

Guide to the FDA Food Safety Modernization Act Traceability Rule

Requirements for Additional Traceability Records for Certain Foods

21 CFR §§ 1.1300-1.1465



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October 5, 2023

This document represents a high-level summary designed to assist members of the National Retail Federation and FMI-The Food Industry Association 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 DOCUMENT IS FOR GENERAL INFORMATION ONLY AND IS NEITHER INTENDED AS NOR DOES IT CONSTITUTE LEGAL ADVICE OR CREATE AN ATTORNEY-CLIENT RELATIONSHIP WITH ANY PERSON OR ENTITY.** Competent legal counsel should be consulted regarding any member's compliance with the FDA's Final Rule, and the information herein should not be used or relied upon in regard to any particular facts or circumstances. This document does not reflect any developments after the date on the first page.

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National Retail Federation and FMI: Guide to FSMA Traceability Rule

This guide is designed to provide retailers and restaurants 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 Foods"¹ ("the traceability rule" or "the rule"). Below you will find an overview of the traceability rule, specific content aimed at addressing questions posed by NRF and FMI members, and examples of how a restaurant or retailer may comply with the rule.

These topics include:

- (1) an overview of the traceability rule;
- (2) how different entities in the supply chain interact with the rule;
- (3) what sharing information and data with FDA may look like; and,
- (4) what complying with the rule may look like for you and your supply chain partners.

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 high-risk foods through the supply chain. Affected entities must come into compliance with the rule by January 20, 2026.² The rule requires any person who manufactures, 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)). 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.³

Central to the rule's operation is the establishment of traceability lot codes, which will follow a food 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, and transformation CTEs.⁴ 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.

¹ 21 CFR §§ 1.1300 - 1.1465.

² In September 2023, FDA announced it would not conduct routine inspections of traceability records required by the final rule until 2027.

³ For the purposes of this guide, we will be focused on the receiving, transformation, and shipping CTEs and specifically when these activities are performed by retail food establishments, restaurants, or distributors.

⁴ Traceability lot codes can also be assigned at the receiving CTE when the receiver is the first covered entity to handle the food as long as the receiver is not a retailer or restaurant.

Food Traceability List

The requirements of the traceability rule are limited to persons who manufacture, process, pack, or hold foods on the Food Traceability List (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 in 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 C and below is a summary of the notable foods that are and are NOT on the FTL.

Foods on the FTL and Covered by the Traceability Rule	Examples of Foods NOT on the FTL and Not Covered by the Traceability Rule
<ul style="list-style-type: none">•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	<ul style="list-style-type: none">•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, and when foods are removed from the FTL the related recordkeeping obligations will terminate immediately.

FAQ: What if you choose to apply the traceability requirements to all products?

Even though the FDA traceability requirements only apply to foods on the food traceability list, 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, then FDA cannot enforce the rule with respect to those foods.

Retail Food Establishments and Restaurants under the Rule

The final rule includes specific definitions for Retail Food Establishments and Restaurants referred to in the rule's provisions.⁵ The full definitions are available in Appendix H – Definitions of Restaurant and RFE. Of note, the definition of restaurant is limited to facilities that prepare and sell “food directly to consumers for immediate consumption” and lists both facilities that provide food to humans and animals (i.e., pet shelters, kennels, etc.) as examples of restaurants.

The rule's definition of a retail food establishment is more involved and is limited to establishments that sell food products directly to consumers as the primary function. This includes facilities that manufacture, process, pack, or hold food as long as the primary function is to sell these food products directly to consumers. Selling food to consumers will be considered an establishment's primary function when the annual value of sales of food products to consumers is greater than the value of sales of food products to other buyers. This definition can include certain farm-operated businesses selling food directly to consumers as their primary function such as roadside stands, community supported agriculture programs, and other direct-to-consumer sales platforms including online platforms.

Exemptions for Retailers and Restaurants

The rule provides several full and partial exemptions for different entities in the supply chain, as well as specific foods. Below is a summary of the exemptions most relevant to retailers and restaurants. For a full list of the available exemptions to the traceability rule, please see Appendix G – Complete List of Exemptions.

Full exemptions to the traceability rule for **retailers and restaurants**:

- 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 \$250,000.⁶ Note that the sales calculation is performed at the location, not brand or owner, level.
- Nonprofit food establishments.⁷
- 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).⁸

Partial exemptions to the traceability rule for **retailers and restaurants**:

- FTL food purchases made by one retail food establishment or restaurant from another retail food establishment or restaurant on an ad hoc basis⁹ outside the buyer's usual purchasing practice, if the purchasing entity maintains a record documenting the (1) name of the product

⁵ 21 CFR § 1.1310.

⁶ 21 CFR § 1.1305(i).

⁷ 21 CFR § 1.1305(o).

⁸ 21 CFR § 1.1305(q).

⁹ In the preamble to the final rule, FDA notes that ad hoc purchases are made not pursuant to contractual agreements to purchase food from the seller and these transactions will usually take the same form as purchases by consumers more generally.

purchased, (2) the date of purchase, and (3) the name and address of the place of purchase.¹⁰ Note that this partial exemption would apply to sales between restaurants and retail establishments within the same brand, so long as the purchases on are on an ad hoc basis.

- FTL food that is produced (including food produced and packaged on the farm) on a farm and sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm, if the retail food establishment or restaurant maintains a record documenting the name and address of the farm for 180 days.¹¹

Exemptions related to particular **foods**:

- Food that is produced and packaged on a farm when the packaging that maintains the integrity of the product and prevents subsequent contamination remains in place until the food reaches the consumer and the packaging label indicates the contact information for the producing farm.¹²
- 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.¹³
- Shell eggs from farms where all eggs produced receive a treatment in accordance with Section 118.1(a)(2) of the Shell Egg Rule.¹⁴ Additionally, shell egg producers with fewer than 3,000 laying hens at a farm, with respect to the shell eggs they produce at that farm are also exempt.¹⁵
- 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.¹⁶
- Produce that is identified as rarely consumed raw in 21 C.F.R. § 112.2(a)(1).¹⁷
- 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

¹⁰ 21 CFR § 1.1305(k). Note that the required partial records are typically listed on a sales receipt.

¹¹ 21 CFR § 1.1305(j).

¹² 21 CFR § 1.1305(c).

¹³ 21 CFR § 1.1305(d)(1).

¹⁴ 21 CFR § 1.1305(d)(2).

¹⁵ 21 CFR § 1.1305(a)(2).

¹⁶ 21 CFR § 1.1305(f).

¹⁷ 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.

that that the receiver will apply a kill step or change the food such that it is no longer on the FTL.¹⁸

Other exemptions of note:

- Transporters of food.¹⁹
- 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.²⁰

FAQ: Does the calculation of sales under the exemption for small retailers or restaurants apply at the location, brand, or franchise level?

FDA clarified in its December 7, 2022 webinar that the calculation to determine whether a small retailer or restaurant is exempt from the traceability rule is determined by looking at the location level sales data. This means some locations associated with large chain retailers or restaurants will not be required to comply with the traceability rule even though the brand as a whole operates above the sales threshold.

Relevant CTEs and Corresponding 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, receiving, transforming, or shipping foods on the FTL. For retail food establishments and restaurants the most relevant critical tracking events are receiving, transforming, and shipping, and these CTEs and their corresponding key data elements are described in more detail below. Keep in mind that it is possible to perform multiple critical tracking events in your handling of a food. For example, a retail food establishment with a central kitchen servicing multiple locations will be responsible for receiving, transforming, and shipping KDEs. See Appendix D – Additional Critical Tracking Events for more information in the harvesting, cooling, initial packing, and first land-based receiving CTEs.

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:** A distribution center receiving produce from an initial packer, a restaurant receiving produce from a distributor, a grocery store receiving a fruit salad from its central kitchen, 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,

¹⁸ 21 CFR § 1.1305(d)(3)-(6). Restaurants and retail food establishments cannot be responsible for applying the referenced kill step that allows for partial recordkeeping exemptions.

¹⁹ 21 CFR § 1.1305(n).

²⁰ 21 CFR § 1.1305(g).

unless they are a retail food establishment or restaurant, must assign a traceability lot code if one has not been already been assigned and maintain the same receiving KDEs.

Key Data Element	Example
Traceability Lot Code	TC0425231
Quantity and Unit of Measure	100 Cases
Date of Receipt	4/25/2023
Product Description for Food	20 ct. Frozen Salmon Fillets
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 Distributor, 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

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 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 (e.g., foods they sell or send directly to consumers).
- **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.

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	Tomato and Mozzarella Salad
Quantity and Unit of Measure	100 boxes
Reference Document Type and Number	BOL 789

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 or shipments directly to consumers.

- **Example Operations:** Distributor shipping frozen fish to grocery store, farm that packed harvested produce shipping produce to food distribution center, shipping food from central kitchen to different retail location, 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 Unit of Measure	80 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

FAQ: When does a transfer between locations require shipping records?

The rule defines shipping as “an event in a food’s supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location.” This does not include the sale or shipment of food directly to consumers or donations of surplus foods, but does include intracompany shipments (e.g., distribution from a central kitchen to multiple locations) and would include the transfer of product from one restaurant or retail food establishment within a brand to another. When a food is briefly cross-docked or held at a location to transfer the product to another carrier it will likely not be considered received and subject to additional recordkeeping.

Additionally, as noted above, when retailers or restaurants buy food from another retailer or restaurant outside of a formal contractual arrangement, only partial recordkeeping is required. Specifically, when FTL food purchases are made by one retail food establishment or restaurant from another retail food establishment or restaurant on an ad hoc basis²¹ outside the buyer’s usual purchasing practice, the purchasing entity only must maintain a record documenting the (1) name of the product purchased, (2) the date of purchase, and (3) the name and address of the place of purchase.²²

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:

²¹ In the preamble to the final rule, FDA notes that ad hoc purchases are made not pursuant to contractual agreements to purchase food from the seller and these transactions will usually take the same form as purchases by consumers more generally.

²² 21 CFR § 1.1305(k). Note that the required partial records are typically listed on a sales receipt.

- 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.
- Description of how you assign traceability lot codes.²³
- Statement identifying a point of contact for questions regarding your traceability plan and records.²⁴

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 maintained for at least two years following the plan update. See Appendix F – Sample Traceability Plan for an FDA provided example of a traceability plan.

LEGAL RESPONSIBILITIES WITHIN THE SUPPLY CHAIN

The traceability rule applies to every person who manufactures, processes, packs, or holds an FTL food, which places the legal obligation to comply with the rule with each retail food establishment location or restaurant. However, the traceability rule does not mandate the form the different key data elements must be kept and this provides franchisors, corporate entities, and other supply chain partners flexibility to work with retail food establishments and restaurants to develop compliance programs that effectively facilitate traceback investigations while not overburdening limited resources. These flexible arrangements or strategies could include third-party maintenance of traceability records, standardized traceability plans created by parent organizations, or the standardization of supplier contracts. The following discussion outlines the roles of distributors, franchisors, or retailers/restaurants and potential solutions to minimize the burdens presented by the traceability rule.

Considerations for Distributors

Distributors who service retailers and restaurants primarily participate in receiving and shipping CTEs and in most cases will be the primary source of traceability data for their retail and restaurant customers. The traceability rule has implications for a number of common distributor practices that should be considered in greater detail, including when cross-docking activities result in traceability recordkeeping obligations and how the rule interacts with Direct Store Delivery programs. In addition, distributors may be able to lessen the recordkeeping burden of retailers and restaurants by providing off-site records storage.

²³ Unless the restaurant or retail food establishment ships foods to entities other than consumers, it will not need to assign traceability lot codes.

²⁴ Entities that grow or raise a food on the FTL (other than eggs) must also include a farm map showing the areas in which the foods are grown or raised 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.

Cross-Docking Considerations

As discussed above, the traceability rule defines shipping as “an event in a food’s supply chain in which a food is arranged for transport from one location to another location.” This broad definition required FDA to clarify how the rule applies to common cross-docking practices. The rule requires that records be kept regarding the locations where the shipping event begins and ends, but does not require records of the route the truck takes or instances where the food may be moved from one carrier to another as transporters of food are exempt from the traceability requirements.

However, when a specific shipping event begins and ends is not clear. FDA has clarified that in situations where a food is arranged for transport from point A to point B but is briefly placed on a loading dock at point X for transfer to another truck, the food would not be considered shipped to point X. As a result no records would need to be kept regarding point X.

However, even this clarification needs further guidance as to what a “brief” hold for transfer to another carrier encompasses. FDA has advised that the following factors will be considered when determining whether a food has been received at a point X:

1. How long the food was held at point X;
2. Whether the food was held under temperature-controlled conditions different than that transportation conditions; and
3. Whether the food was taken into inventory.

If the analysis of these factors results in the determination that the food was formally received at the cross-docking location, the location would be required to maintain receiving records and subsequent shipping records.

Direct Store Delivery

The traceability rule recordkeeping requirements do not require that the relevant entity take the FTL foods into inventory before the obligations are triggered. As a result, direct store delivery arrangements where the supplier maintains responsibility or ownership of the product do not relieve the retailer/restaurant of its requirements under the traceability rule. The food would still be considered “received” and the related KDEs would still need to be maintained. However, the rule does allow for traceability records to be maintained by third-parties so long as the information can be made available onsite within 24 hours of request by the agency. This would allow the Direct Store Delivery vendor to maintain the relevant receiving KDEs on behalf of the retailer/restaurant.

Third-Party Records Maintenance

Consistent with the above discussion on Direct Store Delivery arrangements, the traceability rule allows traceability records to be maintained offsite by third-parties. Since distributors are often the last entity to touch a food before it reaches a retail location or restaurant there may be an opportunity for retailers and restaurants to leverage their distributors as third-party record maintenance providers. For example, a common concern of retailers regarding the traceability rule is that compliance would require labor intensive case-level tracking at each retail location as opposed to the more common and standard practice of pallet-level tracking. Distributors have visibility into both their own shipping KDEs and the retailer’s/restaurants receiving KDEs. The receiver could arrange for the distributor to maintain

the relevant receiving KDEs on its behalf so long as the information could be provided to FDA onsite within 24 hours of request.

Considerations for Franchisors and Corporate Parents

Franchisors and corporate parents are in a unique position to support their franchisees and individual locations in complying with the traceability rule's recordkeeping requirements as these entities can (1) leverage the entire network of the franchise or broader corporate brand to negotiate with suppliers, (2) develop streamlined procedures, (3) provide offsite recordkeeping support, and (4) provide guidance to individual locations.

1. **Standardized Supplier Agreements** – Franchisors and corporate parents have the ability to work with suppliers on behalf of the entire franchise/brand to standardize how traceability records will be handled. This could mean requiring all traceability records being sent in advance shipping notices (ASNs), entering an agreement for distributors to maintain records on the franchise's behalf, or standardizing contract terms to require traceability data be shared before payment would be tendered.
2. **Provide Standardized Compliance Programs** – While the individual franchises/locations are ultimately responsible for compliance with the traceability rule, franchisors and corporate parents can develop streamlined programs or templates to facilitate this compliance such as a standard traceability plan and franchise-wide recordkeeping platform.
3. **Offsite Recordkeeping** – Franchisors and corporate parents can provide “third-party” recordkeeping services that maintain the data required by the rule on behalf of the individual locations.
4. **Provide Guidance** – Franchisors and corporate parents are in the position to act as the “knowledge center” for their franchisees/locations for all traceability issues. By developing expertise in the traceability rule requirements centrally the franchisor or parent can answer questions, develop training and support materials, and act a central resource for FDA inquires.

Considerations for Restaurants and Retailers

For the most part, retailers and restaurants will only participate in the “receiving” CTE. The rule does not require transformation records for foods transformed at restaurants or retail food establishments unless the foods are shipped after transformation (e.g., the restaurant or retailers acts as a central kitchen). Additionally, the definition of “shipping” does not include shipments directly to consumers. With this in mind there are two scenarios that require additional considerations – preparation/central kitchens and shipments between retailers or restaurants.

Preparation at Central Kitchens

Central kitchens take foods delivered to a store or restaurant from a distribution center and process them into a different commodity and then send the new commodity to different retail locations or restaurants. When the end product is on the FTL, transformation records must be established and maintained related to the processing and shipping records would be required for the distribution to other locations. To facilitate this recordkeeping, the central kitchen would need to be able to identify the traceability lot code of each specific FTL food that is used to create the final FTL food. Any program

implemented by restaurants and retailers that use a central kitchen must take into account these additional recordkeeping obligations in implementing a standardized recordkeeping program, such as relying on distributors, parent companies, or other third parties to maintain records on its behalf.

Shipments between Restaurants and Retailers

As discussed above, the rule provides a partial exemption for retail food establishments and restaurants making ad hoc purchases from other retail food establishments or restaurants. This means that regular purchases between retail food establishments/restaurants, including those within the same company/brand, such as a restaurant that contracts to buy all of its meat from a local butcher who also sells to consumers, still require traceability records to be kept. However, if a restaurant must make a onetime purchase from the butcher due to an unforeseen issue with their standard supplier, the restaurant would only be required to maintain a record documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase, all of which should be available on a sales receipt.

COMMUNICATING WITH FDA

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. The information 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 threat of serious adverse health consequences or death (SAHCODAH hazard). This spreadsheet may include weblinks and may be required to be provided in English within a reasonable time if not maintained in English. The request for information in an electronic sortable spreadsheet may be made by phone but also can be put in writing upon request. However, you must still provide the requested information within 24 hours of the phone 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. This means that companies can choose to maintain paper traceability records or use multiple different systems to capture and store traceability records so long as the electronic, sortable spreadsheet can be provided. In addition, you do not have to keep all of the information required by the rule in a single set of records. As a reminder, if you choose to maintain traceability records for foods not on the FTL, you are not obligated to provide these records to FDA upon request. The choice to include additional foods in your traceability program does not increase your recordkeeping obligation.

The following are examples of electronic sortable spreadsheets for different CTEs.

Example 1 – Shipper

Shipping KDE Electronic, Sortable Spreadsheet

Traceability Lot Code	Quantity and Unit of Measure	Product Description for Food	Location Description for next recipient	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
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	Link	BOL 789
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
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	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA, 99999	Invoice 123

Example 2 – Receiver:²⁵

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 32 OZ CONTAINERS	Charles' Cheese Co.	Distro Foodservice DC #45	9/23/2020	EFRN:456456	PO 111101
(01)11411411411404(10)FPP16-092220	100 CASES	FRESH PROCESSOR BRAND, CUT MANGOS, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/18/2020	11231 TLC Source, TLC ville, MN, 55441	PO 456213
(01)11411411411402(10)FPP16-092420	50 CASES	FRESH PROCESSOR BRAND, CUT CANTALOUPE, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/21/2020	https://id.gs1.org/01/11411411411402/10/FPP16-092420	BOL 11401
(01)11411411411401(10)FPP16-092120	100 CASES	FRESH PROCESSOR BRAND, GARDEN SALAD KIT, 10x12 OZ BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/20/2020	https://id.gs1.org/01/11411411411401/10/FPP16-092120	BOL 11401
(01)22322322322302(10)FFI2020-09-20	140 CASES	FreshFish BRAND, FROZEN YELLOWFIN TUNA STEAKS, 25 LB CASE	FreshFish Importer Inc.	Distro Foodservice DC #45	9/22/2020	https://id.gs1.org/01/22322322322302/10/FFI2020-09-20	BOL 22302

*See Master Data Spreadsheet for full location descriptions

²⁵ Example from FDA resource available at [Presentation Slides - Webinar on the Food Traceability Final Rule \(December 7, 2022\) \(fda.gov\)](#)

Example 3 – Transformer

Transformation Electronic, Sortable Spreadsheet

Traceability Lot Code	Product Description for Food (ingredient)	Quantity 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	FF0429231	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	100 Fillets	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	200 lbs	SA0430234	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA, 99999	4/30/2023	Mixed Fruit Salad	200 boxes	BOL 334

FAQ: When will FDA request records?

FDA can request records and to view a company’s traceability plan during a routine inspection or when initiating a traceback investigation. The requirement that the records be provided in an electronic, sortable spreadsheet is only triggered when it is 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.

FAQ: What records need to be provided?

Upon request, the company only needs to provide traceability records for the foods they manufacture, process, pack, or hold which are on the FTL. If the company chooses to collect traceability records for non-FTL foods, it is not obligated to provide these records to FDA upon request.

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 applies to three types of entities:

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

This exception is narrowly tailored to relieve the burden of producing an electronic, sortable spreadsheet. It does not relieve those who qualify from providing this information to FDA in another form.

ENGAGING WITH SUPPLIERS

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.²⁶

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.
- Provide training and education for your supply chain.
- Revisit contract agreements with suppliers.

²⁶ 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>.

APPENDICES

Appendix A – Frequently Asked Questions

Does the calculation of sales under the exemption for small retailers or restaurants apply at the location, brand, or franchise level?

FDA clarified in its December 7, 2022 webinar that the calculation to determine whether a small retailer or restaurant is exempt from the traceability rule is determined by looking at location-level sales data. This means some locations associated with large chain retailers or restaurants will not be required to comply with the traceability rule even though the brand as a whole operates above the sales threshold.

When does a transfer between locations require shipping records?

The rule defines shipping as “an event in a food’s supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location.” This does not include the sale or shipment of food directly to consumers or donations of surplus foods, but does include intracompany/intra-brand shipments. As discussed in more detail above, when a food is briefly cross-docked or held at a location to transfer the product to another carrier it will likely not be considered received and subject to additional recordkeeping. Additionally, when retailers or restaurants buy food from another retailer or restaurant outside of a formal contractual arrangement, only partial recordkeeping is required. See information on pages 5, 9, and 13.

What if I choose to apply the traceability requirements to all products, not just those on the FTL?

Even though the FDA traceability requirements only apply to foods on the food traceability list, 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, then FDA cannot enforce the rule with respect to those foods.

How will the relevant KDEs move through the critical tracking events?

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 provided to 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, made available on a shared database, 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. Other methods of providing information to receivers include electronic links, QR codes, data repositories, or through multiple records such as product labeling or packaging as well as commonly used reference documents such as BOLs and ASNs. The information does not have to physically accompany the food sent to the recipient but must be provided in a way that permits the receiver of the food to keep the records it is required to maintain. The following are a couple of examples of how this information may travel.

Example: Bill of Lading

OP-087G 11/11
Straight bill of lading—original—not negotiable

DATE: _____ Date, Reference Doc. Type and Number

B/L NO.: _____

SHIPPER NO. TRAILER NO. CONSIGNEE NAME AND ADDRESS

SHIPPER NAME

ADDRESS Location Description

CITY STATE ZIP CODE DESTINATION CITY STATE ZIP CODE

ORIGIN CITY (IF DIFFERENT FROM ABOVE) STATE ZIP CODE PHONE NO.

INVOICEE OR COD REMIT TO NAME (IF DIFFERENT FROM SHIPPER) CUSTOMER NO. STORE NO. DEPT.

ADDRESS P.O. NO.

CITY STATE ZIP CODE SPECIAL INSTRUCTIONS

ATTN.

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

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

EMERGENCY CONTACT SHIPMENT CHARGES PREPAID UNLESS MARKED COLLECT: COLLECT TOTAL CHARGES \$

Phone: _____ Name: _____ Contract #: _____

NOTE (1) Where the rate depends on value, shippers must state specifically in writing the agreed or **NOTE (2)** Products requiring special or additional care or attention in handling or stowing must be so marked and

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	

Example: Original Form Sent via Email (shipping KDEs passed to next receiver)

Shipment Traceability Information

Order No/Pallet No./Etc.	Traceability Lot Code	Quantity and Unit of Measure	Product Description for Food	Location Description for next recipient	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	XYZ Food Manufacturer, 123 Factory Way, Produce City, CA, 99999	Invoice 123

What are the consequences of noncompliance with the traceability rule?

As stated in § 1.1460 of the traceability rule, noncompliance with the rule’s provisions is considered a prohibited act under section 301(e) of the Federal Food, Drug, and Cosmetic Act. Additionally, imported foods can be refused admission into the United States if it appears that the recordkeeping requirements of the traceability rule have not been complied with.

Appendix B – FDA Resources

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 C – Food Traceability List as of November 21, 2023

Food Traceability List	Description
Cheeses, other than hard cheeses, specifically:	
<ul style="list-style-type: none"> 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.
<ul style="list-style-type: none"> 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.
<ul style="list-style-type: none"> Cheese (made from unpasteurized milk), other than hard cheese¹ 	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.
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:	
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • 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.
<ul style="list-style-type: none"> • 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
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.

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.

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).

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 D – Additional Critical Tracking Events

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 on 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 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	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

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

Initial Packing of Raw Agricultural Commodities²⁷

- **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.²⁸

Key Data Element	Example
Commodity and variety (if applicable)	Tomatoes, Cherry
Quantity and Unit of Measure (UOM)	200 Cases
Date of Receipt	4/25/2023
Location Description for the farm where harvested	XYZ Farms. 100 Farm Ave., Produce City, CA, 99999
Name of Growing Area	"Field 2," GPS Coordinates, other identifying name
Business Name and Phone Number of Harvester	XYZ Farms (123) 555-1234
Location Description of where the food was cooled	AAA Cooling Services, 55 Freeze Ave., Produce City, CA, 99999
Traceability Lot Code	TC0425231
Product Description of Packed Foods	20 ct. Cherry Tomatoes in Bag
Quantity and UOM of Packed Food	500 boxes
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

First Land-Based Receiver

- **Definition:** The person taking possession of a food for a first time on land directly from a fishing vessel.
- **Example Operations:** Fish brokers preparing catches for auction, food processors receiving fresh catches directly from fishing vessels, etc.

²⁷ Note that this guidance does not address recordkeeping for initial packers of sprouts.

²⁸ 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.

- **Records:** All of the listed KDEs must be linked to the traceability lot code assigned at this CTE.

Key Data Element	Example
Traceability Lot Code	SA1204242023
Species/acceptable market name	Salmons Fillets (12 oz)
Quantity and Unit of Measure (UOM)	150 lbs
Harvest Date Range and Location	4/15/2023-4/22/2023
Location Description for First Land-Based Receiver	ABC Fish Processor, 123 Ocean Road, Port City, ME, 99999
Date the Food was Landed	4/24/2023
Reference Document Type and Number	BOL 772

Appendix E – Key Data Element Definitions

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 – the 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 means 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.

Appendix F – Sample Traceability Plan

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.

Appendix G – Complete list of 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(a). 21 CFR § 1.1305(a)(1).
- Shell egg producers with fewer than 3,000 laying hens at a farm, with respect to the shell eggs they produce at that farm. 21 CFR § 1.1305(a)(2).
- 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. 21 CFR § 1.1305(a)(3).
- Transporters of food. 21 CFR § 1.1305(n).
- Nonprofit food establishments. 21 CFR § 1.1305(o).
- Persons who manufacture, process, pack, or hold food for personal consumption. 21 CFR § 1.1305(p).
- 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). 21 CFR § 1.1305(q).
- 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. 21 CFR § 1.1305(g).
- 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. 21 CFR § 1.1305(i).
- Farms when food is sold or donated directly to consumers. 21 CFR § 1.1305(b).

Full exemptions to the traceability rule for **foods**:

- Food that is produced and packaged on a farm when the packaging remains in place until the food reaches the consumer and the packaging label indicates the contact information for the producing farm. 21 CFR § 1.1305(c).
- 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. 21 CFR § 1.1305(d)(1).
- Shell eggs from farms where all eggs produced receive a treatment in accordance with Section 118.1(a)(2) of the Shell Egg Rule. 21 CFR § 1.1305(d)(2).

- 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. 21 CFR § 1.1305(f).
- Produce that is identified as rarely consumed raw in 21 C.F.R. § 112.2(a)(1).²⁹ 21 CFR § 1.1305(e).
- 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.” 21 CFR § 1.1305(r).
- Commingled RACs *other than produce*, or those that will become commingled RACs provided there is a written agreement in place. 21 CFR § 1.1305(h).
- 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. 21 CFR § 1.1305(d)(3)-(6).

In addition, there are the following partial exemptions:

- 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 earlier in the supply chain must maintain the required records. 21 CFR § 1.1305(d)(4).
- 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 earlier in the supply chain must maintain the required records. 21 CFR § 1.1305(d)(4).
- Retail food establishment and restaurants purchasing directly from a farm. 21 CFR § 1.1305(j).
- Retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant. 21 CFR § 1.1305(k).
- Farm to school and farm institution programs. 21 CFR § 1.1305(l).
- Owners, operators, or agents in charge of fishing vessels. 21 CFR § 1.1305(m).

²⁹ 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.

Appendix H – Definitions of Restaurant and RFE

Retail Food Establishments and Restaurants are defined in 21 CFR § 1.1310 as follows:

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

- (1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and
- (2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail Food Establishment means an establishment that sells food products directly to consumers as its primary function. The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes grocery stores, convenience stores, and vending machine locations. A “retail food establishment” also includes certain farm-operated businesses selling food directly to consumers as their primary function.

- (1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:
 - (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
 - (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- (2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:
 - (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

- (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
 - (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- (3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).