



Produce Traceability Initiative FSMA 204 Traceability Lot Code Source and Reference Guidance

(Revision: Original)

ABOUT THIS IMPLEMENTATION GUIDANCE

Implementation guidance is 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. The Implementation Guidance documents are the recommendations created and agreed to by all facets of the produce industry supply chain and PTI Leadership Council.

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

The creation of this document was a collaborative effort of 108 volunteers from 60 different companies and 9 trade associations.

Disclaimer: Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company’s legal counsel or compliance team (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

Revision History

This section itemizes the changes from the last published Implementation Guidance.

<u>Version No.</u>	<u>Date of Change</u>	<u>Changed By</u>	<u>Summary of Change</u>
Original	02/12/2024	PTI FSMA 204 TLC Working Group	Original guidance

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PRODUCE TRACEABILITY INITIATIVE (PTI)

PTI is focused only on batch or lot tracking at the “case level.” The term “case” is the physical enclosure in which a product is shipped and 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 “case” of citrus (5 lb. case of clementines) that is put on display for retail sale as a saleable unit in the exact same “case” it was originally packed and shipped from the supplier through the supply chain to the retail store and sold to the consumer.

The use of the updated case label described and illustrated in the Appendix section of this document is strongly recommended for use within the produce industry and has been endorsed by a number of U.S. and Canadian buyer organizations. (Please see the PTI website [<https://producetraceability.org/participating-companies/>] for a list of supporting organizations.)

This implementation guidance assumes all cases/cartons/bins/RPCs shipped and received have been labeled with the PTI Harmonized case label. The PTI Harmonized case label contains a GS1-128 format barcode and human readable information that contains important identifiers which combine to communicate product information [AI (01) GTIN], and Traceability Lot Code information [AI (13) Pack Date or AI (15) Use By date + AI (10) Batch/Lot]. This Product Information and Traceability Lot Code information are critical for FSMA 204 compliance and labeling with PTI Harmonized Case Labels when product is produced helps to ensure that FSMA 204 Key Data Elements (KDEs) move with the products across multiple Critical Tracking Events (CTEs) in the supply chain.

Frequently, in an implementation guidance document, sector terms will be used which require definition to align with the greater standards community. See **Table 1** for a guide to those terms.

Table 1. Cross-Referenced Terms/Definitions

Listed below are terms used by the produce industry and their cross-references with the GS1 Glossary of Terms:

Sector Term	GS1 Glossary Term	Definition
<ul style="list-style-type: none"> • Each • Base Unit • Saleable Unit 	Trade Item	Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, ordered, or invoiced at any point in any supply chain.

<ul style="list-style-type: none"> • Case • Traded Unit • Bin • Tote • Pallet • RPC (Returnable Plastic Container) • Tray 	Standard Trade Item Grouping	A standard composition of trade item(s) that are not intended for point-of-sale scanning. The PTI has chosen to use the GTIN-14 for case level traceability.
<ul style="list-style-type: none"> • Pallet • Non-Standard Mixed Case 	Logistics Unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain.
<ul style="list-style-type: none"> • Pallet 	Unit Load	One or more transport packages or other items contained on a platform making them suitable for transport, stacking, and storage as a unit.
<ul style="list-style-type: none"> • PTI voice pick code 	Not Applicable	The PTI voice pick code is printed on the PTI label and designed to integrate with voice pick systems popular in large warehouse management systems (WMS). The PTI voice pick code itself is a 4-digit digest of the Global Trade Item Number (GTIN) and Batch/Lot Number (and optionally, Pack Date) that is calculated using a well proven, standard algorithm. The voice pick code is included as one of the elements on the PTI case label when the label is printed.
	Global Trade Item Number (GTIN)	The globally-unique GS1 System identification number for products and services. A GTIN may be 8, 12, 13, or 14 digits in length. <i>The GTIN-14 has been selected for use in the PTI.</i>
	Indicator Digit	The leftmost digit of a GTIN in a GTIN-14. The digit '0' indicates a base unit Global Trade Item Number, digits 1 to 8 are used to define a packaging hierarchy of a product with the same Item Reference, and digit 9 indicates a variable measure trade item.
	GS1 Company Prefix	A globally unique number assigned to companies by GS1 Member Organizations to create the identification numbers of the GS1 System.
	Check Digit	A digit calculated from the other digits of an element string, used to check that the data has been correctly composed or correctly keypunched.
	Item Reference Number	The part of the GTIN allocated by the user to identify a trade item for a given GS1 Company Prefix.
	Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely identifies its format and meaning within the GS1 System.
	AI (01)	The AI (01) indicates that the GS1 AI data field contains a GTIN . The AI is fixed in length and encodes 14 numeric digits only.

	AI (13)	The AI (13) indicates that the GS1 AI data fields contain a pack or harvest date *. This date is the date when the goods were packed as determined by the packager. The AI is fixed in length and encodes 6 numeric digits only, in an YYMMDD format. *produce industry definition
	AI (10)	The AI (10) indicates the GS1 AI data fields contain a batch or lot number. The data is alphanumeric and is variable field length up to 20
	AI (15)	The AI (15) indicates that the GS1 AI data fields contain a “best if used by/use by/best before” date *. This date 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 an YYMMDD format. *produce industry definition
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.
Quantity and Unit of Measure		Typically, the unit of measure will be a case and the quantity will be the number of cases shipped. Other units of measure are defined by other PTI Implementation Guidance (e.g., RPC). This information will be kept and provided as part of the shipping record.
Traceability Lot Code (TLC)	GTIN Batch/Lot	Means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source. For the purposes of this implementation guidance, the Traceability Lot Code is a combination of the GS1 Global Trade Item Number or GTIN (AI “01” on the case label) and the internally assigned batch or lot (AI “10” on the case label).
Traceability Lot Code Source (TLC Source)		Means the place where a food was assigned a traceability lot code (21 CFR 1.1310 “Traceability lot code source”).

Traceability Lot Code Source Reference (TLC Source Reference)	URL GLN FFRN	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 for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source (21 CFR 1.1310 “Traceability lot code source reference”). The implementation guidance for this KDE is for the covered entity to provide a web site which will allow FDA to access TLC Source location description information by entering the TLC and a government issued email address.
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.
Product Description		Means a description of a food product that includes the product name (including, if applicable, the brand name, commodity and variety), packaging size, and packaging style. Typically, this information will be shared as master data prior to sharing the shipping CTE. However, if that is not the case, it may be shared in an EDI 856 Advanced Shipment Notice, in EPCIS 1.2 as part of master data header, in EPCIS 2.0 as part of GS1 Digital Link or in GS1 US Data Hub. Other master data sharing systems and methods may be developed in response to the needs of FSMA 204. <i>See Appendix for more information on EPCIS.</i>
Immediate Subsequent Recipient Location Description		Means key contact information for the ship-to 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. See product description for master data sharing methods.
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 includes 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.
LGTIN		A new EPC Class URI to represent the combination of a GTIN plus a Batch/Lot

Shipment Date		This is the date that food was actually shipped. Optionally, one may include the date and timestamp when the record was actually created and by whom.
<p>NOTE: Other GS1 AIs available within the GS1 System which can also be utilized within the GS1-128 barcode. For a full list of the GS1 AIs, please see Section 3.0 of the GS1 General Specifications. Rules for concatenating any GS1 AI are covered in Section 4.11 of the GS1 General Specifications, highlighting mandatory associated AIs and invalid pairs of AIs.</p>		

FSMA 204

The Food and Drug Administration (FDA) announced the final rule on November 15, 2022, establishing additional recordkeeping requirements for persons who manufacture, process, pack or hold foods the FDA has designated for inclusion on the [Food Traceability List](#) (FTL).

The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initial packing, shipping, receiving and transforming these foods. The requirements established in the final rule will help the FDA rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. The FDA issued this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).

The Food Traceability Rule requires persons who manufacture, process, pack or hold foods on the FTL to maintain and provide to their supply chain partners with Key Data Elements (KDEs) for certain Critical Tracking Events (CTEs) in the food’s supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording and sharing of Traceability Lot Codes (TLCs) for FTL foods, as well as linking these TLCs to other information identifying the foods as they move through the supply chain.

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.

All entities that manufacture, process, pack or hold foods on the FTL must create and maintain a Traceability Plan.

This rule is effective on January 20, 2023. This rule is enforceable on January 20, 2026.

PTI AND FSMA 204 ALIGNMENT

PTI and FSMA 204 are aligned in many ways, including:

- The PTI Harmonized Case Label Best Practice includes the AI (01) GTIN-14 and AI (10) Batch/Lot, which is the industry standard definition for the FSMA 204 Traceability Lot Code¹.
- PTI Best Practices for capturing AI (01) GTIN and AI (10) Batch/Lot on inbound and outbound cases is from source to destination corresponding to the FSMA 204 Traceability Lot Code Key Data Element (KDE) that must be captured as part of Receiving and Shipping Critical Tracking Events (CTE).
- 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 the PTI Best Practices.

PTI for Capturing, Storing and Sending FSMA 204 KDEs

Companies that practice PTI guidance can leverage those efforts in support of their plan and execution to be compliant with FSMA 204. A traceability system can be used to capture, store and share the required Key Data Elements (KDEs) at the required Critical Tracking Events (CTEs) to enable compliance with the FSMA 204 requirements.

Exemptions

Some entities are exempt from this rule. Please verify [here](#) if your company is excluded from the FSMA 204 requirements.

Persons receiving FTL food(s) from an exempt entity are required to maintain reduced receiving KDEs (outlined in [§1.1345\(b\)](#)). Most receiving KDEs will be sent to the receiver by the shipper.

If handling non-FTL items, check with your customer/trading partner on their FSMA 204 data requirements.

Sharing Required Key Data Elements (KDEs) with Trading Partners

There are several methods for sharing this information, depending on the preferred technology.

¹ <https://www.gs1us.org/industries-and-insights/by-industry/foodservice/standards-in-use/food-safety#fsma>

1. **EDI 856 ASN:** All three data elements (i.e., GTIN, Lot/Batch and Date) may be passed in the Marks and Numbers Segment of an EDI Advanced Ship Notice with Value Code, "AI". *Example shown in Appendix.*
2. **Case Label:** The case label includes a machine-readable GS1-128 barcode, including the three pieces of information delimited by Application Identifiers (AI's).
3. **TLC Digital Link:** The GS1 Digital Link standard provides for incorporating GTIN, Batch/Lot and Date in a web address (URL). This may be shown as human-readable text or a machine readable QR Code on a case label or pallet label.
4. **Spreadsheet, CSV, Custom API:** Shippers and receivers may elect to use spreadsheets (XLS, XLSX, CSV, etc.) or custom Application Programming Interfaces to exchange data.
5. **Printed Shipping Documents:** Although not ideal from an efficiency perspective, printed shipping documents (e.g., bill of lading, packing list, invoice) may include GTIN, Batch/Lot and Date for each line item.
6. **EPCIS with GS1 Digital Link:** The GS1 Digital Link including GTIN, Batch/Lot and Date may be passed as a Quantity Element of LGTIN. The URN format of the LGTIN does not provide for a mechanism for sharing the date code, so it would need to be passed separately.

TRACEABILITY LOT CODE DEFINITIONS

Note: *PTI has defined the Traceability Lot Code as the Case GTIN and the Lot Code.*

Under [21 CFR 1.1340](#) shippers of food on the Food Traceability List (FTL) must keep and provide certain Key Data Elements (KDEs), including the Traceability Lot Code (TLC), the quantity and unit of measure, the product description, the location description for the immediate subsequent recipient, the location from which you shipped the food, the date you shipped the food, the traceability lot code source or source reference and the reference document type and number (keep only).

GTIN

- Is the Product Identifier to use to convey the products which are being shipped.
- The GTIN can be applied to guidance for FSMA compliance by being able to reference Master Product Data for a specific product.
- GTIN is the first Application Identifier (01) in the PTI Label GS1-128 barcode.

Batch/Lot

- PTI Shipper Lot Code (Batch/Lot) is the last Application Identifier (10) in the PTI Label GS1-128 barcode.
- The PTI Batch/Lot Code is used to track produce through the supply chain and to facilitate recalls in the event of a foodborne illness outbreak.

- The PTI Batch/Lot Code is used to track the movement of produce through the supply chain, from the farm to the consumer.

Traceability Lot Code

- For fresh produce, the Traceability Lot Code (TLC) has been defined as the combination of the case GTIN and Lot Number.
- It is the link to all records required to be submitted to FDA in an electronic sortable spreadsheet. This provides an attribute of the FTL product indicating where and when the product was produced.
- The Traceability Lot Code must be assigned to a food at the time of initial packing, or transformation.
- The Traceability Lot Code must be maintained throughout the food's distribution chain.
- At initial packing the Traceability Lot Code must be linked to the relevant Key Data Elements (KDEs) at each Critical Tracking Event (CTE).

TRACEABILITY LOT CODE SOURCE

The FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods:

FSMA 204 defines the Traceability Lot Code (TLC) Source to mean the place where a food was assigned a traceability lot code. Unless the relevant entity is exempt from the rule, this will be the place where the food was initially packed (for RACs not obtained from a fishing vessel), first processed on land (for food obtained from a fishing vessel) or transformed.

During outbreak situations, information about the traceability lot code source will allow FDA to identify key locations and prioritize where they need to collect tracing data, which in turn will help FDA more quickly identify the origin of contaminated foods more quickly.

The rule requires firms to keep a record of the location description for the traceability lot code source. The location description includes 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.

- If brand owners have multiple locations packing the same item and using the same GTIN, brand owners should have sufficient controls in place to prevent multiple packers of the same GTIN from duplicating Batch/Lot numbers. This will ensure the number combination is unique.

- The Traceability Lot Code (TLC) Source in FSMA 204 is the entity that assigns the TLC to a food. The TLC Source can be a producer, packer, distributor, terminal market, retailer, or any other business that handles the food.
- The final rule defines “traceability lot code source” to mean the place where a food was assigned a TLC (i.e., the name, address and phone number).
- The TLC must be linked to the relevant Key Data Elements (KDEs) at each Critical Tracking Event (CTE). The KDEs are the supporting data attributes that define a specific CTE. For example, the KDEs for the CTE of initial packing may include the name of the food, the date of packing and the identity of the packing facility.
- A company that is the Traceability Lot Code Source (company that created the lot code), is required to keep records such that the Traceability Lot Code can be linked to the following:
 - Name of the food: This includes the common name of the food, as well as any other names that may be used to identify the food. (GTINs packed, Product Descriptions, Quantity packed)
 - Date of packing: This is the date on which the food was packed.
 - Identity of the packing facility or farm: This is the name and address of the facility where the food was packed or farm map locations.
 - Batch or lot number: This is a unique identifier for the food that is assigned by the producer or packer.
 - Net weight or volume: This is the weight or volume of the food.
 - Country of origin: This is the country where the food was grown, raised or produced.

Note: The business name and address on the PTI label may be different from the Traceability Lot Code Source business name and address. The business name and address on the PTI label is the responsible party and is a requirement for cross-border shipping.

Communicating required KDE’s to trading partners:

- The ASN 856 is recommended as the most efficient way of communicating the required traceability information to your trading partners. Here is a [link](#) to the PTI guidance on ASN 856.
- Traceability information can be printed on the Bill of Lading.
- Traceability information can be printed on a Load Manifest and attached to the Bill of Lading.
- Traceability information can be shared via an electronic platform or other means agreed to by trading partners.
- Traceability can be shared electronically using this shipping Excel template:

Header Row	Reference Document Number*	Ship Date	Ship From Location	Ship From Location ID	Ship To Location	Ship To Location ID											
H	400472	11/15/2023	Annie's Apple Farm	71430010556	Don's Distribution Co.	0071430010440											
Detail Rows	Buyer PO Number	TLC - GTIN**	TLC - Batch	Date Code	Date Type	TLC - Assigned By	TLC Source Reference	Qty	UOM	Product Description	Shipper Item Number**	Buyer Item Number**	Pallet ID				
D	PO-891011	00611628901701	510398		231110 Pack Date	Grower/Shipper	71430010556	125	CS	Apples, Golden Delicious 88 Ct	1120100001	3636					
D	PO-891011	00611628901701	510524		231111 Pack Date	Grower/Shipper	71430010556	75	CS	Apples, Golden Delicious 88 Ct	1120100001	3636					
D	PO-891011	00611628910802	511246		231109 Pack Date	Grower/Shipper	71430010556	350	CS	Apples, Red Delicious 88 Ct	1120100222	1005					
D	PO-891011	20611628940704	508796		231107 Pack Date	Grower/Shipper	71430010556	100	CS	Apples, Gala	1120100064	2604					
Highlighted Items are Required																	
*The reference document number identifies this specific exchange. This can be an invoice number or a bill of lading number. The two parties should agree on what the source number is.																	
**Item information: Trading partners should agree upon the way in which they will identify items. This will ensure ease in importing this traceability information for the Buyer. They may agree to use GTIN, shipper item number, or buyer item number.																	

or this CSV template:

H	400472	11/15/2023	Annie's Apple Farm	71430010556	Don's Distribution Co.	0071430010440											
D	PO-891011	00611628901701	510398	231110	Pack Date	Grower/Shipper	71430010556	125	CS	Apples, Golden Delicious 88 Ct	1120100001	3636					
D	PO-891011	00611628901701	510524	231111	Pack Date	Grower/Shipper	71430010556	75	CS	Apples, Golden Delicious 88 Ct	1120100001	3636					
D	PO-891011	00611628910802	511246	231109	Pack Date	Grower/Shipper	71430010556	350	CS	Apples, Red Delicious 88 Ct	1120100222	1005					
D	PO-891011	20611628940704	508796	231107	Pack Date	Grower/Shipper	71430010556	100	CS	Apples, Gala	1120100064	2604					

Figure 1. Sample Bill of Lading with Traceability Lot Codes and TLC Source.

Bill of Lading		PAGE 1
ERNESTO PRODUCE 1000 GROWER ROAD SOMEWHERE, FL 11111 TEL# (555) 555-3000		
SHIP TO:	DATE IN.....:	11/11/23
NARDONE SISTERS	SHIP DATE.....:	11/11/23
999 TERMINAL MKT	ORDER NO.....:	400472
ANYWHERE, NY 99999	ASSIGNMENT NO...:	400472
	SHIPMENT NO.....:	400472
	SALE:	FOB
BROKER:	BUYERS P.O.:	5555555
CARRIER NAME.....:	SEAL NO.....:	7168598
PRODUCE TRANSPORTR	TEMPERATURE RECORDER NO:	
CARRIER TELEPHONE #.....:	555-555-7247	
TRK LICENSE # & STATE.....:	XX9999 NC	
RAIL ROUTE.....:	PROOF	FEDERAL INSPECT. NO.....:
RAIL CAR/PIGGYBACK TRL #.:		PHYTO NO.....:
LOCATION #.....:	25	TEMPERATURE SETTING.....:
OTHER	11/04	PAYABLE
CHART NO.....:		INSPECTION NO.....
MANIFEST DESCRIPTION		
QUANTITY	PACK	SIZE LABEL TYPE GRADE VARIETY GROSS WT
800	25 # BOX	5X6 BEEFSTEAK TOMATO . VINE MATURE 21600
	QTY: 400	GTIN:00012345600012 LOT #: 2071231339 PACKDATE: 11/09/23
		TLC SR:1617 Ranch Farm Road Ranch 2 Plant City, FL 32053 (386) 555-1212
	QTY: 130	GTIN:00012345600012 LOT #: 2071231400 PACKDATE: 11/09/23
		TLC SR:1617 Ranch Farm Road Ranch 10 Plant City, FL 32053 (386) 555-7777
	QTY: 270	GTIN:00012345600012 LOT #: 2071361501 PACKDATE: 11/10/23
		TLC SR:1617 Ranch Farm Road Ranch 4 Plant City, FL 32053 (386) 555-8899
320	25 # BOX	5X6 HOME GROWN TOMATO . VINE MATURE 8640
	QTY: 320	GTIN:00012345684413 LOT #: 2071231551 PACKDATE: 11/10/23
		TLC SR:11111 Highway Run 66 Homestead, FL 33030 (305) 555-1115
1120	TOTAL	30240

* SPECIAL INSTRUCTIONS:
PRODUCT OF USA

CARRIER NOTICE: THIS IS A COLLECT SHIPMENT WITHOUT RECOURSE AGAINST CONSIGNOR
THIS BILL OF LADING REFLECTS THE SHIPMENT MANIFEST AS ITEMIZED ABOVE AND HAS
BEEN RECEIVED IN GOOD ORDER BY THE UNDERSIGNED CARRIER.

ERNESTO PRODUCE
(ASSN - AGENT)

11/11/23

SIGNATURE 11/11/23
JOHN SMITH

Figure 2. Sample Bill of Lading with Traceability Lot Codes and a URL as a TLC Source Reference.

Bill of Lading		PAGE 1					
ERNESTO PRODUCE 1000 GROWER ROAD SOMEWHERE, FL 11111 TEL# (555) 555-3000							
SHIP TO: NARDONE SISTERS 999 TERMINAL MKT ANYWHERE, NY 99999	DATE IN.....: 11/11/23 SHIP DATE.....: 11/11/23						
BROKER:	ORDER NO.....: 400472 ASSIGNMENT NO...: 400472 SHIPMENT NO.....: 400472 SALE: FOB BUYERS P.O.: 55555555						
CARRIER NAME.....: PRODUCE TRANSPORTER CARRIER TELEPHONE #.....: 555-555-7247 TRK LICENSE # & STATE.....: XX9999 NC RAIL ROUTE.....: PROOF RAIL CAR/PIGGYBACK TRL #.: LOCATION #.....: 25 OTHER: 11/04 CHART NO.....:	SEAL NO.....: 7168598 TEMPERATURE RECORDER NO: FEDERAL INSPECT. NO.....: PHYTO NO.....: TEMPERATURE SETTING.....: 50 PAYABLE: INSPECTION NO.....:						
MANIFEST DESCRIPTION							
QUANTITY	PACK	SIZE	LABEL	TYPE	GRADE	VARIETY	GROSS WT
800	25 # BOX	5X6	BEEFSTEAK	TOMATO	.	VINE MATURE	21600
	QTY: 400	GTIN:00012345600012	LOT #: 2071231339	PACKDATE: 11/09/23			
	QTY: 130	GTIN:00012345600012	LOT #: 2071231400	PACKDATE: 11/09/23			
	QTY: 270	GTIN:00012345600012	LOT #: 2071361501	PACKDATE: 11/10/23			
320	25 # BOX	5X6	HOME GROWN	TOMATO	.	VINE MATURE	8640
	QTY: 320	GTIN:00012345684413	LOT #: 2071231551	PACKDATE: 11/10/23			
1120	TOTAL						30240
TRACEABILITY LOT CODE SOURCE REFERENCE: VISIT WWW.ENTERYOURGTINANDBATCH.COM							

* SPECIAL INSTRUCTIONS:

Produce Traceability Initiative FSMA 204 Traceability Lot Code Source and Reference Guidance

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Updated: February 9, 2024

Source: www.producetraceability.org

PRODUCT OF USA

CARRIER NOTICE: THIS IS A COLLECT SHIPMENT WITHOUT RECOURSE AGAINST CONSIGNOR
THIS BILL OF LADING REFLECTS THE SHIPMENT MANIFEST AS ITEMIZED ABOVE AND HAS
BEEN RECEIVED IN GOOD ORDER BY THE UNDERSIGNED CARRIER.

ERNESTO PRODUCE
(ASSN - AGENT)

11/11/23

SIGNATURE 11/11/23
JOHN SMITH

For more information on Traceability lot Code Source Reference visit:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/traceability-lot-code>

TLC SOURCE REFERENCE

The Traceability Lot Code Source or physical location where the Traceability Lot Code was assigned/packed is important for FDA to ascertain the Initial Packing or Transformation records.

Traceability Lot Code Source Reference is an alternative method for providing FDA with access to that information.

There are 4 recommended TLC Source References:

1. A URL to a website where authorized FDA personnel or representatives may enter the TLC (GTIN + Lot or GLN) into a web form or click a link to display (or receive via email) the TLC Source location information when needed.
 - It is recommended to test that the URL provided as the TLC Source Reference returns the correct packing location, packing name, packing address and phone number.
2. An FDA Facility Registration Number for the packing location.
3. GS1 Global Location Number (GLN)
 - GLNs are beneficial for businesses that want to improve their supply chain visibility and traceability. GLNs are globally unique and interoperable identifiers that can be used to identify parties and locations in a consistent, standardized way.
 - Provided that FDA has ready access to a GLN database that returns the information per their requirements, a GLN can be used as the TLC Source Reference. This access could come from any of the following:
 - A URL as mentioned in Option 1 above.
 - An internal Master Data system to which FDA is given credentials/access.
 - GS1 Data Hub Location which is a tool provided by GS1 US for companies to create, upload, and exchange location information with their business partners.

- ECCNet Locations which is a tool provided by GS1 Canada for companies to create, upload, and exchange location information with their business partners.
- Single location operations can use corporate GLN and use GS1 Global Registry Platform to give access to address and other details required.
- The GLN must be specific to the physical location where the product was packed and the Traceability Lot Code was assigned (i.e., ranch, field, packing house, processing facility, warehouse, distribution center).
- It is recommended to test each GLN in the GLN database provided to verify the correct Traceability Lot Code Source returns.
- **NOTE: It is strongly recommended to verify with your GS1 Organization that provided your GS1 Company Prefix will publish your GLN to the GS1 Global Registry Platform.**

Note: The best practice is to use different columns for each type of TLC Source Reference and clearly identify the columns. Ensure you indicate enter the TLC Source Reference you are using in the correct column if using the [PTI sample electronic sortable spreadsheets](#) or clearly indicate the type of TLC Source Reference the your electronic sortable spreadsheet.

Example column headings:

- TLC Source Reference URL
- TLC Source Reference FFRN
- TLC Source Reference GLN

Note:

- Since the column heading indicates the type of data in the column, you do not need to specify GLN or FFRN in the cells.
- There are many different URL formats that work. This is based on the GS1 Digital Link Standard: [GS1 Digital Link Implementation Guide](#)
- If you provide FDA with a GLN as the TLC Source Reference, you should also provide them with a website to lookup the address information or provide the address in the sortable spreadsheet.
- FFRN does not require a web address or location description because this is an FDA database.

APPENDIX

PTI RESOURCES

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 Global Fruit and Vegetable Traceability Implementation Guide \(Feb 2021\)](#)
- [GS1 Fresh Fruit and Veg Traceability Guide Online Version \(Feb 2021\)](#)
- [GS1 US Application of GS1 System of Standards to Support FSMA 204 Guideline \(Mar 2023\)](#)

Sharing Data with the FDA

- [PTI Guidance for Sharing Traceback Data \(Jul 2020\)](#)
- [PTI Traceback Template \(Nov 2020\)](#)

Other Information

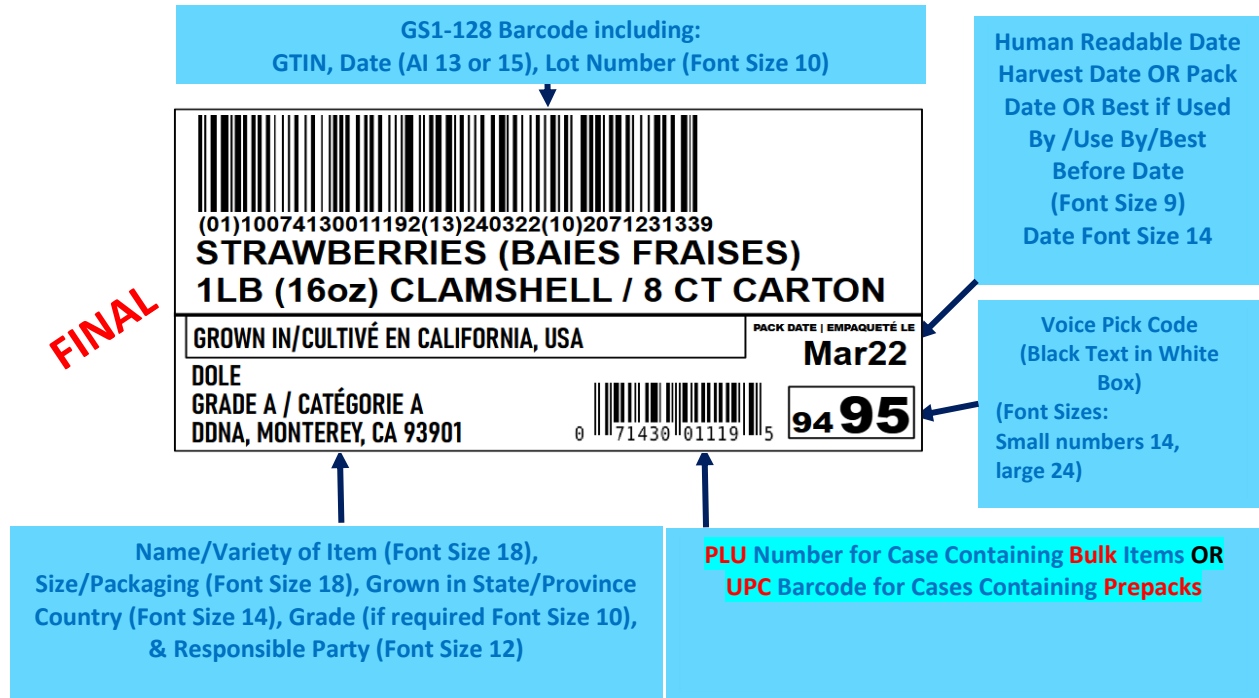
- [PTI Best Practice for Cross Docking and Load Only Services \(Dec 2011\)](#)
- [PTI Best Practice for Produce Brokers \(Mar 2012\)](#)
- [PTI Best Practice for Repacking and Commingling \(Mar 2012\)](#)
- [PTI Best Practice for Product Substitutions \(Nov 2011\)](#)
- [PTI Best Practice for Private Label/Brand \(Sep 2016\)](#)
- [PTI Guidance on Choosing a Technology Provider \(Feb 2012\)](#)
- [GS1 US Dairy, Deli, & Bakery Traceability Implementation Guide \(2013\)](#)
- [GS1 US Meat and Poultry Traceability Implementation Guide \(2014\)](#)

PTI Sample Case Label

Sample Case Label (2" x 4" label size): (Please note

font sizes used are in Swis721 Cn BT – If a different font is used please strive to maintain a similar size.)

The use of native fonts on your thermal barcode printer are recommended.



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 Food for Canadians Regulations, Schedule 6). Although the PTI sponsoring organizations are unaware of any action taken on non-compliant

FDA RESOURCES

- [FSMA Food Traceability Rule Traceability Lot Code Examples with BOL templates](#)
- [FDA Traceability Lot Code Landing Page](#)
- [Full Traceability Rule with Comments and Responses - PDF](#)
- [Full Traceability Rule with Comments and Responses - online](#)
- [FDA FAQs and Additional Tools for the Food Traceability Rule](#)
- [Food Traceability Rule: Critical Tracking Events \(CTEs\) and Key Data Elements \(KDEs\)](#)
- [FDA FSMA 204 FAQs](#)
- [FDA Webinar on the Food Traceability Final Rule](#)
- [Small Entity Compliance Guide:](#)

GSI RESOURCES

- [GS1 FSMA 204 FAQs PDF](#)
- [GS1 US Application of GS1 System of Standards to Support FSMA 204 Guideline PDF](#)