



The Global Language of Business

Retail Grocery and Foodservice

Application of GS1 System of Standards to Support FSMA 204

Guideline

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About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About the Foodservice GS1 US Standards Initiative

The Foodservice GS1 US Standards Initiative serves as a strategic effort in which industry trade associations and individual companies may choose to join on a voluntary basis to assist with their company's adoption and implementation of GS1 Standards.

About the GS1 US Retail Grocery Initiative

The GS1 US Retail Grocery Initiative represents a broad cross section of industry. Today, suppliers, manufacturers, distributors, wholesalers, retailers, academic institutions, regulatory agencies, and trade associations are working together to help address challenges where GS1 Standards can have a positive impact in enhancing data quality, enabling end-to-end supply chain visibility, and improving operational efficiencies.

Table of Contents

1	Preface	5
1.1	History and Background	5
1.2	Introduction to the FSMA 204 Final Rule	5
1.3	Purpose	5
1.4	Future Releases	6
1.5	Scope	6
1.6	Normative References.....	7
2	Overview of the FSMA 204 Final Rule	7
2.1	The Food Traceability List (FTL)	7
2.2	Product and Location Identification, Description, and Traceability Lot Code.....	8
2.2.1	Product and Location Descriptions.....	8
2.3	Records of Critical Tracking Events (CTEs) and Key Data Elements (KDE).....	9
2.4	Traceability Plan Requirements	9
2.5	Implementation Timeline, Record Retention, and Response Timing.....	9
2.6	What Foods and Persons are Exempt from the Final Rule?	10
3	Overview of GS1 Standards	10
3.1	Identify.....	11
3.1.1	The Importance of Using GS1 Identification Keys for Traceability	11
3.1.2	Unique Identification of Foods – Global Trade Item Numbers (GTINs).....	12
3.1.3	Unique Identification of Locations – Global Location Numbers (GLNs)	13
3.1.4	Unique Identification of Logistics Units – Serial Shipping Container Code (SSCC)	15
3.2	The Traceability Lot Code in the GS1 System of Standards	16
3.2.1	GTIN Plus Batch/Lot in the GS1 System of Standards	16
3.2.2	FSMA 204 GTIN Plus Batch/Lot Application.....	16
3.3	Capture	16
3.3.1	Application Identifiers (AIs).....	16
3.3.2	Guidance on Data Carrier Usage	17
3.3.3	Barcode Types and Uses	19
3.3.4	RFID	20
3.4	Share	21
3.4.1	FSMA 204 Data Sharing Application.....	21
3.4.2	Master Data	21
3.4.3	Global Data Synchronization Network (GDSN)	21
3.4.4	Global Data Model (GDM).....	22
3.4.5	Transactional Data	23
3.4.6	Electronic Data Interchange (EDI).....	23
3.4.7	Physical Event Data.....	23
4	Applying the GS1 System of Standards to FSMA 204	23
4.1	Supply Chain Process Flows for FSMA 204	23
4.1.1	End-to-End Flows and the Final Rule	24
4.2	Critical Tracking Events (CTEs) and Key Data Elements (KDEs) Recordkeeping and Sharing ...	29
4.2.1	Data Sharing Under the Final Rule	29
4.2.2	Overview of the CTEs and KDEs of the Final Rule	30
4.3	Product Description KDEs	32

4.3.1	Brand Name.....	33
4.3.2	Commodity	33
4.3.3	Variety	34
4.3.4	Product Name	34
4.3.5	Packaging Size	34
4.3.6	Packaging Style	35
4.4	Location Description KDEs	35
4.4.1	Business Name	36
4.4.2	Physical Location Address	36
4.4.3	City.....	37
4.4.4	State.....	37
4.4.5	Zip Code.....	37
4.4.6	Phone Number	37
4.4.7	Comparable Information for Locations Outside the US	37
4.4.8	Harvester Business KDEs	38
4.4.9	Growing Areas Coordinates	38
4.5	Shipping CTE and the Advance Ship Notice (ASN)	38
4.5.1	GTIN (not required by the Final Rule) and Traceability Lot Code	38
4.5.2	Quantity and Unit of Measure of the Food	39
4.5.3	Product Description of the Food	39
4.5.4	Location Description of Immediate Subsequent Recipient (other than Transporter)	39
4.5.5	Location Description for the Location From Which You Shipped the Food.....	39
4.5.6	Date the Food Was Shipped	40
4.5.7	Location Description for the Traceability Lot Code Source or the Traceability Lot Code Source Reference.....	40
4.5.8	Shipment Reference Document Type.....	41
4.5.9	Shipment Reference Document Identifier	41
4.6	Other CTEs and Mappings to GS1 Standards.....	41
4.6.1	Receiving CTE	42
4.6.2	Additional CTEs and Mappings to GS1 Standards	43
5	Best Practices for Mixed Pallets	43
6	Appendix A - Additional CTEs and Mappings to GS1 EPCIS Standards.....	47
6.1	Transformation CTE.....	47
6.2	Harvest CTE	47
6.3	Cooling CTE.....	48
6.4	Initial Packing CTE	49
6.5	First Land-Based Receiver CTE.....	50
7	Appendix B – Detailed Steps for Supply Chain Process Flows	51
7.1	Whole Tomatoes Detailed Process Steps	51
7.2	Ready to Eat Salad Detailed Process Steps	52
7.3	Frozen Shrimp Aquaculture Farmed Detailed Process Steps	54
7.4	Peanut Butter Crackers Detailed Process Steps	57
8	Appendix C - Overview of GS1 System of Standards to Support Traceability	60
9	Proprietary Statement	61

1 Preface

1.1 History and Background

In July 2020, the FDA announced its 10-year plan to improve food safety, [The New Era of Smarter Food Safety](#). This is a framework to “respond more rapidly to outbreaks, address new business models, reduce contamination of food, and foster the development of food safety cultures.” It encourages the use of technology, improved traceability, and establishes a food safety culture throughout all members of the supply chain. For more information go to: <https://www.fda.gov/food/new-era-smarter-food-safety>.

On November 21, 2022, the United States Food and Drug Administration (FDA) published a Final Rule titled, Requirements for Additional Traceability Records for Certain Foods, which is a key component of the FDA’s New Era of Smarter Food Safety Blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA), which was signed into law in 2011. This rule is commonly referred to as “FSMA 204”. Throughout the remainder of this document, ‘Final Rule’ and FSMA 204 will be used interchangeably as shorthand for referring to this regulation. The FDA website can be accessed [HERE](#). The FDA’s Federal Register website can also be accessed [HERE](#).

The FDA has also provided its public response to all the comments received from all the different stakeholders in the food supply chain. This document will reference these public comments and responses as additional sources of information to help support how GS1 Standards can be leveraged.

1.2 Introduction to the FSMA 204 Final Rule

The Final Rule requires companies that physically handle certain foods across the supply chain to keep additional records, which can assist in tracebacks during an investigation of a foodborne illness outbreak. These requirements do not apply to all foods, but to a subset listed in the [FDA’s Food Traceability List](#) (FTL). This list developed by the FDA is intended to cover which foods necessitate additional record-keeping requirements to protect public health.

The rule outlines specific Key Data Elements (KDEs) of Critical Tracking Events (CTEs) that need to be recorded and shared with the FDA, upon request, and at minimum, through a sortable electronic spreadsheet. With the exception of the Shipping CTE and select upstream activities, the rule does not require companies to share these records with their trading partners, only to keep records in case the FDA requests them. The rule does not specify the use of data carriers (e.g., barcodes or RFID tags) or additional formats beyond a sortable spreadsheet for the exchange of data with the FDA or between trading partners. The rule includes several exceptions for specific foods or entities where records are not required.

1.3 Purpose

This implementation guideline was prepared by the GS1 US FSMA 204 Workgroup to assist the United States’ food industry with implementing GS1 Standards for traceability and specifically to help meet the requirements outlined in the Final Rule. **The guidance excludes the point of consumption and is limited to batch/lot traceability.**

In response to this, members of the food industry in the US are preparing their systems and business processes to meet the requirements. Specifically, many food supply chain stakeholders have been implementing or exploring the benefits of using the following GS1 Standards and business solutions:

- Global Trade Item Number™ (GTIN®) for unique product identification
- Global Location Number™ (GLN®) for unique party and location identification
- Global Data Synchronization Network® (GDSN®) and Global Data Model (GDM) for consistent descriptions of products
- Electronic Data Interchange (EDI) and Electronic Product Code Information Services (EPCIS) for structured data capture and sharing internally and among trading partners.

Leveraging GS1 Standards provides consistency and interoperability across different environments and systems while meeting a wide variety of business needs. More than 65 organizations of the GS1 US retail grocery and foodservice industry initiatives, including leading manufacturers, distributors, retailers, foodservice operators, solution providers, and industry associations have worked together to analyse business processes and business requirements, and consider how the standards can be applied to support requirements outlined in the Final Rule. The result of this effort is summarized in this guideline to help industry members apply the standards to their own business processes to support the requirements of the FSMA 204 Final Rule.

● Important

As with all GS1 Standards and solutions, this guideline is voluntary, not mandatory. It should be noted that the use of the words “must” and “require” throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

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.

Nothing herein should be construed as constituting or implying an agreement among foodservice and/or retail grocery companies to adopt or implement GS1 Standards. Nothing herein should be construed as constituting or implying an agreement regarding any company’s prices, output, markets, or dealings with customers and suppliers. Nothing herein is inconsistent with the proposition that each participating company must and will exercise its independent business judgment on all standards adoption.

1.4 Future Releases

This guideline presents the current insight within industry for how GS1 Standards can be applied to United States food supply chain business processes to support product and location identification, structured product descriptions, and recording common industry defined events. It may be updated to reflect feedback from industry pilots, updates to GS1 Standards, and other industry efforts which advance the level of thought. The content may be of assistance as a resource for understanding current thinking or as an aid for pilot preparation. The reader should be aware that changes may be made and should not expect any particular section of content to remain unchanged.

1.5 Scope

This guideline defines the recommendations for product and location identification, structured product descriptions, and recording common industry defined events to support the additional traceability records required in the Final Rule. **It does not provide any guidance or advice regarding regulatory compliance.** The Critical Tracking Events (CTEs) and Key Data Elements (KDEs) have been determined by the FDA and are intended to show the business steps and supply chain members responsible for capturing the KDEs required for the additional traceability records in the Final Rule. Federal requirements for traceability recordkeeping in the food supply chain are specified in the [Additional Traceability Records for Certain Foods](#) and any future subsequent FDA Guidance(s) they publish after this guideline is released.

This guideline reflects current industry understanding of the Additional Traceability Records for Certain Foods. Those requirements, and the statutes and regulations affecting them, are subject to change and may evolve in a manner this guideline cannot anticipate.

1.6 Normative References

This implementation guideline is based on the *GS1 General Specifications*, and other GS1 Standards guidance listed below. The relevant provisions of these standards/specifications are to be considered provisions of this guideline:

1. [Get started with GS1 Standards](#)
2. [A Guide to GS1 Standards Adoption for Supply Chain Visibility](#)
3. [GS1 General Specifications](#)
4. [GS1 US Foodservice Booklet](#)
5. [GS1 US Standards in Use for Fresh Foods](#)
6. [EPCIS 2.0](#)
7. [Core Business Vocabulary \(CBV\) 2.0](#)
8. [GTIN Management Standard](#)
9. [Global Data Model Solution Standard](#)
10. [EDI 856 Foodservice Ship Notice Explained](#)
11. [GS1 US Supply Chain Visibility](#)
12. [EPC Tag Data Standard \(TDS\) 2.0](#)
13. [GS1 Data Matrix Guideline](#)
14. [2D Overview in General Distribution](#)
15. [North American Industry Guidance for Standard Case Code Labelling](#)
16. [An Introduction to the SSCC](#)
17. [Food Industry Guidance for Streamlining Your Logistics Labels](#)
18. To access the full ASN for Foodservice Guideline, follow these steps:
 - a. You need to be a **GS1 US Member company** (such as when you license a Company prefix)
 - b. Go to <https://my.gs1us.org/>
 - c. Go to myGS1 US on the top menu
 - d. Go to Member-Only EDI Documents
 - e. Select **Uniform Communication Standard (UCS) EDI**
 - i. Navigate to UCS Implementation Guideline 007050
 - ii. Go to 2.2 Transaction Sets
 - iii. Go to 856 **UCS v7050 - Foodservice.pdf**

All section references to the GS1 General Specifications refer to Release 22.0. Section numbers may change with subsequent releases.

2 Overview of the FSMA 204 Final Rule

Important: Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. This overview is meant to be a brief summary created by industry, and in no way a replacement for the FDA's documentation linked in the [Introduction Section](#) of this document.

2.1 The Food Traceability List (FTL)

To define which commodities are subject to the additional record-keeping requirements in the Final Rule, the FDA developed a list of foods called the [Food Traceability List \(FTL\)](#). The FTL applies to foods that contain ingredients that are on the FTL and are not subject to a kill step. A kill step is

defined by the FDA as any lethality processing that significantly minimizes pathogens in a food. Food that goes through a kill step is not subject to the Final Rule unless otherwise specified. The current version of the FTL includes but is not limited to foods such as soft cheeses, fresh/cut produce, peanut butter, seafood, and ready-to-eat deli salads. Each organization should review the full list and determine what applies to its business operations.

The FDA indicated that the foods subject to the Final Rule requirements will evolve over time and the FTL will be updated periodically. This most current version of the FTL can be found on the FDA FSMA 204 website.

2.2 Product and Location Identification, Description, and Traceability Lot Code

The Final Rule requires food products and locations, referenced in the CTE and KDEs, to be described with attributes that give a clear indication of the food or location referenced in the record. The FDA has noted that ambiguity in product and location identification has impeded the accuracy and response time of previous foodborne illness investigations.

2.2.1 Product and Location Descriptions

While most of the KDEs defined in the Final Rule describe what, when, and where, of the various CTEs, additional KDEs are required to round out the descriptions of food products and locations. For food products, the rule calls this group of additional KDEs the *Product Description*. It includes the brand name, product name, and packaging size/style. For locations, the Final Rule groups the KDEs under the name *Location Description* and includes attributes like the name of the business, physical location, and street address.

2.2.1.1 The FDA Definition of Traceability Lot Code

The Final Rule requires each food to have a product description and be assigned a Traceability Lot Code (TLC). Under Key Features of the [FDA's FSMA webpage](#), the TLC is defined as: "a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the firm that assigned the traceability lot code."

"You must assign a traceability lot code to a food on the Food Traceability List (FTL) when you do any of the following:

- initially pack a raw agricultural commodity (RAC) other than a food obtained from a fishing vessel;
- perform the first land-based receiving of a food obtained from a fishing vessel;
- or transform a food.
- If you receive an FTL food from an entity that is exempt from the final rule, you must assign a TLC if one has not already been assigned (unless you are a retail food establishment or restaurant).
- Otherwise, you must not establish a new TLC when you conduct other activities (e.g., shipping) for a food on the Food Traceability List.

Once a food has been assigned a TLC, the records required at each CTE must include that TLC. All the KDEs including the TLC, must be linked to the relevant traceability lot.

The Final Rule requires the receiver to utilize previously assigned traceability lot codes (TLC) in their CTE/KDE records instead of utilizing a newly assigned internal reference. This means that companies further downstream in the supply chain will need to have processes in place for routinely receiving the TLC from their trading partners instead of depending solely on internal references.

2.2.1.2 Method for Assigning Traceability Lot Codes

In Final Rule [response 324](#), the FDA does not define a particular method or system by which firms must assign traceability lot codes. It further mentions in comment [response 324](#) that "several food industry-supported traceability initiatives offer best practices and standards for uniquely identifying

a food using a combination of a globally unique product identifier, firm-assigned internal lot code, and standard date code. This information, taken together, could be used as a traceability lot code, provided it meets the definition of “traceability lot code” in § 1.1310 of the final rule.”

Furthermore, in Final Rule [response 361](#), the FDA states that “a traceability lot code may include a product identifier such as a Global Trade Item Number (GTIN) and/or an internal lot code, provided the definition of “traceability lot code” in § 1.1310 is met.”

[Section 3.1.5.1.1](#) provides information on how firms can use GS1 Standards to use a combination of a globally unique identifier with an internal lot code to meet the TLC requirements.

2.3 Records of Critical Tracking Events (CTEs) and Key Data Elements (KDE)

When companies/persons physically handle food products, the Final Rule names certain supply chain activities as CTEs, where records of the KDEs are required. The required KDEs vary from CTE to CTE but generally describe **where** the event took place, **when** the event took place, **what** foods were involved, and provide ties to the records that substantiate the data.

As food progresses through the supply chain, it may undergo a variety of different processes to be changed, packaged/re-packaged, labeled/re-labeled, or combined with other ingredients. For this reason, the framework of CTEs and KDEs is intended to be flexible to accommodate the variety in the food supply chain but this means companies will need to determine which CTEs and KDEs apply to their specific situation.

2.4 Traceability Plan Requirements

The rule also requires companies to maintain additional records which explain the company’s traceability program roadmap, company/personnel procedures who are subject to the rule, as well as where commodities subject to the Final Rule are located. The traceability plan must be updated as needed to ensure that the information reflects current practices for compliance with the rule. Companies must retain their previous traceability plans for two years after the plan is updated. The traceability plan must include the following:

- A description of the company’s procedures used to identify FTL foods they manufacture, process, pack or hold.
- A description of how the company assigns traceability lot codes to FTL foods, if applicable.
- A statement identifying the point of contact for questions regarding the company’s traceability plan and records.
- If a company grows or raises a food on the FTL, it must keep a farm map showing the location and name of each field or container where food is grown or raised on the FTL. The map must include geocoordinates and any other information needed to identify the location of each field/growing area or container.

2.5 Implementation Timeline, Record Retention, and Response Timing

The Final Rule also specifies details about when the rule will go into effect, how long records are expected to be retained, the window for responding to requests from the FDA, and the potential for delegating record-keeping duties. **The Final Rule states January 20, 2026, as the compliance date for all subject to the rule.**

The FDA states that the required records be available to an authorized FDA representative, upon request, within [24 hours](#) (or within some reasonable time to which FDA has agreed), along with any information needed to understand these records. If the FDA’s request for information is made by phone, they indicate that the request will also be provided in writing upon request. However, the requested information must be provided within 24 hours (or within some reasonable time to which the FDA has agreed) of the [phone request](#). There is no requirement for the records to be maintained in electronic form, although it is encouraged. Records are not required to be stored on-site as long as they are retrievable in the necessary time, at a minimum through an electronic spreadsheet.

While the rule expects each location that physically handles the foods to be primarily responsible for record-keeping, it also acknowledges that in some situations that responsibility may be delegated to another entity. In these cases, records must be retrieved and provided onsite within 24 hours of the

request for official review. Please review the appropriate section of the Final Rule for complete information on [Records Maintenance and Availability](#).

FDA also requires that persons subject to the rule maintain records containing the information required for [2 years](#) from the date they were created. For more information, see [Record Retention](#) in the Final Rule.

2.6 What Foods and Persons are Exempt from the Final Rule?

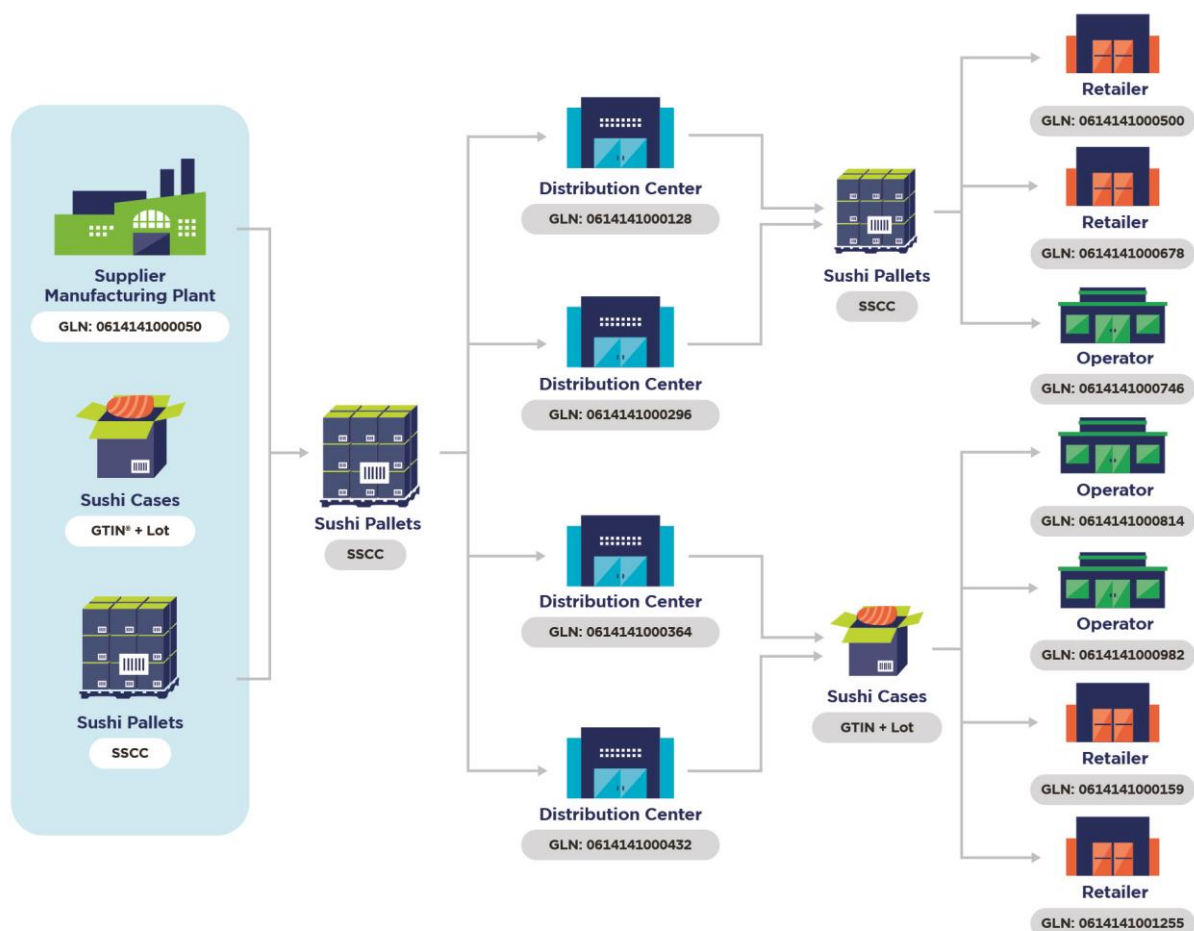
The Final Rule specifies detail about foods and persons who are exempt from this additional recordkeeping or the sortable spreadsheet. Companies must review these exemptions in detail from the source to verify applicability to their company: <https://www.federalregister.gov/d/2022-24417/p-1910>

3 Overview of GS1 Standards

In the Final Rule [responses 506 and 516](#), the FDA encourages “the use of any tools that will improve a firm’s procedures for traceability and support the maintenance and sharing of the required traceability records under the final rule.”

Standards lay the foundation for a more visible supply chain, and in situations like traceability and

Figure 1



recalls, time is of the essence. With GS1 Standards in place, affected items may be more quickly removed with minimal impact. This level of visibility helps create greater efficiency and resilience as well as the ability to pivot when supply chain disruptions occur.

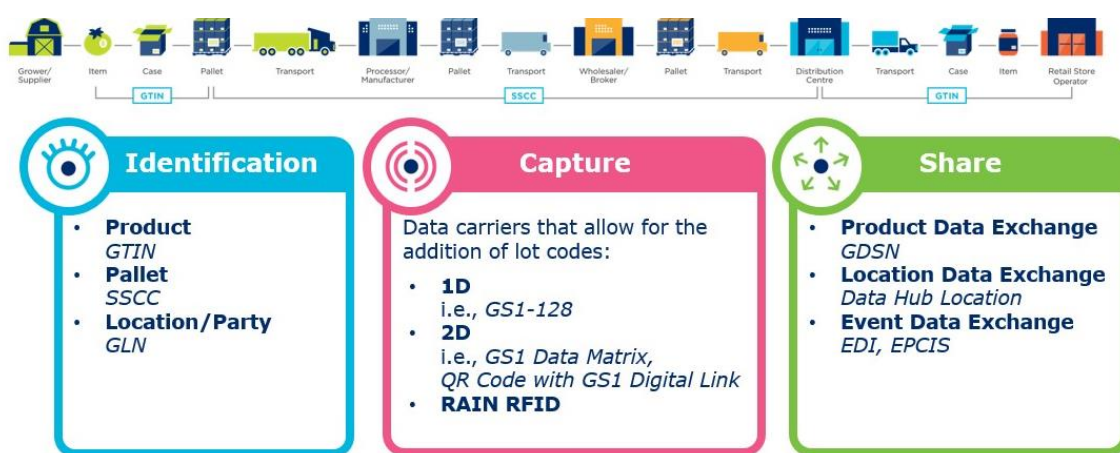
- Traceability starts with the unique identification of products: Global Trade Item Numbers (GTINs) and parties/locations: Global Location Numbers (GLNs).
- Additionally, at the item, case, or pallet level, companies may be capturing information via a GS1 data carrier such as barcodes and then sharing that information with standardized data structures such as EDI and EPCIS.

By implementing standards-based traceability, companies are better prepared to locate, identify, and remove a product that is a public health concern.

*What is RAIN RFID?

Radio frequency identification or RFID is a technology that enables the sharing of data encoded in RFID tags via RFID scanners. The term RAIN RFID specifies the use of the UHF frequency band which leverages the GS1 air interface protocol and drives read ranges and read rate capabilities.

Figure 2



GS1 refers to "RAIN RFID" tags in this document whenever referring to UHF RFID tags.

NOTE: Within the UHF RFID technology space, GS1 only endorses RAIN RFID implementations that are encoded per GS1's EPC standards (which is a subset of all RAIN RFID implementations).

3.1 Identify

The GS1 system provides for the use of unambiguous identification keys to identify goods, services, assets, locations, etc. worldwide. These keys can be represented in data carriers, such as barcodes or EPC/RFID tags, to enable automatic data capture. They may also be used in electronic communications, improving speed and accuracy when sharing master data, transactional data, and visibility event data.

This guidance will illustrate how some of the GS1 identification keys apply to food traceability even if not required by the Final Rule. In later sections, this guideline will illustrate how GS1 Standards for data capturing and sharing work together with GS1 identification keys to reliably communicate data with trading partners and other stakeholders, such as the FDA.

3.1.1 The Importance of Using GS1 Identification Keys for Traceability

A crucial aim of the FDA's Final Rule is distinguishing affected foods and locations from unaffected ones during a food safety investigation. Being unable to identify foods in scope for a food safety investigation prevents officials from making an ultimate determination of the root causes of an outbreak and taking action. To alleviate this, the FDA has required companies subject to the rule to describe the foods through a handful of descriptive attributes and descriptions of physical locations.

Figure 3



In the comment section of the Final Rule, [response 507](#), FDA acknowledges the use of globally unique identifiers as a helpful tool for improving traceability.

3.1.2 Unique Identification of Foods – Global Trade Item Numbers (GTINs)

3.1.2.1 GTIN Definition

The Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification Key used to identify trade items and one of the main building blocks of the GS1 System. GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain.

NOTE: A trade item is any product or service that may be priced, ordered, or invoiced at any point in the supply chain. Trade items include individual items as well as all other packaging configurations offered for sale (e.g., two-pack, case, pallet, etc.). Each packaging level is identified by a unique GTIN. For example, a brand might use a different GTIN to uniquely identify an each, a pack and a case along with any other product configurations that will move through the supply chain.

A company can license a GS1 Company Prefix or single GTIN from a GS1 member organization before their food products can be identified by a GTIN. More information on obtaining a GS1 Company Prefix or a single GTIN from GS1 US can be found on the GS1 US website at <https://www.gs1us.org/>.

3.1.2.2 GTIN Structure Example

A GTIN-14 or GTIN in a 14-digit format is commonly used to identify cases in general distribution and can be included in data carriers such as GS1-128 barcodes to enable traceability.

Figure 4

The GTIN-14 cannot be used in EAN/UPC barcodes. Components include:

Indicator	GS1 Company Prefix →								← Item reference	Check digit			
N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄

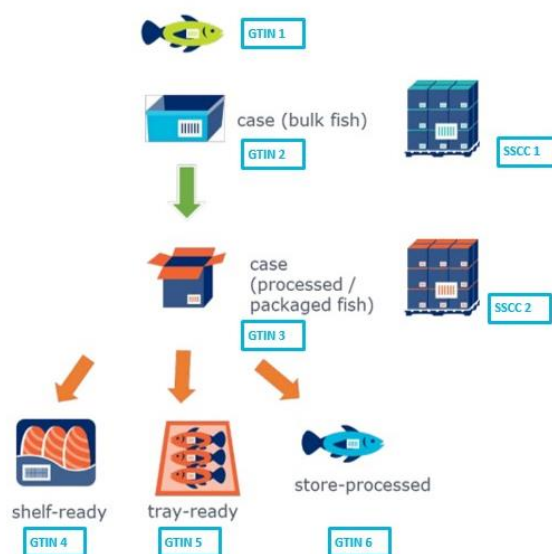
- The Indicator Digit to indicate packaging level (1-8) or that the product is variable measure (9).
- Twelve digits containing your GS1 Company Prefix and the Item Reference
- Check digit

For more information on GTINs please reference: [An Introduction to the Global Trade Item Number \(GTIN\)](#)

3.1.2.3 Where are GTINs Used?

GTINs are used anywhere that a product or service needs to be identified along the supply chain. This includes the internet, business transactions, IT systems, physical products, and more. GS1 Standards define how to format and structure the GTIN in a wide variety of applications so that the same GTIN can be used to identify the product for any of those needs.

Figure 5



3.1.2.4 FSMA 204 GTIN Application

While, in Final Rule [response 508](#), the FDA does not require product identification by a GTIN, it does note that companies who use the GTIN for unique identification might already be linking to several of the required KDEs such as elements of the product description. These KDEs may be linked to a GTIN in a database and entities who use this practice, would not need to maintain this information separately.

3.1.3 Unique Identification of Locations – Global Location Numbers (GLNs)

3.1.3.1 GLN Definition

The Global Location Number (GLN) is a 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.

- **A party** is an entity that needs to be represented in a business-related transaction. A GLN identifying a party answers the question of “who” is involved within the use case leveraging GS1 Standards. This may be a legal entity or function.
- **A location** is a particular place or position. A GLN identifying a location is used to answer the question of “where” something has been, is, or will be and can be physical or digital. A physical location is a tangible place that may be represented by an address, coordinates, or other means. A digital location is an electronic (non-physical address) such as an Electronic Data Interchange (EDI) gateway or enterprise resource planning (ERP) system.

3.1.3.1.1 Where are GLNs Used?

GLNs may be used anywhere that a party or location needs to be identified throughout the supply chain. This includes business transactions, IT systems, a physical location itself, and more. GS1 Standards define how to format and use the GLN in a wide variety of applications so that the same GLN can be used to identify the party or location for any of those needs.

Commodities in the food supply chain pass through many different physical locations such as farms, packing houses, cold storage facilities, manufacturing plants, distribution centers, stores, restaurants, etc. Effective traceability relies on distinguishing these various locations and retrieving necessary information about them. Within the GS1 System of Standards, unique GLNs can be assigned to each party, physical location, and sub-locations (that could be in the same facility) companies own and/or interact with throughout the supply chain.

3.1.3.1.2 GLN Structure

A GLN can be constructed utilizing the same GS1 Company Prefix that is licensed to construct GTINs or it can be obtained independently. The number of GLNs that can be created is based on the length of the GS1 Company Prefix just like the creation of a GTIN.

The GLN is a 13-digit number that includes three components:

- **GS1 Company Prefix:** A globally unique number licensed to a company by a GS1 Member Organization to serve as the foundation for generating GS1 identification keys (e.g., GLN, GTIN). GS1 Company Prefixes are assigned in varying lengths depending on the company's needs.
- **Location Reference:** A number, containing no logic, assigned by the user to identify the party or location. The Location Reference varies in length based on GS1 Company Prefix length.
- **Check Digit:** The final digit is calculated from the preceding digits of the GLN. This digit is used to check that the data has been correctly composed. GS1 US provides a check digit calculator to automatically calculate check digits for you.

Figure 6



More information on [GLNs](#) can be found on the GS1 US website and in [An Introduction to Global Location Number](#).

3.1.3.1.3 FSMA 204 GLN Application

With the exception of farms, in which sub-locations such as individual fields, growing areas, or aquaculture containers on each farm are in scope, the Final Rule primarily focuses on locations as places at different street addresses, not sub-locations. However, in Final Rule [Response 267](#), the FDA states that businesses that use location identifiers, to differentiate between inter-company locations (e.g., store numbers), may choose to include that information as part of their location description. This can be shared either by adding the identifier "to the required information or by using it as a shorthand for some or all of the required information, provided that a glossary or key is maintained (and, if necessary, shared) to indicate the complete physical address and other required information relating to the specific location." For this reason, this guideline will illustrate how GLNs can be applied and used to link to descriptive attributes about a location for fulfilling the traceability required by the FDA's Final Rule.

3.1.4 Unique Identification of Logistics Units – Serial Shipping Container Code (SSCC)

3.1.4.1 SSCC Definition

The Serial Shipping Container Code (SSCC) is the GS1 Identification Key used to identify a logistic unit. This unique identifier is comprised of an Extension Digit, a GS1 Company Prefix, a Serial Reference, and a Check Digit.

3.1.4.2 Where are SSCCs Used?

The SSCC identifies a single logistic unit throughout its transport journey. Like a parcel tracking number, it acts as a single reference for the unit over its journey from source to destination. The SSCC can be encoded in a data carrier and placed directly on the unit's logistics label to be a physical representation of the identity of the object. The SSCC can be expressed in data records (e.g., Advance Ship Notice (ASN)), exchanged between trading partners and shipping/receiving locations to provide a complete context on the unit. This enables companies to efficiently load/unload shipments without sacrificing accurate records about individual foods' journeys.

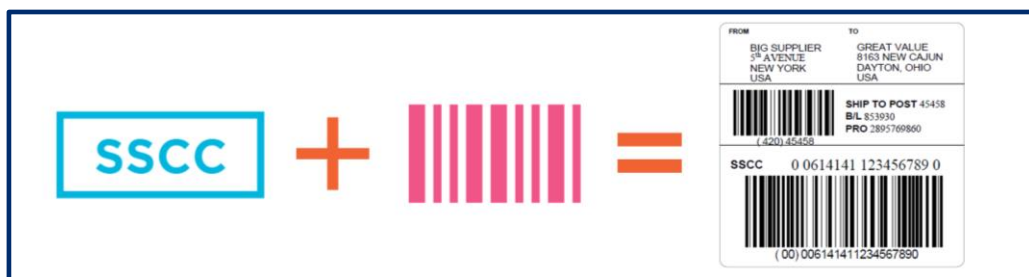


Figure 7

3.1.4.3 SSCC Structure

The SSCC can be constructed from the same prefixes utilized to construct GTINs and GLNs and does not limit the number of products and locations that can be allocated by any single prefix.

The SSCC's 18-digit number includes five components:

- **Applications Identifier (AI):** AI (00) to indicate an SSCC-
- **Extension Digit:** Used to increase the capacity of the Serial Reference within the SSCC
- **GS1 Company Prefix:** A globally unique number issued to a GS1 member company
- **Serial Reference:** The number allocated to identify a logistic unit
- **Check Digit:** A modulo 10-digit used to check for input errors

The Application Identifier (00) indicates that the barcode contains an SSCC. When printed in a barcode the most common symbology is GS1-128. GS1 DataMatrix and GS1 QR Code are also allowed with restrictions. For details on the use of GS1 DataMatrix and GS1 QR Code, see [section 2.2 of the GS1 General Specifications](#)

Figure 8

Application Identifier	Extension Digit	GS1 Company Prefix								Serial Reference								Check Digit
(00)	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄	N ₁₅	N ₁₆	N ₁₇	N ₁₈

For more information on SSCCs please reference [An Introduction to the Serial Shipping Container Code \(SSCC\)](#) and [Section 5](#) in this document.

3.1.4.4 FSMA 204 SSCC Application

While SSCCs are not required, the FDA acknowledges that they can be a helpful tool for improving traceability, and firms may wish to use them together with the required traceability lot codes. For more information in the Final Rule, [see Response 516](#).

For example, a retail store might order several different kinds of foods to be delivered together on the same truck. The retail distribution center will select the different food products that were ordered and pack them together into a mixed pallet for rapid loading/unloading of the truck. Objects placed together for transport and/or storage can be referred to as logistics units and can be identified by an SSCC.

3.2 The Traceability Lot Code in the GS1 System of Standards

3.2.1 GTIN Plus Batch/Lot in the GS1 System of Standards

Throughout the world today, many items are identified with GTINs. Once a company has assigned a GTIN to a trade item, it provides a common language for all its entities and trading partners worldwide to uniquely identify the item. The GTIN can be used to identify types of products at any packaging level (e.g., consumer unit, inner pack, case, pallet).

Today, many companies assign batch/lot codes to groups of trade items with similar usage characteristics and production batches (e.g., production date, production batch, expiration date). Batch/lot numbers allow for greater granularity when tracking specific groups of items throughout the supply chain.

Within the GS1 System of Standards, batch/lot information is considered attribute information and must be accompanied in data carriers and data sharing mechanisms by a GTIN. GS1 Application Identifiers (AI) are used to indicate GS1 identification keys, attribute information, and secondary information in data carriers and data sharing mechanisms.

3.2.2 FSMA 204 GTIN Plus Batch/Lot Application

As referenced in Section 2, in the Final Rule [response 361](#), the FDA states “traceability lot code may include a product identifier such as a GTIN and/or an internal lot code (provided the definition of “traceability lot code” in § 1.1310 is met.” Therefore, a GTIN+batch/lot is one example of a traceability lot code that could be used to support the Final Rule’s requirement in section [§ 1.1310](#).

The batch/lot attribute in the GS1 System is indicated by AI (10) and is considered an attribute identifier. Attribute identifiers cannot be expressed without a primary identifier. Within the GS1 System, AI (10) must be expressed in conjunction with the GTIN since a batch/lot number is an attribute of a product.

For this reason, this guidance will define the TLC as both a GTIN (GS1 AI (01)) and a lot (GS1 AI (10)).

NOTE: AI (10) can be recorded as any number of characters from one to twenty and be expressed as letters, numerals, and a defined subset of special characters. More information can be found in section 3 of the GS1 General Specifications.

3.3 Capture

3.3.1 Application Identifiers (AIs)

In GS1 Standards, GS1 Application Identifiers (AIs) are used in certain barcodes or RFID tags to tell systems what information is being interacted with and enable systems to process it accordingly. AIs can be used in certain food sectors within data carriers for greater transparency and traceability even though they are not required to meet FSMA 204 requirements.

The full list of AIs can be found in section 3.2 of the [GS1 General Specifications](#).

Below are the most common AIs used for traceability in food distribution.

Table 1

Name	AI	Purpose
Global Trade Item Number (GTIN)	01	Uniquely identifies the trade item
Batch or Lot Number	10	Identifies a group of the same product, all of which were manufactured under identical conditions to support traceability and other use cases.
Sell By Date	16	Indicates the date specified by the manufacturer as the last date the retailer is to offer the product for sale to the consumer
Expiration Date	17	Indicates the last date on which the quality attributes (e.g., nutrient content, color, flavor, texture, etc.) expected by the consumer are guaranteed. The product should not be marketed after this date.
Serial Number	21	Identifies an individual instance of a product for its lifetime
Variable Count of Items	30	Indicates the number of items contained in a variable measure product
Net Weight, Pounds	320n	Indicates the net weight of a variable measure product in pounds. Additional options exist for other units of measure.

Logistic units are defined as an item of any composition that is established for transport and/or storage that needs to be managed through the supply chain. These AIs are generally seen on a GS1 Logistic Label.

Table 2

Name	AI	Purpose
Serial Shipping Container Code (SSCC)	00	Uniquely identifies a logistic unit
Trade Items Contained in Logistic Unit	02	Indicates the GTIN of the trade items contained is the GTIN of the highest level of trade item contained in the logistic unit and is used in combination with SSCC (00) and count of trade item pieces (37)
Count of Trade Item Pieces Contained in a Logistic Unit	37	Indicates the number of products or number of product pieces contained in the respective logistic unit. Used in combination with AI (00) and (02)
Global Location Number (GLN) of the Production or Service Location	416	Indicates where something was produced or serviced

3.3.2 Guidance on Data Carrier Usage

While the Final Rule does not require the use of data carriers, in [response 524](#), FDA states that “firms may use product labels to provide the information required to their supply chain partners if that suits their business practices”. Data carriers are used by businesses to enable faster, more accurate data capture and traceability in addition to allowing information about a physical object to be captured, shared, and used.

As companies investigate ways to make their processes more efficient and enable seamless communication and integration between trading partners as the product moves throughout the supply chain, they can choose to adopt one or more data carriers. Pallets, cases, inner packs, and individual items if priced, invoiced, or ordered, at any point in the supply chain can be assigned a GTIN, marked with a data carrier that encodes that GTIN (examples of this can be barcodes, RFID

tags, etc.), then scanned or read by an RFID reader. That information can then be stored and shared as appropriate with supply chain partners or externally.

Please note, the scope of the Final Rule excludes sales or service to consumers, meaning scanning at the point-of-sale or consumption is not in focus for the regulation, but may be relevant for other business purposes of the readers of this guidance. Companies should always discuss the use of data carriers with their trading partners to align appropriately.

Most of the CTEs and KDEs outlined in the Final Rule are required to be linked to the TLC of the foods under examination. As will be discussed later, this maps closely to a GTIN, and batch/lot number is captured as AI (10). See Final Rule [Response 423](#) for more information.

For additional resources on data carriers, please reference [Section 1.5](#) of this guideline.

The following sub-sections will detail some of the top considerations for companies evaluating the use of data carriers in support of traceability for the Final Rule. They cover which data can be encoded, the syntaxes that can be used to encode that data, and the different kinds of data carriers available in the GS1 System of Standards.





3.3.2.1 FSMA 204 Data Carrier Application

The Final Rule focuses on records that the FDA will request of companies in the event of an investigation, not on the practices a company needs to have in place to routinely implement traceability between trading partners. Data Carriers are not required to meet the requirements of the Final Rule. For this reason, there is no clear prescription of what data must be present in a data carrier to fulfill traceability for the Final Rule. Instead, companies must evaluate what data will enable rapid access to the necessary information in the event the FDA requests their records.

3.3.2.2 Data Carrier Syntax Overview

Different types of data carriers can hold varying amounts of data. In addition to that, the data itself is structured to enable specific capabilities. This data formatting, known as the syntax, is an important consideration point when determining what type of data carrier is best suited to support the business requirements. The three barcode syntaxes in the GS1 System of Standards are plain, GS1 element string, and GS1 Digital Link URI. Additionally, Electronic Product Code (EPC) is the syntax used for RFID.

Table 3 GS1 Barcode Syntax Comparison Table

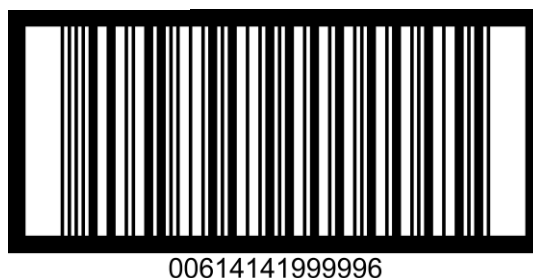
	Plain (1D)	GS1 Element String (1D and 2D)	GS1 Digital Link URI (2D)	EPC URI (RAIN RFID)
				
Type of Data	Contains only the primary identifier	Can contain the primary identifier plus attribute data	Can contain the primary identifier plus attribute data in a web compatible format	Can contain the primary identifier with a serial number plus attribute data for use in RFID tags.
Syntax Example (GTIN, Expiration Date, Batch/Lot Number)	00614141999996	(01)00614141999996 (17)280115 (10)123456	https://example.com/ /01/00614141999996 /10/123456?17=280115	(01)00614141999996 (17)280115 (10)123456

	Plain (1D)	GS1 Element String (1D and 2D)	GS1 Digital Link URI (2D)	EPC URI (RAIN RFID)
Barcodes	EAN/UPC and ITF-14	GS1-128 and GS1 DataMatrix	QR Code and Data Matrix	However, the most common application is in the memory of an RFID tag.
Best For	Use cases that only require a GTIN	Use cases that require GTIN and additional information	Use cases that benefit from connecting users to an online resource	Use cases that require data capture without a line of site (RFID only). Use cases that benefit from item level serialization.
Limitation	Cannot encode more than GTIN	The size of GS1-128 can be a barrier for small packages or when large amounts of data are required. It has a 48-character limit. GS1 DataMatrix is not approved in the GS1 System for open supply chain use due to limited system scanning capabilities.	Scanning capabilities are not widely available for GS1 Digital Link URI in general distribution. As a result, it is not approved for use in the GS1 System. Updates would be required to process both barcode types and contained data.	The length of the EPC, including attribute data, is limited to the memory of the RFID tag. Therefore, the data requirements of the EPC must be known to select the appropriate tag.

3.3.3 Barcode Types and Uses

3.3.3.1 1D Barcodes

Figure 9



ITF-14 barcodes are often used in general distribution because they can be directly printed on corrugate. This type of barcode works best for use cases where only the GTIN is required as this is the only data that can be encoded in an ITF-14 barcode.

GS1-128 barcodes can encode the GTIN and additional attribute data, such as expiration date, batch/lot number, GLN, SSCC, etc. This type of barcode can be up to 6.5 inches in length and hold up to 48 data characters.

Figure 10



3.3.3.2 2D Barcodes

GS1 DataMatrix uses GS1 element string syntax that is seen in other GS1 barcodes, such as the GS1-128. This data format is heavily used throughout the supply chain to support getting important

Figure 11



(01) 0 0614141 99999 6 (17) 280115 (10) 123456

data where it is needed in healthcare, with fresh foods, on logistic units, and in a variety of other places. It does not offer the web compatibility associated with the QR Code and Data Matrix used with GS1 Digital Link URI.

2D barcodes with GS1 Digital Link URI encode GS1 data in a web-friendly format that allows information to be used for traditional supply chain applications, while also connecting to online resources. This allows GS1 Digital Link in the QR Code and the Data Matrix to combine GS1 identifiers with the benefits of the web.

Figure 12



<https://example.com/01/00614141999996/10/123456?17=280115>

Data Matrix with GS1 Digital Link URI can also be used to connect users to the web, however, not all mobile device cameras can automatically process the barcode type at this time.

Figure 13



<https://example.com/01/00614141999996/10/123456?17=280115>

QR Code with GS1 Digital Link URI is the current preference for engagement through mobile devices because the default camera application on a mobile device is able to automatically scan the QR Code and connect the user to the website or other resource.

- Important: 1D barcodes cannot be removed until all stakeholders expected to scan the barcode are fully capable of interacting with 2D barcodes. This means that both a 1D and 2D barcode would be required during any transition period.

3.3.4 RFID

There has been an increased interest in the food industry for RFID. Several pilots are developing to demonstrate its applicability, specifically in the following areas:

- **Traceability**
 - Quickly find pallets or cartons meeting specific criteria
- **Operational Efficiencies**

- Automatically trigger alerts
- Detect and prevent freshness rotation issues

The main benefit of RFID is the ability to capture information quickly and accurately with no line of sight needed. Data in RFID tags are read through RFID readers, which come in a variety of formats, including fixed (overhead, door portals) and hand-held readers.

3.4 Share

Electronic data sharing has many benefits, including reducing communication errors, increasing the speed of trade transactions, and supporting real-time product information updates. Within the GS1 System, there are three main ways to share: Electronic Data Interchange (EDI), The Global Data Synchronization Network™ (GDSN®), and Electronic Product Code Information Services (EPCIS). There are also global data sharing models such as the Global Data Model (GDM) and the Global Location Number (GLN) Data Model that establish standardized attributes to be shared around the world. For more information on GS1 Data Sharing Standards please reference:

- <https://www.gs1us.org/upcs-barcodes-prefixes/how-to-use-your-upc-barcodes/share-information-electronically>
- <https://mocdn.gs1.org/services/gdsn/global-data-model>
- <https://www.gs1.org/standards/gln-data-model-solution-standard/current-standard>

3.4.1 FSMA 204 Data Sharing Application

In Final Rule [response 504](#), the FDA encourages firms to use available technologies to share information with supply chain partners. However, it does not require the use of electronic records, nor does it prescribe any specific technologies for records maintenance or sharing. Therefore, firms may use any system or standards that help them meet the requirements to keep and provide information that is required by the Final Rule.

One of the core elements of the FDA's [New Era of Food Safety Blueprint](#) focuses on leveraging technology and other tools to create a safer, and more digital, traceable food system. Tech-enabled traceability and the use of smarter food safety tools help to prevent outbreaks and allow for faster outbreak responses, thus protecting consumers from contaminated products. Within the Blueprint, the FDA mentions that the first phase of enhancing traceability will be releasing FSMA Section 204 to harmonize the KDEs and CTEs needed for enhanced traceability. In the [New Era of Food Safety Blueprint](#), the FDA recognizes that "establishing this foundation for traceability will allow stakeholders in the supply chain to adopt and leverage digitally-enabled technologies, enable data sharing, and introduce approaches that greatly reduce the time it takes to identify the origin of a contaminated food tied to a recall and/or outbreak."

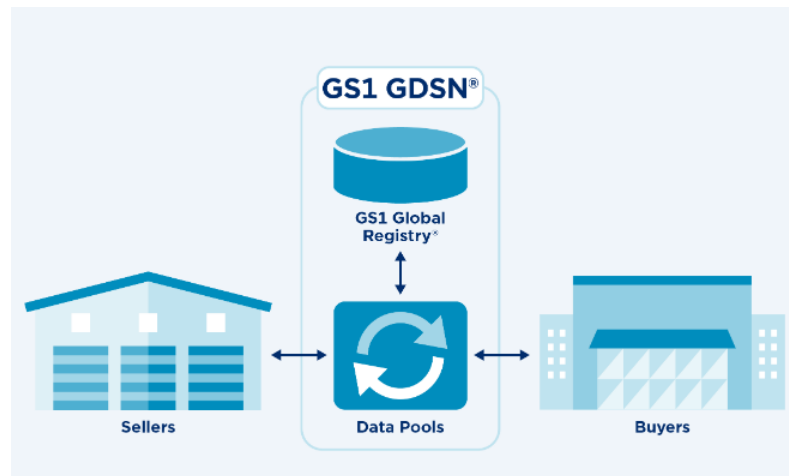
3.4.2 Master Data

Master Data is the core information about the "who" and "what" in a trading relationship. The "who" can include the name, address, and identification codes of the buyer and seller plus details of shipping, delivery, and billing locations. The "what" is product information such as product name, description, size, and unique product identifier, such as the GTIN.

3.4.3 Global Data Synchronization Network (GDSN)

GDSN is the electronic transfer of standardized product information between trading partners and the continuous synchronization of that information over time. The GDSN helps to support all partners in having access to the same, accurate information. It includes product master data, which includes product attributes such as weight, description, brand name, product information, GTIN, and manufacturer information. GS1 GDSN makes it possible for any company, in any market, to share product information between trading partners within a closed network via a Certified Data Pool. Businesses can optimize their processes by sharing product content with multiple trading partners simultaneously within local and global markets and then can pass on product information to consumers and patients. For more information go to: <https://www.gs1.org/standards/gdsn>

Figure 14



NOTE: A GDSN attribute can be used to identify the foods that are part of the FTL and communicate them to trading partners. The attribute name is “RegulationTypeCode = TRACEABILITY_REGULATION” with a US Local Code List for regulatoryAct (BMS ID 3071) = FSMA204. Companies should work with their GDSN data pool providers to implement this.

3.4.4 Global Data Model (GDM)

The GS1 Global Data Model (GDM) and Attribute Definitions for Business (ADB) standards (Global Master Data Attributes) help enable greater data quality within the GS1 Global Data Synchronization Network (GS1 GDSN). The GS1 Global Data Model Standard defines a globally consistent set of foundational product attributes needed to list, order, store, move, and sell products.

For more information go to: <https://www.gs1.org/standards/gs1-global-data-model>

3.4.4.1 Global Location Number (GLN) Data Model

The GLN Data Model Solution Standard is designed to share party data. It provides a robust, extensible set of attributes to give meaning to the party or location being identified and to help **enable interoperable business solutions**.

The GS1 Global Data Model provides standards to support sharing quality product data within solutions like the GDSN while the GLN Data Model provides ways to share party and location data across systems. The [Location Description KDEs Section](#) of this document describes how the GLN Data Model can be leveraged to help meet FSMA 204 requirements.

Figure 15



For more information go to: <https://www.gs1.org/standards/id-keys/gln>.

3.4.4.2 GS1 US Data Hub | Location

Locally and globally, GS1 is enhancing existing registry systems and creating new ones to share core party and location attributes. GS1 US offers a solution to help industry keep track of valuable data that is key to business processes through the GS1 US Data Hub. GS1 US Data Hub is not considered a GS1 Standard, but rather is a suite of tools that allows users to create both Global

Trade Item Numbers (GTINs) and Global Locations Numbers (GLNs). This robust tool also provides the ability to add important attributes to those identifiers, manage and store the information, and exchange it with business partners.

The GS1 US Data Hub | Location tool helps drive reliable party and location identification to improve business efficiencies. For more information go to: <https://www.gs1us.org/tools/gs1-us-data-hub/location>.

3.4.5 Transactional Data

Transactional Data is the information exchanged between two organizations about the products and services they are selling, ordering, delivering, receiving, invoicing, and paying for. This process is also known as the Order-to-Cash cycle.

3.4.6 Electronic Data Interchange (EDI)

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. EDI has helped thousands* of companies achieve significant operational savings through process improvements to common business operations, such as order, delivery, invoice, payment, warehouse, and inventory processes. When these documents are exchanged as EDI transactions, they often reference products, logistics units, locations, and parties. Often, these references simply utilize a GS1 Identification Key instead of full descriptions. This is possible since these companies have previously exchanged data elements (i.e., attributes) that make up the full description.

For more information, please see the [GS1 EDI Standard](#) and [GS1 educational offerings](#) on EDI.

For more information on EDI go to: <https://www.gs1us.org/upcs-barcodes-prefixes/how-to-use-your-upc-barcodes/share-information-electronically>

3.4.7 Physical Event Data

Physical Event Data is the information generated by an item as it moves through the supply chain. Physical Event Data Sharing is facilitated by the Electronic Product Code Information Services (EPCIS).

3.4.7.1 GS1 Electronic Product Code Information Services (EPCIS)

EPCIS is a GS1 Standard that helps to enable trading partners to share information about the physical movement and status of products as they travel throughout the supply chain—from business to business and ultimately to consumers. It helps answer the “what, where, when, and why” questions to meet consumer and regulatory demands for accurate and detailed product information.

[Section 4.6](#), this guideline describes how specific CTEs/KDEs required in the Final Rule can be mapped to the EPCIS Standard.

For more information go to: <https://www.gs1.org/standards/epcis>

4 Applying the GS1 System of Standards to FSMA 204

4.1 Supply Chain Process Flows for FSMA 204

The Final Rule requires persons who manufacture, process, pack, or hold foods to maintain and provide to their supply chain partners specific information (key data elements or 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 Final Rule varies

depending on the type of supply chain activities they perform, from harvesting or production of the food through processing, distribution, and receipt at retail or other points of service.

The CTEs required by the rule are:

- Harvesting (for Raw Agricultural Commodities (RAC) not obtained from a fishing vessel)
- Cooling (before Initial Packing) (RACs not obtained from a fishing vessel)
- Initial Packing (RACs not obtained from a fishing vessel)
- First Land-based Receiver (Food obtained from a fishing vessel)
- Shipping
- Receiving
- Transformation

Please reference the FDA document on KDEs required for each CTE performed [HERE](#).

The FSMA 204 Workgroup defined four supply chain process flows to aid in describing the CTEs/KDEs for each step as described in section 4.1.1 below.

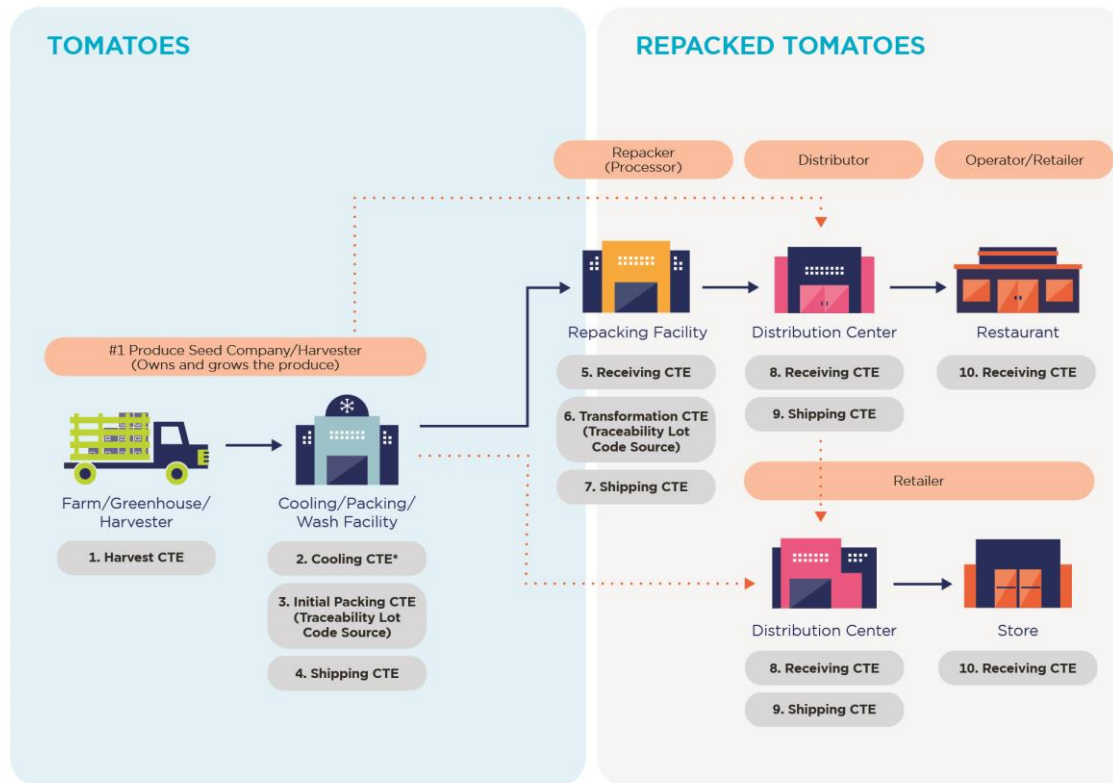
4.1.1 End-to-End Flows and the Final Rule

The following examples show Critical Tracking Events that the GS1 US food industry stakeholders have developed to suggest which supply chain partners are responsible for maintaining information for the Final Rule.

Important note: Manufacturing (Transformation) Initial Packing and other Transformation events may include comingling practices that need to be recorded internally to ensure the continuity of the data. The following supply chain processes and steps found in Appendix C of this document are meant to illustrate examples of the parties, locations, and steps that could be involved to meet FSMA 204 requirements.

4.1.1.1 Traceability for Whole Tomato

The whole tomato end-to-end traceability process below depicts 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.

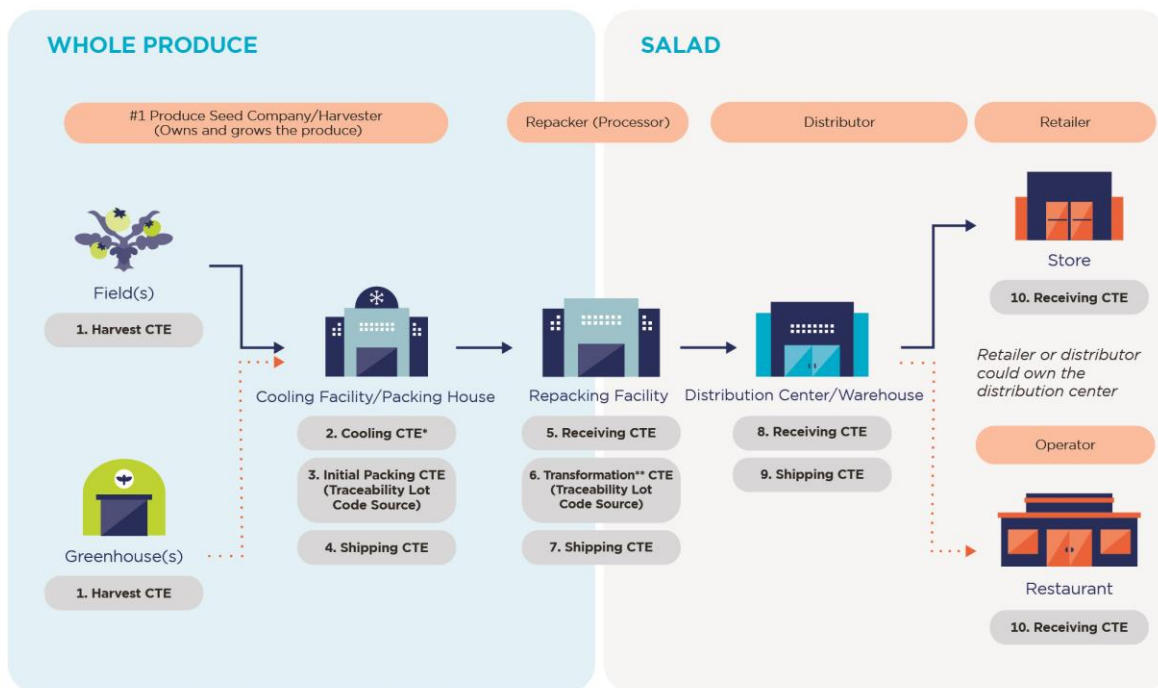


*The rule states: "For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed..." - [Link](#)

Go to [Appendix C](#) in this document for detailed process steps.

4.1.1.2 Traceability for Ready to Eat Salad

The Ready to eat salad (or diced tomato) end-to-end traceability process below depicts produce being harvested from more than one facility. The produce is placed into totes and sent to a cooling facility/packing house where produce may be sorted/graded and shrink-packed into cases for cooling; with initial packing, traceability lot codes are assigned. 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 shipped to a distribution center and then to retail outlets or restaurants.



**Transformation could occur over 1 or more steps

*The rule states: "For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed..." - [Link](#)

Go to [Appendix C](#) in this document for detailed process steps.

4.1.1.3 Traceability for Frozen Shrimp Aquaculture Farmed

In the example below, shrimp is harvested from a pond (FDA defines it as a container) by a broker who is the first receiver (Harvester). The head on shrimp is sorted, size graded (Initial Packing) and a TLC is assigned. The broker sells and transports the sorted shrimp to a processor.

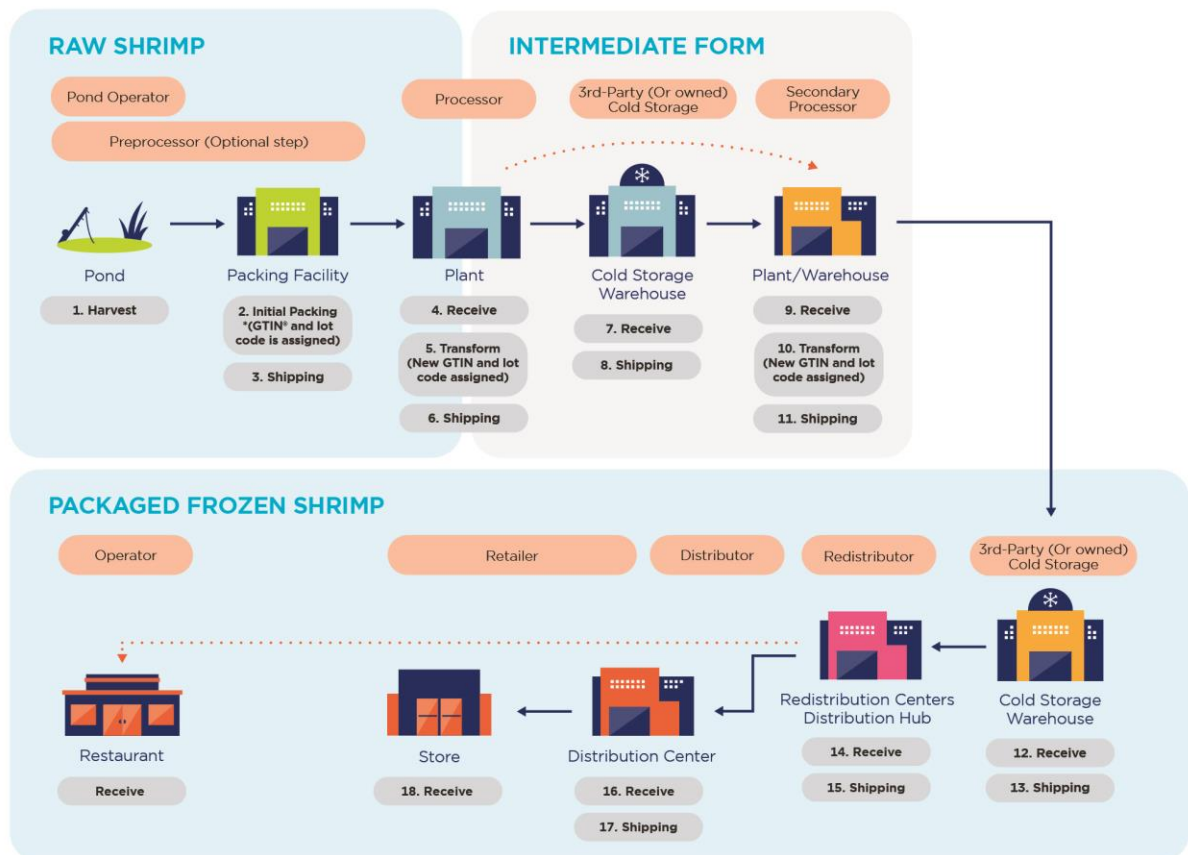
The graded head-on shrimp are Shipped to the Processor who Receives them. Commingling and Transformation occur at the Processor (head removed, shelled, deveined, size graded). A new TLC is assigned, and the Processor is the TLC Source.

If additional processing is required by a secondary processor (freezing and packaging) another Transformation occurs. The secondary processor receives and keeps a record of the primary processor's TLC and lot code source. After freezing into bulk (Transformation) the secondary processor may assign a new TLC if the packaging is done later. When the secondary processor packages the frozen shrimp as a finished product (Transformation) a new traceability lot code is assigned, and the secondary processor becomes the TLC source.

The secondary processor sells the frozen packaged shrimp (Shipper) to an importer who places the product into a third-party cold storage (3PL). *The 3PL (Receiver) shall not assign a new TLC and keeps the secondary processor as the TLC source.* The importer sells the frozen shrimp to a retail or food service distributor and the product is shipped from the 3PL (Shipper). The retail or food service distributor (both Receiver and Shipper *cannot change the TLC and keeps the TLC Source as a record*). *When the Distributor ships the product, they pass along the TLC and TLC Source.* The restaurant or a grocery store (*Final Receiver*) keeps the passed along TLC and TLC source as a record.

- **Important:** Fishing vessel supply chain process requires different CTEs.

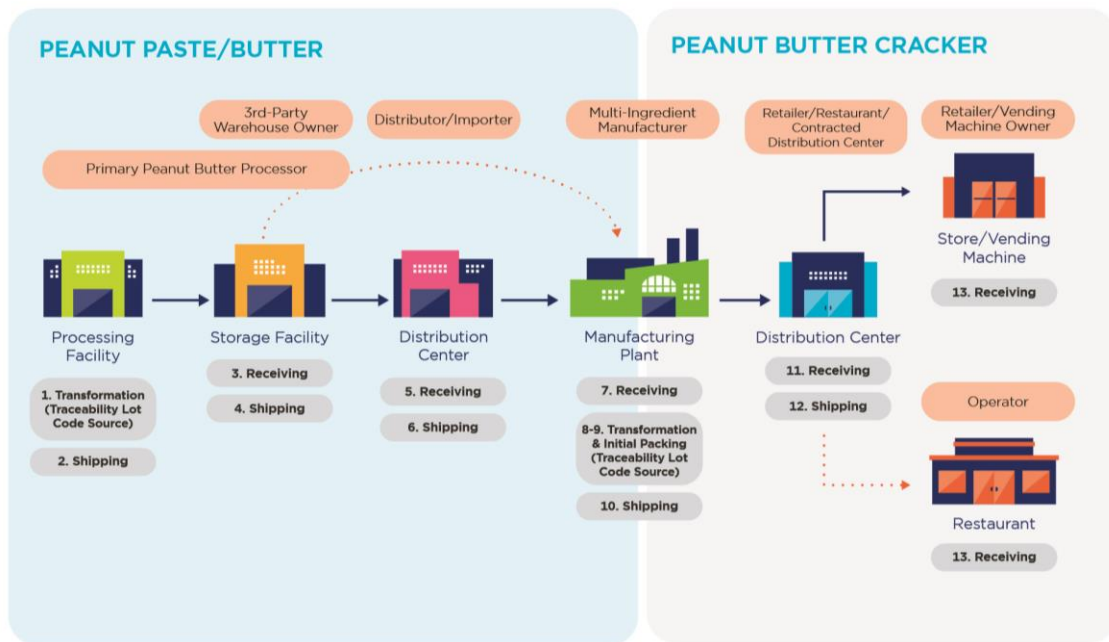
Figure 18



Go to [Appendix C](#) in this document for detailed process steps.

4.1.1.4 Traceability for Peanut Butter Cracker

In the final example, below, peanut butter crackers are created. First, the peanut butter/paste is manufactured, and TLCs are assigned by the primary peanut butter processor. Peanut butter/paste is transported to a 3rd party warehouse in tankers, where it is received. The 3rd party warehouse ships peanut butter/paste to a distributor/importer or directly to a multi-ingredient manufacturer. After receipt, the multi-ingredient manufacturer maintains existing TLCs of all ingredients used to make the peanut butter crackers and creates a new TLC for the finalized product (the peanut butter crackers), which would be considered initial packing. The peanut butter crackers are shipped to a retailer/vending machine/restaurant.



Go to [Appendix C](#) in this document for detailed process steps.

4.2 Critical Tracking Events (CTEs) and Key Data Elements (KDEs) Recordkeeping and Sharing

4.2.1 Data Sharing Under the Final Rule

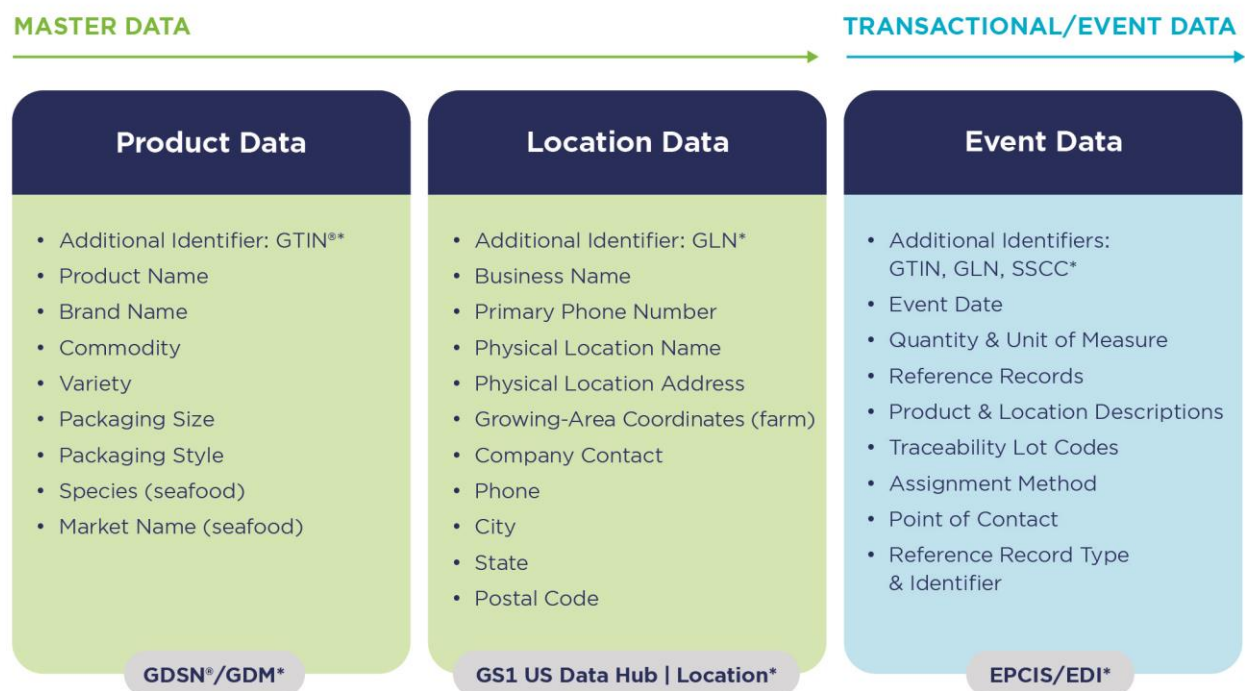
This section will detail the CTE and KDE record keeping requirements of the Final Rule and map to existing data sharing standards within the GS1 System of Standards.

The Final Rule lays out requirements for what data the FDA will request during an investigation. As a part of those data requirements, the FDA also defines a subset of that data which is required to accompany foods as they are sent from one location to another so different companies subject to the rule are able to fulfill their obligations. The Final Rule does not segment the required data by specific data channels since it will all need to be combined when requested by the FDA. The FDA also does not specify a particular method for storing or exchanging data between trading partners.

Many companies use these GS1 Data Sharing Standards today in different business transactions such as EDI as well as in their Master Data systems, such as GDSN. The KDEs required in the Final rule could come from different existing sources of data such as Master Data and then be pulled from an EDI transaction through the GTIN, GLN, or SSCC.

Figure 20

Data Framework Example



*Denotes possible use of GS1 Standards for FSMA 204

4.2.2 Overview of the CTEs and KDEs of the Final Rule

The following table details the complete set of CTEs and KDEs required by the Final Rule:

Table 4

Final Rule KDE Name	Applicable Final Rule CTEs							Corresponding GS1 Standards
	Harvesting	Cooling	Initial Packing	First Land-Based Receiver	Shipping	Receiving	Transformation	
Traceability Lot Code of the food (Initial Packing, Shipped, output of Transformation, or First Land-Based Receiver)			X	X	X		X	GTIN + AI (10)
Product Description of the food (Initial Packing, Shipped, output of Transformation, or First Land-Based Receiver)			X		X		X	GTIN + GDSN or GDM attributes
Quantity and Unit of Measure of the food (Initial Packing, Shipped, the output of Transformation, or First Land-Based Receiver)			X		X		X	Quantity + Unit of Measure in ASN or EPCIS events
Commodity, and, if applicable, variety of the food (Harvested, Cooled, or received by Initial Packer)	X	X	X					GTIN + GDSN or GDM attributes, if assigned a GTIN
Species and/or acceptable market name for unpackaged food (First Land-Based Receiver)				X				GTIN + GDSN or GDM attributes, if assigned a GTIN
Quantity and Unit of Measure of the food (Harvested, Cooled, received by Initial Packer or First Land-Based Receiver)	X	X	X	X				Quantity + Unit of Measure in ASN or EPCIS events
Traceability lot code of the food (Received or input of Transformation)						X	X (If on FTL)	GTIN + AI (10)
Product Description of the food (Receiving or input of Transformation)						X	X (If on FTL)	GTIN + GDSN or GDM attributes
Quantity and Unit of Measure of the food (Receiving or input of Transformation)						X	X (If on FTL)	Quantity + Unit of EPCIS events
Location Description for the farm where the food was harvested	X	X	X					GLN + GLN Data Model attributes of farm
For Produce: Name of the field or other growing area from which the food was harvested (must correspond to name used by the grower) OR Other information identifying the harvest location at least as precisely as field or growing area name	X		X					GLN + GLN Data Model attributes of field or other growing area
For aqua cultured food: Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), OR Other information identifying the harvest location at least as precisely as the container name	X		X					GLN + GLN Data Model attributes of aquaculture container or other growing area

Final Rule KDE Name	Applicable Final Rule CTEs							Corresponding GS1 Standards
	Harvesting	Cooling	Initial Packing	First Land-Based Receiver	Shipping	Receiving	Transformation	
Location(s) for the fishing trip where the food was caught				X				CBV ILM of EPCIS ObjectEvent action=ADD w/ bizStep=commissioning or create_class_instance
Location Description for where you cooled the food		X	X					GLN + GLN Data Model attributes of cooling facility
Location Description of Immediate Subsequent Recipient (other than transporter) / Receiving Location	X	X			X	X		GLN + GLN Data Model attributes of receiving location
Location description for the location from which you shipped the food / Immediate Previous Source					X	X		GLN + GLN Data Model attributes of receiving location
Location description for where the food was initially packed (i.e., traceability lot code source) and (if applicable), the traceability lot code source reference			X					GLN + GLN Data Model attributes of Initial Packing location
Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference				X				GLN + GLN Data Model attributes of First Land-Based Receiver location
Location description for the traceability lot code source or the traceability lot code source reference					X	X		GLN + GLN Data Model attributes of TLC source or GS1 Digital Link URI which can direct to TLC source
Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference							X	GLN + GLN Data Model attributes of Transformation location or GS1 Digital Link URI which can direct to Transformation location
Date of harvesting	X		X					Event Date & Time in EPCIS Object Event of commissioning the food
Date of cooling		X	X					Event Date & Time in EPCIS Object Event with action=Observe; BizStep=other
Date of received food			X			X		Event Date & Time in EPCIS Object Event with action=Observe; BizStep=Receiving
Date of initial packing			X					Event Date & Time in EPCIS Transformation Event

Final Rule KDE Name	Applicable Final Rule CTEs							Corresponding GS1 Standards
	Harvesting	Cooling	Initial Packing	First Land-Based Receiver	Shipping	Receiving	Transformation	
Date of shipping food					X			DTM (Date/Time Reference) Segment within Shipment Hierarchical Level of ASN
Date of transformation completion							X	Event Date & Time in EPCIS Transformation Event
Harvest date range of the fishing trip				X				CBV ILMID of EPCIS ObjectEvent action= ADD w/ bizStep= commissioning or create_class_instance
Date food was landed				X				Event Date & Time in EPCIS Object Event of commissioning the food
Business Name of the Harvester	X		X					GLN + GLN Data Model attributes of harvesting company
Phone Number of the Harvester	X		X					GLN + GLN Data Model attributes of harvesting company
Reference Document Type(s)	X	X	X	X	X	X	X	
Reference Document Identifier(s)	X	X	X	X	X	X	X	

4.3 Product Description KDEs

As noted earlier, this guide illustrates how a GTIN in conjunction with standardized attributes describing the food can fulfill the product description KDEs of the Final Rule. The following is the definition of Product Description contained within the Final Rule:

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 [Reference link](#).

In the Final Rule, the FDA provided an example table of what the Product Description (called Traceability Product Description) KDEs could look like. It is recreated here for ease of review and comparison to applicable standards:

Table 5

GTIN or Other Product Identifier (Not a KDE required by Final Rule)	Brand Name	Commodity	Variety	Product Name	Packaging Size	Packaging Style
614141007349	Brand ABC	Tomatoes	Cherry	n/a	25 LB	Carton
183859303020	Brand ABC	n/a	n/a	Sprout Mix	4 oz	Clamshell
20614141004366	Brand 123	Tuna	Atlantic Bluefin	n/a	10 KG	Bin

GTIN or Other Product Identifier (Not a KDE required by Final Rule)	Brand Name	Commodity	Variety	Product Name	Packaging Size	Packaging Style
498265800732	Brand XYZ	N/A	N/A	Queso Fresco	12 x 8 Ounce	Vac Pack
5 1462872318 2	Brand 999	N/A	N/A	Small Vegetable Tray w/ dip	6 oz	Tray
7483945748383	Brand 111	N/A	N/A	Peanut Butter Sandwich Cracker	12 oz	Box

Reference link

When the FDA asks for records from a company subject to the rule, the product description KDEs could be defined by one of their trading partners. For example, a restaurant operator purchases many different foods from several different suppliers. The restaurant operator will receive descriptions of those foods from the suppliers instead of generating their own new product descriptions. However, if the FDA requests data from the restaurant operator, the FDA will still expect the operator to have quick access to the product description KDEs. This means trading partners will need to have a reliable method for exchanging the attributes which will fulfill the FDA's requirements around product descriptions.

Companies following GS1 Standards commonly turn to the Global Data Synchronization Network (GDSN) and the Global Data Model (GDM) to serve as this reliable data sharing method. The following sub-sections will illustrate mappings between the product description KDEs defined by the FDA in the Final Rule and attributes within those sharing standards. Unless otherwise noted, the attributes detailed in these sub-sections apply to both GDSN and GDM. This section is only intended to illustrate mappings between the Final Rule and attributes from applicable GS1 Standards. It is not intended to provide all the information necessary to implement these standards but can serve as a foundation for discussion between compliance teams and teams responsible for product information.

4.3.1 Brand Name

For the Brand Name KDE, this guidance recommends utilizing the `brandName` attribute. Details of the attribute:

- Definition from Attribute Definitions for Business (ADB): The name provided by the brand owner that is intended to be recognized by the consumer as represented on the product.
- Business Message Standard (BMS) ID: 3541
- Format: A free-form text string accommodating 1 to 105 characters

4.3.2 Commodity

For the *Commodity* KDE, this guidance recommends utilizing the `importClassificationTypeCode` and `importClassificationValue` attributes supplemented by the `functionalName` attribute. This set of attributes can be further augmented by the `gpcCategoryCode` which is an attribute for expressing the GS1 Global Product Classification (GPC) code value, a product classification scheme already required by GDSN and GDM.

4.3.2.1 `importClassificationTypeCode` and `importClassificationValue`

- Definition from Attribute Definitions for Business (ADB): The code that describes the customs classification system and the tariff value applied to a product associated with the Customs Classification Type Code.
- Business Message Standard (BMS) ID: 2776 & 2777
- Format: Code value and a free-form text string accommodating 1 to 70 characters

- Comment: This pair of attributes can be utilized for declaring the US Harmonized Tariff Schedule code value and accompanying description, which can be recognized as a helpful attribute for describing a food as a commodity.

4.3.2.2 functionalName

- Definition from Attribute Definitions for Business (ADB): The generic description provided by the seller to describe the type, form, or function of the product or service.
- Business Message Standard (BMS) ID: 3508
- Format: A free-form text string accommodating 1 to 35 characters
- Comment: this attribute is commonly used with fresh foods, like produce, to declare the product family name. Apples, Lemons, and Grapes are all examples of fruits.

4.3.3 Variety

For the *Variety* KDE, this guidance follows the Trade Item Implementation Guidance (TIIG) prescription to utilize the variantDescription attribute. Additionally, this guidance recommends using the context of the GPC Class and Family values as further context. Details of the variantDescription attribute:

- Definition from Trade Item Implementation Guidance (TIIG): In Fresh Foods, the attribute 'variant' will be used to express the particular variety of the product. Information providers may specify the distinguishing characteristics that differentiate similar products of the same type, brand, family, and functionality.
- Business Message Standard (BMS) ID: 3520
- Format: Code value & a free-form text string accommodating 1 to 500 characters
- Comment: Golden Delicious is a recognized variety of apples that are marketed in the United States and would populate the variantDescription attribute.

4.3.4 Product Name

For the *Product Name* KDE, this guidance recommends utilizing the tradeItemDescription attribute. Details of the tradeItemDescription attribute:

- Definition from Attribute Definitions for Business (ADB): An understandable and useable description of a product using a combination of key elements such as Brand Name, Sub-Brand (if applicable), Functional Name, Variant, and Net Content. The description should be unique and meaningful for the Retailers to manage the product through their business and describe the product to their consumers e.g., Brand, flavor, scent, etc.
- Business Message Standard (BMS) ID: 3517
- Format: Code value & a free-form text string accommodating 1 to 200 characters

4.3.5 Packaging Size

For the *Packaging Size* KDE, this guidance recommends utilizing the grossWeight and @measurementUnitCode pair of attributes supplemented by additional attributes. Details of the recommended pair and supplement attributes are listed here:

4.3.5.1 grossWeight and @measurementUnitCode – Recommended

- Definition from *Attribute Definitions for Business (ADB)*: The total weight of the product including the weight of all its packaging materials.
- Business Message Standard (BMS) ID: 3777 & 3778
- Format: A free-form text string accommodating 1 to 70 characters and code value

4.3.5.2 netContent and @measurementUnitCode – Supplement

- Definition from *Attribute Definitions for Business (ADB)*: The quantity (or quantities) of the product contained in the package along with its unit of measure typically printed on the label for the country or market where the product is sold.
- Business Message Standard (BMS) ID: 3733 & 3734
- Format: A free-form text string accommodating 1 to 70 characters and code value

4.3.5.3 netContentStatement – Supplement

- Definition from *Attribute Definitions for Business (ADB)*: The literal reproduction of the net content(s) as displayed on the product packaging.
- Business Message Standard (BMS) ID: 3741
- Format: a free-form text string accommodating 1 to 500 characters

4.3.5.4 netWeight and @measurementUnitCode – Supplement

- Definition from *Attribute Definitions for Business (ADB)*: The weight of the product excluding the weight of all its packaging materials.
- Business Message Standard (BMS) ID: 5470 & 5471
- Format: a free-form text string accommodating 1 to 70 characters and code value

4.3.6 Packaging Style

For the *Packaging Style* KDE, this guidance recommends utilizing the `packagingTypeCode` attribute supplemented by the `TradeItemUnitDescriptorCode` and `PackagingMaterialTypeCode` attributes. Details of the attributes are listed here:

4.3.6.1 packagingTypeCode – Recommended

- Definition from *Attribute Definitions for Business (ADB)*: The code for the type of package or container of the product.
- Business Message Standard (BMS) ID: 2186
- Format: code value

4.3.6.2 TradeItemUnitDescriptorCode – Supplement

- Definition from *Attribute Definitions for Business (ADB)*: The code that describes the product's packaging level.
- Business Message Standard (BMS) ID: 66
- Format: code value

4.4 Location Description KDEs

The *Location Description* KDEs of the Final Rule can be fulfilled through the use of a GLN to identify a physical location and accompanying standardized attributes describing the location. The following is the definition of Location Description contained within the Final Rule:

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), city, State, and zip code for domestic locations, and comparable information for foreign locations, including country. Reference link.

In the Final Rule, the FDA provided an example table of what the Location Description KDEs could look like. It is recreated here for ease of review and comparison to applicable standards:

Table 6

Data Attributes of <i>Location Description</i>	Examples of Each attribute
Business Name	Fin-to-Tail Processing Co.
Primary Phone Number	222.222.2222
Physical Location Street Address	456 Blue Water Way
City	Sarasota
State	FL
ZIP code	98765

Source: <https://www.federalregister.gov/d/2022-24417/p-837>

When the FDA asks for records from a company subject to the rule, the location description KDEs could be defined by one of their trading partners since the locations a product is being shipped to, received from, or the traceability lot code source will likely each be a different company for many CTEs recorded in the supply chain.

Exchanging data describing the physical locations between trading partners has been a routine part of business but utilizing a channel that follows a standard convention is still rather novel. The following sub-sections will illustrate mappings between the Location Description KDEs defined by the FDA in the Final Rule and attributes defined in the GS1 GLN Data Model Solution Standard. This section is only intended to illustrate mappings between the Final Rule and attributes from that GS1 Standard. It is not intended to provide all the information necessary to implement the standards but can serve as a foundation for discussion between compliance teams and teams responsible for location information.

4.4.1 Business Name

For the *Business Name* KDE, this guidance recommends utilizing the `gs1:organizationName` attribute. Details of the attribute:

- Definition from GLN Data Model: The default name of the organization expressed in text.
- Format: a language qualified, free-form string of text (`rdf:langString`)

The GLN data model also includes `gs1:organizationLegalName` and `gs1:organizationTradingName` as additional options for expressing the name used to recognize the business in varying circumstances. These may be appropriate attributes to use in conjunction with `gs1:organizationName`.

4.4.2 Physical Location Address

For the *Physical Location Address* KDE, this guidance recommends utilizing the `gs1:streetAddress` attribute. Details of the attribute:

- Definition from GLN Data Model: The street address expressed as free-form text. The street address is printed on paper as the first lines below the name. For example, the name of the street and the number in the street or the name of a building.
- Format: a language qualified, free-form string of text (`rdf:langString`)

The GLN data model includes four different attributes for exchanging different lines of a street address. The additional lines can be used in conjunction with the first. These attributes are a part of the `gs1:PostalAddress` class within the GLN Data Model.

4.4.2.1 GPS Coordinates – alternative

The definition for *Location Description* notes that the *Physical Location Address* can also be fulfilled by geographic coordinates. The GLN Data Model enables physical locations to express a single pair of coordinates (i.e., Latitude and Longitude) or a group of coordinates expressing the shape of a location. These can be expressed in place of the `gs1:PostalAddress` attributes or in conjunction.

4.4.3 City

For the *City* KDE, this guidance recommends utilizing the `gs1:addressLocality` attribute. Details of the attribute:

- Definition from GLN Data Model: Text specifying the name of the locality, for example, a city.
- Format: a language qualified, free-form string of text (`rdf:langString`)

The GLN data model includes additional attributes for expressing a suburb or county of the location (`gs1:addressSuburb` and `gs1:countyCode`). This level of detail is not explicitly mentioned by the Final Rule but might be relevant to some members if the expressing the city of their locations often requires further clarification. These attributes are a part of the `gs1:PostalAddress` class within the GLN Data Model.

4.4.4 State

For the *State* KDE, this guidance recommends utilizing the `gs1:addressRegion` attribute. Details of the attribute:

- Definition from GLN Data Model: Text specifying a province or state in abbreviated format, for example, NJ.
- Format: A language qualified, free-form string of text (`rdf:langString`)

This attribute is a part of the `gs1:PostalAddress` class within the GLN Data Model.

4.4.5 Zip Code

For the *Zip Code* KDE, this guidance recommends utilizing the `gs1:postalCode` attribute. Details of the attribute:

- Definition from GLN Data Model: Text specifying the postal code for an address.
- Format: a free-form string of text (`xsd:string`)

This attribute is a part of the `gs1:PostalAddress` class within the GLN Data Model.

4.4.6 Phone Number

For the *Phone Number* KDE, this guidance recommends utilizing the `gs1:telephone` attribute. Details of the attribute:

- Definition from GLN Data Model: A telephone number for example +44 217 992 9999.
- Format: a free-form string of text (`xsd:string`)

The `gs1:telephone` attribute is a part of the `gs1:ContactPoint` class within the GLN Data Model and can be expressed alone or with attributes to give more complete context about the phone number such as the department behind the phone number. The class also includes other means of contact such as email, fax, website, and social media. While this additional context and means of contact are not requirements of the Final Rule, they may be helpful additional context for companies.

4.4.7 Comparable Information for Locations Outside the US

The *Location Description* KDEs reflect the typical attributes that make up an address for a US based location. The definition for *Location Description* notes that comparable information is expected for non-US locations including the country. The GLN Data Model can accommodate the country of an address through the `gs1:addressCountry` attribute which accommodates a code value representing a country.

The GLN Data Model was developed through the Global Standards Management Process and is flexible for accommodating both US and non-US addresses when exchanging data between trading partners.

4.4.8 Harvester Business KDEs

The Business Name and Phone Number of the Harvester of a Raw Agricultural Commodity are required to be supplied to the initial packer. This is pair is a shorter set of KDEs than the Location Description but can also be fulfilled by using a GLN + GLN Data Model. A Harvester company, as a party, can be identified by a GLN and have its business name and phone number associated with it using the GLN Data Model. The same GLN Data Model Attributes mapped to the Business Name and Phone Number of the Location Description can be utilized for these two KDEs of the Harvester. Consult the mappings above for the specific KDEs.

4.4.9 Growing Areas Coordinates

The Final Rule includes requirements for farms to keep a record of fields, growing areas, or aquaculture containers as a part of their Traceability Plan. For a farm that grows or raises a food on the FTL (other than eggs), this means including a map of the areas where the good is grown or raised.

- The farm map needs to include the name, coordinates, and any other information used to identify each field, growing area, etc.
- For aquaculture farms, the expectation for the farm maps is similar to the non-aquaculture farms but specifically mentions containers (e.g., pond, pool, tank, cage) instead of fields.

Each of these locations could also be identified by a GLN and have descriptive KDEs recorded as attributes from the GLN Data Model. Attributes noted above, as a part of the Location Description KDEs, could also be utilized here with special attention on the GPS coordinates than can be used for Physical Location Address.

4.5 Shipping CTE and the Advance Ship Notice (ASN)

The FDA's requirements for the Shipping CTE maintain the need to have a reliable conduit for exchanging the attributes which will fulfill the FDA's requirements around shipping information.

Companies following GS1 Standards commonly turn to an existing transaction dataset, the Advance Ship Notice (ASN) to serve this requirement. The following sub-sections will illustrate mappings between the product KDEs defined by the FDA in the Final Rule and attributes within this EDI sharing standard. This section is only intended to illustrate mappings between the Final Rule and attributes from applicable GS1 Standards. It is not intended to provide all of the information necessary to implement these standards but can serve as a foundation for discussion between compliance teams and teams responsible for shipping information.

In July 2020, GS1 US published a new release of the 856 Ship Notice/Manifest – Foodservice guideline for v7050 of the Uniform Communication Standard (UCS). An 856 Ship Notice/Manifest (frequently referred to as Advance Ship Notice (ASN)) is an EDI transaction from a party shipping goods to notify the receiver that a shipment will be forthcoming. This transaction is commonly used in the U.S. food industry. The data in the examples below compare the Final Rule Shipping CTE and the data in the Advance Ship Notice (ASN).

4.5.1 GTIN (not required by the Final Rule) and Traceability Lot Code

The *Shipping* CTE requires a handful of KDEs to be linked to the *Traceability Lot* and for this lot to be recorded as the *Traceability Lot Code*. For the *Traceability Lot Code* KDE, this guidance recommends recording both the GTIN and the batch/lot number of the food.

Within the Pack Hierarchical Level, a "LIN" segment can express a GTIN followed by a lot number with the following data format:

- Code Value of "UK" indicating "GTIN-14"; "UP" for "GTIN-12", as well
- Identifier: free-form field of up to 80 characters
- Code Value of "LT" indicating "Lot Number"
- Identifier: free-form field of up to 80 characters

*Example: LIN*01*UK*10614141000002*LT*ABCDE12345~*

This pack is identified by a GTIN-14 (10614141000002) and lot # ABCDE12345

4.5.2 Quantity and Unit of Measure of the Food

For the *Quantity and Unit of Measure* KDEs, this guidance recommends utilizing an SN1 - Item Detail (Shipment) segment within the Pack Hierarchical Level

Within the Pack Hierarchical Level, an "SN1" segment can express a numeric quantity of the item followed by a unit of measure:

- Number of units: numeric value up to 10 characters
- Code Value of primary Unit of Measure for the product (e.g., Case, Net Kilograms, Pound, Pounds Gross)

*Example: SN1*25*CA~*

This pack has 25 cases

4.5.3 Product Description of the Food

By utilizing the GTIN as a part of the *Traceability Lot Code* KDE, companies can link to the other mechanisms they are already utilizing for exchanging attributes with trading partners which describe food products. The GTIN can act as the bridge between the two different data sets when pulling data together for an FDA request under the Final Rule.

4.5.4 Location Description of Immediate Subsequent Recipient (other than Transporter)

For the *Location Description of Immediate Subsequent Recipient* KDE, this guidance recommends recording a GLN of the Ship-To location. This GLN can then link to the attributes exchanged following the GLN Data Model which fulfills the *Location Description* KDEs requirement. In an ASN, this is expressed as an N1 – Party Identification segment.

Within the Shipment Hierarchical Level, an "N1" segment expresses a GLN preceded by three other descriptive fields in the following data format:

- Code Value of "ST" indicating the "Ship To"
- Name: 1 to 60 characters, alpha-numeric
- Code Value of "UL" indicating the following identifier is a GLN
- Identifier: field for the GLN of the "Ship To"

*Example: N1*ST*Ewing DC*UL*0840002011112~*

This was shipped to Ewing DC (GLN=0840002011112)

4.5.5 Location Description for the Location From Which You Shipped the Food

For the *Location Description for the Location From Which You Shipped the Food* KDE, this guidance recommends recording a GLN of the Ship-From location. Like with the previous KDE, this GLN can then link to the attributes exchanged following the GLN Data Model which fulfills the *Location Description* KDEs requirement. In an ASN, this is expressed as an N1 – Party Identification segment. This segment can be expressed more than once within a hierarchical level which enables both a Ship-to and Ship-from to be expressed.

Within the Shipment Hierarchical Level, an "N1" segment expresses a GLN preceded by three other descriptive fields in the following data format:

- Code Value of "SF" indicating the "Ship From"

- Name: 1 to 60 characters, alpha-numeric
- Code Value of "UL" indicating the following identifier is a GLN
- Identifier: field for the GLN of the "Ship From"

*Example: N1*SF*GS1 US*UL*0614141000005~*

This was shipped from GS1 US (GLN=0614141000005)

4.5.6 Date the Food Was Shipped

For the *Date the Food Was Shipped* KDE, this guidance recommends recording a date in the DTM – Date/Time Reference segment. The Final Rule only requires the date that food was shipped within this CTE, however, companies can express time within this segment if necessary.

Within the Shipment Hierarchical Level, a "DTM" segment expresses a qualifier for the nature of the date and the actual date. Here is the format:

- Code Value of "011" indicating what follows is a "Shipped" date
- Date: format of CCMYYDD; CC is the first two digits of the calendar year

*Example: DTM*011*20220818~*

Shipment departed on August 18, 2022

4.5.7 Location Description for the Traceability Lot Code Source or the Traceability Lot Code Source Reference

When a company ships a food from the FTL, they are expected to not only record the places it ships from and is received but also the Traceability Lot Code Source. Here is the definition from the Final Rule:

Traceability lot code source means the place where a food was assigned a traceability lot code. [Reference link.](#)

For the *Traceability Lot Code Source* KDE, this guide will illustrate how a GLN can be recorded alongside each TLC expressed within an ASN. Like with the previous KDE, this GLN can then link to the attributes exchanged following the GLN Data Model which fulfills the *Location Description* KDEs requirement.

Like the Shipping Location and Immediate Subsequent Recipient location KDEs above, this KDE can utilize the N1 – Party Identification segment. Unlike those other KDEs, this "N1" segment is expressed within the Pack Hierarchical Level to distinguish that it only applies to the items in that instance of the hierarchical level instead of to the shipment, overall.

This "N1" segment expresses a GLN preceded by three other descriptive fields in the following data format:

- Code Value of "MP" indicating "Manufacturing Plant"; OR "16" for "Plant"
- Name: 1 to 60 characters, alpha-numeric
- Code Value of "UL" indicating the following identifier is a GLN
- Identifier: field for the GLN of the "Manufacturing Plant"

*N1*MP*Plant 4 - Harvest Salad Co.*UL*0812345002119~*

Pack made at Plant 4 of Harvest Salad Co. (GLN=0812345002119)

4.5.7.1 The Traceability Lot Code Source Reference

In response to the proposed rule, the FDA received comments expressing concern that passing forward a TLC Source would expose commercially sensitive information. In the Final Rule, the FDA proposed an alternative method for providing access to the FDA with the Location Description of the TLC Source. That is named the Traceability Lot Code Source Reference and here is the definition from the Final Rule:

Traceability lot code source reference means an alternative method for providing the 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.

Based on this definition, it may be sufficient to provide a GLN identifying the TLC Source if the FDA has means of determining where to get the Location Description KDEs. This may be sufficient for companies looking to limit the exposure of commercially sensitive information.

The definition also mentions utilizing a web address for enabling the look up of the Location Description for the TLC source. This could be enabled through the use of GS1 Digital Link URI syntax. More on this opportunity is described later in this document.

4.5.8 Shipment Reference Document Type

For the *Shipment Reference Document Type* KDE, this guidance recommends utilizing the ST – Transaction Set Header which is a mandatory component of the EDI document and identifies the document that follows as an ASN.

The “ST” contains these elements in the following data format:

- Code Value of “856” indicating “Ship Notice/Manifest”
- Transaction Set Control Number: 4 to 9 characters, alpha-numeric

*Example: ST*856*0001~*

This EDI document is an 856 and the first of the functional group

4.5.9 Shipment Reference Document Identifier

For the *Shipment Reference Document Identifier* KDE, this guidance recommends utilizing the BSN – Beginning Segment for Ship Notice which is a mandatory component of the ASN.

The “BSN” contains these elements in the following data format:

- Code Value of “00” indicating “Original”
- Identifier: 2 to 30 characters, alpha-numeric
- Date: format of CCMYYDD; CC is the first two digits of the calendar year
- Time: format of HHMM, HHMMSS, HHMMSSD, or HHMMSSDD; (24-hr)
- Code Value of “0008” indicating ASN has Shipment/Order/Tare/Pack

*Example: BSN*00*SI39383092*20220818*0600*0008~*

1st submission of shipment #SI39383092 on Aug 18, 2022, at 6 am, contains Shipment/Order/Tare/Pack hierarchical levels are used

4.6 Other CTEs and Mappings to GS1 Standards

The following sub-sections focus on the remaining CTEs defined within the Final Rule. The previous sections were emphasized first because trading partners will need to exchange data with each other to meet the requirements of the Final Rule. With a couple of exceptions, this is not the requirement for the remaining CTEs.

Even though a requirement for data sharing with trading partners is not present, mappings to GS1 Standards are provided below to illustrate how to use those structures as a vision for enhanced Supply Chain Visibility with robust record keeping. These mappings will focus on the use of EPCIS since it is a natural way of modeling CTEs and KDEs. Often, the data exchanged via EPCIS is described as Physical Event Data to distinguish it from other data sharing channels.

EPCIS has an accompanying standard, the Core Business Vocabulary (CBV), which defines the vocabularies that can populate EPCIS events. At the time of publishing this guideline, uptake of EPCIS is still early within the US food industry. These mappings are simply a vision for how data structures can be applied to the Final Rule. This section is not intended to provide all of the information necessary for implementing EPCIS, just mappings to the key fields. Each remaining CTE will have its own sub-section below with the required KDEs.

4.6.1 Receiving CTE

4.6.1.1 GTIN (not required by the Final Rule) and Traceability Lot Code

Like the *Shipping* CTE, the *Receiving* CTE requires a handful of KDEs to be linked to the *Traceability Lot* and for this lot to be recorded as the *Traceability Lot Code*. For the *Traceability Lot Code* KDE, this guidance recommends recording both the GTIN and the Batch/Lot number of the food.

The `epcClass` field of an EPCIS event can record a GTIN + Lot Number.

4.6.1.2 Quantity and Unit of Measure of the Food

For the *Quantity and Unit of Measure* KDEs, this guidance recommends utilizing the quantity and Unit of measure, expressed as “uom”, fields of an EPCIS event. Quantity can accept a numeric value for the amount of food products identified by the value in the `epcClass`. The `uom` field is used for expressing a code value of standard units of measure to qualify the amount expressed in the quantity field.

4.6.1.3 Product Description of the Food

By utilizing the GTIN as a part of the *Traceability Lot Code* KDE, companies can link to the other channels they are already utilizing for exchanging attributes with trading partners which describe food products. The GTIN can act as the bridge between the two different data sets when pulling together for an FDA request under the Final Rule.

4.6.1.4 Location Description for the Immediate Previous Source (other than a transporter)

For the *Location Description for the Immediate Previous Source* CTE, this guidance recommends recording a GLN within the EPCIS event to represent this location. This GLN can then link to the attributes exchanged following the GLN Data Model which fulfills the *Location Description* KDEs requirement. In EPCIS, this GLN would be recorded in the `source` field with a type declaring that it is a location versus a party.

4.6.1.5 Location Description for Where the Food Was Received

For the *Location Description of Where the Food Was Received* CTE, this guidance recommends recording a GLN within the EPCIS event to represent this location. This GLN can then link to the attributes exchanged following the GLN Data Model which fulfills the *Location Description* KDEs requirement. In EPCIS, this GLN would be recorded in the `bizLocation` field of the event. The `bizLocation` field represents where the objects are as a result of the event. In the case of the receiving CTE, this is where the objects are after unloading from transport. A GLN is expressed in a URI format within the `bizLocation` field.

4.6.1.6 Date the Food was Received

For the *Date the Food was Received* CTE, this guidance recommends utilizing the `eventTime` and `eventTimeZoneOffset` fields within an EPCIS event. The Final Rule only requires a date but

sequencing events appropriately is a key part of EPCIS, so time is recorded in conjunction with the date.

4.6.1.7 Location Description for the Traceability Lot Code Source or the Traceability Lot Code Source Reference

With EPCIS, the location where a lot code was assigned would be recorded in a separate event. If a downstream company was interested in this information, they could query to request that event. The location would be identified with a GLN and the Location Description KDEs could be linked through that GLN.

4.6.1.8 Reference Document Type and Reference Document Number

The bizTransaction list within an EPCIS event enables declaring different business transactions that are relevant context for the event. This could be a document such as a Bill of Lading or Receiving Advice. This guidance recommends using these fields to express the document number and its type.

4.6.2 Additional CTEs and Mappings to GS1 Standards

Reference [Appendix A – Additional CTEs and Mappings to GS1 Standards](#) for information on the remaining CTEs: Transformation, Harvest, Cooling, Initial Packing and First Land-Based Receiver.

5 Best Practices for Mixed Pallets

Shipping and receiving homogenous pallets with the same product GTIN and lots is the simplest form of a logistics unit. However, supply chain partners frequently break homogeneous pallets to create either a new pallet with mixed products, a new pallet with the same product from different lots, or different GTINs and lots within the same pallet.

The Serial Shipping Container Code (SSCC) is a GS1 identifier that can be used to identify a logistic unit. This unique identifier is comprised of an Extension Digit, a GS1 Company Prefix, a Serial Reference, and a Check Digit. A logistic unit can be any combination of units put together in a case or on a pallet or truck where the specific unit load needs to be managed throughout the supply chain. The SSCC enables this unit to be tracked individually, which brings benefits for order and delivery tracking and automated goods receiving.

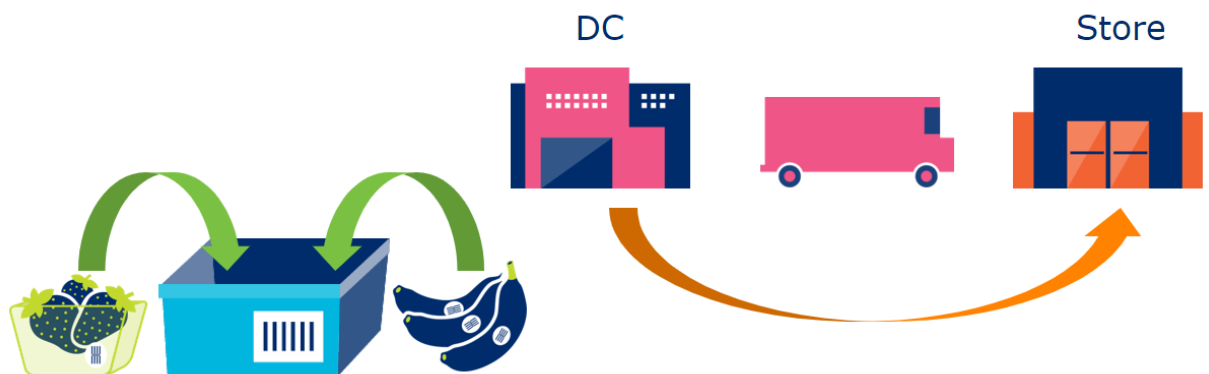
Because the SSCC provides a unique number for the delivery, it can be used as a lookup number to provide not only detailed information regarding the contents of the load but can also be linked to the additional information in a pre-received ASN. Some entities will use the SSCC at the pallet level in conjunction with an ASN. This provides the greatest benefit, as it allows for visibility with CTEs along the supply chain.

Below illustrates the different types of configurations that can be created and shipped as a logistics unit on a pallet.

- Same Trade Items: all units on the pallet are of the same GTIN and lot number
- Mixed Trade Items: the units on the pallet are of different GTINs
- Mixed Trade Items and Lots: the units on the pallet are of different GTINs along with different lots for the same GTIN.

Figure 21

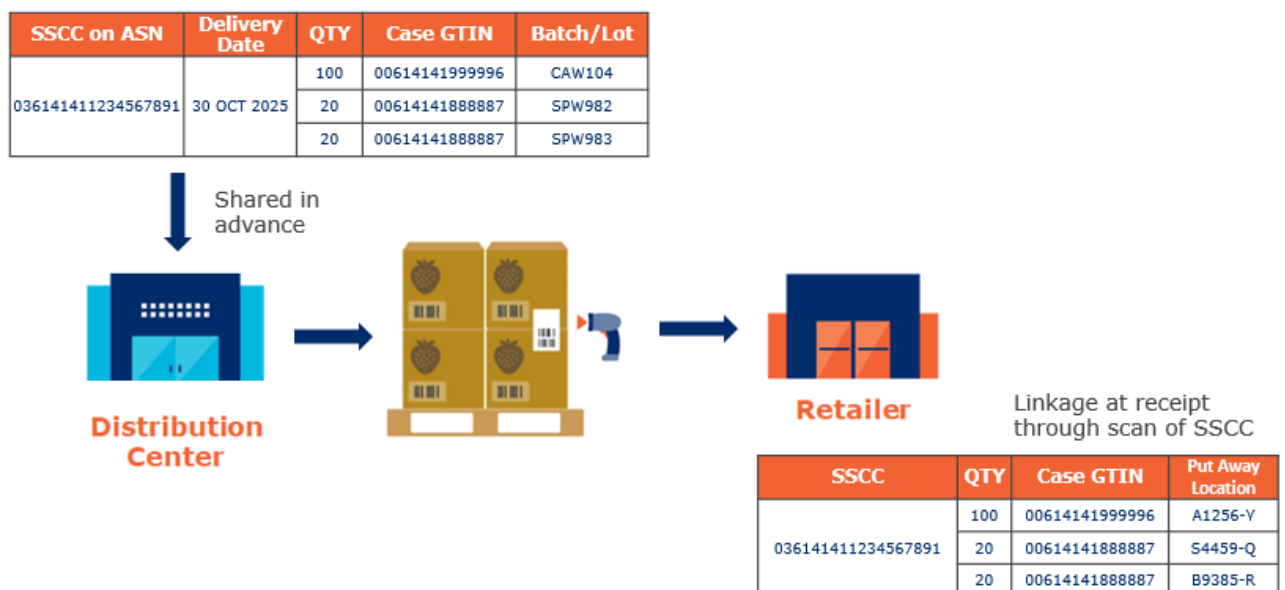

In addition to the examples above, break packs need also be addressed; when a case is broken down (reducing the GTINs in the case or on the pallet) or when different items are placed in totes and shipped to a store.

Figure 22


The SSCC is a unique identifier for a pallet that is encoded in GS1-128 barcodes and printed on the pallet label. It can aid in linking to the data in the ASN to determine the details of the logistics unit. Note the illustration below.

Figure 23


The EDI ASN can be sent in advance of the shipment to trading partners, communicating exactly how many GTINs, lots, etc. are on a given pallet (a logistics unit). The receiver can scan the SSCC barcode and can capture all the information needed to identify what is on the pallet by linking to the information previously stored from the ASN.

Figure 24


The use of SSCCs on the logistics unit label in a GS1-128 barcode and the information in a corresponding ASN can be used to help comply with the Final Rule.

Figure 25


Source: [Food Industry Guidance for Streamlining Your Logistics Labels](#)

The pallet has the SSCC barcode on a label, which can be linked to an ASN where the SSCC is shared in the MAN and the GTINs and lots in the LIN, as illustrated below.

Because the SSCC provides a unique number for the delivery, it can be used as a lookup number to provide not only detailed information regarding the contents of the load but can also be linked to the additional information in a pre-received Advance Ship Notice (ASN). Some entities will use the SSCC at the pallet level and using this in conjunction with an ASN provides the greatest benefit, as it allows for visibility with (CTEs along the supply chain).

SSCCs identify logistics units (pallets, shipping containers, etc.). They act as a license plate for a specific shipment. When used in conjunction with an ASN, the SSCC will identify the contents of that shipping unit. Because it identifies shipment contents, the SSCC is only relevant from the time of shipment to the time of receipt. Once the logistics unit (pallet, shipping container, etc.) is received, the SSCC is no longer of any value (except if the recipient is storing the SSCC in their system and need to trace which items were included in a specific SSCC, i.e., re-tracing in the event of cross-contamination of products).

6 Appendix A - Additional CTEs and Mappings to GS1 EPCIS Standards

6.1 Transformation CTE

For FTL food(s) used as ingredient(s)

KDEs must be linked to the new traceability lot for the food

KDE1 - Traceability lot code for the food EPCIS Field: epcClass

Format: EPC URI of a GTIN + Lot Number; additional encoding exists

<epcClass>urn:epc:class:lgtn:08400020.10000.7029WW1827</epcClass>

KDE2 - Product description for the food to which the traceability lot code applies

This is data exchanged at different intervals and often called master data; can be accessed by using GTIN as the identifier.

KDE3 - For each traceability lot used, the quantity and unit of measure of the food used from that lot

EPCIS Field: quantity & uom

Format: xsd:double & Code Value

<quantity>10</quantity>

<uom>LBR</uom>

New food produced

KDEs must be linked to the new traceability lot for the food

KDE1 - New traceability lot code for the food

EPCIS Field: epcClass

Format: EPC URI of a GTIN + Lot Number; additional encoding exists

<epcClass>urn:epc:class:lgtn:08400020.10000.7029WW1827</epcClass>

KDE2 - Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference This data is

exchanged at different intervals and often called master data; can be accessed by using GLN as the identifier.

KDE3 - Date transformation was completed

EPCIS Field: cbvmmda:transformedStartDate & cbvmmda:transformedEndDate in ILMD

Format: xsd:date (Numerals in the form of YYYY-MM-DD)

<cbvmmda:transformedStartDate>2022-08-15</cbvmmda:itemExpirationDate>

<cbvmmda:transformedEndDate>2022-08-31</cbvmmda:sellByDate>

KDE4 - Product description for the food

This is data exchanged at different intervals and often called master data; can be accessed by using GTIN as the identifier.

KDE5 - Quantity and unit of measure of the food

EPCIS Field: quantity & uom

Format: xsd:double & Code Value

<quantity>10</quantity>

<uom>LBR</uom>

KDE6 - Reference document type and reference document number

EPCIS Field: bizTransaction ('type' attribute & element contents)

Format: Code Value & EPC URI of an identifier of a business transaction preceded by a GLN of the organization responsible for the transaction

<bizTransaction type="urn:epcglobal:cbv:btt:recadv">

urn:epcglobal:cbv:bt:0812345002003:861-100037169

</bizTransaction>

6.2 Harvest CTE

Harvesting KDEs (Raw agricultural commodities (RACs) not obtained from a fishing vessel)

KDE1 - Location description for the immediate subsequent recipient (other than a transporter) of the food

This data is exchanged at different intervals and is often called master data; can be accessed by using GLN as an identifier.

KDE2 - Commodity and, if applicable, variety of the food Commodity

For the *Commodity* KDE, this guidance recommends utilizing the `importClassificationTypeCode` and `importClassificationValue` attributes supplemented by the `functionalName` attribute. This set of attributes can be further augmented by the `gpcCategoryCode` which is an attribute for expressing the GS1 Global Product Classification (GPC) code value, a product classification scheme already required by GDSN and GDM.

KDE3 - Quantity and unit of measure of the food

EPCIS Field: quantity & uom

Format: xsd:double & Code Value

<quantity>10</quantity>

<uom>LBR</uom>

KDE4 - Location description for the farm where the food was harvested

For produce: - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or - Other information identifying the harvest location at least as precisely as field or growing area name

This data is exchanged at different intervals and is often called master data; can be accessed by using GLN as identifier.

For aquacultured food: - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or - Other information identifying the harvest location at least as precisely as the container name

This data is exchanged at different intervals and often called master data; can be accessed by using GLN as identifier.

KDE5 - Date of harvesting

EPCIS Field: cbvmdata:harvestStartDate & cbvmdata:harvestEndDate in ILMD

Format: xsd:date (Numerals in the form of YYYY-MM-DD)

<cbvmdata:harvestStartDate>2022-08-15</cbvmdata:itemExpirationDate>

<cbvmdata:harvestEndDate>2022-08-31</cbvmdata:sellByDate>

KDE6 - Reference document type and reference document number

EPCIS Field: bizTransaction ('type' attribute & element contents)

Format: Code Value & EPC URI of an identifier of a business transaction preceded by a GLN of the organization responsible for the transaction

<bizTransaction type="urn:epcglobal:cbv:bt:recadv">

urn:epcglobal:cbv:bt:0812345002003:861-100037169

</bizTransaction>

6.3 Cooling CTE

Cooling KDEs (RACs not obtained from a fishing vessel)

KDE1 - Location description for the immediate subsequent recipient (other than a transporter) of the food

This data is exchanged at different intervals and often called master data; can be accessed by using GLN as the identifier.

KDE2 - Commodity and, if applicable, variety of the food

For the *Commodity* KDE, this guidance recommends utilizing the `importClassificationTypeCode` and `importClassificationValue` attributes supplemented by the `functionalName` attribute. This set of attributes can be further augmented by the `gpcCategoryCode` which is an attribute for expressing the GS1 Global Product Classification (GPC) code value, a product classification scheme already required by GDSN and GDM.

KDE3 - Quantity and unit of measure of the food

EPCIS Field: quantity & uom

Format: xsd:double & Code Value

<quantity>10</quantity>

<uom>LBR</uom>

KDE4 - Location description for where you cooled the food

This data is exchanged at different intervals and often called master data; can be identified by using GLN as the identifier.

EPCIS Field: cbvmdata:coolerIdentification in ILMD

Format: EPC URI of a GLN + an Optional Extension Component; additional encoding exists

<cbvmdata:CoolerList>

<cbvmdata:cooler>

<cbvmdata:coolerIdentification>urn:epc:id:sgln:0614141.00001.0</cbvmdata:coolerIdentification>

<cbvmdata:coolerIdentificationTypeCode>EPC-GLN</cbvmdata:coolerIdentificationTypeCode>

</cbvmdata:cooler>

```
</cbvmdata:coolerList>
```

KDE5 - Date of cooling

EPCIS Field: cbvmdata:coolingStartDate & cbvmdata:coolingEndDate in ILM

Format: xsd:date (Numerals in the form of YYYY-MM-DD)

```
<cbvmdata:coolingStartDate>2022-08-15</cbvmdata:itemExpirationDate>
```

```
<cbvmdata:coolingEndDate>2022-08-31</cbvmdata:sellByDate>
```

KDE6 - Location description for the farm where the food was harvested

This data is exchanged at different intervals and often called master data; can be accessed by using GLN as the identifier.

EPCIS Field: cbvmdata:farmIdentification in ILM

Format: EPC URI of a GLN + an Optional Extension Component; additional encoding exists

```
<cbvmdata:farmList>
```

```
<cbvmdata:farm>
```

```
<cbvmdata:farmIdentification>urn:epc:id:sgln:0614141.00001.0</cbvmdata:farmIdentification>
```

```
<cbvmdata:farmIdentificationTypeCode>EPC-GLN</cbvmdata:farmIdentificationTypeCode>
```

```
</cbvmdata:farm>
```

```
</cbvmdata:farmList>
```

KDE7 - Reference document type and reference document number

EPCIS Field: bizTransaction ('type' attribute & element contents)

Format: Code Value & EPC URI of an identifier of a business transaction preceded by a GLN of the organization responsible for the transaction

```
<bizTransaction type="urn:epcglobal:cbv:btt:recadv">
```

```
urn:epcglobal:cbv:bt:0812345002003:861-100037169
```

```
</bizTransaction>
```

6.4 Initial Packing CTE

Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel) KDEs must be linked to the traceability lot you assign for the food that you pack

KDE1 - Commodity and, if applicable, variety of the food received

For the *Commodity* KDE, this guidance recommends utilizing the importClassificationTypeCode and importClassificationValue attributes supplemented by the functionalName attribute. This set of attributes can be further augmented by the gpcCategoryCode which is an attribute for expressing the GS1 Global Product Classification (GPC) code value, a product classification scheme already required by GDSN and GDM.

KDE2 - Date you received the food

EPCIS Field: eventTime and eventTimeZoneOffset

Format: xsd:dateTimeStamp & xsd:string

following this form: +/-00:00

```
<eventTime>2022-09-08T20:45:00.000-04:00</eventTime>
```

```
<eventTimeZoneOffset>-04:00</eventTimeZoneOffset>
```

KDE3 - Quantity and unit of measure of the food received

EPCIS Field: quantity & uom

Format: xsd:double & Code Value

```
<quantity>10</quantity>
```

```
<uom>LBR</uom>
```

KDE4 - Location description for the farm where the food was harvested

- For produce: - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or - Other information identifying the harvest location at least as precisely as field or growing area name

This data is exchanged at different intervals and is often called master data – can be accessed by using GLN as the identifier.

- For aquacultured food: - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or - Other information identifying the harvest location at least as precisely as the container name

This data is exchanged at different intervals and is often called master data; can be accessed by using GLN as the identifier.

6.5 First Land-Based Receiver CTE

First Land-Based Receiver KDEs (food obtained from a fishing vessel) KDEs must be linked to the traceability lot for the food

KDE1 - Traceability lot code assigned

EPCIS Field: epcClass

Format: EPC URI of a GTIN + Lot Number; additional encoding exists

<epcClass>urn:epc:class:lgtin:08400020.10000.7029WW1827</epcClass>

KDE2 - Species and/or acceptable market name for unpackaged food, or the product description for packaged food

This is data exchanged at different intervals and is often called master data; can be accessed by using GTIN as the identifier.

KDE3 - Quantity and unit of measure of the food

EPCIS Field: quantity & uom

Format: xsd:double & Code Value

<quantity>10</quantity>

<uom>LBR</uom>

KDE4 - Harvest date range and locations for the trip during which the food was caught

EPCIS Field: cbvmdata:harvestStartDate & cbvmdata:harvestEndDate in ILMD

Format: xsd:date (Numerals in the form of YYYY-MM-DD)

<cbvmdata:harvestStartDate>2022-08-15</cbvmdata:itemExpirationDate>

<cbvmdata:harvestEndDate>2022-08-31</cbvmdata:sellByDate>

KDE5 - Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference

This data is exchanged at different intervals and often called master data; can be accessed by using GLN as the identifier.

KDE6 - Date the food was landed

EPCIS Field: cbvmdata:landedStartDate & cbvmdata:landedEndDate in ILMD

Format: xsd:date (Numerals in the form of YYYY-MM-DD)

<cbvmdata:landedStartDate>2022-08-15</cbvmdata:itemExpirationDate>

<cbvmdata:landedEndDate>2022-08-31</cbvmdata:sellByDate>

KDE7 - Reference document type and reference document number

EPCIS Field: bizTransaction ('type' attribute & element contents)

Format: Code Value & EPC URI of an identifier of a business transaction preceded by a GLN of the organization responsible for the transaction

<bizTransaction type="urn:epcglobal:cbv:btt:recadv">

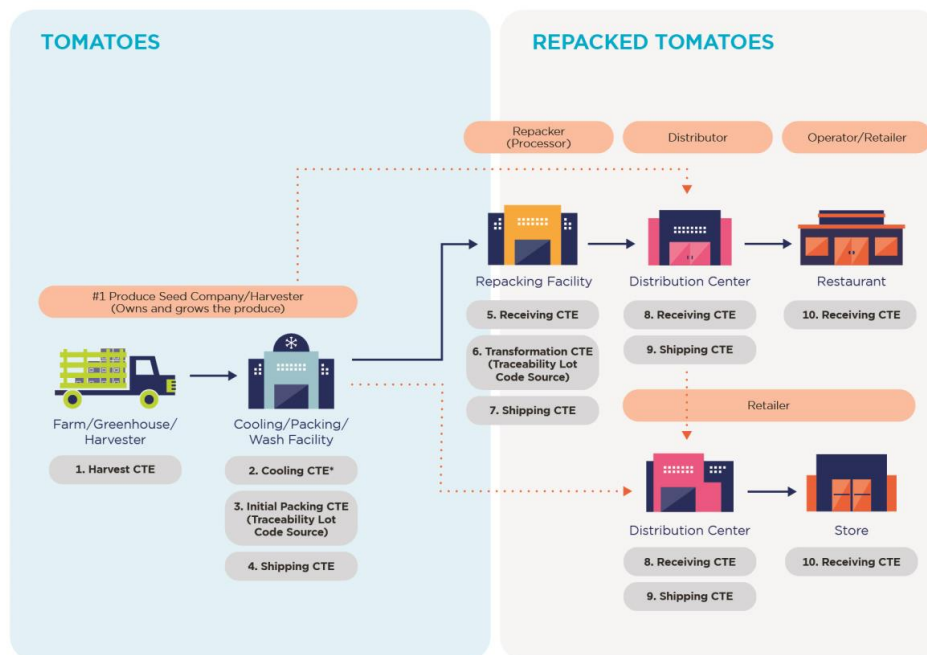
urn:epcglobal:cbv:bt:0812345002003:861-100037169

</bizTransaction>

7 Appendix B – Detailed Steps for Supply Chain Process Flows

7.1 Whole Tomatoes Detailed Process Steps

The whole tomato end-to-end traceability process below depicts 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.



*The rule states: "For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed..." - [Link](#)

1. Produce is picked in the field of Produce Seed Company/Harvester and placed into totes - Harvest CTE
 - a. Produce totes can be comingled with similar items from other farms and lot/batch numbers should be assigned
 - b. Produce undergoes sorting/grading and is placed into additional totes
 - c. GTIN is assigned to produce
 - d. GLN identifies Farm/Greenhouse (harvest location)
 - e. Produce totes are taken to a Packing House owned by the farm
 - f. GLN identifies Packing House
2. Produce undergoes cooling/washing at Packing House – Cooling CTE
 - a. Packing House tests produce for freshness/disease and rinse/washes produce
3. Produce is sorted/graded and placed into cases ** – Initial Packing CTE
 - a. GTIN and TLC are assigned and can be encoded in a data carrier
 - b. Packing House is identified as the TLC Source with a GLN

4. Produce is packed for transport in cases and/or pallets and shipped to Re-packer (Processor) – Shipping CTE
 - a. GLN identifies Re-Packing Facility
 - b. Produce GTIN + TLC (assigned in step 3) quantities are recorded
 - c. SSCC can be assigned and encoded in a data carrier if pallets are created
5. Produce is received at Re-packer (Processor) – Receiving CTE
 - a. GLN identifies Re-packing Facility
 - b. Produce GTINs + TLC (assigned in step 3) quantities are captured and recorded
6. Produce could be trimmed/repackaged at Re-packer/Processor – Transformation CTE
 - a. New GTIN + TLC is assigned if cases are repackaged/processed
7. Produce is packed for transport to Distributor – Shipping CTE
 - a. GLN identifies Distribution Center
 - b. Produce GTIN + TLC (assigned in step 6) quantities are recorded
 - c. SSCCs can be assigned and encoded in a data carrier if new pallets are created
8. Produce is received at Distribution Center – Receiving CTE
 - a. GLN identifies Distribution Center
 - b. GTINs + TLC (assigned in step 6) quantities are captured and recorded
9. Distribution Center picks cases to create a shipment to Restaurant/Store – Shipping CTE
 - a. GLN identifies Restaurant/Store
 - b. Produce GTINs + TLC (assigned in step 6) quantities are captured/recorded
 - c. SSCCs can be assigned and encoded in a data carrier for new pallets
10. Produce is received by Restaurant/Store – Receiving CTE
 - a. GLN identifies Restaurant/Store
 - b. Produce GTINs + TLC (assigned in step 6) quantities are captured/recorded

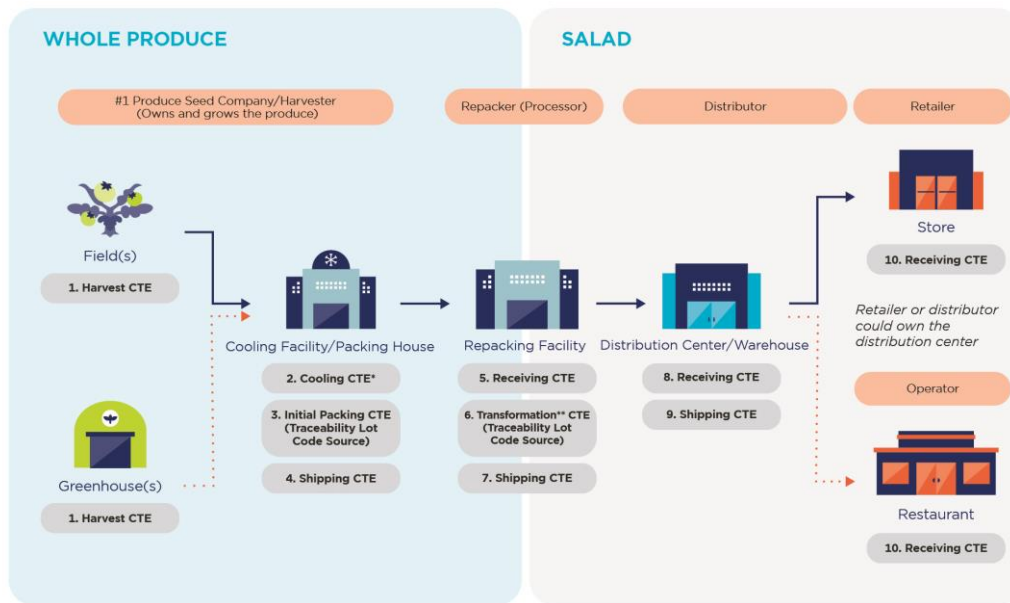
*Note: For retailers, there could be a retailer-owned distribution center prior to the final destination

**Note: Produce can be packed in cases, totes, bins, or any other container throughout the supply chain.

7.2 Ready to Eat Salad Detailed Process Steps

The Ready to eat salad (or diced tomato) end-to-end traceability process below depicts produce being harvested from more than one facility. The produce is placed into totes and sent to a cooling facility/packing house where produce may be sorted/graded and shrink-packed into cases for cooling; with initial packing, traceability lot codes are assigned. 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 shipped to a distribution center and then to retail outlets or restaurants.

The Ready to eat salad (or diced tomato) end-to-end traceability process below depicts produce being harvested from more than one facility. The produce is placed into totes and sent to a cooling facility/packing house where produce may be sorted/graded and shrink-packed into cases for cooling; with initial packing, traceability lot codes are assigned. 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 shipped to a distribution center and then to retail outlets or restaurants.



**Transformation could occur over 1 or more steps

*The rule states: "For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed..." - [Link](#)

1. Produce is picked in the Field or from Greenhouse and placed into totes - Harvest CTE
 - a. Produce totes can be comingled with similar items from other Fields/Greenhouses and lot/batch numbers should be assigned
 - b. Produce undergoes sorting/grading and is placed into totes
 - c. GTIN is assigned to produce
 - d. GLN identifies Field/Greenhouse (harvest location)
 - e. Produce totes are taken to Cooling Facility/Packing House owned by Farm/Greenhouse
 - f. GLN identifies Cooling Facility/Packing House
2. Produce undergoes cooling/washing – Cooling CTE
 - a. Packing house tests produce for freshness/disease and rinse/washes produce
3. Produce is sorted/graded and placed into cases – Initial Packing CTE
 - a. GTIN and TLC are assigned and encoded in a data carrier
 - b. Packing House is identified as the TLC Source with a GLN
4. Produce is packed for transport in cases and/or pallets and shipped to Re-packer (Processor) – Shipping CTE
 - a. GLN identifies Re-packer (Processor)
 - b. Produce GTIN + TLC (assigned in step 3) quantities are recorded
 - c. SSCC can be assigned and is encoded in a data carrier if pallets are created
5. Produce is received at Re-packer (Processor) – Receiving CTE
 - a. GLN identifies Re-packing Facility
 - b. Produce GTINs + TLC (assigned in step 3) quantities are captured

6. Produce is combined to make Ready-to-Eat Salad at Re-packer (Processor) – Transformation CTE
 - a. New GTIN + TLC is assigned when Read-to-Eat Salad are created
 - b. Re-packer (Processor) is identified as the TLC source with a GLN
7. Ready-to-Eat Salad is packed for transport and shipped to Distributor – Shipping CTE
 - a. GLN identifies Distribution Center/Warehouse
 - b. Ready-to-Eat Salad GTIN + TLC (assigned in step 6) quantities are recorded
 - c. SSCCs can be assigned and encoded in a data carrier on new pallets
8. Ready-to-Eat Salad is received at Distributor – Receiving CTE
 - a. GLN identifies Distribution Center/Warehouse
 - b. GTINs + TLC (assigned in step 6) quantities are captured and recorded
9. Distributor picks cases to create a shipment to Restaurant/Store – Shipping CTE
 - a. GLN identifies Restaurant/Store
 - b. GTINs + TLC (assigned in step 6) quantities are captured and recorded
 - c. SSCCs can be assigned and encoded in a data carrier for new pallets
10. Produce is received by Restaurant/Store – Receiving CTE
 - a. GLN identifies Restaurant/Store
 - b. Produce GTINs + TLC (assigned in step 6) quantities are captured/recorded

*Note: For retailers, there could be a retailer-owned distribution center prior to the final destination

7.3 Frozen Shrimp Aquaculture Farmed Detailed Process Steps

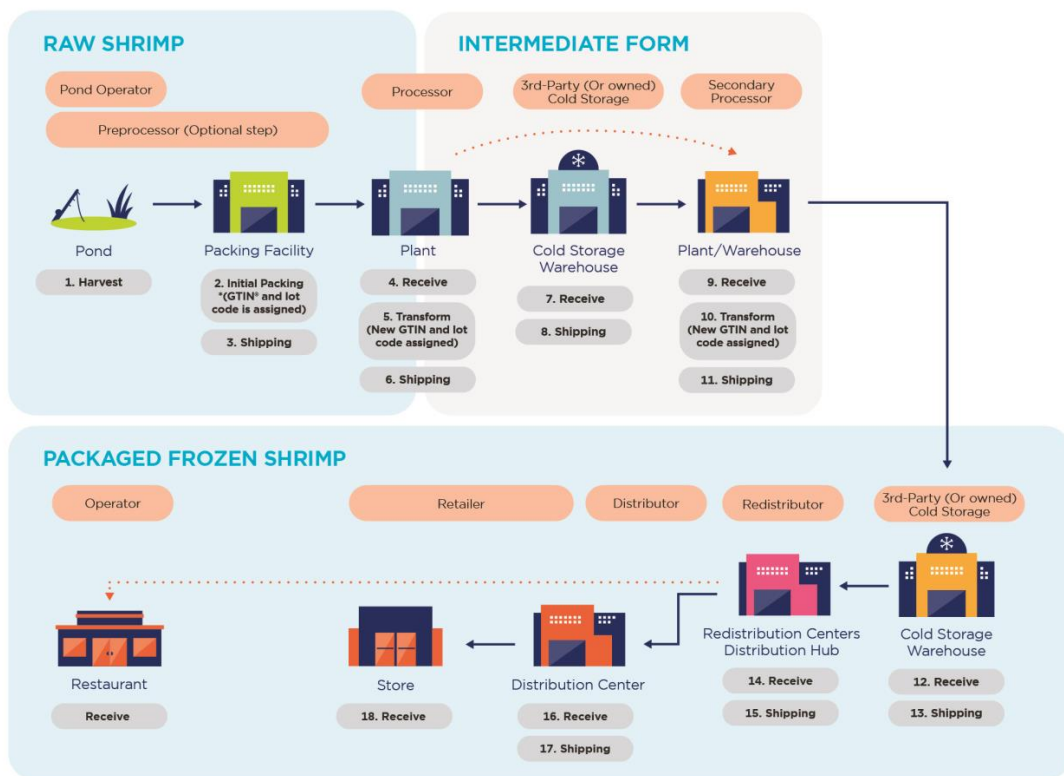
In the example below, shrimp is harvested from a pond (FDA defines it as a container) by a broker who is the first receiver (Harvester). The head on shrimp is sorted and size graded (Initial Packing) and a TLC is assigned. The broker sells and transports the sorted shrimp to a processor.

The graded head-on shrimp are Shipped to the Processor who Receives them. Commingling and Transformation occur at the Processor (head removed, shelled, deveined, size graded). A new TLC is assigned, and the Processor is the TLC Source.

If additional processing is required by a secondary processor (freezing and packaging) another Transformation occurs. The secondary processor receives and keeps a record of the primary processor's TLC and lot code source. After freezing into bulk (Transformation) the secondary processor may assign a new TLC if the packaging is done later. When the secondary processor packages the frozen shrimp as a finished product (Transformation) a new traceability lot code is assigned, and the secondary processor becomes the TLC source.

The secondary processor sells the frozen packaged shrimp (Shipper) to an importer who places the product into a third-party cold storage (3PL). The 3PL (Receiver) shall not assign a new TLC and keeps the secondary processor as the TLC source. The importer sells the frozen shrimp to a retail or food service distributor and the product is shipped from the 3PL (Shipper). The retail or food service distributor (both Receiver and Shipper cannot change the TLC and keeps the TLC Source as a record). When the Distributor ships the product, they pass along the TLC and TLC Source. The restaurant or a grocery store (Final Receiver) keeps the passed along TLC and TLC source as a record.

Important Note: The fishing vessel supply chain process requires different CTEs.



Note: For retailers, there could be a retailer-owned distribution center prior to the final destination

1. Shrimp are harvested from grow-out ponds by the pond operator or subcontractor □ Harvest CTE
 - a. Shrimp totes can be comingled with similar items from other ponds (containers); lot/batch numbers can be assigned but are not required for FSMA 204.
 - b. GLN identifies the pond (container) as the harvest location
2. Shrimp are sorted/graded and placed into totes or vats – Initial Packing CTE
 - a. GTIN and TLC are assigned and can be encoded in a data carrier
 - b. The processor is identified as the TLC Source with a GLN
3. Shrimp is shipped to Processor – Shipping CTE
 - a. Ship to GLN identifies Processor
 - b. Shrimp GTINs + TLC (assigned in step 2) quantities are recorded
4. Shrimp is received at Primary Processor – Receiving CTE
 - a. GLN identifies Primary Processor
 - b. Shrimp GTINs + TLC (assigned in step 2) quantities are recorded/captured
5. Shrimp may be comingled (multiple farms), head removed, and may have shell removed and/or be deveined to create an intermediate product that is packed in totes/vats – Transformation CTE
 - a. New GTIN + TLC is assigned to shrimp (intermediate product)
 - b. The processor is identified as a TLC source with a GLN

Note: Shrimp may be sent to a secondary processor for freezing and packaging if not done by the primary Processor

6. Shrimp is sent or shipped to 3rd Party (or Owned) Cold Storage Warehouse – Shipping CTE

- a. Ship to GLN identifies 3rd Party (or owned) Cold Storage
 - b. Shrimp GTIN + TLC (assigned in step 5) quantities are recorded
 - c. SSCCs can be assigned and encoded in a data carrier on new pallets
 - d. Shipping Containers clear customs during import (if crossing international borders)
7. The 3rd Party (or owned) Cold Storage receives product from the processing plant ☐ Receiving CTE
 - a. Ship to GLN identifies 3rd Party (or owned) Cold Storage
 - b. GTINs + TLC (assigned in step 5) quantities are recorded/captured

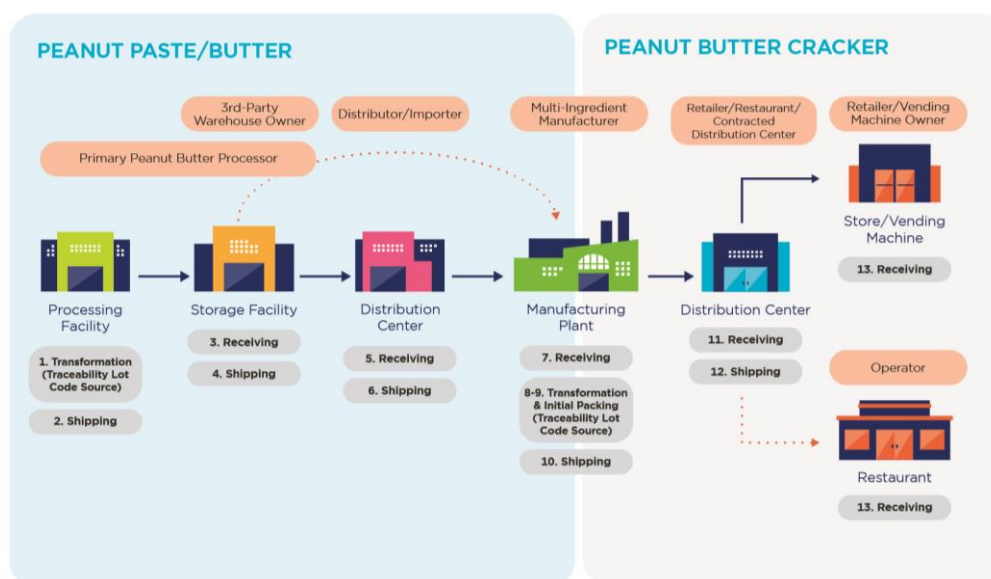
Note: Alternately, the product could bypass 3rd Party Cold Storage (steps 6 & 7) and head directly to Secondary Processor (steps 8 -11)
8. 3rd Party Cold Storage ships product out from Cold Storage Warehouse to Secondary Processor ☐ Shipping CTE
 - a. Ship to GLN identifies Secondary Processor
 - b. GTINs + TLC (assigned in step 5) quantities are recorded/captured
 - c. SSCCs can be assigned to new pallets and encoded in data carriers
9. Shrimp is received at Secondary Processor – Receiving CTE
 - a. GLN identifies Secondary Processor (Traceability Lot Code Source)
 - b. GTINs + TLC (assigned at step 5) quantities are captured and recorded
10. The secondary Processor processes the intermediate product into cases of finished goods frozen shrimp ☐ Transformation CTE
 - a. New GTIN + TLC is assigned to finished goods frozen shrimp
 - b. The secondary Processor is identified as the TLC source
 - c. GTINS + TLC quantities are recorded
 - d. GTINs + TLC can be encoded in a data carrier
 - e. Secondary processor packs cases of finished goods frozen shrimp on pallets
 - f. SSCCs can be assigned to new pallets and can be encoded in a data carrier
11. The secondary Processor sends pallets to Cold Storage Warehouse ☐ Shipping CTE
 - a. Ship to GLN identifies external Cold Storage Warehouse
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded
 - c. SSCCs can be assigned and encoded in a data carrier on new pallets
12. Cold Storage Warehouse receives the pallets from Secondary Processor ☐ Receiving CTE
 - a. GLN identifies external Cold Storage Warehouse
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded
13. Pallets (mixed or homogenous) are shipped by the 3rd Party (or Owned) Cold Storage to the Re-Distribution Center. ☐ Shipping CTE
 - a. Ship to GLN identifies Re-Distribution Center
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded
 - c. SSCCs can be assigned and encoded in a data carrier for new pallets
14. Product is received into inventory at the Re-Distribution Center – Receiving CTE
 - a. GLN identifies Re-Distribution Center
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded

15. Pallets (mixed or homogenous) or cases are shipped by the Distribution Center (Foodservice/Retail). □ Shipping CTE
 - a. GLN identifies Distribution Center
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded
 - c. Cases can be unpacked from pallets and repacked with other items onto mixed pallets
 - d. SSCCs can be assigned and encoded in a data carrier for new pallets
16. Pallets (mixed or homogenous) or cases are received by the Distribution Center – Receiving CTE
 - a. GLN identifies the Distribution Center
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded
17. Distribution Center picks cases to create a shipment to Restaurant/Store – Shipping CTE
 - a. Ship to GLN identifies Restaurant/Store
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded
 - c. SSCCs can be assigned to new pallets and encoded in a data carrier
18. Pallets or Cases are received by Restaurant/Store – Receiving CTE
 - a. GLN identifies Restaurant/Store
 - b. GTINs + TLC (assigned at step 10) quantities are captured and recorded

Note: For retailers, there could be a retailer-owned distribution center prior to the final destination.

7.4 Peanut Butter Crackers Detailed Process Steps

In the final example, below, peanut butter crackers are created. First, the peanut butter/paste is manufactured, and TLCs are assigned by the primary peanut butter processor. Peanut butter/paste is transported to a 3rd party warehouse in tankers, where it is received. The 3rd party warehouse ships peanut butter/paste to a distributor/importer or directly to a multi-ingredient manufacturer. After receipt, the multi-ingredient manufacturer maintains existing TLCs of all ingredients used to make the peanut butter crackers and creates a new TLC for the finalized product (the peanut butter crackers), which would be considered initial packing. The peanut butter crackers are shipped to a retailer/vending machine/restaurant.



1. Peanut butter/paste is manufactured by Primary Peanut Butter Processor – Transformation CTE
 - a. GLN identifies Primary Peanut Butter Processor
 - b. GTIN + TLC is assigned
2. Peanut butter/paste is put into tankers and shipped to 3rd Party/Warehouse Owner – Shipping CTE
 - a. GLN identifies Storage Facility
 - b. GTINs + TLC (assigned in step 1) quantities are recorded
 - c. If several lots are mixed into one tanker new TLCs are assigned – Transformation CTE
 - d. SSCC (Tanker ID) is recorded
3. Storage Facility receives Peanut Butter/paste into inventory – Receiving CTE
 - a. GLN identifies Storage Facility
 - b. GTINs +TLC (assigned in step 1 (or step 2 if transformed)) quantities are recorded
 - c. SSCC (Tanker ID) is recorded
4. 3rd Party/Warehouse Owner ships peanut butter/paste to Distributor/Importer or directly to Multi-Ingredient Manufacturer – Shipping CTE
 - a. GLN identifies Distributor Center or Manufacturing Plant
 - b. GTINs + TLC (assigned in Step 1 (or step 2 if transformed)) quantities are recorded
 - c. SSCC (Tanker ID) is recorded
5. Peanut butter/paste is received into Inventory by Distribution Center or Manufacturing Plant – Receiving CTE
 - a. GLN identifies Distribution Center or Manufacturing Plant
 - b. GTINs + TLC (assigned in step 1 (or step 2 if transformed)) quantities are recorded
 - c. SSCC (Tanker ID) is recorded
 - d. If the Distributor mixes peanut butter/paste lot codes into a different tanker new TLCs are assigned; Distributor would be identified as TLC Source with a GLN
6. Distributor/Importer ships peanut butter/paste to Multi-Ingredient Manufacturer – Shipping CTE
 - a. GLN identifies Manufacturing Plant
 - b. GTIN + TLC (assigned in step 1 (or step 2,5 if transformed)) quantities are recorded
 - c. SSCC (Tanker ID) is recorded
7. Multi-Ingredient Manufacturer receives peanut butter/paste tankers into inventory – Receiving CTE
 - a. GLN identifies Manufacturing Plant
 - b. GTIN + TLC (assigned in Step 1 (or step 2,5 if transformed)) quantities are recorded
 - c. SSCC (Tanker ID) is recorded
8. Peanut Butter Paste is mixed with other ingredients in Peanut Butter Mixing Area at Manufacturing Plant – Transformation CTE
 - a. GLN identifies Manufacturing Plant (Peanut Butter Mixing Area)
 - b. New GTIN + TLC is assigned to the new peanut butter product
 - c. The peanut butter Mixing Area at Manufacturing Plant is identified as the TLC source with a GLN
9. Cracker and Peanut Butter are put together in transformation lines (different lot codes) at Manufacturing Plant – Transformation CTE
 - a. GLN identifies Manufacturing Plant (transformation line)

- b. Peanut Butter Sandwich Crackers are packaged individually
 - c. New GTIN + TLC is assigned to Peanut Butter Sandwich Crackers
 - d. GTIN + TLC is encoded in a data carrier on individual package
 - e. Individual Peanut Butter Sandwich Crackers are packed into cases
 - f. New GTIN + TLC is assigned to the Peanut Butter Sandwich Cracker case
 - g. Transformation Line at Manufacturing Plant is identified as TLC Source with a GLN
 - h. GTIN + TLC (assigned in step 9) is encoded in a data carrier on the case
 - 10. Multi-Ingredient Manufacturer ships peanut butter cracker pallets to Distribution Center (contracted by Retailer or Restaurant) – Shipping CTE
 - a. GLN identifies Distribution Center
 - b. GTIN + TLC (assigned in step 9) quantities are recorded/captured
 - c. SSCCs can be assigned to new pallets and encoded in data carriers
 - 11. Peanut butter cracker pallets are received into inventory by Distribution Center – Receiving CTE
 - a. GLN identifies Distribution Center
 - b. GTIN + TLC (assigned in step 9) quantities are recorded/captured
 - 12. Distribution Center ships mixed pallets to retailer/vending machine/restaurant – Shipping CTE
 - a. GLN identifies retailer/vending machine/restaurant
 - b. GTIN + TLC (assigned in step 9) quantities are recorded
 - c. The Distributor can re-palletize peanut butter crackers onto mixed pallets (with other products or lot codes)
 - d. SSCCs can be assigned to new pallets and encoded in data carriers
 - 13. Peanut butter crackers (mixed pallets- could have other products) are received into inventory by Retailer/Vending Machine/Restaurant – Receiving CTE
 - a. GLN identifies retailer/vending machine/restaurant
 - b. GTIN + TLC (assigned in step 9) quantities are recorded/captured
- *Note: For retailers, there could be a retailer-owned distribution center prior to the destination

8 Appendix C - Overview of GS1 System of Standards to Support Traceability

From an information management point of view, supply chain applications like serial-level management and item-level traceability require all parties to systematically associate the physical flow of products with the flow of information about them. This is best attained by deploying a common business language within the framework of a comprehensive standards system. The GS1 System is such a system, providing a comprehensive platform for companies to identify products and other business entities, capture supply chain data, and share data with trading partners.

Table 7

The GS1 System of Standards encompasses identification standards, data standards, automatic identification data capture (AIDC) standards, and data communication standards. The table below summarizes some of the GS1 Standards that support item-level traceability.

GS1 Standards Supporting Item-Level Traceability			
Identification Standards	Trade Items	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
AIDC Standards	GS1 Barcodes	GS1-128 GS1 DataMatrix QR Code with GS1 Digital Link URI Data Matrix) with GS1 Digital Link URI	
	GS1 EPC/RFID	RAIN RFID	
Data Standards	Master Data: Global Data Dictionary (GDD) Item Business Messaging Standard Party Business Messaging Standard	Transactional Data: eCom/EDI	Event Data: EPCIS Schema EPCIS Core Business Vocabulary
Sharing & Communication Standards	Master Data: Global Data Sharing Network (GDSN) GS1 US Data Hub Location EPCIS Master Data	Transactional Data: AS2	Event Data: EPCIS Capture EPCIS Query Discovery Services

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IAPMO

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