3. Data for catfish were excluded from the Risk-Ranking Model because Siluriformes fish (such as catfish) are primarily regulated by the U.S. Department of Agriculture.

4. "Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 CFR 123.3(s).

Key Data Element	Example
Crustaceans (fresh and frozen)	Includes all crustacean species. Examples include but are not limited to shrimp, crab, lobster, and crayfish.
Molluscan shellfish, bivalves (fresh and frozen) ⁵	Includes all species of bivalve mollusks. Examples include, but are not limited to, oysters, clams, and mussels. Does not include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 CFR part 123, subpart C, and 21 CFR 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish are exempt from the requirements of the rule under § 1.1305(f).
Ready-to-eat deli salads (refrigerated)	Includes all types of refrigerated ready-to-eat deli salads. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. Does not include meat salads.

5. Under 21 CFR 123.3(h), molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

APPENDIX B – KEY DATA ELEMENT DEFINITIONS.²⁴

Term	Definition
Location description	Key contact information for the location where food is handled specifically the business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code for domestic locations and comparable information for foreign locations, including country.
Point of contact	An individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number.
Product description	A description of a food product and includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market name.
Reference document	A business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.
Reference document number	An identification number assigned to a specific reference document.
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	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
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 this subpart. 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.

24. 21 CFR 1.1310

APPENDIX C – SAMPLE TRACEABILITY PLAN²⁵

The following is the Traceability Plan for Lizzie's Lettuce. **This is an example of a Traceability Plan. Please refer to §1.1315 of the Final Rule for the information that should be included in a Traceability Plan.*

Procedures to Maintain the Records

Digital records of all required KDEs are captured and stored in our commercial software solution.

Hard copies of Bills of Ladings are provided to subsequent recipients containing all KDEs except TLC/TLC Source Reference which is barcoded on product case labels. Some companies also receive digital advanced shipment notices containing all required KDEs.

Procedures to Identify FTL Foods

All products packed at this facility are on the FTL.

Assigning Traceability Lot Codes

Unique products/pack sizes are assigned a 14-digit case GS1 GTIN. Internal lot codes are assigned using date (MMDDYY) and packing line ("AAA" – "ZZZ"). Together the case GTIN and Internal Lot code represent our **traceability lot code**.

Point of Contact

Sarah Tree, Traceability Manager, 123-456-7899

Farm Map

See Appendix

Traceability Plan Updates

This plan is reviewed annually as part of our management review of our food safety system, as well as whenever something changes in our traceability procedure. Each previous traceability plan is kept in a [folder on SharePoint](#) for at least two years after it is updated.

25. Example from FDA resource available at <https://www.fda.gov/media/163838/download> Presentation Slides - Webinar on the Food Traceability Final Rule (December 7, 2022) (fda.gov)

APPENDIX D – FARM MAP EXAMPLE²⁶

Appendix: Lizzie’s Lettuce Field Map

Lizzie’s Farm
Address: 113 Farm St, Farms, CA 11311

Field Name	Field Geographic Coordinates
Field A-08	-24.500145, -11.107417
Field D-03	-24.500144, -11.107418
Field C-02	-24.500146, -11.107419
Field B-09	-24.500147, -11.107416

26. Example from FDA resource available at <https://www.fda.gov/media/163838/download>"Presentation Slides - Webinar on the Food Traceability Final Rule (December 7, 2022) (fda.gov).



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