GS1 US

The Global Language of Business

The What's Next: Preparing to Meet FSMA 204 Requirements – Tools and Resources

FMI THE FOOD INDUSTRY ASSOCIATION

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*If applicable

Speaker Introductions

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FSMA 204

FDA's Path to Advancing Food Safety

1 — New Era for Smarter Food Safety

- 1st Public Meeting Sept. 2019
- New Era Blueprint announced July 2020
- 10-year strategic blueprint
- 4 core elements

Policy

2 — FSMA 204

- FDA heal public meeting Nov. 2020
- Public comment period ended February 2021
- Final Rule published Nov 2022
- Developed a Food Traceability List (FTL) and additional record keeping requirements

Regulation

3 — IT Modernization

- FDA started an agency-wide data modernization and enhanced tech initiative in 2021
- FDA Technology Modernization Action Plan (TMAP) Sept 2021
- FDA Data Modernization Action Plan (DMAP) March 2021
- FDA Enterprise Modernization Action Plan (EMAP) May 2022

Agency Wide Initiative

4 — Human Food Program

- Program designed to ensure the most strategic use of resources
- Recommendations came from the expert panel of the Reagan-Udall Foundation
- Restructure will impact the Office of Regulatory Affairs (ORA)

Restructuring

GS1 US - Who We Are

Neutral and not-for-profit	**User-driven and governed**
Global and local	**Inclusive and collaborative**

We bring communities together.

More than 10 billion
GS1 barcodes are scanned every day.

25 million
products are assigned U.P.C.s in the GS1 US Data Hub | Product tool.

1.5 million
companies around the world use GS1 Standards.

More than 30 million
products are registered by brand owners in the GS1 Global Data Synchronization Network™ (GDSN®).

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.

FMI Strategy

Advocate

Collaborate

Educate

Implementation Resources

Tools
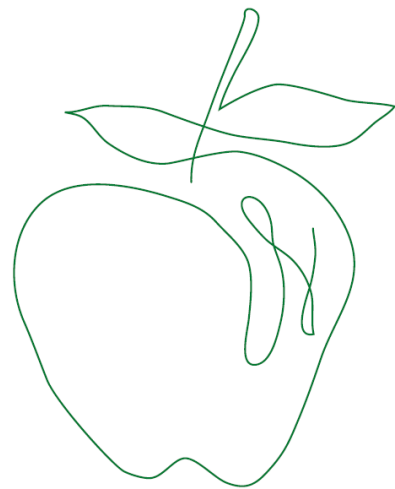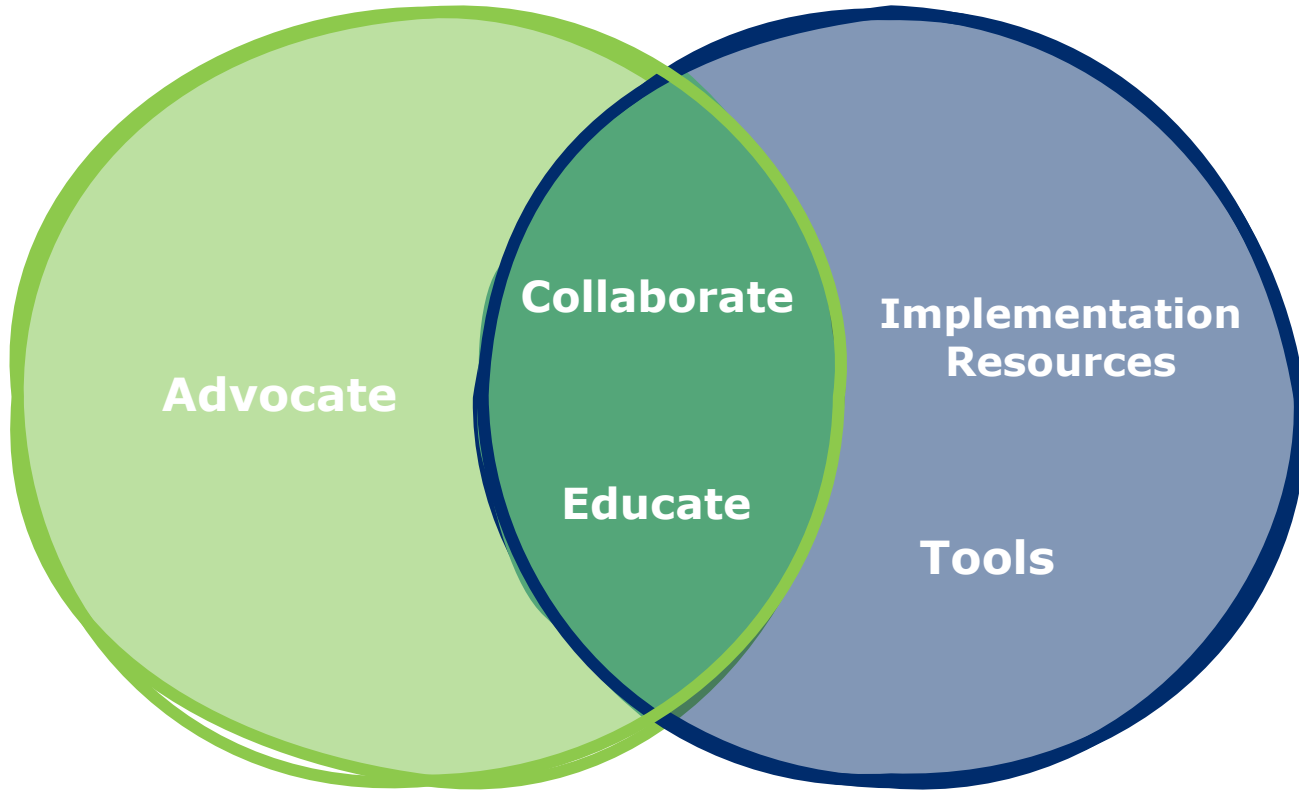
GS1 US Strategy

Growing need for standardization

FDA is no longer just a science organization, but now a data-centric one

What is FSMA Final Rule Section 204?

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

Traceability Plan

Foods on Food Traceability List

Each Key Data Element (KDE) at relevant Critical Tracking Events (CTE)

Records 2-year retention

Sortable Spreadsheet

Food Traceability List

Cheeses
(other than hard cheeses)

Crustaceans
(fresh and frozen)

Cucumbers
(fresh)

Finfish
(fresh and frozen)

Fruit
(fresh cut)

Herbs
(fresh)

Leafy Greens
(fresh)

Leafy Greens
(fresh cut)

Melons
(fresh)

Molluscan
Shellfish, Bivalves
(fresh and frozen)

Nut Butters

Peppers
(fresh)

Ready-to-Eat
Deli Salads
(refrigerated)

Sprouts
(fresh)

Shell Eggs

Smoked
Finfish
(refrigerated
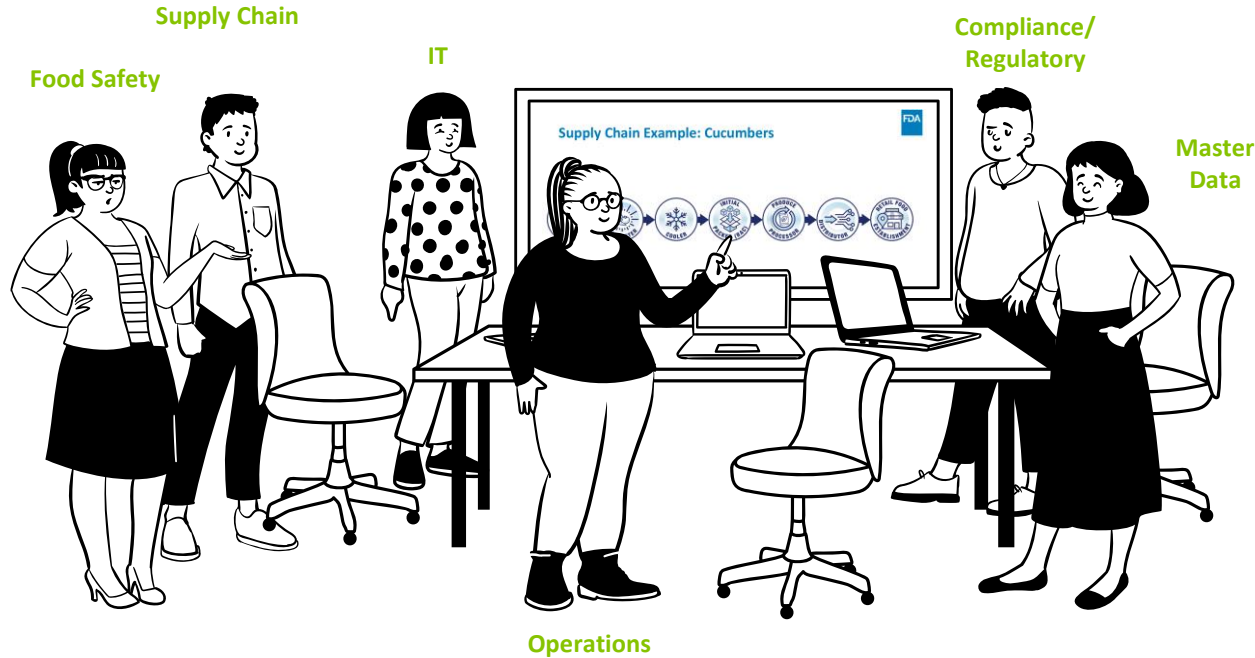and frozen)

Tomatoes
(fresh)

Tropical Tree
Fruit
(fresh)

Vegetables
Other Than
Leafy Greens
(fresh cut)

The FSMA 204 Journey

**Assemble
the Team**

**Evaluate Current
Systems**

Plan

Implement

Assemble the team

Food Safety

Supply Chain

IT

Compliance/
Regulatory

Master
Data

Operations

Supply Chain Example: Cucumbers

Senior Leadership

Legal

Finance

Category Management

Logistics

Distribution

Warehousing

Architecture

EDI

Planning

Procurement

Evaluate Current Systems

For example;

- Inventory Management
- PIM (Product Information Management)
- Master Data
- Warehouse Management System (WMS)
- Product Lifecycle Management (PLM)
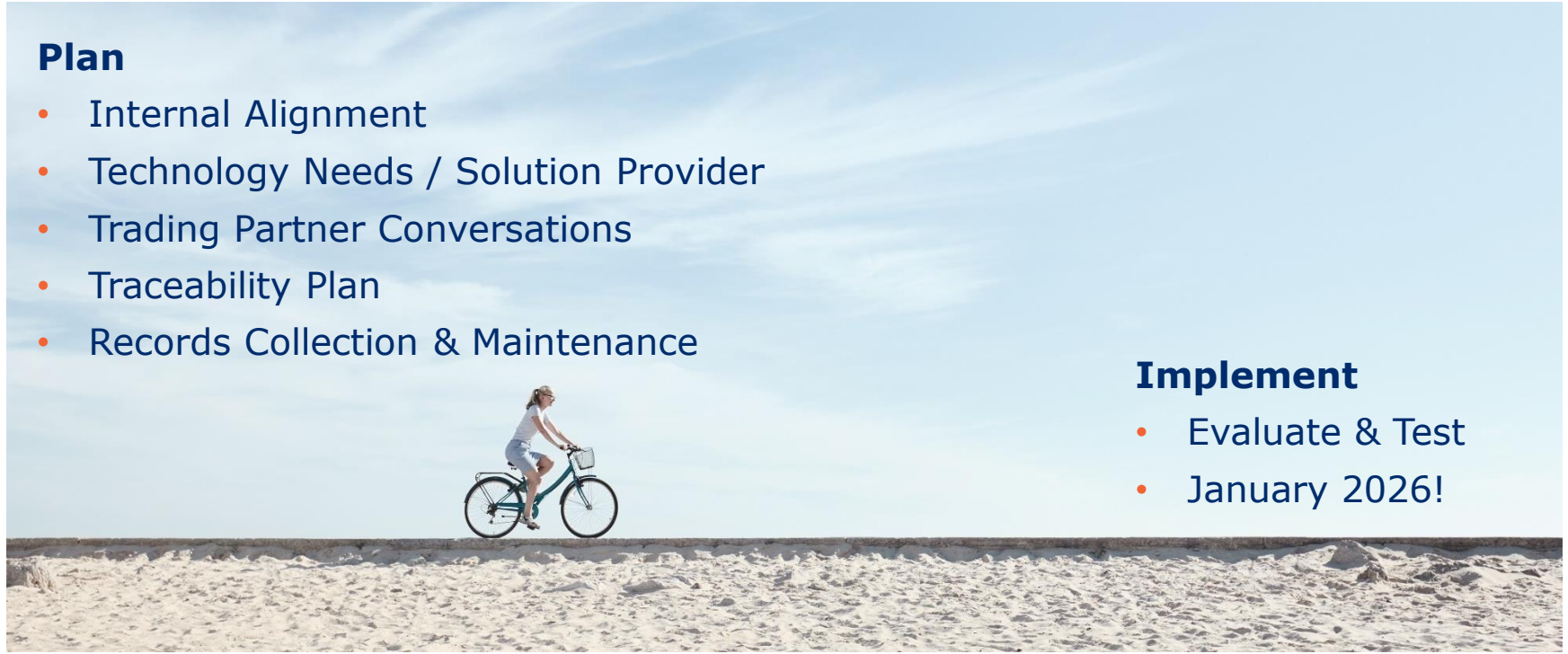- Supplier Database
- Compliance Programs

Plan & Implement

Plan

- Internal Alignment
- Technology Needs / Solution Provider
- Trading Partner Conversations
- Traceability Plan
- Records Collection & Maintenance

Implement

- Evaluate & Test
- January 2026!

Tools

Checklist to help get started

Gain Organizational Support

Launch Support and Resources Discovery	
☐ Secure leadership buy-in and support.	▪ Communicate final regulatory deadline to leadership: Jan. 2026. ▪ Assign full-time project lead.
☐ Assemble Task Force; RACI (responsible, accountable, consulted, informed).	▪ Look at functions to involve: Operations, Food Safety and Quality, Food Science, Procurement, Logistics, Distribution, Planning, IT, Architecture, Master Data, EDI, Warehousing, Transportation, Account Managers, Business Development, Regulatory/Compliance, Legal, Finance, etc.
☐ Map out processes, systems, and teams that capture FSMA 204 CTEs/KDEs.	▪ Understand physical/digital data flows and address gaps where new data needs to be captured or shared. ▪ Estimate financial requirements
☐ Determine trading partners need to be involved.	▪ These can be suppliers, distributors, customers, third-party storage providers, etc. ▪ Keep in mind these can be domestic or international entities.
☐ Communicate FSMA 204 requirements with trading partners.	▪ Align on common goals and deadlines.

Checklist to help get started

Assess GS1 Standards Capabilities

Identify Product and Location, Master Data	
☐ Survey trading partner's GS1 capabilities and ensure understanding of FSMA 204 requirements.	▪ Review the following documents for more information: **_Guide to GS1 Standards Adoption for Supply Chain Visibility_** GS1 Traceability Checklist Assessor's Guide v1.0
☐ Understand how GS1 Standards can help in meeting FSMA 204 requirements.	▪ Review GS1 US FSMA 204 Resources
☐ Confirm if GTINs are assigned to products in the Food Traceability List (FTL) and determined how they will be identified. *Note: Internal asset identifiers are different than GTINs*	▪ Assign GTINs as needed and create a list of applicable products (shipped or received). Review section 3.1.2 of the GS1 US FSMA Guideline for more details. ▪ Determine if products identified as "in scope for FSMA 204" for downstream partners are using GDSN Local Code Value or establish how that communication will happen if GDSN is not used. Review section 3.4.3, Figure 14 of the GS1 US FSMA Guideline for more information.
☐ Determine if FSMA 204 Product Description KDEs are shared using GDSN or other share method using GDM (Global Data Model) defined attributes.	▪ Review section 4.3 of the GS1 US FSMA Guideline for more details.
☐ Confirm if companies or locations – where products are processed, manufactured, packed, and held – are identified with GLNs.	▪ Assign GLNs as needed and create a list of applicable locations (shipped or received). Review section 3.1.3 of the GS1 US FSMA Guideline for more details.
☐ Confirm if FSMA 204 Location Description KDEs are captured using GLN Data Model attribute formats and definitions. Also, check that they are stored/shared from a single source, such as GS1 Data Hub | Location.	▪ Review section 4.4 of the GS1 US FSMA Guideline for more information.
☐ Assess your capabilities for the sortable electronic spreadsheet that includes all FSMA-required KDEs for each product and location. *Note: Examples of systems include Product Information Management Systems, Trading Partner Information Management Systems, and Master Data Management Framework.*	▪ Identify each department/position responsible for providing each KDE. ▪ Assess IT systems/vendor capabilities. ▪ Ensure you can store/exchange this information promptly with partners to ensure accurate master data is referenced in all transactions. ▪ Evaluate current data governance processes and create new plans as needed. ▪ Review section 4.2.2 of the GS1 US FSMA Guideline for more details.

Checklist to help get started

Capture Data Carriers

☐ **Identify the data carrier (i.e., barcodes, RFID Tags) used (if any) for each item by the supplier and customer.**	▪ Review the following documents for more information: EPC Tag Data Standard (TDS) 2.0 GS1 US RFID Webpage GS1 Data Matrix Guideline NA Case Labeling Guideline 2D Overview in General Distribution
☐ **Assess customer requirements and supplier/distributor capabilities to capture this information.**	
☐ **With your trading partners, choose a specific data carrier to meet FSMA 204 requirements, and agree on Application Identifuers to use based on product type.**	▪ Consider if the data carriers support the traceability lot code requirements as defined by the rule? ▪ Identify the type of product date that will be used per category. ▪ Review section 3.2, 3.3.1, and 3.3.2 of the GS1 US FSMA Guideline for more information
☐ **Confirm if SSCCs are assigned to pallets or other logistics units and and tied to an EDI 856 – ASN (Advance Ship Notice).**	▪ Review the following documents for more information: Food Industry Guidance for Streamlining Your Logistics Labels An Introduction to the Serial Shipping Container Code (SSCC) Section 3.1.4 of the GS1 US FSMA Guideline

Share Transaction and Physical Event Data

☐ **Confirm if the ASN (EDI 856) is being used and sent to partners as product is shipped, detailing how many cases/trade items (GTINs) of each lot code they will receive.** *Note: Full ASN document can be accessed by members through www.mygs1.org. See section 1.6 of GS1 US FSMA Guideline for further instructions.*	▪ Are GTNs included in ASNs? ▪ Is lot-level information included in ASNs for direct trading partners? ▪ Review the following documents for more information: EDI 856 Foodservice Ship Notice Explained Full ASN for Foodservice 856 UCS v7050 Guideline Section 4.5.1 of the GS1 US FSMA Guideline
☐ **Confirm if all FSMA 204 Shipping KDEs are included in ASNs. If not, determine how will they be captured/added to the ASN.**	
☐ **If ASNs are not used, are the ASN standard field names, formats, and definitions used and recognized in other systems?**	▪ Review section 4.2.2 of the GS1 US FSMA Guideline for more information
☐ **Confirm if EPCIS is used to share physical event data. Consider:** *Note: Examples of other data gathering/storing/sharing methods: Online forms, CSV files via FTP folder, EDI, API, XML, cloud-based systems, blockchain.*	▪ If yes, are the required FSMA CTEs captured/recorded using EPCIS or a sortable spreadsheet? ▪ If no, are the EPCIS standard field names/formats/definitions recognized in other systems? ▪ Review the following documents for more information: EPCIS Guidance Section 4.2.2 and 6 of the GS1 US FSMA Guideline
☐ **Define how transactional/event data will be stored and maintained for the 2-year requirement specified in FMSA 204.**	
☐ **Determine how this transactional / event data will be exchanged as needed.**	
☐ **Determine how quickly data can be retrieved and validated (within the 24 hour window).**	
☐ **Review if systems need to be upgraded and/or purchased to enable data retrieval & validation. Include in fiscal planning as necessary.**	

GS1 US CTE/KDE Guideline

- Overview
  - FSMA 204 Rule
  - GS1 Standards
- How to Apply GS1 Standards to FSMA Rule 204 Requirements
- Best Practices for Mixed Pallets
- Appendix
  - EPCIS
  - Detailed Supply Chain Examples
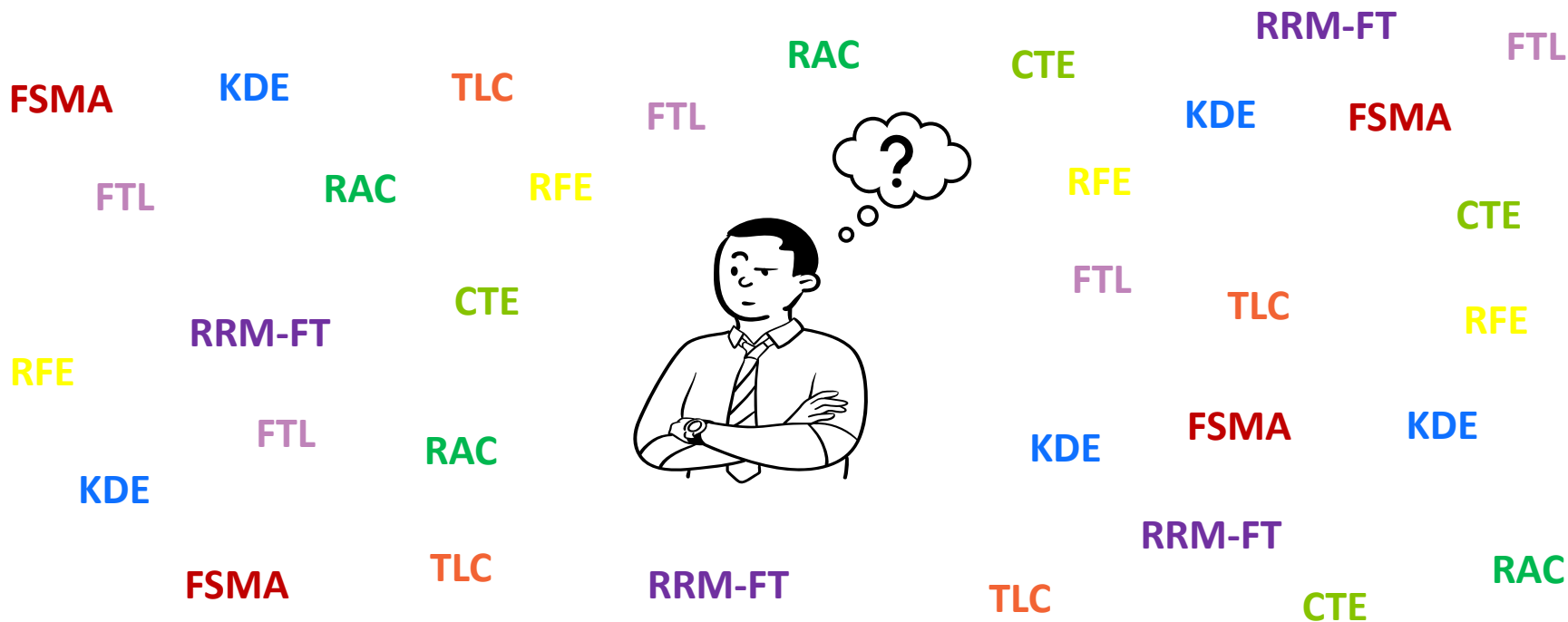
Challenge areas

Scope of Food Traceability List

Distribution Center Operational Challenges
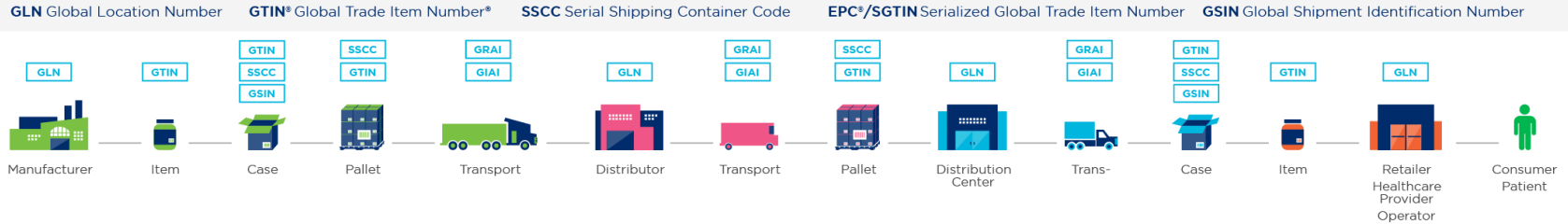
What does compliance look like?

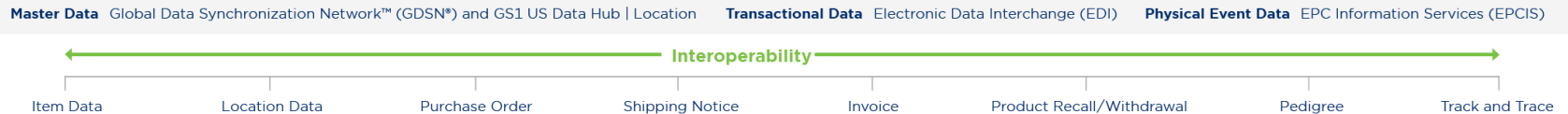# Importance of Sharing Standardized Information

GS1 Standards

Identify: GS1 Identification Numbers

GLN Global Location Number **GTIN®** Global Trade Item Number® **SSCC** Serial Shipping Container Code **EPC®/SGTIN** Serialized Global Trade Item Number **GSIN** Global Shipment Identification Number

| Manufacturer | Item | Case | Pallet | Transport | Distributor | Transport | Pallet | Distribution Center | Trans- | Case | Item | Retailer Healthcare Provider Operator | Consumer Patient |

Capture: GS1 Data Carriers

Barcodes   **EPC-Enabled RFID Tags**   **GS1 Digital Link**

| EAN/UPC | GS1 DataBar® | GS1 DataMatrix | ITF-14 | GS1-128 | HF RFID | UHF RFID | QR Code | Data Matrix |

Share: GS1 Data Exchange

Master Data Global Data Synchronization Network™ (GDSN®) and GS1 US Data Hub | Location   **Transactional Data** Electronic Data Interchange (EDI)   **Physical Event Data** EPC Information Services (EPCIS)

Interoperability

| Item Data | Location Data | Purchase Order | Shipping Notice | Invoice | Product Recall/Withdrawal | Pedigree | Track and Trace |

Identify: GS1 Identification Numbers

GS1 Standards begin with **GS1 Identification Numbers** used to uniquely distinguish all products (trade items), logistics units, locations, assets, and relationships across the supply chain from manufacturer to consumer.
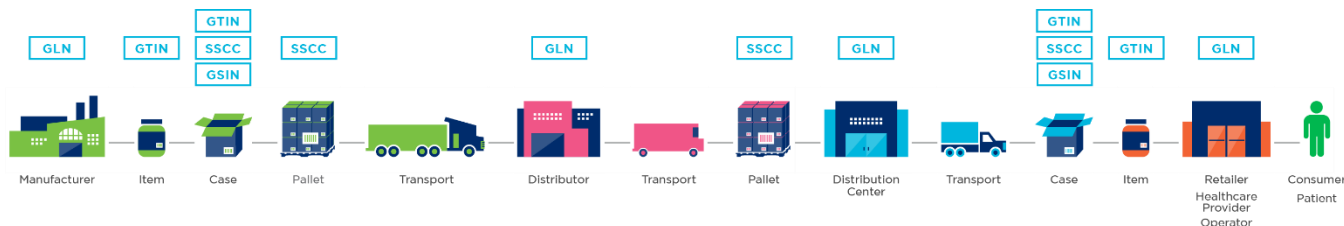
Company	Location	Assets
Global GS1 Company Prefix **GLN** Global Location Number	**GLN** Global Location Number	**GIAI** Global Individual Asset Identifier **GRAI** Global Returnable Asset Identifier

Product	Logistics	Services and Other
GTIN® Global Trade Item Number® **EPC**®/**SGTIN** Serialized Global Trade Item Number	**SSCC** Serial Shipping Container Code **GSIN** Global Shipment Identification Number	**GSRN** Global Service Relation Number **GDTI** Global Document Type Identifier

GLN Introduction

Global Location Number (GLN) provides answers to "who" and "where" by identifying parties and locations throughout the global value chain.

Who

Legal entity	Function

Party

Where

Fixed physical location	Mobile physical location	Digital location

Location

Global Location Number

GLN is Interoperable

- Same identifier used across supply chain

- Significantly reduce or eliminate data mapping

- Uses same GS1 Company Prefix as the one for GTINs, without consuming capacity

- FDA accepted as a Traceability Lot Code Source Reference

GS1 US
DATA HUB

GS1 US's Trusted Source of Information

Data Hub is Centralized

- Permission-based

- Single source of truth

- Access to real time information, eliminate redundancy and manual errors

- Easily share Location Description KDEs for FSMA 204 without adding it to transactional/event data

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

EAN/U.P.C.: 6 14141 98765 8

GS1 DataBar®: (01) 0 0614141 987658

GS1 DataMatrix:
(01) 00614141987658
(17) 120831
(10) A1B2C3D4E5
(21) 00098522

ITF-14: 2 06 14141 98765 2

GS1-128: (01) 0 0614141 987658 (11) 120715 (10) ABC123

EPC®-Enabled RFID Tags		GS1 Digital Link	
HF RFID	UHF RFID	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.

Master Data		Transactional Data	Physical Event Data
GDSN® Global Data Synchronization Network™	**GS1 US Data Hub® | Location**	**EDI** Electronic Data Interchange	**EPCIS** 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.	GS1 US Data Hub | Location provides trading partners with a single source of information for locations (GLNs), how they are related, and how they are used by trading partners.	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	What Goes Into It

• GTINs
• Product Descriptions
• Product Classification
• GLN of Brand Owner
	• GLNs for:
	  - Ship-To/From
	  - Bill-To
	  - Deliver-To
		• GTIN®
		• GLN
		• SSCC
		
		EDI Document Types
		• Purchase Order
		• Advance Ship Notice
		• Invoice
		• Payment
			• What GTIN
			• Where GLN
			• When Date and Time Stamp
			• Why Business Step and
			              Product Disposition
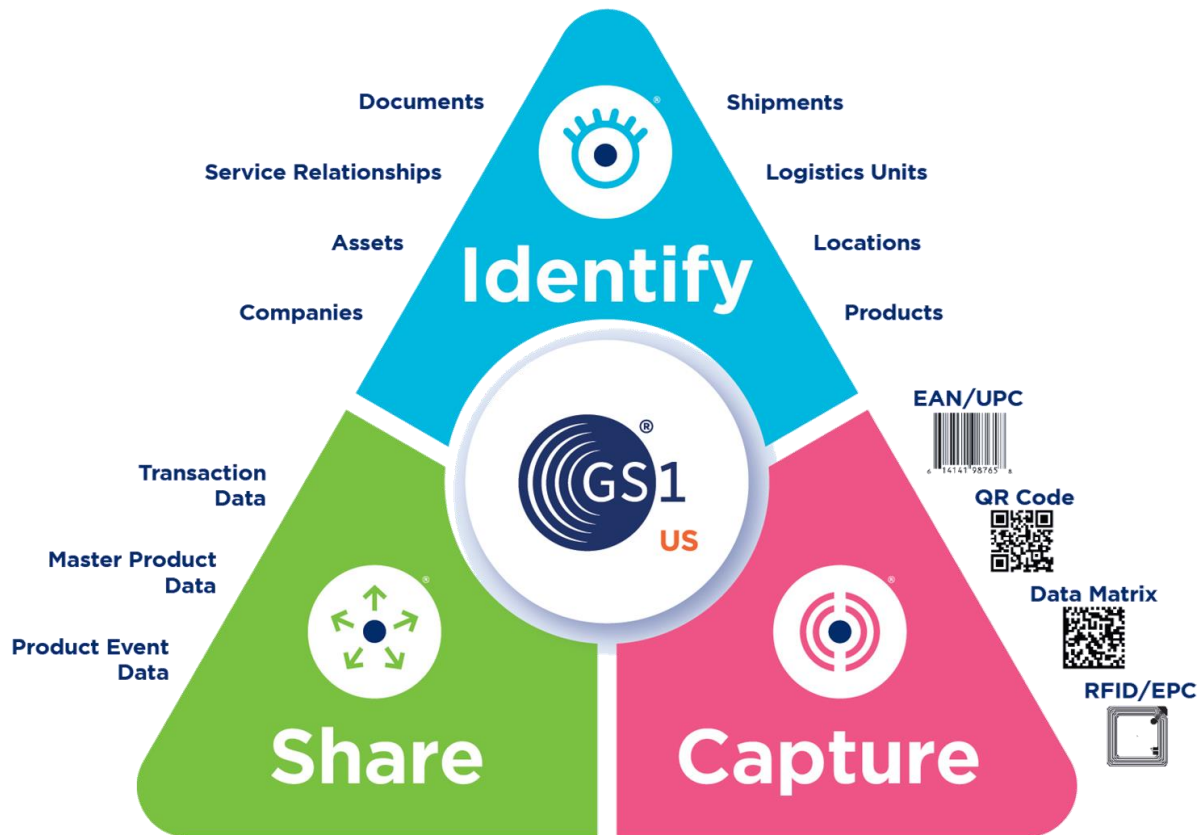
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USDA Foods Requirement in Schools

USDA Foods vendors are required to submit food product information to GS1 Global Data Synchronization Network (GDSN)

❑ Fulfill a requirement in the National School Lunch Act to make nutrition, allergen and ingredient information available for participants of the National School Lunch Program.

❑ State agencies and food service operators leverage data to help with school menu planning and procurement

❑ USDA Food vendors are businesses that have a contract with USDA

How GDSN® Works

Any company that needs to send or receive product information can take advantage of GDSN® by **subscribing to a data pool**.

Your data pool will enable you to **set up your product content and synchronize it with all your trading partners**, so you can plug in reliable data for all markets at one time.

Data pools are certified by GS1, and data in **GDSN follow GS1 Standards**.

GS1 is the global organization for product identification and product data.
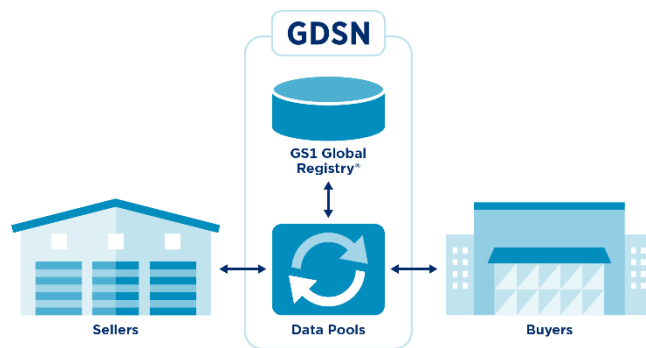
Resources

FDA Food Traceability Tools and Resources

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 |

Shipping KDEs (maintain and provide)
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 subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

*This section does not apply to the shipment 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).

FSMA Technical Assistance Network (TAN)

Share | Tweet | LinkedIn | Email | Print

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.

Frequently Asked Questions

The Technical Assistance Network staff has compiled answers to frequently asked questions on FSMA. You may also use FSMA Guidance Documents to find answers to your questions.

Submit Your Question Electronically

Didn't find your question above?

For assistance with **human food** topics, submit your question to the TAN.
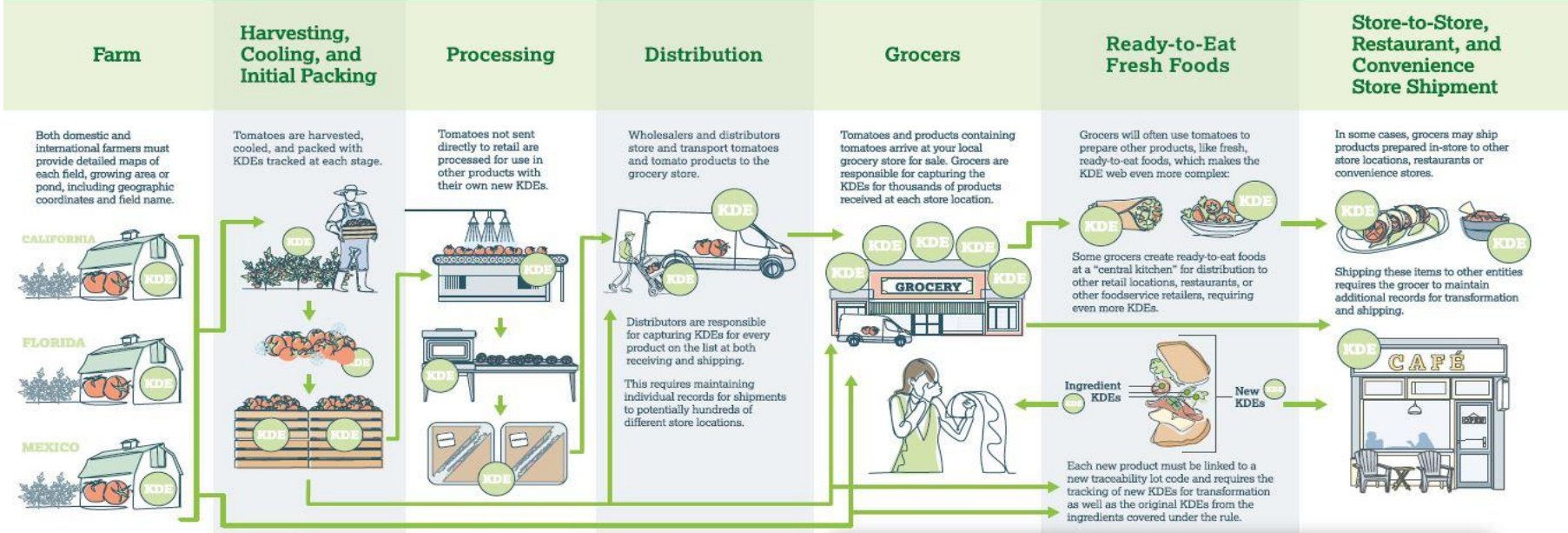
FMI Resources

FDA'S FOOD TRACEABILITY RULE
DOCUMENTING A TOMATO FROM FARM TO GROCER

The U.S. Food and Drug Administration (FDA) issued a highly complex Food Traceability Rule 11 years after passage of the Food Safety Modernization Act. This law was originally designed by Congress to quickly identify and mitigate risk associated with a small number of "high risk" foods more prone to contamination, such as sprouts. However, when the rule was published, the scope expanded dramatically to include a lengthy list of foods impacting well above 10,000 products. The sheer complexity of FDA's mandates puts an unnecessary paperwork burden on an already stressed food supply chain without any focus on prevention – which should be the core of FDA's mission.

Look at all the steps involved in tracking the journey of a tomato from farm to grocery store:

Farm	Harvesting, Cooling, and Initial Packing	Processing	Distribution	Grocers	Ready-to-Eat Fresh Foods	Store-to-Store, Restaurant, and Convenience Store Shipment

Farm
Both domestic and international farmers must provide detailed maps of each field, growing area or pond, including geographic coordinates and field name.

CALIFORNIA

FLORIDA

MEXICO

Harvesting, Cooling, and Initial Packing
Tomatoes are harvested, cooled, and packed with KDEs tracked at each stage.

Processing
Tomatoes not sent directly to retail are processed for use in other products with their own new KDEs.

Distribution
Wholesalers and distributors store and transport tomatoes and tomato products to the grocery store.

Distributors are responsible for capturing KDEs for every product on the list at both receiving and shipping.

This requires maintaining individual records for shipments to potentially hundreds of different store locations.

Grocers
Tomatoes and products containing tomatoes arrive at your local grocery store for sale. Grocers are responsible for capturing the KDEs for thousands of products received at each store location.

GROCERY

Ready-to-Eat Fresh Foods
Grocers will often use tomatoes to prepare other products, like fresh, ready-to-eat foods, which makes the KDE web even more complex:

Some grocers create ready-to-eat foods at a "central kitchen" for distribution to other retail locations, restaurants, or other foodservice retailers, requiring even more KDEs.

Ingredient KDEs → New KDEs

Each new product must be linked to a new traceability lot code and requires the tracking of new KDEs for transformation as well as the original KDEs from the ingredients covered under the rule.

Store-to-Store, Restaurant, and Convenience Store Shipment
In some cases, grocers may ship products prepared in-store to other store locations, restaurants or convenience stores.

Shipping these items to other entities requires the grocer to maintain additional records for transformation and shipping.

CAFÉ

KDE
A total of 117 Key Data Elements (KDEs) must be tracked for nine Critical Tracking Events (CTEs) in the supply chain.

3 billion
Number of records FDA estimates the food industry will need to keep each year

10 million
Number of hours FDA estimates it will take to maintain the 3 billion data points

$24.6 billion
FDA's estimated cost to the food industry

2.8 billion
Share of the 3 billion records — or 94% — grocers and food retailers are responsible for maintaining

24 hours
Timeframe to produce all records in a sortable electronic spreadsheet upon FDA request

2 years
Length of time records must be kept for fresh foods that will have long been consumed or expired

Business models are rapidly changing, and any regulatory framework should provide flexibility to adapt with business practices. FDA's Food Traceability Rule **inhibits** progress by:

- Creating an unnecessary paperwork burden that diverts resources from the primary focus of preventing foodborne illness.
- Requiring a level of detail and tracking not achievable or valuable with current technology.
- Imposing unreasonable obligations on small and medium size businesses and farms who are least able to absorb additional costs.
- Creating administrative costs that will significantly increase already elevated food prices for shoppers without a demonstrated public health benefit.

FMI

GS1 US Resources

Wrap Up

FMI / GS1 US Webinar Series

Series Recordings

August 2: The What: Understanding the Basics of FSMA Rule 204 View Recording >

August 9: The How: Industry Defined Guidance to Help Meet FSMA 204 Record Keeping Requirements View Recording >

August 16: The Why: Driving Business Value Beyond FSMA 204 Regulatory Compliance View Recording >

Questions

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