



The Global Language of Business

GS1 US Global Location Number Recommendations for FSMA Rule 204

Release 1.0, October 11, 2024





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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.

Document Summary

Document Item	Current Value
Document Title	GS1 US Global Location Number Recommendations for FSMA Rule 204
Date Last Modified	September 2024
Document Description	This document supplements the Retail Grocery and Foodservice Application of GS1 System of Standards to Support FSMA Rule 204 Guideline and seeks to show how GLNs and GS1 US Data Hub Location can be leveraged to capture and share the Location Description information needed for FSMA Rule 204.

Log of Changes

Release Number -- Date	Change
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1 Introduction

The Food Safety Modernization Act (FSMA) is a pivotal legislation that has revolutionized the approach to food safety in the United States, shifting the focus from reaction to prevention. A key component of FSMA is Section 204, commonly referred to as “Final Rule” or “FSMA Rule 204,” designed to enhance traceability and transparency within the food supply chain. FSMA Rule 204 requires companies handling FTL (Food Traceability List) foods to record and share specific Key Data Elements (KDEs) related to Critical Tracking Events (CTEs). These traceability records must be provided to the U.S. FDA within 24 hours upon request, using a sortable electronic spreadsheet.

GS1 Standards are crucial in helping the food industry achieve these objectives. This document explains how Global Location Numbers (GLNs) and the GS1 US Data Hub Location can assist companies in meeting FSMA Rule 204 requirements for Location Description KDEs. For further details on using GS1 Standards to comply with FSMA Rule 204, refer to the [Retail Grocery and Foodservice Application of GS1 System of Standards to Support FSMA Rule 204](#) and [GS1 US FSMA Rule 204 Resources](#).

2 How to Use this Document

This document focuses on expanding section 3.1.3 of the [referenced document](#) and does not provide comprehensive guidance or advice regarding regulatory compliance or how to apply GS1 Standards to meet each FSMA Rule 204 requirement. This document reflects the current industry understanding of the [FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods](#). These requirements and the statutes and regulations affecting them are subject to change and may evolve in a manner this document cannot anticipate.

This document aims to improve consistency and ease of implementing location information sharing for FSMA Rule 204. It focuses on how unique identification for locations can tie into master data, transactional data, event data, and data carriers, providing explanations, real-world examples, and use cases.

2.1 Who Will Use this Document?

- Food companies looking to capture and share location information in a standardized way to help them with FSMA Rule 204 requirements, while being interoperable within their supply chain network.
- Business users and master data stewards who are implementing location information in support of FSMA Rule 204 or who need to update existing systems to support FSMA Rule 204 requirements.
- Solution Providers and Technical teams looking to connect location information to their transactional (ASN) and event (EPCIS) data for FSMA Rule 204.

2.2 Scope

This document provides guidance on how to include the additional Location Description Key Data Elements required by FSMA Rule 204 into existing systems and share it in an accurate, interoperable way. The document will not explain GLN creation, allocation rules, GS1 US Data Hub Location and its general use, but instead focuses only on the additions needed to support FSMA Rule 204.

2.3 Normative References:

1. [Get Started with GS1 Standards](#)
2. [GS1 General Specifications](#)
3. [An Introduction to the Global Location Number \(GLN\)](#)
4. [Determine How to Assign GLNs](#)
5. [Use a Global Location Number \(GLN\) to maximize supply chain visibility and traceability efficiency](#)
6. [GS1 US Data Hub Help Center](#)
7. [GS1 US Data Hub Location](#)

3 Using GLNs in Support of FSMA Rule 204

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 U.S. FDA has noted that ambiguity in product and location identification has impeded the accuracy and response time of past foodborne illness investigations. Even though the Final Rule does not require unique identification of products and locations, given the amount of data that needs to be collected for each of the CTEs, identifiers help streamline communication, increase operational efficiencies and data accuracy.

For various CTEs, the Final Rule defines most of the KDEs in terms of what, when, and where. However, additional KDEs are necessary to provide a more granularity to descriptions of food products and relevant locations. Additional KDEs that are required for describing locations are termed Location Description KDEs 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."

Final Rule, the U.S. FDA provided an example of [data attributes for the Location Description KDEs](#).

The Global Location Number (GLN) is a unique 13-digit identifier used to accurately identify specific locations within the supply chain. The GLN plays a key role by identifying 'who' is involved and 'where' an event occurred. Implementing GLNs standardizes location identification, allowing accurate tracking and tracing of food products across the supply chain. Key use cases for FSMA Rule 204 include:

1. GS1 US Data Hub | Location:

- Utilize GLNs to store and share Location Description Key Data Elements (KDEs).

2. Transactional Data (EDI 856*/ASN):

- Identify locations using GLNs during product shipment.

3. Event Data (EPCIS):

- Use GLNs to identify locations where CTEs occur.

4. TLC Source Reference:

- Include GLNs in data carriers (e.g., GS1 Data Matrix) for traceability.

* Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets

3.1 How GLNs Can be Used for FSMA Rule 204

- Required for Party and Location Identification in the Global Data Synchronization Network™ (GDSN®) and GS1 US Data Hub
- Encoded in data carriers for specific applications (e.g., GS1 DataMatrix)
- Used in place of internal numbers, DUNS+4, etc. with trading partners to enable uniqueness and interoperability
- Identify locations in electronic business transactions (EDI) and event data (EPCIS) and GS1 Digital Link

3.2 Additional Key Benefits of GLNs

As companies adopt GLNs to help them meet FSMA Rule 204 requirements, they can gain increased transparency, operational efficiencies and data accuracy in many different areas.

Table 3-1 Additional Key Benefits of GLNs

Information sharing: Getting the right information to the right place	<ul style="list-style-type: none"> ■ Supplier onboarding ■ Record consolidation and accuracy ■ Meeting regulatory and trading partner requirements ■ System interoperability ■ System access (GDSN)
Supply chain visibility: Knowing where something has been, is, and will be	<ul style="list-style-type: none"> ■ Traceability – tracking flow of products ■ Recall readiness ■ Product authenticity – anticounterfeiting, provenance, ethical sourcing
Shipping and logistics: How will this get from point A to point B, C and beyond?	<ul style="list-style-type: none"> ■ Transport service efficiency ■ Dynamic fulfillment

4 FSMA Rule 204 Applicable Physical Locations

Location Where CTE Occurs: Physical location where product is being harvested, cooled, manufactured, processed, packed or held such as farms, plants, distribution centers, third party storage warehouses, etc.


Receiving Location (Ship To): Location of the immediate subsequent recipient (other than a transporter) of the food

Ship From: Location from which you shipped the food.

TLC Source: Location where a food was assigned the TLC (Traceability Lot Code) which is the product batch/lot. This can include where a product was initially packed, transformed, first land-based receiving occurred, or location in which an FTL food was received from an exempt entity. GS1 US FSMA Rule 204 Guideline recommends that the TLC contain both the GTIN and product batch/lot.

TLC Source Reference: An alternative method for providing information about the TLC Source to the U.S. FDA. Examples include FDA Facility Registration Number, GLN or web address.


Growing Area 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. Farms that grow or raise a food on the FTL (other than shell eggs), are required to include a map of the areas where the food is grown or raised.

 **Helpful Hint:** For scenarios in which a ranch has different growing fields and a packing house at the same physical address, FDA accepts providing the same main farm address for each sub-location, even if field packing occurs, however, they do specify that the following information must be captured:

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

Adding Geocoordinates:

1. From the *Manage* section within GS1 US Data Hub | Location, select *Create Location*
2. Enter the requested information for creating a new GLN
 - a. Note that GEO Shapes and GPS Coordinates can only be added to Fixed Physical GLN Types
3. From *Step 2* of the GLN Creation UI, select the respective checkbox for *GPS Coordinate* or *GEO Shapes*.
 - a. For *GEO Shapes* you will also need to select the shape that best describes your location
4. Add your respective coordinates in the boxes provided
 - a. *GPS Coordinates* are limited to a single Latitude/Longitude combination
 - b. The number of coordinates required for *GEO Shapes* is dependent on the shape selected
 - i. Circle - One Latitude, One Longitude, One Radius
 - ii. Line - Two Latitudes/Longitude Combinations
 - iii. Polygon - Four Latitude/Longitude Combinations

 **Helpful Hint:** If a user wants to use either GEO Shapes or GPS Coordinates in the import template, they can use the columns AC through AG. Longitude/Latitude combinations should be entered on a single line with a space in between. For shapes requiring multiple sets of coordinates, still use a space to differentiate the values. (Latitude Longitude Latitude Longitude Latitude Longitude Latitude Longitude).


5 Using GLNs in GS1 US Data Hub|Location for FSMA Rule 204

5.1 GS1 US Data Hub and 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 | GS1 US Data Hub is not considered a GS1 Standard but rather is a suite of tools that allows users to create and keep track of Global Trade Item Numbers (GTINs) and GLNs. This robust tool also provides the ability to add important attributes to those identifiers, manage and store the information, and share it with business partners from a central source of truth, enabling governance and accuracy.

The GS1 US Data Hub | Location tool helps drive reliable party and location identification to improve business efficiencies. Additionally, [GS1 US Data Hub | Location](#) allows users to search for and view GLNs from many other GS1 Member Organizations. The tool is integrated into GS1's Global Registry Platform, which allows GLNs from other GS1 Member Organizations, such as GS1 France and GS1 Germany, to be accessed from GS1 US Data Hub. For more information please visit: [GS1 US Data Hub Help Center](#).

The Location Description KDEs in the Final Rule can be fulfilled by using a GLN to identify each unique physical location and accompanying standardized attributes describing the location. GS1 US Data Hub|Location can help companies meet the requirement for the TLC Source repository.

 **Helpful Hint:** Companies can give access to the FDA and/or specific trading partners as needed to reference the Location Description KDEs in GS1 US Data Hub|Location.


5.2 GLN Data Model

Trading partners can also use their own master data systems to store FSMA Rule 204 Location Description KDEs, using standardized attributes. The [GLN Data Model Solution Standard](#) is designed to share party and location 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. These attributes are available in GS1 US Data Hub| Location.

5.3 Add and Manage GLNs for FSMA Rule 204

As a member of GS1 US with a licensed GS1 Company Prefix, your company has access to the [GS1 US Data Hub | Location tool](#), which enables you to create and manage GLNs for your owned locations, at no charge. GS1 US Data Hub|Location also allows you to map an internal identifier (Collaborative ID) to each GLN.


- Your company's Legal Entity GLN is preloaded in GS1 US Data Hub | Location and can serve as the top level of your GLN hierarchy.
- If you have already assigned GLNs to your physical locations and they are not in GS1 US Data Hub | Location, it is recommended you upload these locations before assigning new locations to avoid duplication. Uploading and managing your physical locations in GS1 US Data Hub| Location allows your trading partners and/or FDA to access to view and use your location data if you provide access to them. For more information visit: [Add and Manage GLNs in GS1 US Data Hub](#)
- If you already have GLN information in GS1 US Data Hub and would like to update it visit: [Update Multiple Locations](#)

 **Important Note:** The GLN plus Extension model reflects sublocations within a given GLN (such as loading docks in a warehouse) and does not reflect an association between two GLNs or an operating relationship, therefore we do not recommend the use of extensions for this purpose in FSMA Rule 204 traceability. Those associations can be built as a hierarchy within the party or

location data of each GLN as desired. Furthermore, GS1 US Data Hub | Location does not support extensions.

5.4 View and Use Your Trading Partners' GLNs for FSMA Rule 204

If you wish to view and use GLNs from your trading partners, you should subscribe to the GS1 US Data Hub | Location View/Use option. Annual fees may apply, based on the options you choose and the number of users. Users with access to GS1 US Data Hub can log in [here](#).

- 
Helpful Hint: A View/Use subscription is required to view other companies' location information, including GLNs and location organizational structure provided by location owners. Starting September 2024, a primary contact phone number or email will be required and searchable.


For more information visit: [Location View/Use Instructions](#)

5.5 Connecting via API with GS1 US Data Hub for FSMA Rule 204

API integration documentation can also be provided to GS1 US Members. For more information please contact BusinessDevelopment@gs1us.org.

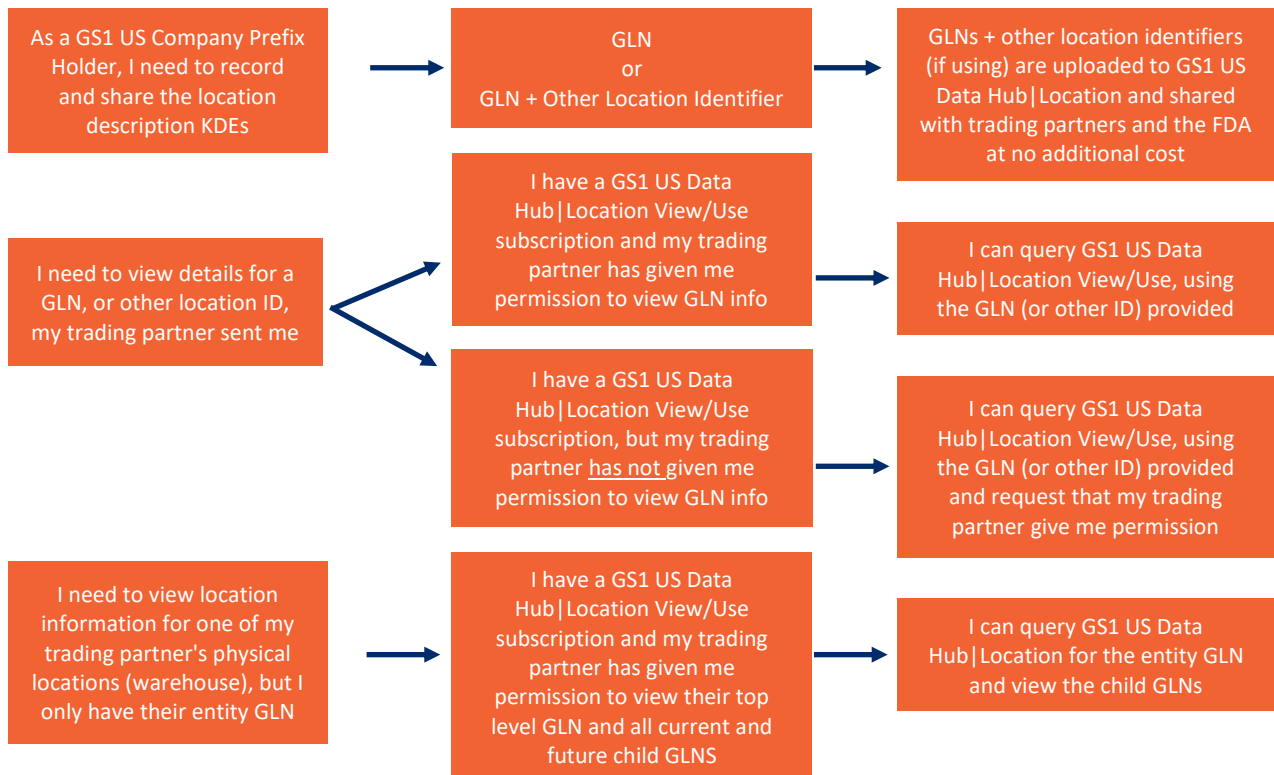
Table 5-1: GS1 Data Model Attributes for Location Description KDEs

Data Attributes Of Location Description	GS1 Data Model Or GS1 US Data Hub Location Attribute
Business Name	gs1:organizationName
Phone Number	gs1:telephone attribute
Physical Location Street Address or GPS Coordinates (alternative)	gs1:streetAddress gs1:GeoCoordinates or gs1:GeoShape
City	gs1:addressLocality
State/Province/Region	gs1:addressRegion
ZIP code or Postal Code	gs1:postalCode attribute
Country	gs1:addressCountry

- 
Helpful Hint: 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 and GS1 US Data Hub | Location is flexible for accommodating both US and non-US addresses when exchanging data between trading partners.

5.6 GS1 US Data Hub | Location and FSMA Rule 204 Scenarios



5.7 Using GLNs in the Advance Ship Notice for FSMA Rule 204

In the context of FSMA Rule 204, Advance Ship Notices (ASNs) used in conjunction with a Serial Shipping Container Code (SSCC) assigned to a pallet barcode label, create efficiencies, and improve traceability and transparency within the food supply chain. By offering real-time information about incoming shipments, ASNs and SSCCs allow stakeholders to track product movement more effectively and ensure that traceability information is accurate and current. The ASN has been used widely in the food industry for over 30 years and the fields required for FSMA Rule 204 exist in the X12 standard and can be compatible with any version of Electronic Data Interchange (EDI).

When a pallet is received by a distribution center, for example, the SSCC encoded in a GS1-128 barcode can be scanned and matched to an ASN that has been previously received. The GLN for the **TLC Source Reference, Ship From, and Ship To** can be shared in the ASN.

Figure 5-1 Using GLNs in the Advance Ship Notice



Shipping KDEs stored in ASN

For more information on how to use ASNs for FSMA Rule 204, including how to incorporate the TLC Source GLN in the N1 Segment using MP (manufacturing plant) visit: [GS1 US EDI Recommendations for FSMA 204 Critical Tracking Events](#). For more information on SSCCs visit: [Food Industry Guidance for Streamlining your Logistics Labels](#).

5.8 Using GLNs in EPCIS Event Data for FSMA Rule 204

Electronic Product Code Information Services or EPCIS is a GS1 Standard that enables trading partners to capture and share information about the physical movement and status of products as they travel throughout the supply chain—not only within and between locations in a single enterprise, but also between trading partners and consumers. The GS1 US FSMA Rule 204 Guideline recommends that companies use EPCIS to capture and share the required KDEs for all the FSMA Rule 204 CTEs except Shipping which is more commonly shared through an ASN.

5.8.1 Location Description for the TLC Source Reference in EPCIS

With EPCIS, the location where a lot code was assigned would be recorded in an EPCIS event related to Initial Packing, Transformation, and First Land-Based Receiver CTEs. If a downstream company was interested in this information, such as during receiving, they could provide an upstream query to request that event. The location would be identified with a GLN and the Location Description KDEs could be linked through that GLN. This information could also be provided at a web address referenced by a GS1 Digital Link representing the Traceability Lot Code in the EPCIS event data. For more information on how EPCIS event data can be exchanged in this manner, please refer to section 6 the [GS1 EPCIS and CBV Implementation Guideline](#).

For EPCIS examples on all other CTEs and KDEs for FSMA Rule 204 visit: [GS1 US EPCIS Recommendations for FSMA Rule 204 Critical Tracking Events](#)

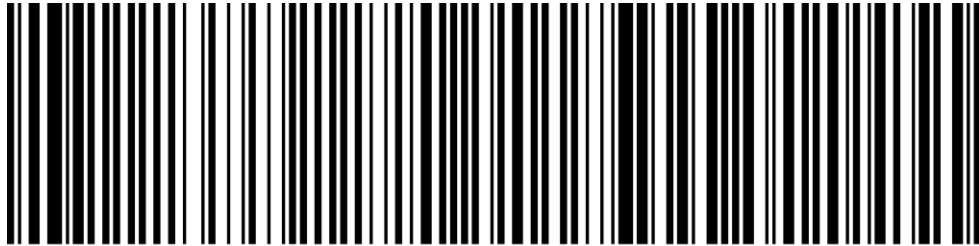
5.9 Using GLN to Include the TLC Source Reference in Data Carriers Such as GS1 Data Matrix

GS1 DataMatrix uses GS1 element string syntax that is seen in other GS1 barcodes, such as the GS1-128. This syntax is used throughout the supply chain to encode more data in general distribution, healthcare point of care environments, on cases containing fresh foods, on logistic units, and in a variety of other places.

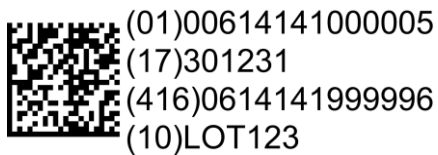
If the TLC Source Reference GLN is to be included in a data carrier, the GS1 Data Matrix would be able to accommodate for this as it allows for up to 2,335 characters and includes built-in error correction all while occupying less space. The GS1-128 barcode has a 48-character limit and will not fit a GLN most of the time if best practice to add a GTIN, Date, and Lot is followed.

Below is an image of a GS1-128 with GTIN+Date+Lot vs a GS1 Data Matrix with GTIN, date, lot, and TLC Source Reference. Best practice is to use AI (416) for the TLC Source Reference, which is Application Identifier (AI) for production or service location.

Figure 5-2 GS1-128 vs GS1 Data Matrix



(01)00614141000005(17)301231(10)LOT123



6 Recap: How the Full Picture Comes Together for FSMA Rule 204 and Beyond

FSMA Rule 204 requires that a recipient of an FTL item in the supply chain must know the **TLC Source** or **physical location** where each FTL food was assigned a **TLC**, along with the **Ship To** and **Ship From** locations.

- Trade items can be tagged or labeled with data carriers where GTIN+Lot (TLC) and a product date are encoded.

GS1 Data Matrix can encode the **TLC Source Reference GLN** as well.

- These data carriers can be scanned throughout the supply chain to accurately track product movement.

6.1 End-to-End Traceability:

Full end-to-end traceability is not mandatory for FSMA Rule 204; however, some retailers or operators may require this from their trading partners.

Achieving end-to-end traceability requires data collection from all supply chain partners, aggregated through a third-party or in-house system using the **TLC and TLC Source Reference** (GLNs) as links to connect the product journey.

- Suppliers should include the **TLC and TLC Source Reference** (GLN) in their ASNs.
- When distributors deliver individual cases to stores or restaurants, they can provide the **TLC and TLC Source Reference** information directly into a traceability system, ensuring they align accurately with the information provided by the supplier.

6.2 Industry Best Practice

Physical location owners (plants, warehouses, DCs, restaurants, stores) can identify their locations with Global Location Numbers (GLNs) and share this information through GS1 US Data Hub Location with trading partners and/or FDA as needed.

- GS1 US Data Hub|Location can serve as a central source of truth for creating and sharing this information.

Pallets are identified using Serial Shipping Container Codes (SSCCs).

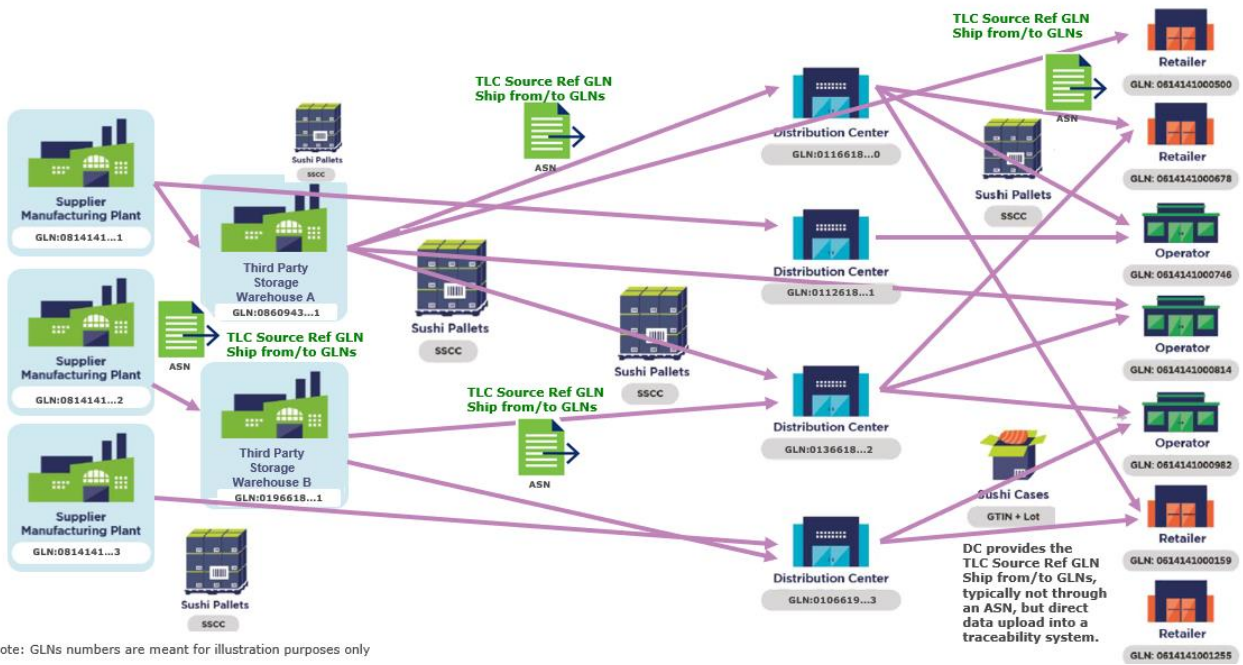
- Advance Ship Notices (ASNs) specify how many cases of each GTIN, lot, and date are in each pallet, the **TLC Source Reference, the Ship To GLN, and Ship From GLN**.

When pallets are broken down or repalletized at a third-party storage warehouse or redistribution center, new SSCCs and ASNs are needed.

The manufacturer can send the ASN to the third-party storage warehouse, which will in turn send another ASN to the DC.

EPCIS can be used to capture and store information for all FSMA Rule 204 related CTEs-KDEs.

Figure 6-1 TLC Source Reference GLNs





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GS1 US Corporate Headquarters

Princeton South Corporate Center, 300 Charles Ewing Boulevard
Ewing, NJ 08628 USA

T +1 937.435.3870 | **E** info@gs1us.org

www.gs1us.org

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