GS1 US

The Global Language of Business

The How

Industry Defined Guidance to Help Meet FSMA 204 Record Keeping Requirements

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FMI THE FOOD INDUSTRY ASSOCIATION

Antitrust Caution

GS1 US is committed to complying fully with antitrust laws.

We ask and expect everyone to refrain from discussing prices, margins, discounts, suppliers, the timing of price changes, marketing or product plans, or other competitively sensitive topics.

If anyone has concerns about the propriety of a discussion, please inform a GS1 US® representative as soon as possible.

Please remember to make your own business decisions and that all GS1 Standards are voluntary and not mandatory.

Please review the complete GS1 US antitrust policy at:
https://www.gs1us.org/antitrust-policy

Agenda

- FSMA 204 Basics

- FMI Supporting the Food Industry

- GS1 US Supporting the Food Industry

  - The Importance of Unique Identification for FSMA 204

  - Industry Developed Guidance

  - **Identify-Capture-Share** for FSMA 204

- End-to-End Supply Chain Process Flow Example

- Benefits Beyond Regulation

How do GS1 Standards Enable Traceability for Enhanced Food Safety?

1 Unique Product Identification

2 Standardized Exchange of Data

3 Precise Recall Readiness

Recap: FSMA 204 Final Rule Basics

|	
What is it and Who is Impacted?	FSMA Final Rule on Requirements for Additional Traceability Records for high-risk products outlined in the **Food Traceability List. Includes foreign and domestic entities. Full and partial exemptions may apply.**
What is Required?	Must keep records on foods from Farm to Store/Restaurant by **production LOT**. Supply chain partners need to share records. Provide **CTEs-KDEs to FDA within 24 hours**. Must keep a documented **Traceability Plan**
When?	FINAL Rule Effective: January 2023 Compliance date: January 2026 Records should be maintained for 2 years

FMI – The Food Industry Association

As the **food industry association**, FMI works with and on behalf of the entire industry to advance a **safer**, **healthier** and **more efficient** consumer food supply.

FMI brings together a wide range of members across the value chain — from **retailers** who sell to **consumers**, to **producers** who supply the food, as well as the wide-variety of companies providing critical services — to **amplify** the collective work of the industry.
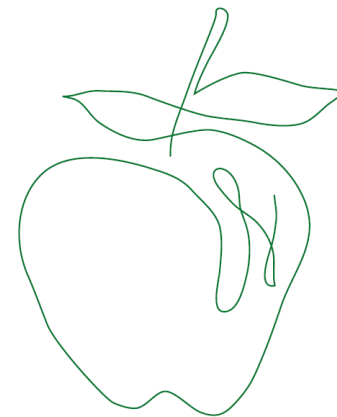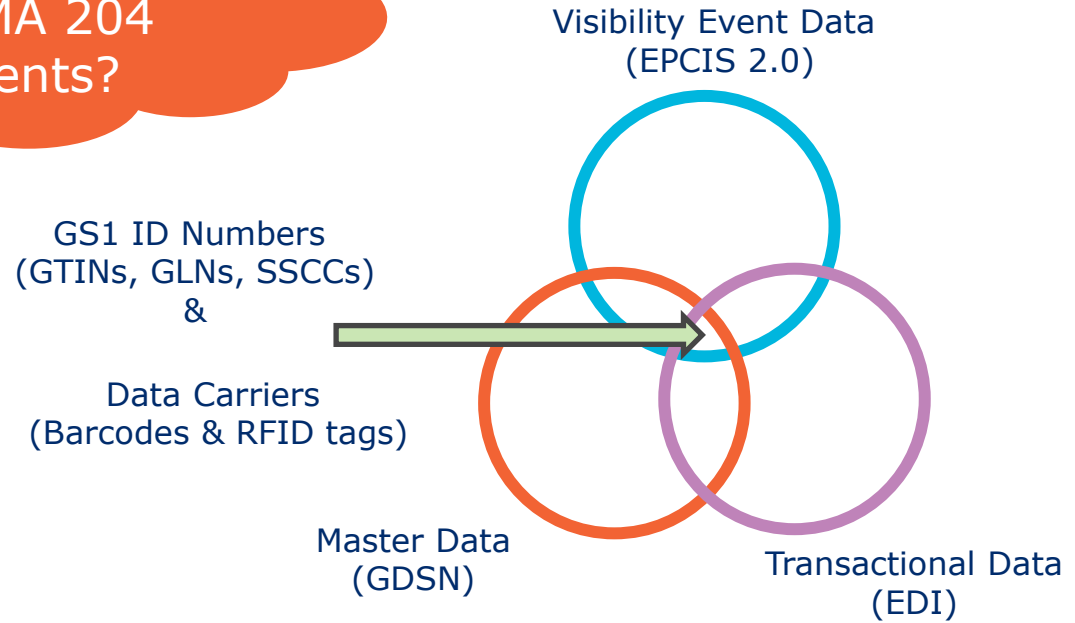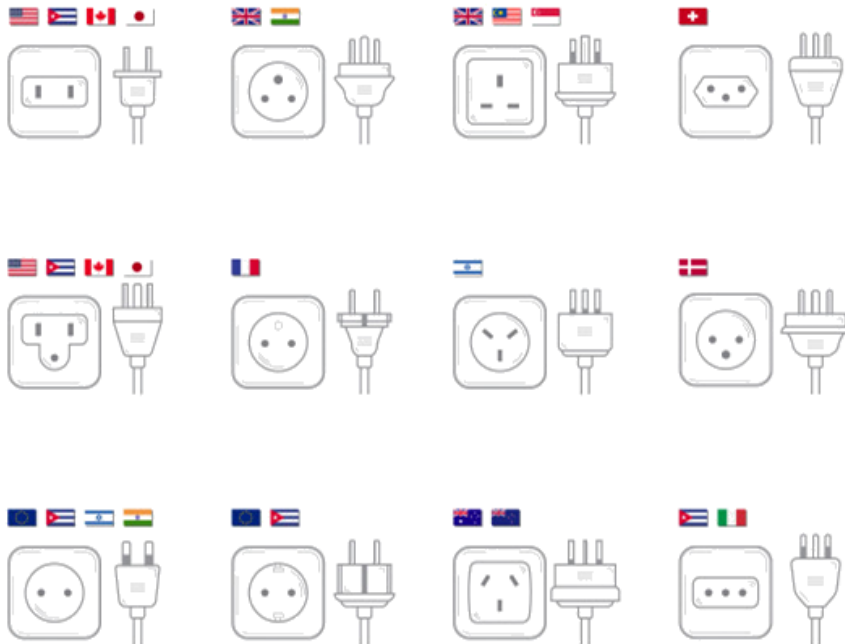
www.fmi.org

GS1 US Supporting the Food Industry

> What do I need to meet FSMA 204 requirements?

Data Exchange Today

Visibility Event Data (EPCIS 2.0)

GS1 ID Numbers (GTINs, GLNs, SSCCs) & Data Carriers (Barcodes & RFID tags)

Master Data (GDSN)

Transactional Data (EDI)

One Common Language

The only way businesses big or small can move forward is to work together. They need to be able to **understand each other** anywhere in the world.

Business requires a common language, and we make that possible.

More than **10 billion** GS1 barcodes are scanned everyday **1 billion** products carry GS1 barcodes.

GS1 US® serves more than **300,000 businesses** in the United States.

Over **2 million** companies around the world use GS1 Standards

GS1 US serves over **25 industries** including retail grocery, food service, health care, apparel, and general merchandise

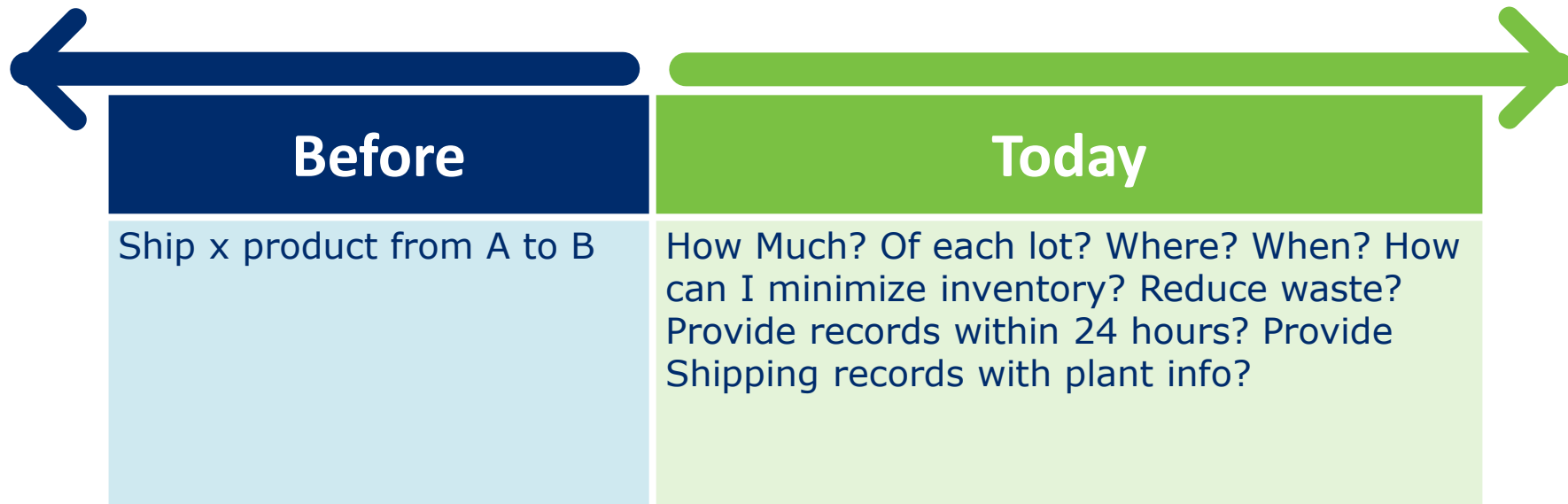More than **40 million** products are registered by brand owners in the GS1 Global Data Synchronization Network™ (GDSN)

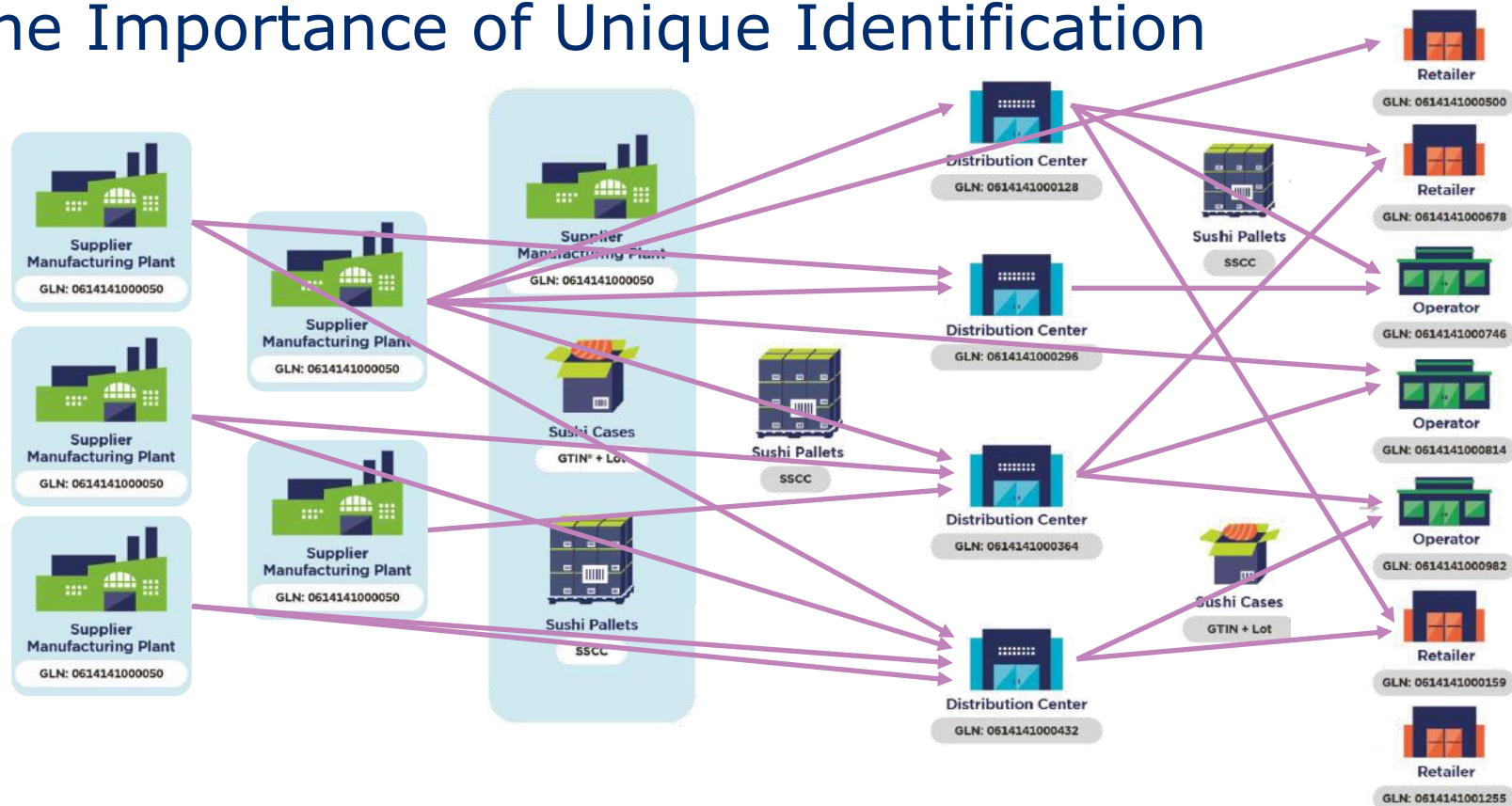Over **45 million** GTINs are in the GS1 US Data Hub Product Tool

GS1 is made up of **116+ member organizations** serving businesses around the world

The Importance of Unique Identification

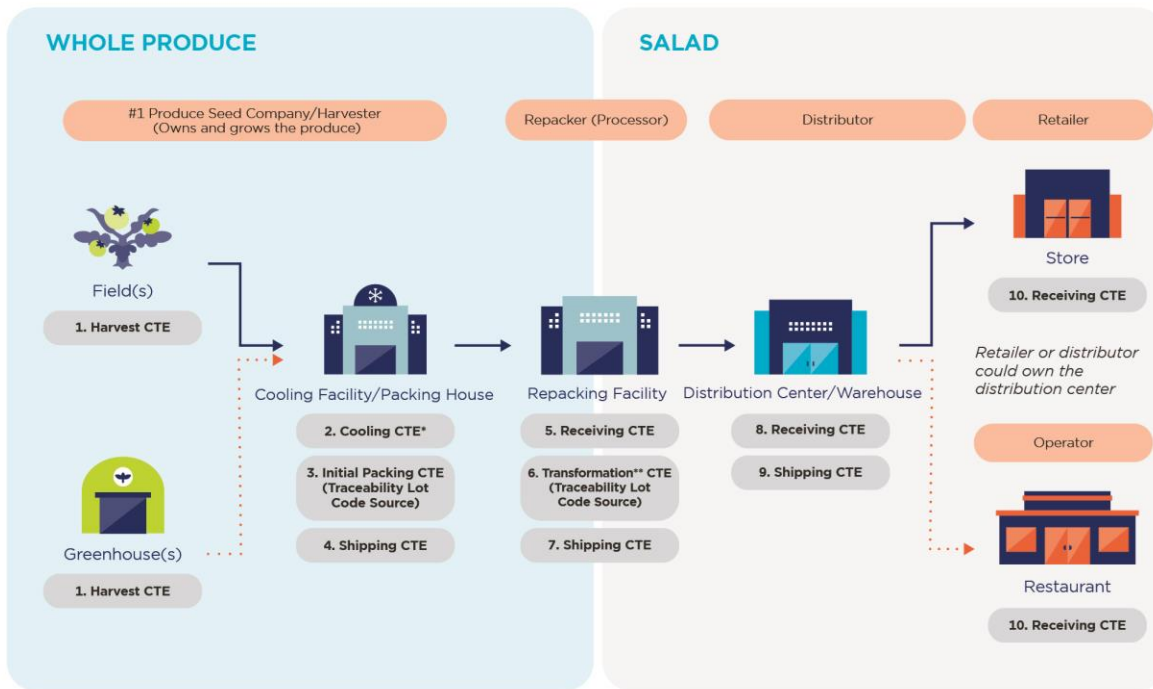| Before	Today
Ship x product from A to B	How Much? Of each lot? Where? When? How can I minimize inventory? Reduce waste? Provide records within 24 hours? Provide Shipping records with plant info?

The Importance of Unique Identification

Food Industry Collaboration

Started in November 2021

1. Prioritized supply chain process examples
2. Identified: Parties, Locations & Steps for products
3. Defined FSMA Required CTEs/KDEs
4. Mapped FSMA 204 KDEs to existing GS1 Standard

WHOLE PRODUCE

#1 Produce Seed Company/Harvester
(Owns and grows the produce)

Field(s)
1. Harvest CTE

Greenhouse(s)
1. Harvest CTE

Cooling Facility/Packing House
2. Cooling CTE*
3. Initial Packing CTE (Traceability Lot Code Source)
4. Shipping CTE

SALAD

Repacker (Processor)

Distributor

Retailer

Repacking Facility
5. Receiving CTE
6. Transformation** CTE (Traceability Lot Code Source)
7. Shipping CTE

Distribution Center/Warehouse
8. Receiving CTE
9. Shipping CTE

Store
10. Receiving CTE

Retailer or distributor could own the distribution center

Operator

Restaurant
10. Receiving CTE

**Transformation could occur over 1 or more steps*

GS1 US FSMA 204 Guideline

Outlines Food Industry best practice to adopt GS1 Standards and meet FSMA 204 Requirements

Includes FDAs comments and direct links as well as other foundational resources

Retail Grocery and Foodservice

Application of GS1 System of Standards to Support FSMA 204

Guideline

Release 1.0, March 1, 2023

FDA Example

Farm → Harvester → Cooler → Initial Packing (RAC) → Produce Processor → Distributor → Retail Food Establishment

Harvesting KDEs	Cooling KDEs	Initial Packing KDEs	Receiving KDEs	Receiving KDEs	Receiving KDEs
		Shipping KDEs	Transformation KDEs	Shipping KDEs	
			Shipping KDEs		

FDA Reference

FSMA 204 Detailed CTEs-KDEs

1. Harvesting
2. Cooling
3. Initial Packing
4. First Land-Based Receiver *(Seafood)*
5. Shipping
6. Receiving
7. Transformation

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

FDA **U.S. FOOD & DRUG** ADMINISTRATION

| Harvesting | Cooling (before Initial Packing) | Initial Packing (RAC) | First Land-Based Receiver | Shipping | Receiving | Transformation | Traceability Plan |

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

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

Receiving KDEs
For food you receive from a person who is exempt from the rule
KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to RFEs or restaurants)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e, traceability lot code source) and (if applicable) traceability lot code source reference
- Date you received the food
- Reference document type and reference document number

*This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

Source: FDA.gov

Master Data & Event Data

Data Framework Example

MASTER DATA → **TRANSACTIONAL/EVENT DATA** →

Product Data	Location Data	Event Data
• Additional Identifier: GTIN**	• Additional Identifier: GLN*	• Additional Identifiers: GTIN, GLN, SSCC*
• Product Name	• Business Name	• Event Date
• Brand Name	• Primary Phone Number	• Quantity & Unit of Measure
• Commodity	• Physical Location Name	• Reference Records
• Variety	• Physical Location Address	• Product & Location Descriptions
• Packaging Size	• Growing-Area Coordinates (farm)	• Traceability Lot Codes
• Packaging Style	• Company Contact	• Assignment Method
• Species (seafood)	• Phone	• Point of Contact
• Market Name (seafood)	• City	• Reference Record Type & Identifier
	• State	
	• Postal Code	
GDSN*/GDM*	**GS1 US Data Hub	Location***	**EPCIS/EDI***

*Denotes possible use of GS1 Standards for FSMA 204

Identify, Capture, Share

Identification
- **Product**
  GTIN
- **Pallet**
  SSCC
- **Location/Party**
  GLN

Capture
Data carriers that allow for the addition of lot codes:
- **1D**
  i.e., *GS1-128*
- **2D**
  i.e., *GS1 Data Matrix,
  QR Code with GS1 Digital Link*
- **RAIN RFID**

Share
- **Product Data Exchange**
  GDSN
- **Location Data Exchange**
  Data Hub Location
- **Event Data Exchange**
  EDI, EPCIS

GS1 Unique Identification

Assigning unique global product, location, party, and logistic unit identifiers is the foundation of visibility across supply chains.

GTIN

Global Trade Item Number® (GTIN®) is used to uniquely identify a trade item.
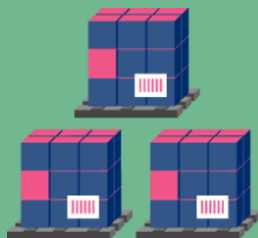
SSCC

A Serial Shipping Container Code (SSCC) is a unique number to identify a logistic unit.

GLN

Global Location Number (GLN) is used to uniquely identify a location or stakeholder.

GLN	GTIN	GTIN SSCC GSIN	SSCC		GLN		SSCC	GLN		GTIN SSCC GSIN	GTIN	GLN
Manufacturer	Item	Case	Pallet	Transport	Distributor	Transport	Pallet	Distribution Centre	Transport	Case	Item	Retailer Healthcare Provider Operator

Capture: GS1 Data Carriers

GS1 Data Carriers are capable of holding varying amounts of data to accommodate different needs such as Batch/Lot information and expiration dates.

Barcodes

EAN/U.P.C.	GS1 DataBar®	GS1 DataMatrix	ITF-14	GS1-128
6 14141 98765 8	(01) 0 0614141 987658	(01) 00614141987658 (17) 120831 (10) A1B2C3D4E5 (21) 00098522	2 06 14141 98765 2	(01) 0 0614141 987658 (11) 120715 (10) ABC123

EPC®-Enabled RFID Tags

HF RFID	UHF RFID

GS1 Digital Link

QR Code	Data Matrix

Share: GS1 Data Exchange

Interoperability, made possible by identification standards, data capture standards, and **data exchange standards**, allows product information to flow through the supply chain.

Product Master Data	Transactional Data	Physical Event Data
GDSN®	**EDI**	**EPCIS**
Global Data Synchronization Network™	Electronic Data Interchange	Electronic Product Code Information Services
The GDSN connects trading partners to the GS1 Global Registry® via GS1-certified data pools, enabling the immediate electronic sharing of standardized, up-to-date, accurate information.	EDI enables the computer-to-computer exchange of structured information between companies using a standardized format.	EPCIS is the standard for sharing information about the movement and status of goods in the physical world.

What Goes Into It	**What Goes Into It**	**What Goes Into It**
• GTINs • Brand Owner Identification • Product Descriptions • Product Classification	• GTIN® • GLN • SSCC	• What GTIN • Where GLN • When Date and Time Stamp • Why Business Step and Product Disposition
	EDI Document Types	
	• Purchase Order • Advance Ship Notice • Invoice • Payment	

Following the Food Supply Chain

Supplier

Supplier's Manufacturing Plant

Distributor/Restaurant places an order with the supplier.

The supplier's plant packs and labels cases with GS1-128 barcodes.

EPCIS helps capture all ingredients that go into a salad and the final product GTIN, Date, Lot that go into the barcode.

Cases are assembled onto pallets that are labeled with unique Serial Shipping Container Codes (SSCCs) and bound for the retailer/ restaurant's distribution center (DC).

Following the Food Supply Chain

Retailer/Restaurant Distribution Center

The Advanced Ship Notice (ASN) listing the order's Global Trade Item Numbers (GTINs), quantity, and other useful information can be sent to alert the DC of the pending arrival.

The DC can scan the SSCC (if present on the pallet) to compare the information provided on the ASN. If an SSCC is not present, DC scans GS1-128 barcodes on cases for inventory and receiving accuracy.

The DC divides the shipment for delivery to the stores or restaurants that have requested the item—each individual retailer/restaurant is identified by a Global Location Number (GLN). Each delivery is tied to the original supplier's GTIN, date, and batch/lot information.

Following the Food Supply Chain

Retail Store/Restaurant

As shipments of the item arrive in stores, the GS1-128 barcodes can be scanned to manage inventory, address quality complaints, or identify impacted product in case of withdrawal.

GS1 Standards at Work

- Help meet regulatory requirements
- Conduct rapid, targeted recalls
- Customer Trust
- Transparency
- End to End Supply Chain Visibility
- Improved Inventory Management

ROI

Information

- Accurate information drives sales
- Clean data saves time, money, and resources

Product

- Less product waste
- Ability to better identify affected lots for recall
- Better freshness management

Process

- Greater efficiency/transparency via automation

Consumer Engagement

- Brand loyalty
- Additional safety

What's Next?

GS1 US Resources

www.gs1us.org/foodsafety

FMI Resources

How to get started

Assemble the Team

Evaluate current systems

Plan

Implement

Up next in series

- **August 16:** The Why: Driving Business Value Beyond FSMA 204 Regulatory Compliance

- **August 23:** The What's Next: Preparing to Meet FSMA 204 Requirements - Tools and Resources

- **August 2:** The What: Understanding the Basics of FSMA Rule 204: Webinar recording

GS1 US and FMI Present
FSMA Rule 204 Webinar Series

Questions

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