Produce Traceability Initiative FSMA 204 Implementation Guidance

(Revision: Original)

About this Implementation Guidance

Implementation guidance comprises generally accepted, informally standardized techniques, methods or processes that have proven themselves over time to accomplish given tasks. The idea is that with proper processes, checks and testing, a desired outcome can be delivered more effectively with fewer problems and unforeseen complications. In addition, implementation guidance can evolve to become better as improvements are discovered.

The Produce Traceability Initiative (PTI) is a voluntary U.S. produce initiative. This Implementation Guidance document represents the recommendations created and agreed to by stakeholders in all facets of the produce industry supply chain and Produce Traceability Initiative (PTI) Leadership Council, developed through a collaborative effort of 108 volunteers from 60 different companies and 9 trade associations.

Consent between trading partners may replace specific recommendations if the minimum traceability information requirements are met in good faith.

Disclaimer: Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and products. Company legal counsel or compliance team (regulatory or quality) should be consulted for more specific information about current statutory and regulatory requirements applicable.

FDA does not require a specific application or technology for keeping records (FDA Food Traceability Rule FAQ TG.1) to meet the Final Food Traceability Rule (FSMA 204). Also, FDA does not require that the Traceability Lot Code is included on the product label or packaging (FDA Food Traceability Rule FAQ TTLC3).

Revision History

This section itemizes the changes from the last published Implementation Guidance

Version No.	Date of Change	Changed By	Summary of Change
Original	2/12/2024	PTI FSMA 204 Working Group	Original Document

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Introduction

ABOUT THE PRODUCE TRACEABILITY INITIATIVE

The **Produce Traceability Initiative** is a voluntary, industry-wide effort designed to help the produce industry maximize the effectiveness of current track and trace procedures, while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future.

Dozens of visionary North American food companies, ranging from small farms and global fruit growers to international retailers and restaurant chains, are taking leadership roles by participating in working groups in the Produce Traceability Initiative.

ABOUT THIS DOCUMENT

The PTI FSMA 204 Implementation Guidance document is meant for all produce audiences. Please read the FSMA 204 Overview and Getting Started, FSMA 204 Requirements, and Maintenance Records and Availability sections before reviewing the Specific Supply Chain Role Considerations. This will give the audience an understanding of the overall FSMA 204 Rule.

FSMA 204 OVERVIEW

The U.S. Food and Drug Administration (FDA) announced the final Food Traceability Rule (Final Rule) on November 15, 2022, establishing additional recordkeeping requirements for foods FDA has included on its Food Traceability List (FTL). The Final Rule fulfills Section 204(b) of the FDA Food Safety Modernization Act (FSMA).

Produce listed on the FTL:

- Cucumbers (fresh)
- Fruits (fresh-cut)
- Herbs (fresh)
- Leafy greens (fresh)
- Leafy greens (fresh-cut)
- Melons (fresh)
- Peppers (fresh)
- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical tree fruits (fresh)
- Vegetables other than leafy greens (fresh-cut)
- Foods that contain listed foods as ingredients in the form listed

Other FTL items:

- Cheeses, other than hard cheeses
- Finfish (fresh and frozen)
- Molluscan shellfish, bivalves (fresh and frozen)

- Nut butters
- Ready to eat deli salads
- Shell eggs
- Smoked finfish (refrigerated and frozen)

The Final Rule requires persons who **manufacture, process, pack or hold** foods on the FTL to maintain specific data records **(Key Data Elements, or KDEs)** pertaining to the steps they perform **(Critical Tracking Events, or CTEs)**. During outbreak investigations, these records will be used by the FDA to rapidly trace implicated FTL foods from retail food establishments and restaurants to processors, packers, farms, and fields. These records may also be used to improve industry and FDA initiated recalls. Beyond compliance, traceability may be used to improve quality, freshness, and reduce food waste.

Although FSMA 204 is applicable to foods listed on the FTL only, major U.S. buyers intend to require the same data set for all produce items received.

Critical Tracking Events

Fresh produce supply chain activities the FDA has designated as Critical Tracking Events include:

- Harvesting (keep and provide to initial packer)
- Cooling before initial packing (keep and provide to initial packer)
- Initial Packing (keep only)
- Transforming (keep only)
- Shipping (keep and provide to subsequent recipient)
- Receiving (keep only)

The information that companies must keep and provide to subsequent recipients under the Rule varies depending on the type of supply chain activities they perform with respect to an FTL food. Central to the requirements is the assignment, recording and sharing of **Traceability Lot Codes (TLCs)** and the Traceability Lot Code Source for FTL foods, as well as linking these TLCs to other information identifying the foods as they move through the supply chain.

Traceability Plan, Records Maintenance, and the Sortable Spreadsheet

In addition to records of Critical Tracking Events, covered persons must create and maintain a Traceability Plan. The rule also requires covered persons keep all required records for at least two years and provide them to FDA within 24 hours of FDA request (or within some reasonable time to which FDA has agreed). Under certain circumstances, FDA may request certain CTEs and KDEs be provided to FDA by covered persons in the form of an electronic sortable spreadsheet.

Compliance Date

Because the Food Traceability Final Rule requires entities to share information with other entities in their supply chain, FDA determined that the most effective and efficient way to implement the rule is to have all persons subject to the requirements come into compliance by

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

Exemptions

Several exemptions apply to farms. FDA developed a simple guide for determining if you are eligible for an exemption.

Companies handling non-FTL items are advised to check with customers/trading partners to understand their FSMA 204 data requirements.

Although the regulations only apply to items on the FTL, buyer expectations may be such that all fresh produce is treated the same (i.e., is expected to adhere to the FSMA 204 regulations). Please check with your buyers to understand expectations.

PTI and FSMA 204 Alignment

The Produce Traceability Initiative endorses the use of standards to capture, store, and share traceability data. This guidance document includes industry recommendations that are not specifically required by the FSMA 204 Final Rule. Companies covered by the rule should make their own decisions regarding approach to enhanced traceability recordkeeping and compliance.

PTI recommendations are aligned with FSMA 204 requirements in many ways, including:

- The use of GS1 standards for traceability to capture and share CTE data. Standards also enable interoperability between systems and solutions.
- The PTI Harmonized Case Label Best Practice includes the AI (01) GTIN-14, AI (10) Batch/Lot, and AI (13) Date to be included in the GS1-128 case label barcode.
- The industry standard definition for the FSMA 204 Traceability Lot Code[1] is the AI (01) GTIN and AI (10) Batch/Lot.
- PTI Best Practices for capturing AI (01) GTIN and AI (10) Batch/Lot on inbound and outbound cases is consistent with the TLC that must be captured as part of Receiving and Shipping for FSMA 204.
- Both PTI and FSMA 204 encompass the capture, storage, and sharing of Product Master Data, Location Master Data, and Traceability Event Data with trading partners.
- FSMA 204 leverages industry nomenclature (i.e., CTEs and KDEs) that is also used in the definition of PTI Best Practices.

Case and Pallet Traceability

The GS1 system of standards enables two types of object identification, Instance-level Identification and Class-level identification.

Barcodes for General Distribution

GS1-128 and ITF-14 are 1D barcodes that enable items to be tracked through global supply chains. The GS1-128 barcode can carry any of the GS1 ID keys (e.g., GTIN-14, SSCC, GLN),

[1] GS1 US FSMA 204 Guideline

plus information like lot numbers, harvest and pack dates, quantities, serial numbers and more. The ITF-14 barcode can only hold the Global Trade Item Number (GTIN) and is suitable for printing on corrugated materials.

PTI focuses on Case and Pallet Identification and Traceability

The Produce Traceability Initiative is focused primarily on Class-level identification of cases using the GTIN and Batch/Lot and the GS1-128 barcode, and Instance-level identification of pallets using the SSCC and the GS1-128 barcode. Saleable items contained within cases may be identified with UPC barcodes, PLU numbers, GS1 Databar, GS1 Data Matrix, and QR Codes with Digital Link.

The term “case” refers to the physical enclosure in which a product is shipped. It can be in the form of a box, carton, returnable plastic container (RPC), bin, bag, tote, etc. Under some circumstances, the “case” may also be the consumer unit if the product is packed, shipped, displayed, and sold to the end user in the same configuration. An example of this could be a 5-pound case of clementines that is displayed at retail as a saleable unit in the exact same “case” it was originally packed and shipped in.

This PTI Implementation Guidance assumes all cases shipped and received have been labeled with the **PTI Harmonized Case Label**, which contains a GS1-128 format barcode and human-readable information including identifiers that combine to communicate product information [AI (01) GTIN], [AI (13) Pack/Harvest Date or AI (15) Use By Date + AI (10) Batch/Lot]. For purposes of FSMA 204, the industry has agreed that the combination of the GTIN + Lot Number create a unique Traceability Lot Code (TLC). Labeling with PTI Harmonized Case Labels when a food is produced helps to ensure that KDEs move with the products across multiple CTEs in the supply chain, as required by FSMA 204.

The use of the updated case label described and illustrated in the **Appendix A** of this document is strongly recommended for use within the produce industry and has been endorsed by numerous U.S. and Canadian buyer organizations. Please see producetraceability.org for a list of supporting organizations.

Companies that practice PTI Guidance can leverage their efforts in support of their traceability system plan and execution to meet FSMA 204 requirements for capturing, storing, and sharing the required KDEs and CTEs.

GETTING STARTED

Are you subject to the rule

The information below can help you determine if FSMA 204 applies to your business and identify actions you should take if it does. Questions to be answered in making this determination include:

- Does your company “manufacture, process, pack, or hold” a food on the FTL?
- If so, do any exemptions apply to you?
- What CTEs apply to your organization? (e.g., Harvesting, Cooling, Initial Packing, Transforming FTL foods, Shipping, or Receiving)
- If you receive foods, how do you identify which are covered by the rule?

- If you harvest, cool, pack or process foods, how do you identify covered foods internally?
- If you ship foods, how do you communicate with your trading partners which foods are covered by the rule?

Perform a gap analysis

Many businesses may already be fulfilling some of the Final Rule's requirements such as recording CTEs, maintaining KDEs and implementing a Traceability Plan. To determine your required actions, consider:

- What KDEs does your organization already capture and maintain? (e.g., TLC, CTE locations, product data, etc.)
- What additional KDEs must you capture and maintain to meet Final Rule requirements? (e.g., Traceability Lot Code Source or Traceability Lot Code Source Reference)
- How can you work with your supply chain partners to meet the requirements of the rule?
- What recordkeeping systems are you using? What systems are your partners using? What is the best way to connect them to enable data sharing?

Start planning

If you determine that you are covered by the rule, your next step is to start planning. This guide will provide your traceability team with necessary information for:

1. Creating and maintaining your Traceability Plan.
2. Capturing and maintaining required CTEs and KDEs for covered foods.
3. Required data sharing with subsequent recipients.
4. Providing sortable spreadsheets to FDA upon request.

FSMA 204 Requirements

For the complete text of the Final Food Traceability rule, see Subpart S – Additional Records for Certain Foods 21 CFR Part 1 Subpart S. For the full text of the Bioterrorism Act of 2002, which applies to foods not covered by FSMA 204, see Subpart J – Establishment, Maintenance, and Availability of Records 21 CFR Part 1 Subpart J.

WHO IS SUBJECT TO THE RULE

This rule applies to persons who manufacture, process, pack, or hold foods that appear on the FDA Food Traceability List, provided they are not fully or partially exempt.

WHAT FOODS AND PERSONS ARE EXEMPT

Certain small producers, including certain produce farms with sales below $25,000 per year are exempt from the rule. Other full and partial exemptions include, foods that are sold or donated from farms directly to consumers; produce that is rarely consumed raw; foods that are produced and packaged on a farm and shipped directly to retail food establishments or restaurants; foods produced for personal consumption or for research or evaluation; and foods that receive certain types of processing such as a kill step, or change of form to one that is not on the FTL (e.g. fresh herbs to dried herbs, or fresh cut fruit to frozen fruit).

The complete list and details of these exemptions are listed under 21 CFR 1.1305.

WHAT DEFINITIONS APPLY TO PTI BEST PRACTICES AND FSMA 204

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in the Food Traceability Rule. In addition, the following edited and annotated list of definitions apply to words and phrases as they are used in this guide.

The full list of FSMA 204 definitions may be found at 21 CFR 1.1310.

Term	Definition
Advance Ship Notice (ASN)	The Advance Ship Notice (ASN) is an Electronic Data Interchange (EDI) 856 transaction that provides the receiving company with advance data on shipments to better plan workloads and receipt processing. In the implementation of the transaction, the ship notice may be created at the time of the shipment. In practice, the ship notice must arrive before the shipment.
Batch/Lot – AI (10)	The AI (10) indicates the GS1 AI data fields contain a Batch or Lot number. The data is alphanumeric with variable field length up to 20 characters
Cooling	Cooling means active temperature reduction of a commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.
Critical Tracking Event (CTE)	Critical tracking event means an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving

	of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.
Electronic Data Interchange (EDI)	Enables the computer-to-computer exchange of business documents, such as purchase orders, advance ship notices (ASN), and invoices, between companies using a standard format, regardless of the kind of computer or software each company is using.
Electronic Product Code Information Services (EPCIS)	A global GS1 Standard for creating and sharing visibility event data to enable users to gain a shared view of physical or digital objects. The five dimensions of EPCIS are Who, What, When, Where, and How.
Farm	Farms may be primary production farms or a secondary activities farm. For full definition of a farm, see it here.
Food Traceability List	The Food Traceability List identifies the foods for which additional traceability records are required under the Final Rule, FSMA 204. The additional recordkeeping requirements apply to the foods specifically listed on the FTL, and to foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list. For additional information about the FTL, view it here.
GLN	The Global Location Number (GLN) is a 13-digit, globally unique GS1 Identification Key used to identify parties and locations. The GLN allows users to answer the questions "who" and "where" within their own organization and throughout the entire, global supply chain. GS1 Intro to GLNs
GS1 Application Identifier (AI)	GS1 Application Identifiers (AIs) are a set of defined identifiers used in barcodes and EPC/RFID tags to define the meaning and format of data attributes. AIs always precede the data they represent and are shown in the HRI (Human Readable Interpretation) in parentheses.
GTIN – AI (01)	The Global Trade Item Number (GTIN), is a globally unique GS1 identification key used to identify products and services (trade items) that are priced, ordered, or invoiced at any point in the supply chain. A GTIN may be 8, 12, 13, or 14 digits in length. The GTIN-14 has been selected for use in PTI. What is a GTIN?
Harvesting	Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agriculture commodities (RACs) from the place they are grown or raised and preparing them for use as food.
Holding	Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as

	blending of the same raw agricultural commodity and breaking down pallets) but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
Homogeneous logistics units	A homogeneous unit containing one type of trade item. All the items at the highest level of packaging are the same and are identified with the same GTIN and lot. Example: a pallet containing 50 trade item groupings of Product X with Lot 123.
Heterogeneous logistics units	A heterogeneous logistic unit containing different types of trade items at the highest level of packaging that are identified with different GTINs. Example: 1: a pallet containing 30 standard trade item groupings (e.g. boxes) of Product X and 20 standard trade item groupings (e.g. boxes) of Product Y. Example 2: a pallet containing 30 standard trade item groupings (e.g. boxes) of Product X Lot 123 and 20 standard trade item groupings (e.g. boxes) of Product X Lot 456.
Initial Packing	Initial Packing means packing a raw agricultural commodity (RAC), other than a food obtained from a fishing vessel, for the first time.
Key Data Element (KDE)	Key data element means information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart. KDEs will vary by event type, based on the activities performed.
Location Description	Location description means key contact information for the location where a 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.
Logistics Unit (e.g., pallet)	A logistic unit is defined as an item of any composition established for transport and/or storage that needs to be managed through the supply chain. It can be identified with a Serial Shipping Container Code (SSCC).
Logistic Label	The GS1 Logistic Label allows users to identify logistic units uniquely so that they can be tracked and traced throughout the supply chain. The only mandatory requirement is that each logistic unit must be identified with a unique serial number, the Serial Shipping Container Code (SSCC). Scanning the SSCC barcode on each logistic unit allows the physical movement of units to be matched with the electronic business messages that refer to them. Using the SSCC to identify individual units (i.e. pallets) provides the opportunity to implement a wide range of applications such as cross docking, shipment routing, and automated receiving. Besides the SSCC, other information can be included on the GS1 Logistic Label. For more information on Logistics Labels see: Logistics Label Guidance for Food Industry (gs1us.org)

Lot or Batch Code – AI (10)	A lot or batch means a definitive quantity of a commodity produced essentially under the same conditions. The conditions may include location, specific period of time, ingredients, production equipment, and personnel. It helps in tracking and recalling products if needed. The exact definition and size of a lot can vary depending on the type of food, the production process, and the establishment. A lot or batch code means an alphanumeric descriptor, used to uniquely identify a lot or batch both physically and within the producer's traceability, food safety, and production records. The PTI Harmonized Case Label guidance provides technical rules and best practices for lot or batch code assignment.
Manufacturing/processing	Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.
Mixed-type facility	Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.
Packing	Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.
Pack or Harvest Date – AI (13) (YYMMDD)	The AI (13) indicates that the GS1 AI data fields contain a Pack or Harvest Date* indicating when the goods were packed. The AI is fixed in length and encodes 6 numeric digits only, in a YYMMDD format. *produce industry definition
Best Before Date – AI (15) (YYMMDD)	The AI (15) indicates that the GS1 AI data fields contain a "Best if Used By/Use By/Best Before" Date* that indicates the ideal consumption or best effective use date of a product. The

	AI is fixed in length and encodes 6 numeric digits only, in a YYMMDD format. *produce industry definition
Person	Person includes an individual, partnership, corporation, and association.
Point of Contact	Point of contact means an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number.
Product Description	Product description means 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.
Receiving	Receiving means an event in a food supply chain in which food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location of the firm at a different street address.
Reference Document	Reference document means a business transaction document, record, or message, in electronic or paper form, which 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	Reference document number means the identification number assigned to a specific reference document.
Serial Shipping Container Code (SSCC) – AI (00)	The Serial Shipping Container Code (SSCC) is an 18-digit GS1 Identification Key used to identify a logistic unit. The SSCC is different from the GTIN, as the SSCC acts as a license plate to track a shipment of logistics units through the supply chain. Serial Shipping Container Code can be used by companies to identify a logistic unit (pallet), which can be any combination of trade items (cases) packaged together for storage and/ or transport purposes, for example a case, pallet or parcel. See GS1 Food Industry Guidance for Logistics Labels.
Shipping	Shipping means 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. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping does include sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.
Traceability Lot	Traceability lot means 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 AI (01) + AI (10)	Traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the firm that assigned the traceability lot code. The Produce Traceability Initiative recommends the use of a Global Trade Item Number (GTIN) and the corresponding Lot code to form a globally unique Traceability Lot Code. This aligns with other industry approaches, including the GS1 US Foodservice and Grocery initiatives. Once a food has been assigned a TLC, the records required at each Critical Tracking Event (CTE) must include that TLC. All Key Data Elements (KDEs), including the TLC, must be linked to the relevant traceability lot. See the FDA Traceability Lot Code page
Traceability Lot Code Source	Traceability Lot Code Source means the place where a food was assigned a traceability lot code. The attributes for a Traceability Lot Code Source include: • business name • phone number • physical location address (or geographic coordinates) • City • State • Zip code for domestic locations and comparable information for foreign locations, including country
Trade Item (e.g., cases)	A trade item is defined as any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain and is identified with a Global Trade Item Number® (GTIN®)
Traceability Lot Code Source Reference	Traceability Lot Code Source Reference means 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 (FFRN), a GLN (Global Location Number) or a web address that provides FDA with the location description for the traceability lot code source.
Transformation	Transformation means an event in a food's supply chain that involves manufacturing/processing or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List (FTL). Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).

TRACEABILITY PLAN

For the full text of the requirements of the Traceability Plan, see 21 CFR Part 1 Subpart S - Traceability Plan.

What Is in A Traceability Plan

If you are subject to the requirements in this subpart, you must establish and maintain a traceability plan. You must also update your traceability plan as needed to ensure that the information provided reflects your current practices and to ensure that you comply. You must retain your previous traceability plan for 2 years after you update the plan.

1. A description of the procedures you use to maintain the records you are required to keep under the rule, including the format and location of these records.
2. A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;
3. A description of how you assign traceability lot codes to foods on the Food Traceability List
4. A statement identifying a point of contact for questions regarding your traceability plan and records; and
5. If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods. The farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area.

When Must I Assign Traceability Lot Codes

a. You must assign a traceability lot code when you initially pack a raw agricultural commodity; transform a food; or receive a food from an exempt entity (21 CFR 1.1345(b)).
b. You must not establish a new traceability lot code when you conduct other activities (e.g., shipping or receiving) for a food on the Food Traceability List.

RECORDS OF CRITICAL TRACKING EVENTS

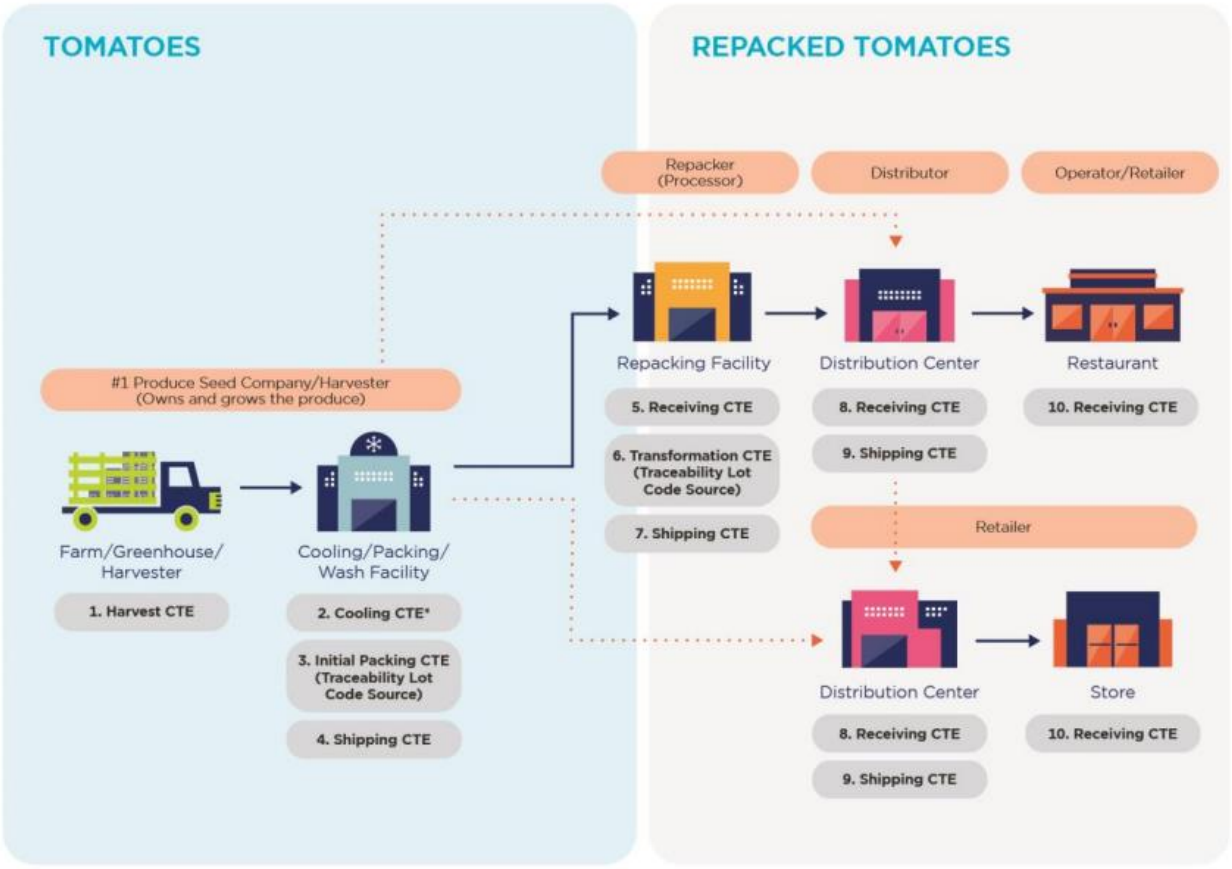
The following section provides a cross reference of FSMA 204 Critical Tracking Events (CTEs) and Key Data Elements (KDEs) to KDEs developed by the Produce Traceability Initiative for use in this guide and in the provide sortable spreadsheet templates. For brevity, not all CTEs and KDEs are listed. For the full text of the CTEs and KDEs, please see 21 CFR Part 1 Subpart S - Records of Critical Tracking Events.

At the core of FSMA 204 is a requirement that persons subject to the rule who manufacture, process, pack, or hold foods on the FTL, maintain records containing Key Data Elements (KDEs), which are the attributes associated with specific Critical Tracking Events (CTEs), activities in the supply chain; and provide information to the FDA within 24 hours or within some reasonable time to which the FDA has agreed.

Traceability For Whole Tomato Example

The whole tomato end-to-end traceability process below depicts a food (tomatoes) being harvested and shipped to a cooling/packing facility where the initial traceability lot code is assigned.

Note that the Cooling CTE is shown if that step takes place. The tomatoes are either shipped directly to a produce distributor who ships them to an operator/retailer or to a repacking house where they may be transformed with a new TLC and shipped to a retailer distribution center and store.



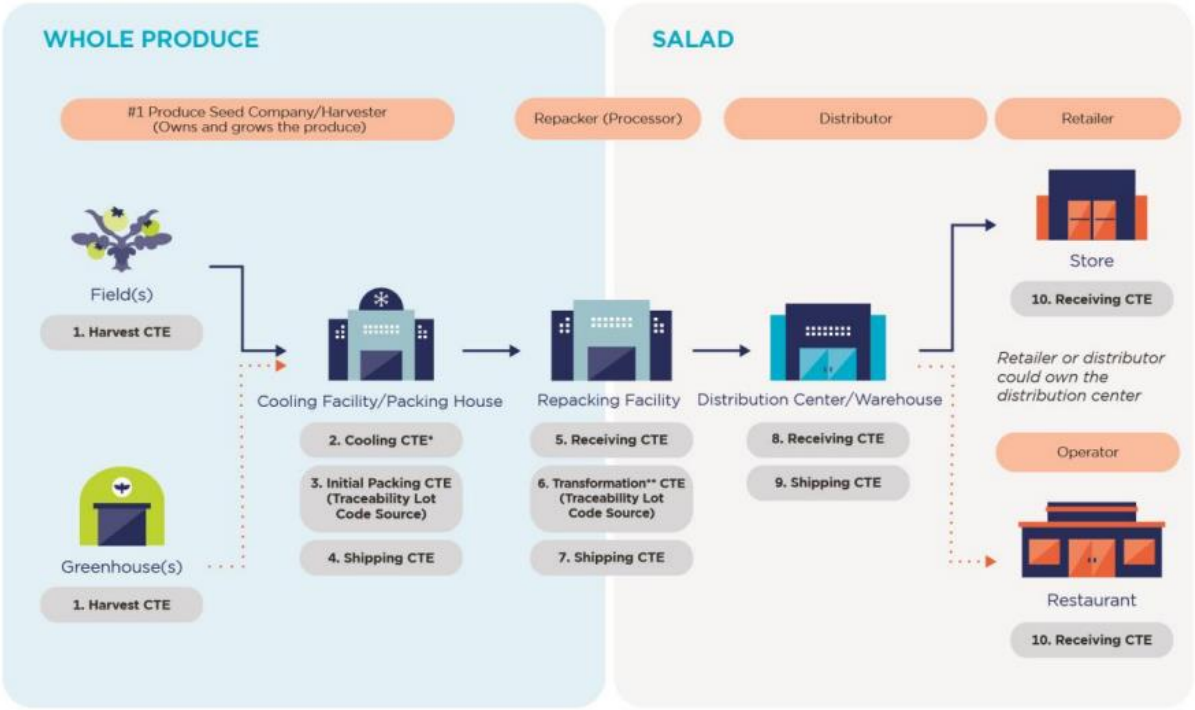
1. **Harvest** – tomatoes are harvested by a harvest company and sent to the Initial Packer. Harvest CTE is recorded and KDEs provided to the Initial Packer.
2. **Cooling** – tomatoes are cooled by the Initial Packer. Cooling CTE is recorded by the Initial Packer.
3. **Initial Packing** – tomatoes are received from the cooler to the packing line. Initial Packing records are recorded by the Initial Packer, including the Harvest KDEs provided by the harvest company. During Initial Packing, the tomatoes are:
    a. Packed into cases (trade items)
    b. Assigned a Traceability Lot Code (GTIN + Lot)
    c. Labeled with a PTI Harmonized Case Label
4. **Shipping** – Tomatoes are aggregated to pallets (logistics units), assigned SSCCs and identified with logistics labels. An ASN is sent to the subsequent recipient with the Shipping KDEs. The Shipping CTE is then recorded by the Initial Packer in their records.

5. **Receiving** – The ASN with Shipping KDEs are received by the repacking facility. Tomatoes are then received by the repacking facility. The repacking facility confirms the receive date and SSCCs received, then records the Receiving CTE in their records.
6. **Transformation** – The repacking facility mixes several lots of tomatoes (foods used in transformation), segregates by ripeness and quality, assigns new Traceability Lot Codes (foods produced through transformation), and packs into new cases. The repacking facility records a Transformation CTE in their records.
7. **Shipping** – The repacking facility aggregates tomatoes onto pallets (logistics units), assigns SSCCs and identified with logistics labels. An ASN is sent to the subsequent recipient with the Shipping KDEs. The Shipping CTE is then recorded by the repacking facility in their records.
8. **Receiving** – The ASN with Shipping KDEs are received by a distribution center. Tomatoes are then received by the distribution center. The distribution center confirms the receive date and SSCCs received, then records the Receiving CTE in their records.
9. **Shipping and Receiving** – The distribution center pick cases (trade items) from the pallets of tomatoes based on orders received. Trade item TLCs are either scanned, recorded using VoiceCode, or calculated based on the pallet and pick slot.
    a. **Restaurant (inter-company)** – Cases are loaded onto delivery trucks without pallet identification. ASN or paper Bill of Lading provided by DC to Restaurant containing most of the Shipping KDEs. TLC and TLC Source Reference may be provided using the Harmonized Case Label or via ASN/BOL. The restaurant uses the Shipping KDEs provided to capture the Receiving CTE in their records.
    b. **Retail Store (intra-company)** – The DC and Store are owned by the same retailer, therefore both locations have access to the same records management system. Cases are aggregated to heterogeneous pallets and assigned an internal License Plate Number that is used by the receiving store to create the receiving record for all products on the pallet.

Traceability For Ready-To-Eat Salad Example

The ready-to-eat salad (with diced tomato) end-to-end traceability process below depicts produce being harvested from more than one facility.

Note that the Cooling CTE is shown if that step takes place. Packing house ships to the processor/re-packer where a transformation (and new TLCs assigned) may occur. The cases are aggregated to pallets (logistics units) which are identified with SSCCs and shipped to a distribution center with an Advanced Shipping Notice (ASN).



Source: Application of GS1 System of Standards to Support FSMA 204

CRITICAL TRACKING EVENTS (CTES) AND KEY DATA ELEMENTS (KDES)

For this guidance document, Critical Tracking Events and Key Data Elements are defined as:

Harvesting

The process of gathering crops from fields, orchards or from controlled environments such as greenhouses or vertical farms. Crops may be put in bins to send to a packing facility or field packed in containers that will remain the same throughout the supply chain.

For each food covered by the rule that you harvest, you must maintain records containing the following information and provide them to the Initial Packer in electronic or paper format.

PTI KDE	FSMA 204 KDE	Comments
ISR Location	The location description for the immediate subsequent recipient (other than a transporter) of the food	Generally, this will be the Initial Packer location but could be a cooling location if the product is cooled before initial packing.
Commodity Variety	The commodity and, if applicable, variety of the food	The commodity and variety should be the same as the commodity and variety captured during Initial Packing and associated to the packed product.
Quantity and UOM	The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds)	Before packing, this will probably be field bins (e.g. 3 x 500lb field bins) but for field packed, it may be cases.

Harvest Location	The location description for the farm where the food was harvested	Farm location description includes the business name, physical address or geo coordinates, city, state, zip, country (or equivalent for foreign locations) phone number.
Field Name	For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name	Should be the same name found on the grower's farm map. It could be a GLN or GLN and GLN extension; or an internal coding scheme that you use already for planting, crop protection, harvesting.
Harvest Date	The date of harvesting	If the harvest stretches for multiple days, list the end date of harvest.
Reference Document Type and Reference Document Number	The reference document type and reference document number.	Relevant document for harvesting. Could be a harvest ticket, production order, sales order, purchase order, logbook, etc.

Cooling Before Initial Packing

Depending on the item, fresh produce may need to be cooled to remove heat from the field and ensure item quality throughout the supply chain prior to packing. This can be room cooling, forced-air cooling, water or hydrocooling, ice cooling, or vacuum cooling depending on the product needs and characteristics.

For each food covered by the rule that you cool prior to initial packing, you must maintain records containing the following information and provide them to the Initial Packer in electronic or paper format.

PTI KDE	FSMA 204 KDE	Comments
ISR Location	The location description for the immediate subsequent recipient (other than a transporter) of the food	Generally, this will be the Initial Packer location but could be a cooling location if the product is cooled before initial packing.
Commodity Variety	The commodity and, if applicable, variety of the food	The commodity and variety should be the same as the commodity and variety captured during Initial Packing and associated to the packed product.
Quantity and UOM	The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds)	Before packing, this will probably be field bins (e.g. 3 x 500lb field bins) but for field packed, it may be cases.
Cooling Location	The location description for where you cooled the food	Cooling location could be the same location as the Initial Packer or could be a different location.
Cooling Date	The date of cooling	If cooled for multiple days, this would be the last day of cooling before the product is initially packed

Harvest Location	The location description for the farm where the food was harvested	Farm location description includes the business name, physical address or geo coordinates, city, state, zip, country (or equivalent for foreign locations) phone number. While not required by the rule, you may want to capture the full Harvest CTE and KDEs on behalf of the Initial Packer.
Reference Document Type and Reference Document Number	The reference document type and reference document number.	Relevant document for cooling. Could be a purchase order, sales order, production order, logbook, etc.

Initial Packing

Crops are packed in containers that will be shipped in this format throughout the supply chain. The containers may be cases containing bulk product for repacking downstream in the supply chain or for sale at retail by the each or weight. Alternatively, the product may be packed in consumer containers such as clamshells, plastic sleeves, etc., for sale in this format at retail or to foodservice operators.

Initial Packing for Produce

For each traceability lot of food covered by the rule you initially pack, you must maintain records containing the following information and linking this information to the traceability lot:

PTI KDE	FSMA 204 KDE	Comments
Commodity Variety	The commodity and, if applicable, variety of the food	This is the information for each unique batch or lot of harvested raw agricultural commodities (RACs). Note, there may be more than one batch or lot listed for a single Traceability Lot Code. It is especially common for crops like tomatoes to be packed together from multiple fields since they are washed, graded, then packed.
Receive Date	The date you received the food	
Quantity Received and UOM Received	The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds)	
Harvest Location	The location description for the farm where the food was harvested	
Field Name	For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;	
Harvest Company	The business name and phone number for the harvester of the food;	
Harvest Date	The date of harvesting;	

Cooling Location	The location description for where the food was cooled (if applicable);	
Cooling Date	The date of cooling (if applicable);	
Traceability Lot Code (TLC)	The traceability lot code you assigned	**- Required by PTI -** AI (01) Case GTIN and AI (10) Case Batch/Lot **- Optional -** AI (00) Pallet SSCC AI (13) Pack Date AI (13) Harvest Date AI (15) Best if Used by Date AI (21) Serial Number
Product Description	The product description of the packed food;	This is the description for the Case, not the saleable unit in the case. Product description should include: product name (including, if applicable, the brand name, commodity, and variety) packaging size packaging style
Quantity Packed and UOM Packed	The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)	This is usually going to be the number of cases packed.
Initial Packing Location	The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;	This is the Traceability Lot Code Source. The TLC Source Reference should point FDA to this location. The attributes for a Traceability Lot Code Source include: • business name • phone number • physical location address (or geographic coordinates) • City • State • Zip code for domestic locations and comparable information for foreign locations, including country
Pack Date	The date of initial packing; and	If packing spans more than one day, use the last day of packing.
Reference Document Type and Reference Document Number	The reference document type and reference document number.	Relevant document for the CTE. BOL, PO, WO, ASN, etc.

Initial Packing for Sprouts

For each traceability lot of sprouts (except soil- or substrate-grown sprouts harvested without their roots) you initially pack, you must also maintain records containing the following information and linking this information to the traceability lot:

PTI KDE	FSMA 204 KDE
Seed Grower Location	The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available.
Seed Conditioner Location, Seed Lot Code, and Date of Conditioning / Processing	The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing.
Seed Packinghouse Location, Packed Seed Lot Code, and Seed Pack Date	The location description for the seed packinghouse (including any repackers), the date of packing (and of repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse.
Seed Supplier Location, Seed Supplier Lot Code, and Sprouter Seed Lot Code	The location description for the seed supplier, any seed lot code assigned by the seed supplier (including the master lot and sub-lot codes), and any new seed lot code assigned by the sprouter.
Seed Description, Seed Type, Taxonomic Name, Growing Specifications, Type of Packaging, and Antimicrobial Treatment	A description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment.
Sprouter Receive Date	The date of receipt of the seeds by the sprouter.
Reference Document Type and Reference Document Number	The reference document type and reference document number.

Initial Packing for Produce from Exempt Entities

For each traceability lot of food covered by the rule you initially pack from a person exempt from the rule, you must maintain records containing the following information and linking this information to the traceability lot:

PTI KDE	FSMA 204 KDE	Comments
Commodity and Variety	The commodity and, if applicable, variety of the food.	This is the information for each unique batch or lot of harvested raw agricultural commodities (RACs). Note, there may be more than one batch or lot listed for a single Traceability Lot Code.
Receive Date	The date you received the food.	
Quantity Received and UOM Received	The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds).	

Receive From Location	The location description for the person from whom you received the food.	It is especially common for crops like tomatoes to be packed together from multiple fields since they are washed, graded, then packed.
Traceability Lot Code (TLC)	The traceability lot code you assigned.	**- Required -** AI (01) Case GTIN and AI (10) Case Batch/Lot **- Optional -** AI (00) Pallet SSCC AI (13) Pack Date AI (13) Harvest Date AI (15) Best if Used by Date AI (21) Serial Number
Product Description	The product description of the packed food.	This is the description for the Case, not the saleable unit in the case. Product description should include: product name (including, if applicable, the brand name, commodity, and variety) packaging size packaging style
Quantity Packed and UOM Packed	The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)	This is usually going to be the number of cases packed.
Initial Packing Location	The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;	TLC Source location is the actual physical location where TLC was assigned during initial packing. The description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • zip code for domestic locations and comparable information for foreign locations, including country Initial Packers may provide a TLC Source Reference instead. This may be a web site where the TLC Source Location Description may be looked up by FDA from the GTIN and Lot Code. The Initial Packer may provide the FDA Facility Registration Number that FDA may look up in their own registry. TLC Source Reference could also be provided as a GLN from a registry that FDA has access to.

Pack Date	The date of initial packing; and	If packing spans more than one day, use the last day of packing.
Reference Document Type and Reference Document Number	The reference document type and reference document number.	Relevant document for the CTE. BOL, PO, WO, ASN, etc.

Shipping

For each traceability lot of food covered by the rule you ship, you must maintain records containing the following information and linking this information to the traceability lot:

PTI KDE	FSMA 204 KDE	Comments
Traceability Lot Code (TLC)	The traceability lot code for the food	**- Required -** AI (01) Case GTIN and AI (10) Case Batch/Lot **- Optional -** AI (00) Pallet SSCC AI (13) Pack Date AI (13) Harvest Date AI (15) Best if Used by Date AI (21) Serial Number
Quantity and UOM	The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)	This is the number of cases shipped.
Product Description	The product description for the food.	This is the description for the Case, not the saleable unit in the case. Product description should include product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style.
Ship To Location	The location description for the immediate subsequent recipient (other than a transporter) of the food.	Ship-to location is the actual physical location where the product was shipped to. Location description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • Zip code...zip code for domestic locations and comparable information for foreign locations, including country
Ship From Location	The location description for the location from which you shipped the food.	Ship-from location is the actual physical location where product was shipped from. Location description includes:

		business name phone number physical location address (or geographic coordinates), city State zip code for domestic locations and comparable information for foreign locations, including country
Ship Date	The date you shipped the food	The ship date is the actual date when product leaves the physical ship-from location.
TLC Source or TLC Source Reference	The location description for the traceability lot code source, or the traceability lot code source reference;	TLC Source is the actual physical location where TLC was assigned during initial packing or transformation. The description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • zip code for domestic locations and comparable information for foreign locations, including country. Suppliers may provide a TLC Source Reference instead of a TLC Source. This could include: • Web site • FDA FFRN • GLN from a registry available to FDA
Reference Document Type and Reference Document Number	The reference document type and reference document number.	May list more than one document. For example, a shipper may list the customer's purchase order, their outbound packing list, bill of lading, invoice and advanced ship notice numbers. By capturing the document type and number, the shipper can provide FDA with additional information about the shipment that may assist in an outbreak investigation. This information is useful for double-checking your traceability records.

Receiving

For each traceability lot of a food on the Food Traceability List you receive, you must maintain records containing the following information and linking this information to the traceability lot:

PTI KDE	FSMA 204 KDE	Comments
Traceability Lot Code (TLC)	The traceability lot code for the food.	**- Required -** AI (01) Case GTIN

		AI(10) Case Batch/Lot **- Optional -** AI (00) Pallet SSCC AI (13) Pack Date AI (13) Harvest Date AI (15) Best if Used by Date AI (21) Serial Number
Quantity and UOM	The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)	This is the number of cases received
Product Description	The product description for the food.	This is the description for the case, not the saleable unit in the case. Product description should include: • product name (including, if applicable, the brand name, commodity, and variety) • packaging size • packaging style.
Ship To Location	The location description for where the food was received	Ship-to location is the actual physical location where the product was shipped to. Location description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • zip code for domestic locations and comparable information for foreign locations, including country
Ship From Location	The location description for the immediate previous source (other than a transporter) for the food	Ship-from location is the actual physical location where the product was shipped from. Location description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • zip code for domestic locations and comparable information for foreign locations, including country
Receive Date	The date you received the food.	The receive date is the actual date when product reaches the physical ship-to location.
TLC Source or TLC Source Reference	The location description for the traceability lot code source, or	TLC Source location is the actual physical location where TLC was assigned during

	the traceability lot code source reference; and	initial packing or transformation. The description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • zip code for domestic locations and comparable information for foreign locations, including country. Suppliers may provide a TLC Source Reference instead of a TLC Source. This could include: • Web site • FDA FFRN • GLN from a registry available to FDA
Reference Document Type and Reference Document Number	The reference document type and reference document number.	One may list one or more than one document. For example, a receiver may list their original purchase order, their supplier's packing list or bill of lading, invoice and advanced ship notice numbers. By capturing the document type and number, the receiver can provide FDA with additional information about the receipt that may assist in an outbreak investigation. This information is useful for double-checking your traceability records.

Transformation

This can include repacking, commingling when items from various original bins, packs, etc. are combined, or cutting, trimming, etc., to create a fresh-cut product (i.e., minimal processing).

For each new traceability lot of food, you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot code:

PTI KDE	FSMA 204 KDE	Comments
FTL Food Used TLC	The traceability lot code for the food used	**Minimum attributes:** AI (01) Case GTIN and AI (10) Case Batch/Lot **Optional attributes:** AI (00) Pallet SSCC AI (13) Pack Date AI (13) Harvest Date AI (15) Best if Used by Date AI (21) Serial Number
FTL Food Used Product Description	The product description for the food to which the	This is the description for the Case, not the saleable unit in the case. Product description should include:

	traceability lot code applies.	• product name (including, if applicable, the brand name, commodity, and variety) • packaging size • packaging style.
FTL Food Used Qty and FTL Food Used UOM	For each traceability lot used, the quantity and unit of measure of the food used from that lot.	Could be a variety of UOMs including cases, lbs., bins, etc.
FTL Food Produced New TLC	The new traceability lot code for the food.	**Minimum attributes:** AI (01) Case GTIN and AI (10) Case Batch/Lot **Optional attributes:** AI (00) Pallet SSCC AI (13) Pack Date AI (13) Harvest Date AI (15) Best if Used by Date AI (21) Serial Number
Transformation Location	The location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference.	TLC Source is the actual physical location where TLC was assigned during initial packing or transformation. The description includes: • business name • phone number • physical location address (or geographic coordinates), • city • State • zip code for domestic locations and comparable information for foreign locations, including country. Suppliers may provide a TLC Source Reference instead of a TLC Source. This could include: • Web site • FDA FFRN • GLN from a registry available to FDA
Date Transformed	The date transformation was completed.	This is the actual date when transformation activities were completed.
FTL Food Produced Product Description	The product description for the food.	This is the description for the Case, not the saleable unit in the case. Product description should include: • product name (including, if applicable, the brand name, commodity, and variety) • packaging size • packaging style.

FTL Food Produced Quantity and FTL Food Produced UOM	The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds).	Usually this is expressed in the number of cases.
Reference Document Type and Reference Document Number	The reference document type and reference document number.	One may list one or more than one document. For example, a receiver may list their original purchase order, their supplier's packing list or bill of lading, invoice and advanced ship notice numbers. By capturing the document type and number, the receiver can provide FDA with additional information about the receipt that may assist in an outbreak investigation. This information is useful for double-checking your traceability records.

RECORDS MAINTENANCE AND AVAILABILITY

The following is an abbreviated and produce-specific discussion of records maintenance and availability. For the full text of the rule, please see 21 CFR Part 1 Subpart S - Records Maintenance and Availability.

General Recordkeeping Requirements

You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Electronic records may include valid, working electronic links to the information required to be maintained under the rule. All records must be legible and stored to prevent deterioration or loss.

Third-Party Record Management

You may have another entity establish and maintain records required under the rule on your behalf, but you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review.

Record Availability

Make records available in 24 hours

You must make all records required under the rule available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request, along with any information needed to understand these records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records you provide correspond to the information required under this subpart.

Offsite storage of records

Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

Sortable spreadsheet

When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, you must make available, within 24 hours (or within some reasonable time to which FDA has agreed) of a request made in-person or remotely (e.g., by phone) by an authorized FDA representative, the information you are required to maintain under the rule, for the foods and date ranges or traceability lot codes specified in the request. Some partial exemptions apply for religious beliefs, and for small farms and small retail food establishments.

When the information requested by FDA is information you are required to maintain, you must provide such information in an electronic sortable spreadsheet, along with any other information needed to understand the information in the spreadsheet.

English translation

Upon FDA request, you must provide within a reasonable time an English translation of records required under the rule in a language other than English.

Record Retention

Except as specified otherwise, you must maintain records containing the information required by the rule for 2 years from the date you created or obtained the records.

Electronic Records

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. Records that satisfy the requirements of the rule, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11, if not otherwise exempt.

Existing Records

You do not need to duplicate existing records you have (e.g., records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this rule. You may supplement any such existing records as necessary to include all of the information required by this subpart.

Multiple Sets of Records

You do not have to keep all of the information required by this rule in a single set of records. However, your traceability plan must indicate the format and location of the records you are required to keep under the rule, in accordance with your Traceability Plan, § 1.1315(a)(1).

Supply Chain Role Considerations

In addition to the requirements outlined above, individuals performing specific CTEs in the supply chain have role-specific requirements and guidelines outlined below.

PERSONS WHO GROW, HARVEST, COOL, AND INITIALLY PACK COVERED FOODS

In addition to keeping the CTEs and KDEs identified under the FSMA 204 Requirements section above, we provide the following guidance for providing Harvesting and Cooling KDEs to Initial Packers and Shipping KDEs from Initial Packers to trading partners.

Exemptions

There are several important exemptions that farms and packers should be aware of:

- Full exemption for farms with sales ≤ $25,000, 21 CFR 1.1305(a)(1)(ii)
- Exemption from sortable spreadsheet requirement for farms with sales ≤ $250,000, 21 CFR 1.1455(c)(3)(iii)(A)
- Full exemption for food sold or donated by a farm directly to consumers, 21 CFR 1.1305(b)
- Full exemption for foods that will be subjected to certain types of processing if there is a written agreement in place. 21 CFR 1.1305(d)(6)
- Partial exemption for retail food establishments and restaurants purchasing directly from a farm. 21 CFR 1.1305(j)
- Partial exemption for farm to school and farm to institution programs. (21 CFR 1.1305(l))
- Inapplicability to certain food produced and packaged on a farm. (21 CFR 1.1305(c))
- Certain produce farms. (21 CFR 1.1305(a)(1)(i))

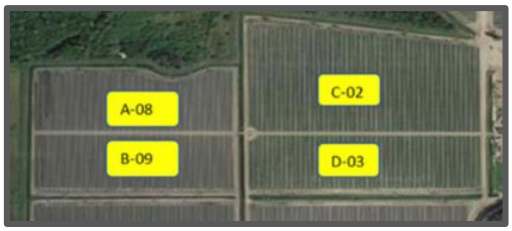
Traceability Plan

Procedures related to traceability records management need to describe how employees record harvest, cooling, and initial packing records, and share required harvest and cooling KDEs to the initial packer. The plan should also incorporate verification steps to assure that the foods packed match the records kept. The plan should include lot code assignment methodology and point of contact information. Finally, the plan should include Farm Maps and Field Identification.

To simplify operations, one may consider handling all foods as if they are on the Food Traceability List.

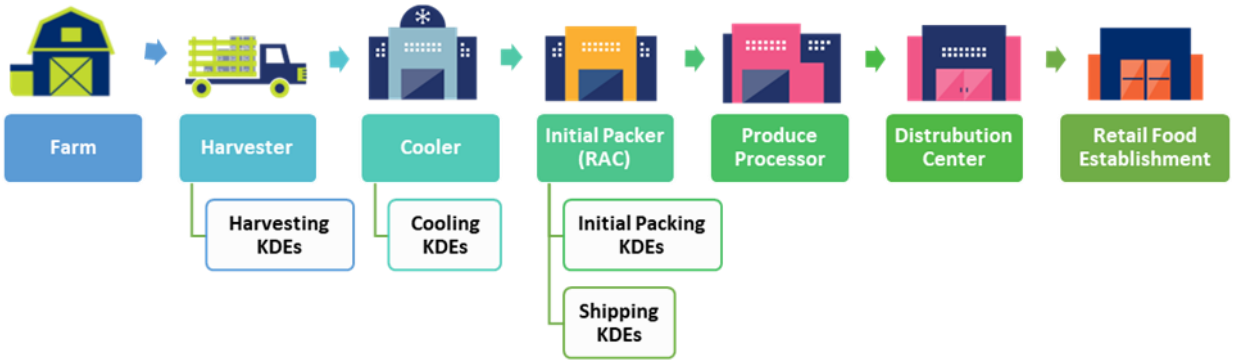
Farm Maps and Field Identification

To simplify data sharing between growers, harvesters, and initial packers, growers may elect to assign a GLN to a farm and use GLN extension to identify each field. The following example is provided.



Farm Location Description			Field Names & Location {GLN.GLN Extension}	
Farm Name	Lizzie's Farm		1234567890123.A-08	-24.5000145, -11.107417
Address	113 Farm Street		1234567890123.D-03	-24.5000144, -11.107418
City	Springfield		1234567890123.C-02	-24.5000146, -11.107419
State or Region	FL		1234567890123.B-09	-24.5000147, -11.107416
Postal Code	11311			
Country	US			
Telephone	+1.999.999.9999			
GLN	1234567890123			

CTEs and KDEs



Sharing Harvesting and Cooling KDEs

Harvest and Cooling records may incorporate the GLN and GLN extension into their records that are shared with Initial Packers. The following examples of Harvest and Cooling records are provided.

Sharing Shipping KDEs from Initial Packers

Product Identification and Description – AI (01)
PTI Best Practice is to identify FTL Foods with Case GTIN-14s and descriptions according to produce industry GTIN assignment standards.

Lot Code Assignment - AI (10)
PTI Best Practice is to assign lot codes that, together with the Case GTIN, identify a food to a packing location and a packing date. The rule requires that a traceability lot code should be "used to uniquely identify a traceability lot within the records of the traceability lot code source." This means that your lot code assignment method must allow you to find one and only one Initial Packing Event record per GTIN and Internal Lot Code.

Traceability Lot Code PTI Best Practice
GS1 and PTI recommend that the Traceability Lot Code be composed of two data elements in the GS1-128 PTI Case Label, Case GTIN and lot code. These are represented on the PTI Case Label in the GS1-128 barcode as Application Identifier (01) GTIN and (10) Batch/Lot.

In addition to the TLC, PTI recommends a date to be included in the GS1-128 barcode for the PTI Case Label.

Serial Numbers – AI (21)

Some buyers are electing to use Radio Frequency Identification (RFID) and Ambient Internet of Things (IoT) devices to identify cases. These devices are serialized, meaning that they each have a GTIN-14 and Serial number encoded into the devices. These devices may be applied with PTI standard case labels, applied separately, or incorporated into the cases themselves. In some situations, the product's GTIN-14 and lot code is encoded into the device in addition to the serial number. In other situations, the device manufacturer may use their own GTIN-14 and exclude the internal lot number. In the latter case, it is important for the Initial Packer to provide the product's Case GTIN-14 and internal lot code linked to the device GTIN and serial number to subsequent recipients that intend to electronically read the IoT or RFID device, rather than scan the barcode.

Pallet Identification – AI (00)

According to GS1 standards and guidelines, logistics units (e.g., pallets) should be identified with an SSCC and a GS1 Logistics Labels. The GS1 Logistic Label allows users to identify logistic units uniquely so that they can be tracked and traced throughout the supply chain. The only mandatory requirement is that each logistic unit must be identified with a unique 18-digit serial number, the Serial Shipping Container Code (SSCC).

Scanning the SSCC barcode on each logistic unit allows the physical movement of units to be matched with the electronic business messages that refer to them. Using the SSCC to identify individual units provides the opportunity to implement a wide range of applications such as cross docking, shipment routing, and automated receiving. Besides the SSCC other information can be included on the GS1 Logistic Label.

TLC Data Sharing using Pallet SSCC

The pallet SSCC may be used to simplify Traceability Lot Code Sharing between trading partners by aggregating trade item Traceability Lot Code to the SSCC. The ASN is designed to provide the subsequent recipient with a list of all pallet SSCCs associated with a shipment, and a list of all TLCs (GTIN + Lot + Quantity + UoM) associated with each pallet SSCC.

The subsequent recipient may capture the SSCC from the pallet label upon receipt and "look up" the TLCs associated with the pallet from the ASN received from the immediate previous source. This eliminates the need to scan case labels during receiving.

An alternative to the ASN is the GS1 Logistics Label which includes a barcode for the SSCC and a barcode for the GTIN + Lot + Case Quantity aggregated to the pallet.

Master Data Sharing

Product description associated with the GTIN should be shared with subsequent recipients. This allows the recipient to "look up" the product description when a GTIN is provided in an ASN or as part of a PTI Harmonized Case Label. Sharing methods include but are not limited to:

- GS1 Global Data Sharing Network
- GS1 Data Hub
- Traceability data sharing network
- Spreadsheet

Location description associated with GLNs should be shared with subsequent recipients. This allows for the recipient to “look up” the location description when a GLN is provided via ASN or as part of a PTI Harmonized Case Label. Sharing methods include but are not limited to:

- As part of the ASN
- GS1 Data Hub
- Traceability data sharing network
- Spreadsheet

Shipping Event KDE Sharing

The Shipping event includes eight key data elements, seven of which must be shared to subsequent recipients. Options to share this information with subsequent recipients include:

- Advanced Ship Notice may provide some or all Shipping KDEs using an EDI 856 or an EPCIS Shipping Event
- Bill of Lading, some or all KDEs.
- PTI Harmonized Case Label (Product Description, TLC, TLC Source or TLC Source Reference)
- GS1 Logistics Label (SSCC, GTIN, Lot, Case Quantity)
- Spreadsheet

Traceability Lot Code Source or Source Reference should be shared with trading partners in a way they can easily receive it. This may be through master data sharing or as part of the ASN. One may also elect to incorporate a TLC Source Reference on bills of lading or on the case label to assure compliance with the rule in all cases, regardless of the technical readiness of subsequent recipients.

Sprouts

Sprouts have several additional KDEs required during initial packing. Once packed, they are treated just like any other case of produce.

Products Received from Exempt Entities

For products received by initial packers from exempt entities, they have a reduced set of Initial Packing KDEs. Once packed they are handled like any other case of produce.

Sortable Spreadsheets

The Final Rule requires that "Firms must provide an electronic sortable spreadsheet ‘containing information FDA requests on CTEs involving particular FTL foods for the date ranges or traceability lot codes specified in our request."

From FDA, a complete list of KDEs required in sortable spreadsheets is available here

The PTI sample sortable spreadsheet is provided here including tabs for:

- Harvest CTE
- Cooling CTE
- Initial Packing CTE

- Initial Packing CTE of food from an exempt entity
- Initial Packing Sprouts
- Transformation (re-pack)

Pilot and Audit

One should consider the following during FSMA 204 pilots and audits.

- The TLC and TLC Source assigned by initial packers may not be changed by subsequent recipients unless they transform the food. One may test both scenarios with trading partners.
- Test initial packing for foods from covered and exempt growers (if applicable).
- Records must be captured and stored for two (2) years. Create simulated data for multiple years and generate sortable spreadsheets for various time periods.
- Match the physical products being shipped with your records to make sure that the correct TLC and TLC Source information is shared with subsequent recipients. Test all different types of data sharing methods (digital, paper, labels, and tags, etc.).
- Consider situations where cases are opened by subsequent recipients, and saleable items or inner packs are shipped directly to stores. Does the GTIN of the inner pack or saleable item link to the case GTIN via product hierarchy? If the item is marked with the same type of date code, do the dates match? If a lot of code is shown, is it the same as the lot code on the case?

Recommendations

- Map out the different scenarios in your organization and identify where CTEs need to be captured and the source of each KDE.
- List the types of companies and technology capabilities of the companies that you will need to integrate with (growers, harvesters, coolers, suppliers, customers).
- Identify methods of capturing and storing KDEs.
- Identify methods of sharing the Shipping KDEs to subsequent recipients.
- Develop pallet tagging with SSCC.
- Develop aggregation methods of TLCs to SSCC.
- Develop methods for linking pallets to shipments.
- Develop methods for associating Pallet SSCC, TLC, TLC Source/Reference, Quantity, UoM to outbound shipments.
- Work with trading partners to understand data sharing capabilities (for both Shippers and Receivers). Consider developing lower-tech methods of sharing the FSMA 204 Shipping KDEs if the company that is being shipped to cannot handle an EDI ASN.

PERSONS WHO RE-PACK OR TRANSFORM COVERED FOODS

Transformation means an event in a food's supply chain that involves manufacturing or processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).

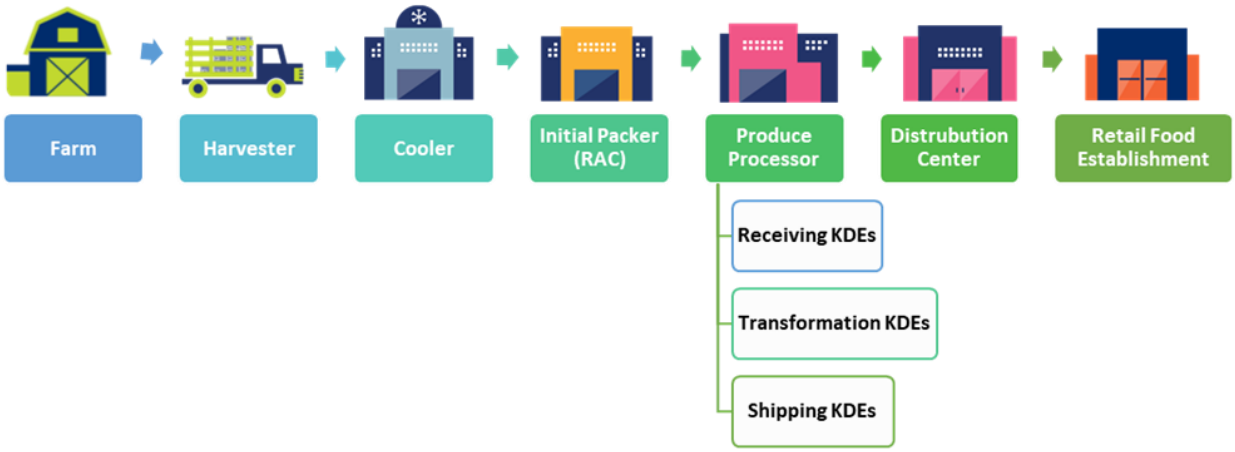
Exemptions

If the food is prepared onsite at a restaurant or retail food establishment, it is not subject to the food transformation requirements if those products are being sold directly to consumers. If the products are transformed in a commissary or food facility and then shipped to another location before sale to a consumer, then the transformation CTEs will need to be collected.

Traceability Plan

Procedures related to traceability records management need to incorporate how employees handle FTL and Non-FTL ingredients, work in process, and finished goods. To simplify operations, one may consider handling all foods, or at least finished products, as if they are on the Food Traceability List.

CTEs and KDEs



Transformation CTE: for foods used in transformation:

- For each FTL food used in a transformation the following information should be recorded:
  - Traceability lot code
  - Product description
  - Quantity and Unit of Measure
- For each non-FTL food used in a transformation one may record the same or similar information as an FTL food, if available. This is not required by the rule, but is a best practice to capture all ingredients, whether or not they have a GTIN and Lot or not.

Foods produced through transformation.

- For each FTL food produced through transformation, the following information should be recorded:
  - Traceability lot code
  - Product description
  - Quantity and Unit of Measure
  - Transformation date

- The location where you transformed the food. This is also known as the TLC Source and may be pointed to using TLC Source Reference.
- Referenced Document Type and Number.
- For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) Initial Packing or (c) Initial Packing of foods from exempt entities, and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b) Initial Packing of Sprouts.

Sortable Spreadsheets

The sortable spreadsheet for Transformation is a bit challenging since it could contain multiple inputs and multiple outputs. One approach is to list the inputs first, then the outputs. Another is to connect each input with each output.

Either way, it would be good to note this in your traceability plan and on the header of your sortable spreadsheet.

Please see the following example of a sortable spreadsheet here.

Pilot and Audit

One should consider the following during FSMA 204 pilots and audits.

- For a finished product's TLC and TLC Source, you find one and only one transformation record. By definition, the TLC means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Recommendations

- Map out the different scenarios in your organization.
- Identify methods of capturing and storing Transformation KDEs.
- Identify methods to capture KDEs that may happen internally (e.g., moving inventory to into production locations, aggregating cases to pallets, etc.).

Work with trading partners to understand how ingredients will be labeled to simplify KDE capture during transformation.

PERSONS WHO SHIP COVERED FOODS TO LOGISTICS FACILITIES

Persons who perform Initial Packing and Transformation typically Ship logistics units to logistics facilities. Logistics facilities include warehouses, terminal markets, distribution centers, cross docks, and consolidators.

Exemptions

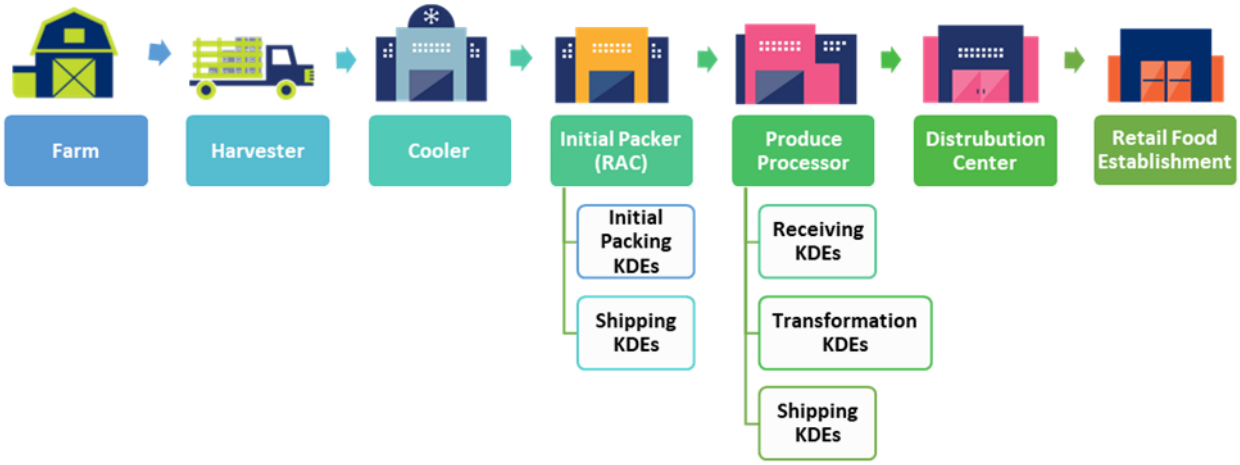
If foods will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food

establishment, restaurant, or consumer, such that the food will no longer be on the Food Traceability List, provided that there is a written agreement to that effect, per 21 CFR 1.1305(d)(6).

Traceability Plan

Procedures related to traceability records management need to describe how employees record shipping records, and share required shipping KDEs to subsequent recipients. The plan should also incorporate verification steps to assure that the foods shipped match the records kept and provided. To simplify operations, one may consider handling all foods as if they are on the Food Traceability List.

CTEs and KDEs



As the product is shipped, different Receivers will have different levels of technology capabilities. Shipping KDEs and methods must be able to support the full range of low-tech to high-tech Receiver capabilities, such as:

- Low tech
  - Printed paper with the Shipping KDEs
  - Added to existing paperwork (shipping order, bill of materials, etc.)
- Mid tech
  - Emailing the details of the Shipping KDEs to an email at the Receiver with the details in the email body or in an attachment
  - Upload to a cloud storage repository (i.e., Dropbox, Google Drive, etc.)
  - May include a web link to the data electronically if the Receiver needs to access it later
  - May contain a QR code to easily find the data on the web link
  - SMS Text sent to the Receiver with a web link to the electronic Shipping KDEs
- High tech
  - EDI 856 ASN with the FSMA data elements for Shipping KDEs
  - Custom API that some Receivers may set up and require shipments to have the Shipping KDEs posted via API
  - Flat File sent via email, AS2, FTP, SFTP, etc.

- System to System (various custom integrations)

A link to the Shipping Worksheet is included in the Appendix of this document.

Sortable Spreadsheets

The sortable spreadsheet for Shipping is straightforward. A shipment may contain multiple line items. Each row in the spreadsheet represents a line item. The document reference type and number may be used to group together line items for the same purchase order or bill of lading.

TLC. The template provides two columns for the Traceability Lot Code – the Case GTIN and the Batch or Lot Number. These should match AI(01) and AI(10) on the PTI Case Label for the food.

Date. Since either harvest or pack date is also included in the PTI Case Label Best Practice, columns for date code and date types.

VoiceCode. This is an optional data element but is useful for recipients who use voice picking systems and for receivers who want to visually inspect cases to assure that the information provided as part of the advanced shipment notice matches the cases received. This value is computed from the data in the GS1-128 barcode. The VoiceCode may be computed by the recipient, but providing it eliminates the possibility for error and simplifies usage for entities without the ability to compute the Voice Code.

Pallet ID. This column provides the pallet number, if available. Usually, it is an SSCC but may be an internally assigned license plate number. Its primary purpose is to facilitate traceability by grouping together foods by GTIN and Lot. A pallet ID may be linked to one or more than one GTIN/Lot/Qty/UoM combination.

Product Description. The product description column provides the required information under the definition of product description from the rule. More information about the product may be listed under the Products tab (e.g., Category and GTIN).

Ship-To and Ship-From Locations and IDs. These columns provide for a brief description of locations and the location GLNs. Detailed location information may be listed under the Locations tab (e.g., address, phone, and email address).

Ship Date. Is the date of shipment required by the rule.

TLC Source Reference. This spreadsheet assumes that the data provider is taking advantage of the information privacy afforded by the rule regarding the Traceability Lot Code Source by providing a reference to the source rather than the full address. The spreadsheet offers four options: GS1 GLN, FDA Food Facility Registration Number, a web site URL, or a Global Gap Number (GS1 GLN assigned by GlobalG.A.P.).

- **GS1 GLN.** If a GLN is provided, it is recommended that a web address also be provided where FDA may retrieve the additional information about the location.
- **FFRN.** This may be a stand-alone number since FDA assigns FFRNs.
- **Web site URL.** This may be a standalone identifier if the URL includes either the GTIN and Lot or the TLC Source GLN. Or it may be a website that requires the entry of the GLN or the GTIN and Lot.

- **GGN.** The GlobalGAP number may be looked up on the GlobalGAP website by FDA, so no additional information is required.

TLC Source Reference – Assigned By. This enables the recipient to understand who assigned the TLC and TLC Source. In some cases, growers may be exempt from the rule, so a subsequent recipient may be required to assign a traceability lot code and source.

Reference Document Type and Number. This field is required for shippers to keep and provide to FDA. It is optional, but recommended, to provide to subsequent recipients.

Please see the following example of a sortable spreadsheet under the "Guides" section of the *PTI Resources and Tools* webpage.

Pilot and Audit

One should consider the following during FSMA 204 pilots and audits.

- Test to assure all covered foods have the required case and pallet labeling.
- Check the data collection systems to make sure the pallet SSCC and case GTIN/Date/Lot/Quantity/UoM information is captured, stored, shared, and received correctly – in both electronic and paper formats.
- Key considerations and responsibilities of Shipping companies:
    - How will they create and share their Shipping KDEs when they ship products?
    - What is your customer/trading partner requirements for Shipping CTE data sharing?
    - Do they reconfigure pallets? Have cross-dock items?

Recommendations

- List the types of companies and technology capabilities of the companies you ship to.
- Identify methods of sharing the Shipping KDEs when products are shipped out.
- Target the Palletized FSMA ASN as the best and most scalable method to share FSMA 204 Shipping KDEs.

Work with trading partners to understand data sharing capabilities (for both Shippers and Receivers). Consider developing lower-tech methods of sharing the FSMA 204 Shipping KDEs if the company that is being shipped to cannot handle an EDI ASN.

PERSONS WHO MANAGE LOGISTICS FACILITIES

Logistics facilities include warehouses, terminal markets, distribution centers, cross docks, and consolidators. These facilities primarily Receive logistics units of FTL foods from persons who perform Initial Packing and Transformation, then Ship logistics units or trade items to Retail Food Establishments, Restaurants, and other logistics facilities.

Exemptions

Foods subject to regulation by the USDA are exempt from the FDA Food Traceability Rule. See 21 CFR 1.1305(g) for more information.

For operational purposes, a distribution center may elect to handle FTL and non-FTL foods using the same procedures.

Traceability Plan

Procedures for maintaining records

Distribution centers receive many paper records from suppliers including bills of lading and packing lists containing relevant key data elements. To simplify production of sortable spreadsheets, one should consider digitizing this information. This may be a two-step process, where the Receiving KDEs are stored in a database record linked to a scanned image of the bill of lading or packing list (reference document). If Traceability Lot Code and Source are not included on the bill of lading, the receiver will need to capture this information from pallet or case labels.

To simplify the process, a distribution center may request that suppliers provide the bill of lading or packing list and Traceability Lot Code + Source digitally through an ASN. If the required KDEs are provided digitally by the supplier, the receiving record may be created directly from the ASN and the reference record type + number may be “ASN” + ASN number. This would eliminate the need to digitize paper documents.

Shipping records may be created directly from the distribution center’s warehouse management system, provided all KDEs, including Traceability Lot Code and Source are captured either during picking or shipping.

Records must be stored for two years and must be maintained in such a way that the distribution center may access the records and generate sortable spreadsheets within 24 hours upon request by FDA.

Procedures for identifying FTL foods

A distribution center handles products from many different suppliers. Rather than rely on suppliers to notify the distributor whether the food is on the FTL list during the shipping/receiving process, one may prefer to identify FTL foods within the distributor’s purchasing and master data management systems ahead of time. This enables a distribution center to proactively monitor the compliance of inbound orders.

Flagging FTL foods at receiving facilitates communication with subsequent recipients that certain foods are covered by the rule, and in some cases, which FTL category applies.

Traceability Lot Code assignment

For FTL foods received from exempt entities, the distribution center should develop a procedure for assigning a TLC and TLC Source or Source Reference that works with their warehouse management system and with their customer systems. A simple method could be to use the pallet License Plate Number (LPN) assigned by the distributor’s warehouse management system combined with the facility’s GLN.

Point of contact for questions regarding your traceability plan and records

An organization covered by the rule should create a traceability team, with contact information including a centralized phone number and email address that routes to the traceability team. This information should be made available to FDA and trading partners.

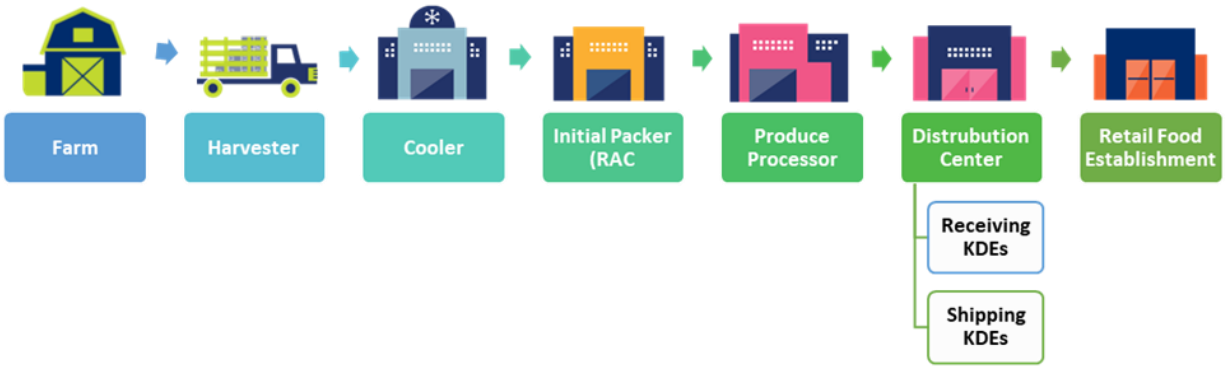
Farm Map

Farm maps are not required by distribution centers.

Procedures for updating the Traceability Plan

Each version of the Traceability Plan must be maintained for two years. Distribution centers should use the same document and version management system they use for their food safety program.

CTEs and KDEs



Traceability Lot Code

Distribution center best practice is to receive products in cases identified with GTIN + Lot on pallets identified with SSCCs with an associated ASN (GS1 Food Industry Guidance for Logistics Labels). Optionally, cases may also be identified with serial numbers in addition to lot numbers.

Quantity and Unit of Measure

Produce is usually sold in fixed weight cases, so the unit of measure is “Case” or “CS.”

Product Description

The product description for a case is shown on PTI Case Labels, bills of lading, and in ASNs. It may also be shared using master data management systems and networks (e.g. the GS1 Global Data Sharing Network and GS1 US Data Hub).

Traceability Lot Code Source or Source Reference

The TLC Source or Source Reference may be shown on PTI Case Labels, bills of lading, and in ASNs. This could take the form of the actual TLC Source Location Description, or a reference to the location description in the form of a web address, an FDA Facility Registration Number, or a GLN if a lookup database is provided at no charge to FDA.

Distribution centers need to capture this information from many sources and provide this information to multiple subsequent recipients. TLC Source Reference in the form of a web address is the easiest way to do this. A web address may be clicked on from a sortable spreadsheet or scanned in the form of a QR code. Information provided by suppliers may be converted into a uniform TLC Source Reference by distributors prior to outbound shipping to subsequent recipients.

GLN usage is recommended.

Ship-From Location

This must be the physical address of the location that food was received from, not the corporate headquarters. Many bills of lading and ASNs do not include the actual ship-from location. This requirement should be communicated to suppliers.

For outbound shipments, this should be the physical location of your distribution center.

GLN usage is recommended.

Ship-To Location

This must be the physical address of the location that food was shipped to. Many bills of lading and ASNs do include the actual ship-to location already. To be safe, this requirement should be communicated to suppliers as well.

For outbound shipments, this should be the physical location of the subsequent recipient.

GLN usage is recommended.

Receive Date

The receive date is recorded by the receiver when the product is received. Time is not required but may be useful for your internal processes.

Ship Date

The ship date is recorded by the shipper when the product is shipped. Time is not required but may be useful for your internal processes.

Reference Document Type and Number

For received products, this will be documents such as purchase order, bill of lading, and ASN. For shipped products, this will be documents such as sales order, bill of lading, and ASN. However other documents may be appropriate. You may record more than one document

number and type. Shippers are not required to share this information with subsequent recipients, but it is best practice.

Receiving KDEs from immediate previous source

GS1 US has developed guidance for sharing shipping KDEs using GS1 standards. They may be used with PTI Case Label Best Practices to develop supplier requirements for the following:

- PTI Case labels for all fresh produce with GTIN and Lot in a GS1-128 barcode.
- Logistics labels for all pallets with, at minimum, an SSCC in a GS1-128 barcode.
- Case product description (GTIN) and ship-from location description (GLN) shared to distribution center's system prior to receipt of a shipment of fresh produce.
- ASN with all required FSMA 204 Shipping KDEs sent with each shipment of fresh produce and received prior to arrival.
- For FTL Foods, provide TLC Source Reference via ASN.

Put away and pick

Distribution centers typically assign a License Plate Number (LPN) to each pallet received. Purchasing and supplier information is linked to the LPN, which is used to track the pallet through the warehouse, during picking, to the subsequent recipient.

Locations or "slots" within the distribution center are assigned slot numbers. LPNs are associated with slots when pallets are put away in the warehouse. Often pallets are put in "reserve" slots, above floor level. For operations that ship by the case, "Pick" slots are ground level slots where a picker may select individual cases and place them on a new pallet, which will be shipped to a subsequent recipient. When an LPN is moved to a pick slot, it is important to record the date and time. Until a new LPN is placed in the slot, one may assume that cases picked from the slot are associated with the LPN.

TLC ambiguity

In practice, picking cases from a pick slot may result in TLC ambiguity for two primary reasons. First, a pallet may have multiple TLCs on it. Second, there may be carryover of TLCs from the prior pallet.

While it is a best practice to include the TLC on case labels, it is not a requirement of the FDA Food Traceability Rule. In fact, FDA explicitly states that "the final rule does not require that the TLC be included on food labeling or food packaging. The TLC could be sent to the next recipient of the food in a variety of ways, such as via a bill of lading, an advanced shipment notice (ASN), in a separate email, or by embedding the information in a quick response (QR) code that appears on the packaging of the food or on a related document. The information would 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 under the rule." (Source: Traceability Lot Code at fda.gov)

If the cases do not carry the TLC or if one does not have the ability to capture the TLC from the cases, one should capture and share all TLCs associated with the current LPN/SSCC in the pick slot based on the TLC information provided by the immediate previous source.

Recommended best practice is to verify which TLCs were selected using the PTI Case Label (if available) using either a scan of the GS1-128 barcode or vocally using the PTI VoiceCode. In some cases, facilities may elect to use advanced data carriers such as 2D Barcodes, or RFID/IoT devices.

Providing KDEs to subsequent recipients

FDA does not prescribe a specific method for data sharing of Shipping KDEs. However, PTI provides the following best practices and recommendations:

- Option 1: Printed or Electronic Bill of Lading and PTI Label
    - *Label:* Traceability Lot Code, Product Description, TLC Source, or TLC Reference. Example provided in Appendix.
    - *Bill of Lading:* Product Description, Quantity and Unit of Measure, Ship-From and Ship-To Location Descriptions, optional: Bill of Lading Number and Customer's Purchase Order (PO) and PO Line Number
- Option 2: Electronic Sortable Spreadsheet
    - All shipping KDEs required sent in CSV, XLSX format
    - Provide files via email, FTP, API or other file sharing method
- Option 3: EDI 856 Advanced Ship Notice or EPCIS Shipping Event. Examples provided in Appendix.
- Option 4: GS1 Scan4Transport QR Code which includes all Shipping KDEs
- Option 5: Paper or digital manifest, proof of shipment or passing could include all KDEs including TLC and TLC Source Reference

Sortable Spreadsheets

Typically, during an outbreak investigation, the FDA will ask for sortable spreadsheets for specific locations, date ranges, FTL food categories, and product descriptions. It is unlikely that FDA would know Traceability Lot Codes early in an outbreak investigation.

In terms of format, FDA would expect each CTE to be represented by a spreadsheet where the columns are the KDEs, and the rows are the records.

The following are examples of receiving and shipping sortable spreadsheets from producetraceability.org.

- Receiving Sortable Spreadsheet
- Shipping Sortable Spreadsheet

Pilot and Audit

It is imperative to conduct pilots with trading partners to test the communication of Shipping KDEs and accurate, timely recording of Receiving KDEs.

- Within food companies and distributors, it is important to regularly test the linkage of received foods to shipped foods and compare those results with the information shared with trading partners.

- Cross reference the ASN information with the physical pallets once they arrive.
- Perform barcode/data carrier quality checks and issue reporting/resolution details for data monitoring.
- Perform regular mock investigation and recall tests based on record keeping requirements.
    - Retrieve records, supporting information (e.g., Reference Documents, Master Data), and electronic sortable spreadsheets with required CTEs and KDEs within 24 hours of FDA request.
    - Outbreak request example criteria:
        - Ship-to and/or Ship-from Locations
        - Date ranges
        - Categories, varieties, species, ingredients
        - Brand names
        - Specific product names
        - In some cases, SKUs, PLUs, or UPCs may be provided.
- Recall criteria
    - Supplier information
    - Product description, including UPC and PLU (may be provided).
    - Possibly TLC range (if available)
    - Locations or regions
    - Date range
- Company-owned DC will keep traceability records
- Non-company owned distributor who maintains records
- 3 PL distributor will electronically share traceability records with shipment
- Wholesaler/Terminal Market with or without electronic records shared – manually provided
- Direct from farm shipment – reduced data required
- DC to DC, wholesaler to wholesaler, warehouse to warehouse transfers
- Grocery/Retail store to a warehouse
- Cross-dock
- Document Source by data element in an electronic sortable spreadsheet.

Recommendations

The following additional guidance may be used to reduce TLC ambiguity during picking, shipping, and delivery. Procedures are used for data capture, monitoring and sharing should be reflected in your Traceability Plan. Remember, traceability is a journey, not a destination. Continuous improvement and monitoring are required to assure data quality and confidence in your traceability system. Comparing the physical pallet/case to the digital information (ASN) will help catch and remediate data errors that will benefit other processes such as invoicing and ordering. Recommendations include:

- Adjust WMS or reporting systems to anticipate TLC carryover.
- Train pickers to finish picking the prior pallet before picking cases from a new pallet.
- Perform regular slot inspections and inventory adjustments.
- Incorporate new technology in addition to the barcode, such as RFID.
- Work with receiver to confirm actual TLC received.
- Establish a monitoring program, scorecards/dashboards to measure accuracy, capture errors and create corrective actions.

- Leverage internal and third-party auditors to verify accuracy of program.

PERSONS WHO MANAGE RETAIL FOOD ESTABLISHMENTS

The Implementation Guidance described in this section is designed to enable retail food establishments (grocery, convenience, club stores, etc.) to receive produce items on the FDA's Food Traceability List. A retail food establishment is defined as an establishment that sells food product directly to consumers as its primary function. Guidance for convenience stores can be found in the Persons Who Manage Foodservice Outlets section in this document.

Under the Final Rule, Retail Food Establishments (RFEs) need to maintain **Receiving KDEs** for all FTL foods they receive. Many

However, § 1.1350(c) states that the requirement to maintain **Transformation KDEs** does not apply to RFEs with respect to **foods they do not ship** (e.g., foods they sell or send directly to consumers). Similarly, RFEs do not need to maintain shipping records for food they sell to consumers because the definition of shipping (21 CFR 1.1310 "Shipping") states that shipping does not include the sale or shipment of a food directly to a consumer.

However, if an RFE ships an FTL item, or transforms FTL items and ships these products to another location, such as a store-to-store transfer, then those shipping events, and any transformations where the output is an FTL item, will need to be captured.

Exemptions

For retail food establishments and restaurants, exemptions apply to retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

There are also partial exemptions provided for items purchased direct from the farm, and for certain purchases from another retail food establishment or restaurant. The full details of these exemptions can be found in 21 CFR 1.1305.

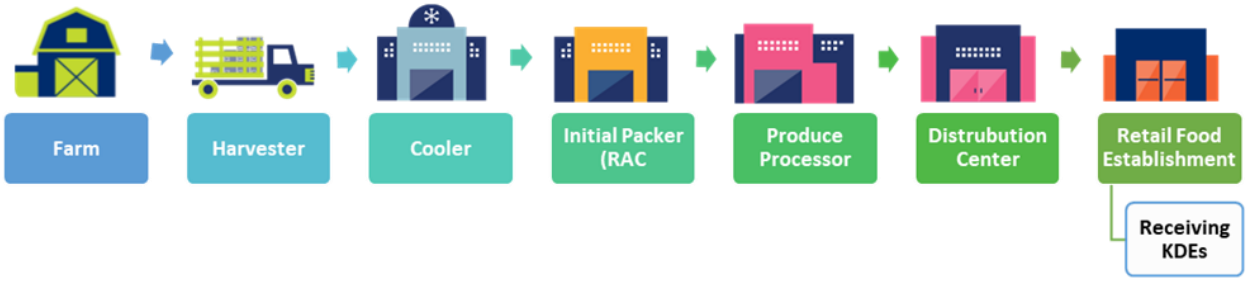
Traceability Plan

- Describe how your company identifies items covered by the Rule. This may include:
  - Requesting information from your suppliers and/or distributors,
  - Utilizing product category information,
  - Requiring suppliers to use the FTL flag in GDSN,
  - Asking for FTL information in your new item setup, and
  - Other sources.
- Describe how you will connect FTL items sold (consumer units) to which items are received (case units).
- Include details of who is collecting and storing the CTE information for FTL items received at your stores and who will create the electronic sortable spreadsheet. If utilizing a third party, such as your distributor, include details of that written agreement.

- Include Receiving process requirements.
- Include how and where data will be stored.
- Include who receives items into store
- Include how items are sold (unit/case etc.)
- Document the frequency of mock recalls performed.
- Describe how you will validate accuracy and format of data stored by the distributors or others.
- Include documenting agreements on data keeping arrangements.
    - Companies may enter agreements with individuals or firms to create and keep the records they must maintain under the rule, including records documenting KDEs for the CTEs the person performs. When this type of arrangement is in place, the terms of this arrangement must be included in your traceability plan in accordance with § 1.1315(a)(1).
- Retail food establishments (RFEs) and restaurants: What you need to know about establishing and maintaining a traceability plan for the Food Traceability Rule

For a full list of attributes required in a Traceability Plan, see *LINK* to section What is in a traceability plan? (p.20)

CTEs and KDEs



Generally, each Retail Food Establishment and restaurant covered by the rule must maintain receiving records as described in CFR § 1.1345. This includes capturing lot-level information for all FTL produce items that are received at your stores.

For retail stores, the FDA FSMA 204 critical tracking event is RECEIVING.

A full list of KDE's for Receiving events can be found in Receiving Section of this document.

Sortable Spreadsheets

Access an example of the Retail Store Example Sortable Spreadsheet under the "Guides" section of the *PTI Resources and Tools* webpage.

- Determine how the store creates a list of products received containing FTL items
- Understand how stores determine who shipped the FTL (use romaine as example) to stores during the time period. Resources include:

    - Corporate DCs are first to verify (some foodservice operators have their own DC's)
    - If from a third-party distributor, put a process in place to contact and retrieve information.
    - Determine other sources during timeframe:
        - Receiving Logs
        - Invoices
        - Purchase Orders
        - Bills of Lading
        - Load Manifests
        - EDI Records
- Consider when the products are received based on store inventory conditions and turnover.
- If a third party is collecting and storing the data, formalize the agreement and make data accessible to meet compliance timelines.
    - Company owned DC or third-party distributor captures and maintains records.
    - 3PL distributor will electronically share traceability records with shipment.
    - Wholesaler/Terminal Market without electronic records shared – manually provided.
    - Direct from farm shipment – reduced data capture required.
    - Store to Store transfers requires data capture

Note: *Regardless of who and where the data is captured and stored, retailers should put a review process in place, to ensure that event data is complete and accurate. This may include comparing spreadsheet data to receipts, inventory logs, and other store information.*

Here you can find a sample of the spreadsheet for retail store receiving.

An implementation example is included in the Appendix.

Pilot and Audit

It is imperative to conduct pilots with trading partners to test the communication of Shipping KDEs with accurate and complete data. RFE's may choose to collect Receiving KDEs or use the data from Shipping CTE's and compare the data from their distributor partners with other trusted sources, such as Invoices, and Purchase Orders.

- Perform regular mock investigation and recall tests based on record keeping requirements.
    - Retrieve records, supporting information (e.g., Reference Documents, Master Data), and electronic sortable spreadsheets with required CTEs and KDEs within 24 hours of FDA request.
    - Outbreak request example criteria:
        - Ship-to and/or Ship-from Locations
        - Date ranges
        - Categories, varieties, species, ingredients
        - Brand names
        - Specific product names
        - In some cases, SKUs, PLUs, or UPCs may be provided.

- Recall criteria
  - Supplier information
  - Product description, including UPC and PLU (may be provided).
  - Possibly TLC range (if available)
  - Locations or regions
  - Date range
- Company-owned DC may keep traceability records
- Non-company owned distributor who maintains records and shares traceability records with shipments
- Make sure you can produce a sortable spreadsheet with the required KDEs within 24 hours.

Recommendations

Procedures used for data capture, monitoring and sharing should be reflected in your Traceability Plan. Remember, traceability is a journey, not a destination. Continuous improvement and monitoring are required to assure data quality and confidence in your traceability system. Comparing the physical pallet/case to the digital information will help catch and remediate data errors that will benefit other processes such as invoicing and ordering.

Recommendations include:

- Perform regular spot inspections and inventory adjustments.
- Plan to incorporate new technologies in the future, in addition to the barcode, such as RFID.
- Work with distributor partners to confirm actual TLC Source or TLC Source Reference is received.
- Establish a monitoring program, scorecards/dashboards to measure accuracy, capture errors and create corrective actions.
- Leverage internal and third-party auditors to verify accuracy of program.

PERSONS WHO MANAGE FOODSERVICE OUTLETS

The implementation guidance described in this section are designed to enable Foodservice outlets to meet the requirements of Subpart S—Additional Traceability Records for Certain Foods, 21 CFR 1.1340, “What records must I keep and provide when I receive product on the Food Traceability List?”

For the purposes of this guidance document, Foodservice includes and is not limited to full services, quick services, fast food chains, self-service, cafés, schools, food pantries, congregations and hospitals.

Exemptions

For retail food establishments and restaurants, exemptions apply to retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than $250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

There are also partial exemptions provided for items purchased direct from the farm, and for certain purchases from another retail food establishment or restaurant. The full details of these exemptions can be found in 21 CFR 1.1305.

Traceability Plan

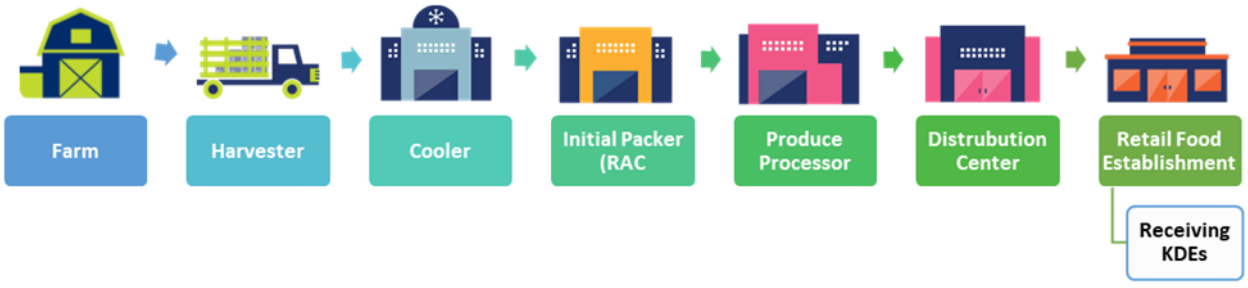
All persons covered by the rule must establish, document, and maintain a traceability plan (21 CFR 1.1315). This plan outlines how your company complies with the rule and must reflect your current processes. In the event of an investigation or inspection, the FDA may request a copy of your plan.

Basic components for restaurants:

1. Procedures to maintain the records, including format and location. This should detail how you capture the information and where it is stored.
2. Procedures to identify foods on the Food Traceability List. Most end-of-chain trading partners will identify FTL items as best they can, and work with their supplier partners to confirm that items are covered by the rule.
3. How you assign traceability lot codes (if applicable). Restaurants will only need to assign traceability lot codes if they produce FTL items that will be shipped to another location before sale to a consumer.
4. Point of contact for your traceability plan and records
5. If you engage a 3rd party to collect traceability records on your behalf, provide details of that agreement

Plan updates: You must update your traceability plan as needed to ensure that the information provided reflects your current practices and to ensure that you are in compliance with the requirements of this subpart. You must retain your previous traceability plan for 2 years after you update the plan. 21 CFR 1.1315(b)

CTEs and KDEs



Receiving CTES

Foodservice entities are responsible for the Receiving CTE. Because the foodservice entity is the last node in the supply chain required to comply with FSMA 204, they will only have to

capture the previous source KDEs and their own. They will not need to send the KDEs to any entity other than the FDA should there be a recall or withdrawal event.

Generally, each Retail Food Establishment and restaurant covered by the rule must maintain receiving records as described in CFR § 1.1345. This includes capturing lot-level information for all FTL produce items that are received at your stores.

For retail food establishments, the FDA FSMA 204 critical tracking event is RECEIVING.

A full list of KDE's for Receiving events can be found in Receiving Section of this document.

Restaurants should determine the method for suppliers or distributors to provide the Shipping CTE data and determine how and where this information will be stored in your systems:

- Electronic (supplier portals, etc.)
- Paper
- EDI
- Email
- Logistics systems
- Traceability software systems

This data should include the required KDEs for the Receiving CTE. Case receiving is recommended to validate data accuracy. Once confidence in accuracy is achieved, perform random verification. Storage of data can be accomplished by scanning, digitizing, or manual entry.

Sortable Spreadsheets

Access an example of the PTI FSMA 204 Electronic Sortable Spreadsheet Template: Foodservice Operation/Restaurant

Pilot and Audit

Retail stores should determine the method for suppliers or distributors to provide the Shipping CTE data and determine how and where this information will be stored in your systems.

This data should include the required KDEs for the Receiving CTE. Case receiving is recommended to validate data accuracy. Once confidence in accuracy is achieved, perform scheduled audits to verify compliance.

Procedures used for data capture, monitoring and sharing should be reflected in your Traceability Plan. Remember, traceability is a journey, not a destination. Continuous improvement and monitoring are required to assure data quality and confidence in your traceability system. Comparing the physical pallet/case to the digital information will help catch and remediate data errors that will benefit other processes such as invoicing and ordering.

Recommendations include:

- Perform regular spot inspections and inventory adjustments.
- Plan to incorporate new technologies in the future, in addition to the barcode, such as RFID.
- Work with distributor partners to confirm actual TLC Source or TLC Source Reference is received.
- Establish a monitoring program, scorecards/dashboards to measure accuracy, capture errors and create corrective actions.
- Leverage internal and third-party auditors to verify accuracy of program.

Recommendations

Practice I – Receiving and Put Away via Electronic Data Exchange

The following method is recommended for foodservice entities that have a high level of revenue, high location count and/or a high FTL SKU impact. This method also relies heavily on the immediate previous source of the food having complete and accurate KDEs, as well as the foodservice operator's comfortability with relying on the validity of the processes that enable their data.

The implementation guidance for creating an inventory record based on the KDEs provided by the immediate previous source is through standardized real-time electronic data exchange. In the Resources section of this document, a sample EDI spec has been created and can be used from the previous supply chain partner. This method does not have to be exclusive to EDI, as there are many different formats that can be submitted via electronic data exchange, like CSV, CSV via FTP, API and others.

The KDEs that foodservice operators will receive are the Shipping KDEs, which do not cover all KDEs that are required of the recipient of the food. Thus, there will be two enhancements that are required of the foodservice entity. These KDEs are the Location Description for where the food was received and the Date the food was received.

These records will be consolidated, stored and made available in an internal database that will then be used to generate the electronic sortable spreadsheet upon FDA request.

Practice II – Receiving and Put Away via Sortable Spreadsheet

This method is recommended for foodservice entities that have a lower level of revenue, low location count and/or a low FTL SKU impact. This method also relies heavily on the immediate previous source of the food having complete and accurate KDEs, as well as the foodservice's comfortability with relying on the validity of the processes that enable their data.

The implementation guidance for creating an inventory record based on the KDEs provided by the immediate previous source is via real-time electronic sortable spreadsheet. The accumulative spreadsheet will be sent via a website URL with two (2) years' worth of data or via email with cumulative quarterly data. This will then be used to generate the spreadsheet upon FDA request.

Practice III – Receiving and Put Away via Individual Case Scan at the Back of House

This method is recommended for foodservice entities that have a lower level of revenue, low location count and/or a low FTL SKU impact. This method takes reliance off the immediate previous source of the food due to the foodservice entity taking responsibility for capturing all Receiving KDEs.

The implementation guidance for creating an inventory record based on the KDEs being captured by the foodservice itself is via scanning labels applied to each case received. Labels inclusive of KDEs will be a requirement for upstream partners to apply. This label will be scanned by a handheld or cellular device. The scanned data will be stored in an Excel file or

database, depending on the foodservice entity's preference, and will have to be enhanced with the additional Receiving KDEs, Date of receipt and Location of receipt.

There may be instances of broken-down cases, poor quality barcodes, and/or no label applied at all, which would not allow for a successful barcode scan. This will need to be identified in the Traceability Plan by documenting an SOP on how the foodservice entity plans to escalate when these instances occur.

Direct Store Delivery (DSD) Vendors

In comment Response 424, FDA addresses Direct Store Delivery. DSD Vendors are required to keep and provide shipping KDEs to Retail Food Establishments under § 1.1340. Shippers, in this instance, the DSD vendor, must share in electronic, paper, or other written form, the shipping KDEs to the immediate subsequent recipient (in this case, with the retail store) of each traceability lot that they ship.

The Final Rule also specifies that a person may have another entity establish and maintain records required on the person's behalf, but the person is responsible for ensuring that such records can be retrieved and provided onsite to FDA within 24 hours of request. See the full content in 21 CFR 1.1455(b).

Therefore, a Vendor and a Retailer participating in a DSD system could make an arrangement under which the DSD Vendor establishes and maintains the relevant receiving records on the Retailer's behalf. However, the Retailer would still be the entity that is subject to the Receiving requirements of, and as stated in, the Retailer would be responsible for ensuring that the records can be retrieved and provided onsite within 24 hours of request for official review.
In most situations, the Shipper of the food will capture and share the Shipping KDEs. The DSD vendor may be required to keep other records if performing any other CTEs.

Appendix A – Resources

PTI FSMA 204 ELECTRONIC SORTABLE SPREADSHEET TEMPLATES

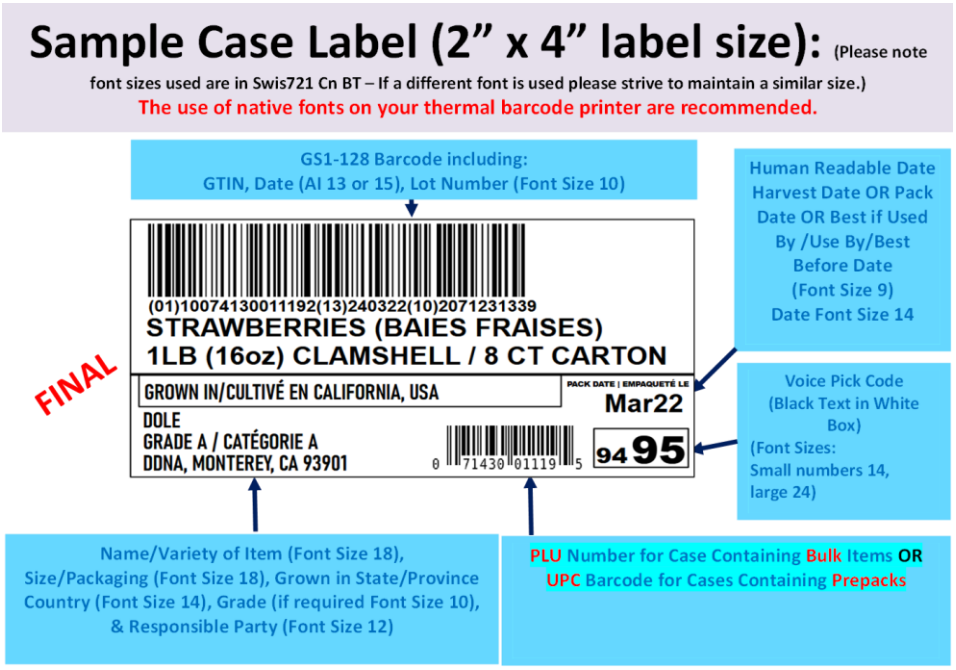
These sortable spreadsheets can be accessed in the "Guides" section of the *PTI Resources and Tools* webpage.

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

PTI RESOURCES

The resources used to develop this Implementation Guidance include:

PTI BASIC CASE LABEL*



Please Note: Every effort was made to ensure the PTI Case Label reflects both business and regulatory needs while fitting on a 2" x 4" label. However, Canadian regulations are prescriptive relative to font size for certain labelling information, including for case labels. For case labels, the font size for country of origin, grade, and size designation, if applicable, varies depending on the area of the principal display surface measurements of the case as noted here (Safe TLC ambiguity Food for Canadians Regulations, Schedule 6). Although the PTI sponsoring organizations are unaware of any action taken on non-compliant font size on case labels, it is important to understand all regulations which apply to case labels and make decisions accordingly.

PTI VOICECODE

The role of the VoiceCode voice pick code is to provide a quick and simple way to identify a case with a given GTIN/Lot/Date in a warehouse environment to reduce the cost and simplify the process of tracing cases. The VoiceCode is printed on the PTI label and designed to integrate with voice pick systems popular in large warehouse management systems (WMS).

The VoiceCode can also be used to:

- Visually identify mixed pallets at receiving, in a storage location or during shipping
- Differentiate between lots by using voice picking systems, fixed or mobile digital cameras with optical character recognition, data entry on mobile or desktop computers or by handwriting the code on receiving, picking, shipping or inspection forms.

SETUP PRODUCT GTINS, LOCATION GLNS, AND MASTER DATA

- PTI Best Practice for Assigning GTIN (Jan 2012)
- GS1 Fruit & Vegetable GTIN Assignment Implementation Guideline (June 2016)
- GS1 Fruit & Vegetable Master Data Attribute Implementation Guide (Aug 2017)
- PTI Guidance for GLN Assignment (Sep 2015)

DATA SYNCHRONIZATION

- Best Practices for Communicating GTINs (March 2012)
- Data Synchronization: Grade Codes (February 2012)
- Data Synchronization: Commodity and Variant Codes (February 2012)
- Data Synchronization: Growing Method Codes (February 2012)
- Data Synchronization: Units of Measure Codes (February 2012)
- Data Synchronization: Package Type Codes (February 2012)
- Data Synchronization: Country of Origin Codes (February 2012)
- Data Synchronization: Worksheet Example (February 2012)
- Data Synchronization Template (February 2012)

PRINT CASE, PALLET, AND CONSUMER ITEM LABELS

- PTI Best Practice for Formatting Case Labels (Dec 2020)
- GS1 NA Industry Guidance for Standard Case Code Labeling (Sep 2022)
- PTI Harmonized Case Label (2021)
- PTI Best Practice for Direct Print (Dec 2011)
- GS1 Fresh Fruit & Vegetable Labeling Consumer Units Guideline (Jul 2015)
- GS1 Retail Grocery Implementation Roadmap for GS1-128 Barcodes on Retail Grocery Cases
- GS1 US Foodservice Traceability Resources

READ AND STORE INFORMATION ON INBOUND AND OUTBOUND SHIPMENTS EDI AND EPCIS

- PTI Why and How to Use EDI 856 ASN/Manifest Trans Set (June 2020)
- PTI Guidance on Benefits of ASN vs Hybrid Pallet Label (Nov 2013)

- GS1 EPCIS and CBV Information
- GS1 EDI Implementation Information

Traceability Guides

- GS1 US Application of GS1 System of Standards to Support FSMA 204 Guideline (Mar 2023)
- GS1 Global Fruit and Vegetable Traceability Implementation Guide (Feb 2021)
- GS1 Fresh Fruit and Veg Traceability Guide Online Version (Feb 2021)
- GS1 US A Guide to GS1 Standards Adoption for Supply Chain Visibility
- GS1 US North American Industry Guidance for Standard Case Code Labeling
- 2D Overview in General Distribution
- GS1 Standards for the Food Industry for Capturing Electronic Product Code Extended Attributes

Sharing Data with the FDA

- PTI Guidance for Sharing Traceback Data (Jul 2020)
- PTI Traceback Template (Nov 2020)

Other Information

- PTI Best Practice for Cross Docking and Load Only Services (Dec 2011)
- PTI Best Practice for Produce Brokers (Mar 2012)
- PTI Best Practice for Repacking and Commingling (Mar 2012)
- PTI Best Practice for Product Substitutions (Nov 2011)
- PTI Best Practice for Private Label/Brand (Sep 2016)
- PTI Guidance on Choosing a Technology Provider (Feb 2012)

FDA RESOURCES

- Requirements for Additional Traceability Records for Certain Foods
- FAQs and Additional Tools for the Food Traceability Rule
- Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)
- Frequently Asked Questions: FSMA Food Traceability Rule
- Webinar on the Food Traceability Final Rule
- eCFR Subpart S - Additional Traceability Records for Certain Foods
- Full Traceability Rule with Comments and Responses
- Small Entity Compliance Guide:

GS1 RESOURCES

- Frequently Asked Questions: FSMA 204
- Application of GS1 System of Standards to Support FSMA 204

Appendix B – Digital Data Sharing

EPCIS VISIBILITY EVENTS

EPCIS is a GS1 standard that defines a common data model for visibility data and interfaces for capturing and sharing visibility data within an enterprise and across an open supply chain. The goal of EPCIS is to enable disparate applications to create and share visibility event data, both within and across enterprises. Ultimately, this sharing is aimed at enabling users to gain a shared view of physical or digital objects within a relevant business context.

Visibility data can describe the origin of an object (virtual or physical), each location where it is subject to a business process throughout the supply chain or other process, when those processes took place and what was occurring to that object at each point. Visibility data is the WHAT, WHERE, WHEN, WHY and HOW about an object. Capturing and sharing visibility data, either internally or across trading partners provides a view into the history of the manufacture, shipping, receiving and selling processes that allow for a more efficient, affordable and safe supply chain.

Source: GS1 EPCIS and CBV Implementation Guideline Release 2.0

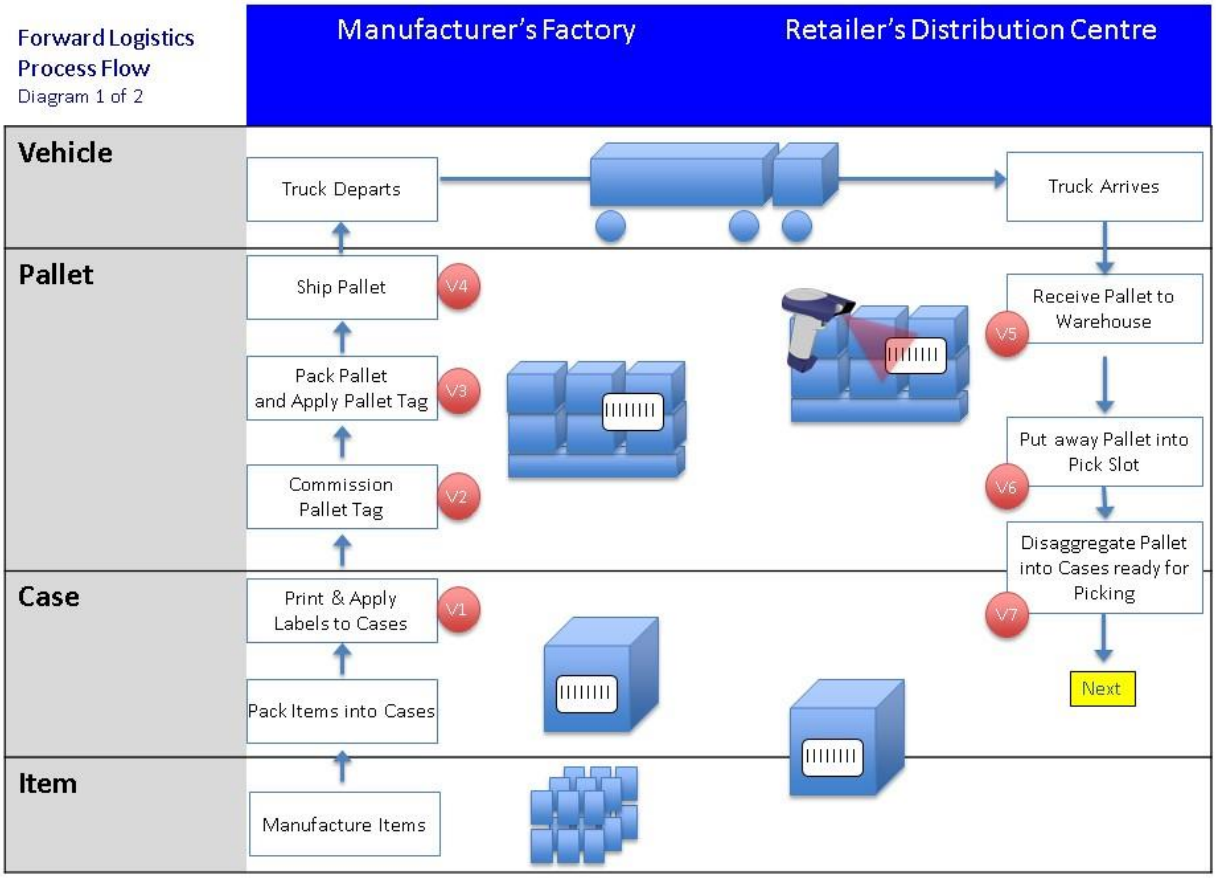


Figure 4-4 Forward Logistics Process Flow with Visibility Capture Indicated

Event	Description	Event Type	Comment
V1	Print and apply case label	ObjectEvent ADD	This is the beginning of life for the TLC (GTIN + Lot) that identifies the cases for a particular lot
V2	Print and apply pallet label	ObjectEvent ADD	This is the beginning of life for the SSCC that identifies the pallet
V3	Pack cases onto pallet	AggregationEvent ADD	The cases are packed onto the pallet. In the EPCIS event, the parent is the SSCC, and the children are the TLCs (GTIN + Lot + Quantity + UOM).
V4	Ship pallet	AggregationEvent OBSERVE	The pallet contents (SSCC, GTIN, Lot, Qty) are fully declared and shipped to the subsequent recipient with a business step of Shipping.

Table 4-1 Assignment of Event Types to Business Process Steps in Example Business Process

EDI 856 ADVANCED SHIP NOTICE

An advanced ship notification is an electronic document that provides confirmation that goods have been sent from a supplier to a customer. It is typically used in the food industry to provide shipment and delivery information. The message can contain details such as the date and time of delivery, the total number of items to be received, descriptions of each item, product and lot codes, and both the sender and receiver details.

Below is an example of an EDI message provided pallet SSCC, GTIN, Lot, Quantity, UOM details related to a shipment. Source: GS1 Foodservice Industry Logistic Label Guidance

MASTER DATA SHARING

Product and location master data may be shared through EPCIS headers or EDI messages, but it is more common to use systems such as the Global Data Sharing Network and the GS1 US Data Hub to share data that does not change from lot to lot, such as product description and location address.

GS1 Global Data Sharing Network

GS1 US Data Hub