The Why

Driving Business Value Beyond FSMA 204 Regulatory Compliance

FMI THE FOOD INDUSTRY ASSOCIATION

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*If applicable

Speaker Introductions

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FMI

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GS1 US

Who We Are

GS1 – The Global Language Of Business

GS1 is a global standards organization

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

115 Member Organizations

**Serving 150 Countries**

Over 10 billion scans a day

Standard of choice by +65 governments globally

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.
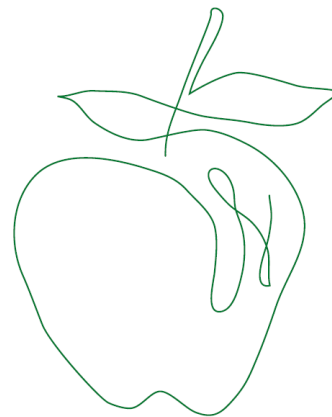
www.fmi.org

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

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)

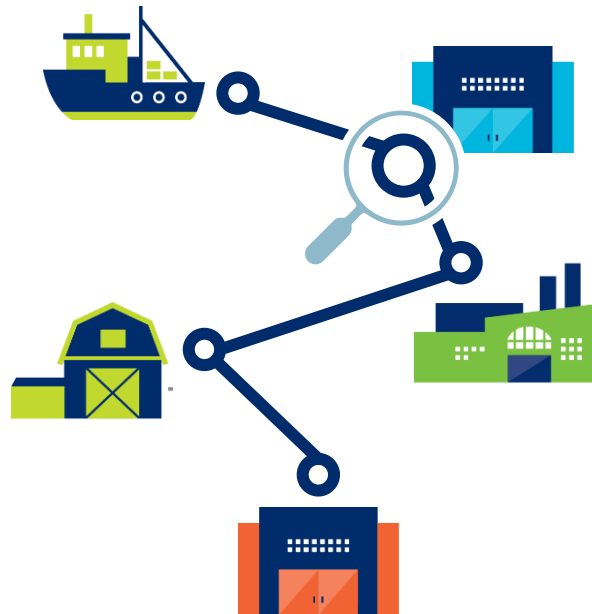**Vegetables Other Than Leafy Greens**
(fresh cut)

Traceability

trace·a·bil·i·ty

noun

the quality of having an origin or course of development that may be found or followed.

How do GS1 Standards Enable Traceability for Enhanced Food Safety?

Unique Product Identification 1

Standardized Exchange of Data 2

Precise Recall Readiness 3

Increasing Consumer Confidence

FMI

Comments submitted on Food Traceability Proposed Rule

FDA Final Rule Published

GS1US FSMA 204 Workgroup Forms

Proposed rule published

Comments on draft methodology for high-risk foods

Active engagement with Congress on the language in FSMA

Traceability Workshops, FBIA

Deli, Dairy, Bakery Traceability

Meat Traceability

GS1 Standards

Produce Traceability Initiative

Seafood Traceability Guidance

Pilot Projects to Improve Product Tracing

IFT Global Food Traceability Center established

Leafy Greens Traceability Pilots

GS1 US

Healthcare went first

Leverage Standards, Beyond Regulation, for Supply Chain Visibility

- **Medical Devices:** The U.S. FDA's Unique Device Identification System final rule (UDI Rule) is aimed to identify medical devices sold in the United States, from manufacturing through distribution to patient use.

- **Pharmaceutical Drugs:** The Drug Supply Chain Security Act (DSCSA) has its final milestone in November of this year,
which will require item-level serialized traceability in an interoperable manner across the U.S. pharmaceutical industry.

Pharmaceutical Community Example

The stakeholders of the Pharmaceutical community leaned in together to solve how the industry could meet the requirements of the Drug Supply Chain Security Act (DSCSA)

- DSCSA mandates the industry to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

- This creates interdependencies with all stakeholders in the supply chain.

- The industry has responded by collaborating to construct the means to meet these requirements **and more to improve the overall supply chain**.

DSCSA Timeline with GS1 Rx Secure Supply Chain Workgroup Actions

Regulatory Requirements →

		Federal licensure standards for distributors raised
		Transaction information provided by Manufacturer, Wholesaler, and Repackager. Transact only with authorized trading partners
		FDA enforcement discretion ends

DSCSA Enacted	3PLs must report licensure information to FDA annually	Transaction information accepted by Dispensers		Manufacturers must serialize and verify products	Repackagers must serialize products
2013	**2014**	**2015**	**2016**	**2017**	**2018**
Applying GS1 Standards for DSCSA and Traceability, R1.0 implementation guideline published	**Applying GS1 Standards for DSCSA and Traceability, R1.1** implementation guideline published		Guideline Addendums: • Guidance and XML Examples for Supply Chain Choreographies in Lot-Level Management, • Diagrams and XML Examples for Lot-Level Management • Exceptions Processing • Diagrams and XML Examples for Serialized Exceptions Processing	Frequently Asked Questions (FAQs) by the Pharmaceutical Industry in Preparing for the U.S. DSCSA, R1.0, published	Guidance published for Pharmaceutical Products Marked with Both UPC-A and GS1 DataMatrix, R1.0
				2017 update published: Implementation of DSCSA Serialization Requirements	2018 Update Published: Implementation of DSCSA Serialization Requirements
					GS1 US submitted a comment letter to the U. S. FDA on Product Identifiers
			NDC Labeler Code Program		GS1 US submitted a comment letter to the U. S. FDA on Verification Systems

Workgroup Publications →

DSCSA Timeline with GS1 Rx Secure Supply Chain Workgroup Actions

2019	2020	2021	2022	2023	2023 - Planned
FDA delays enforcement of saleable returns requirement by 1 year for wholesalers	All dispenser must be complying with all verification requirements				Full interoperable electronic serialized unit-level traceability for all stakeholders. Dispensers only receive and ship/dispense serialized products. Dispensers verify product identifiers.
Wholesalers and Distributors only receive and distribute serialized products. Returns verified.	FDA delays enforcement of saleable returns requirement by 3 years for wholesalers and dispensers				
2019 update published Implementation of DSCSA Serialization Requirements	Implementation guideline published: Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers, R1.1	2020 update published Implementation of DSCSA Serialization Requirements	GS1 US submitted a comment letter to the U. S. FDA on Enhanced Drug Distribution Security at the Package Level Under DSCSA	GS1 US submitted a comment letter to the U.S. FDA on Drug Supply Chain Security Act (DSCSA) Implementation and Readiness Efforts for 2023	Applying GS1 Standards for DSCSA and Traceability, Addendum: Diagrams and XML Examples for Serialized Item-Level Exception Handling, R1.3, to be published
GS1 US Lightweight Messaging Standard for DSCSA Verification		Implementation guideline published: Applying GS1 System of Standards to Pharmaceutical Chain of Custody, R1.1	Frequently Asked Questions (FAQs) by the Pharmaceutical Industry in Preparing for the U.S. DSCSA, R1.0.1	Applying GS1 Standards for DSCSA and Traceability, Addendum: Guidance and XML Examples for Supply Chain Choreographies in Serialized Item-Level Management, R1.3	Updates to: FAQs by the Pharmaceutical Industry in Preparing for the U.S. DSCSA, R1.2 Applying GS1 System of Standards to Pharmaceutical Chain of Custody, R1.2
		Implementation guideline published Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers, R1.2	Implementation guideline published: Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Product Identifiers, R1.3	Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Product Identifiers, R1.3.1	
			2022 Update: Implementation of DSCSA Serialization Requirements	Best Practice Guidance for Transition Inventory November 2023 DSCSA	
			Implementation guideline published: Applying GS1 Standards for DSCSA and Traceability, R1.3		

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GS1 Standards

Pilot Projects to Improve Product Tracing

Seafood Traceability Guidance

Leafy Greens Traceability Pilots

GS1 US Resources

- [DSCSA Webpage](#)
  - DSCSA, Guidance by Stakeholder, GLNs, Resources, FAQs
- Rx Secure Supply Chain Workgroup
  - Implementation Guidelines
    - Supply Chain Scenarios
    - Exception Handling
  - FAQs
  - Verification Messaging Standard
- Education and Training:
  - [Overview of GS1 Standards for DSCSA Dispensers](#) (25-30 minutes)
  - [GS1 Standards for DSCSA Suppliers Online Certificate](#) (8 Modules)

Resource	What It Will Help With
Frequently Asked Questions in Preparing for the U.S. DSCSA	Answering frequently asked questions about identifying, capturing and sharing information to help meet DSCSA requirements.
GS1 US DSCSA Implementation Guidelines	Understanding technical requirements for encoding your product with GS1 Identifiers and how to capture GS1 product identifiers when receiving shipments.
Applying Lightweight Messaging Standard for Verification of Product Identifiers	Configuring PI verification business scenarios and technical requirements for responding to verification requests from your direct and indirect trading partners.
How to Identify your Location for DSCSA Requirements	Identifying your locations with a Global Location Number to share information related to Transaction Information (TI) and Transaction Statements (TS) and verify product information through a third-party routing system.
Progress on 2023 DSCSA Interoperability	Understanding the quality of barcodes to ensure scannability by your trading partners.
GS1 US Implementation Guideline for Pharmaceutical Chain of Custody	Capturing GS1 product identifiers when packing and shipping when working with 3rd party agents (CMOs, CPOs, and 3PLs).
GS1 US Pharmaceutical Conformance Test Program	Optimizing the data quality of your EPCIS serialized exchanges with the help of a certified third-party testing service.
GS1 US DataHub	Sharing, searching, and retrieving GLN information with your trading partners.

How to get started...

Traceability Plan

Foods on Food Traceability List

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

Records 2-year retention

Traceability Plan

Procedures to maintain traceability records	**Procedures to identify foods on the FTL**	**Description of how a TLC is assigned (if applicable)**	**Point of Contact for traceability plan and records**	**Farm map or location of each container (for aquaculture farms)**
A description of the procedures you use to maintain the records you are required to keep under this rule, including the format and location of these records.	A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;	A description of how you assign traceability lot codes to foods on the Food Traceability List, if applicable;	A statement identifying a point of contact for questions regarding your traceability plan and records;	If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.

Traceability Plan

FSMA 204 Requirement	Description	Examples to Apply GS1 Standards
Procedures to maintain traceability records	A description of the procedures you use to maintain the records you are required to keep under this rule, including the format and location of these records.	**CTEs-KDEs:** Captured/Shared using ASNs, EPCIS, GDSN, GLN Data Model **TLC**: Encoded in Data Carrier An internal traceability system can collect/aggregate all this data daily.
Procedures to identify foods on the FTL	A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;	Products in scope for FSMA 204 are identified using the **GDSN local code value=FSMA 204** and published to trading partners using GDSN data pool provider.
Description of how a TLC is assigned (if applicable)	A description of how you assign traceability lot codes to foods on the Food Traceability List, if applicable;	**GTIN and Lot Code can be used to represent a TLC**. They can be encoded in GS1-128 barcodes (or other data carrier) labels, placed on cases when product is manufactured.
Point of Contact for traceability plan and records	A statement identifying a point of contact for questions regarding your traceability plan and records;	Name, Title, Phone, email, alternative contact
Farm map or location of each container (for aquaculture farms)	If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.	Geographic coordinates can be captured/shared using **GS1 GLN Data Model attributes, GS1 US Data Hub**

Trading Partner Considerations

Option 1

Printed or Electronic Bill of Lading and PTI Label

Option 2

Electronic Sortable Spreadsheet

Option 3

EDI 856 Advanced Ship Notice or EPCIS Shipping Event
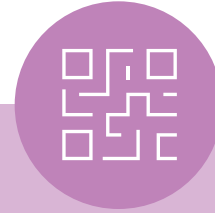
Option 4

GS1 Scan4Transport QR Code which includes all Shipping KDEs

Option 5

Paper or digital manifest, proof of shipment

Solution Provider Conversations

Questions to ask of traceability technology service providers
For use by Retailers, Wholesalers and Product Suppliers

Questions
1. Company Name, URL, contact person

2. Please describe your food traceability solution for the food industry.

3. How does your technology solution address the requirements in FDA's Food Traceability Final Rule?

4. Which of the following components does your solution offer? (Check all that apply)
   - Formatting, storing GS1 Identification Numbers (e.g., Global Trade Item Numbers, Global Location Numbers, Serial Shipping Container Codes, Electronic Product Codes)

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
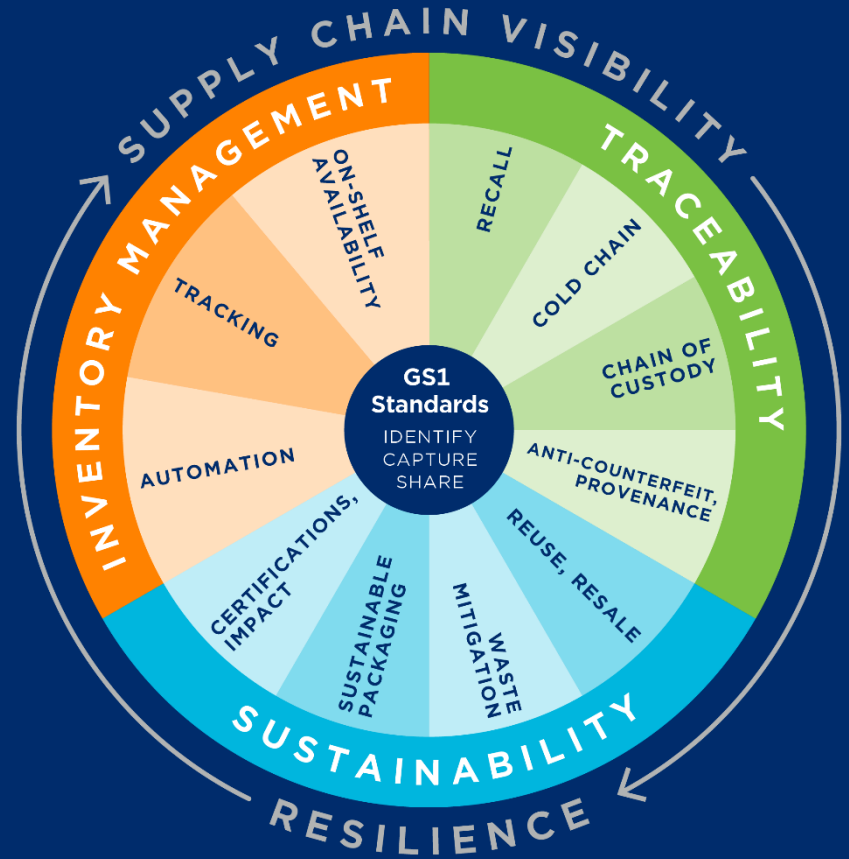
Resources

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)

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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

GS1 US Resources

Next Steps

How to get started

Assemble the Team

Evaluate current systems

Plan

Implement

Up next in series

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

- **August 9:** The How: Industry Defined Guidance to Help Meet FSMA 204 Record Keeping Requirements: Webinar recording

GS1 US and FMI Present
FSMA Rule 204 Webinar Series

Questions

EMAIL:

- foodsafety@gs1us.org

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