



FSMA Rule 204 Implementation Toolkit



FSMA RULE 204

FSMA Rule 204 Implementation Toolkit



Members of the food industry and technology solution providers should align on a common language to help stakeholders meet the U.S. Food and Drug Administration's (U.S. FDA) Food Safety Modernization Act Rule 204 (FSMA Rule 204) requirements in an interoperable, scalable, and efficient manner.



GS1 US is here to help!
This comprehensive toolkit includes information and resources that will:

- Inform you and your customers about key FSMA Rule 204 requirements and how to prepare for them.
- Explain how to integrate GS1 Standards into your traceability solutions.

FSMA RULE 204

Main Menu

Click on each quadrant to learn more and use the navigation buttons in the top right to jump forward and backward throughout the toolkit.





FSMA RULE 204

Executive Summary

FSMA RULE 204: EXECUTIVE SUMMARY 1 OF 3

Prepare to Meet FSMA Rule 204 Requirements and Gain Supply Chain Visibility

The compliance deadline for the requirements of the Food Safety Modernization Act, section 204(d), is **January 20, 2026**. It is critical for organizations to start their implementations and benefit from adopting GS1 Standards.

Targeted, precise recalls reduce the impact, duration, and risk of foodborne illness outbreaks. Each year, **48 million** people get sick from foodborne diseases in the U.S. The yearly average cost of recalls in the U.S. is **\$10 million**. GS1 Standards can help improve your recall management and meet regulatory requirements by enabling traceability.*



WHY GS1 STANDARDS

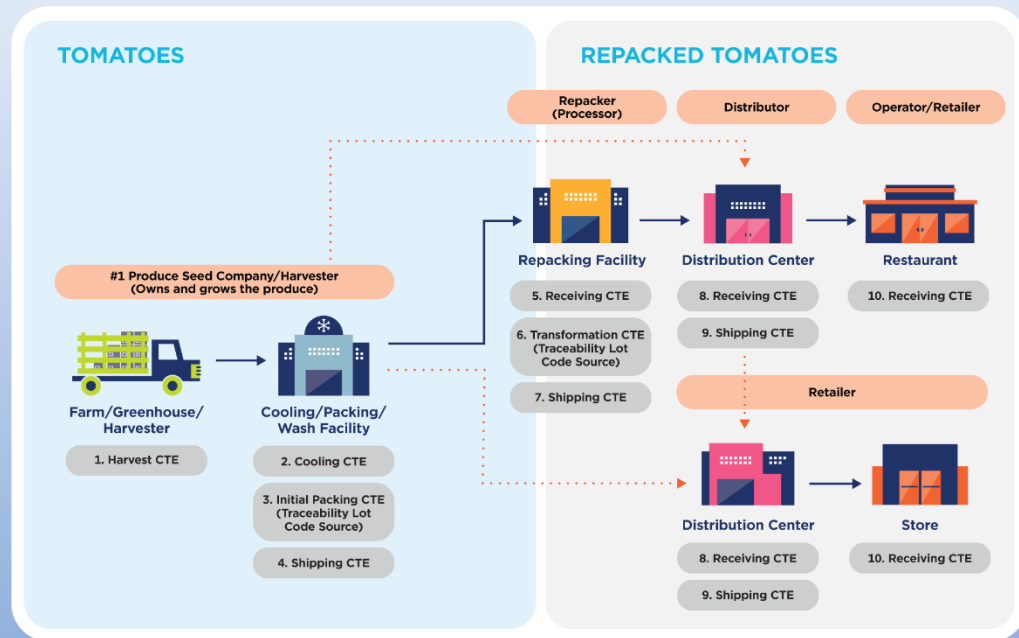
"Traceability is vital to food safety, establishing the legality of ingredients and validating sustainability. GS1 Standards provide the framework for all of it."

— Renée Perry, Vice President, [Culinary Collaborations](#)

*Source: <https://www.cdc.gov/foodborneburden/index.html>

FSMA RULE 204: EXECUTIVE SUMMARY 2 OF 3

Many Stakeholders, One Goal



Retailers, operators, distributors, manufacturers, solution providers, and associations align on leveraging GS1 Standards across the supply chain to help meet FSMA Rule 204 requirements.

How do you enable traceability and visibility along the supply chain?

By recording standardized **Key Data Elements (KDEs)** at **Critical Tracking Events (CTEs)** along a product's journey.

FSMA RULE 204: EXECUTIVE SUMMARY 3 OF 3

ROI Beyond Compliance

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
- Enhanced consumer and patient safety

Consumer Engagement

- Brand loyalty
- Additional safety





FSMA RULE 204

Basics for the Rule

FSMA RULE 204: BASICS FOR THE RULE 1 OF 3

Overview

What is it and who is impacted?

- Final [FSMA Rule 204 on Requirements for Additional Traceability Records](#) for high-risk products are outlined in the **Food Traceability List (FTL)**.
- Anyone who manufactures, processes, packs, or holds foods
- 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 **Critical Tracking Events (CTEs) and Key Data Elements (KDEs) to U.S. Food and Drug Administration (FDA) within 24 hours** in a sortable spreadsheet
- Must keep a documented **Traceability Plan**

When?

- Final Rule Effective: January 2023
- Intended Compliance Date: July 20, 2028
- Records should be maintained for 2 years

FSMA RULE 204: BASICS FOR THE RULE 2 OF 3

Food Traceability List



Cheese
(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)



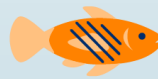
**Ready-to-Eat
Deli Salads**
(refrigerated)



Sprouts
(fresh cut)



Shell Eggs
(fresh)



**Smoked
Finfish**
(refrigerated
and frozen)



Tomatoes
(fresh)







**Tropical
Tree Fruit**
(fresh)



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

FSMA RULE 204: BASICS FOR THE RULE 3 OF 3

Critical Tracking Events & Key Data Elements

Critical Tracking Events	Harvest	Transform	Ship	Receive
	Tomatoes picked and placed into totes 	Tomatoes are repacked at processor 	Tomato cases are packed in pallets at packing house and shipped to distributor 	Tomatoes are received at distributor 
Key Data Elements	When?	When?	When?	When?
	What?	What? [Inputs & Outputs]?	What?	What?
	Where?	Where?	Where?	Where?
	Why?	Why?	Why?	Why?

[U.S. FDA's definition of CTEs and KDEs](#)

Critical Tracking Events (CTEs)

are activities in the supply chain that must be recorded by the capture of key information about a business step for product movement in the supply chain. Typically, these events involve a product's transformation, shipping, or creation.

Key Data Elements (KDEs) are the attributes that describe/support the critical tracking event; this data answers the What, Where, When, Who, and Why of the event.



FSMA RULE 204

Toolkit Central

FSMA RULE 204: TOOLKIT CENTRAL

Overview

REQUIREMENTS

SOLUTIONS

Identify FTL Items & Product Description KDEs

GTIN and GDSN ▶

Parties & Locations Description KDEs

GLN and GS1 US Data Hub ▶

Shipping KDEs

ASN (EDI 856)* ▶

All Other CTEs/KDEs

EPCIS ▶

Capture TLC (Traceability Lot Code) &
TLC Source Throughout Supply Chain

Data Carriers, ASNs, EPCIS ▶

Connecting Master Data to Transactional and Event Data ▶

**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](https://www.gs1.org/standards/x12/transaction-sets)*

FSMA RULE 204: TOOLKIT CENTRAL

GTIN and GDSN

1 OF 2

- **GTINs (Global Trade Item Numbers)** can be used to identify trade items that are in scope for FSMA Rule 204 that are:
 - Part of the U.S. FDA's Food Traceability List (FTL).
 - Contain ingredients that are on this list and have not undergone a kill step.
- **GTINs** can be included in the transactional (Advance Ship Notices—ASNs) and event (Electronic Product Code Information Services—EPCIS) data to point to the rest of the product information in a Master Data System.
 - See ["Connecting Master Data to Transactional and Event Data"](#) for more info.
- **GDSN® (Global Data Synchronization Network™)** can be used to share all Product Description Key Data Elements (KDEs) required by FSMA Rule 204.

FSMA RULE 204: TOOLKIT CENTRAL

Using GTIN and GDSN 2 OF 2

Identify FTL Items

Section 3.3.3 of the GS1 FSMA Rule 204 Guideline specifies the two GDSN attributes that are available to identify items in scope for FSMA Rule 204:

1. RegulationTypeCode = **TRACEABILITY_REGULATION**
2. U.S. Local Code Value for RegulatoryAct (BMS ID 3071) = **FSMA204**
3. isTradeItemRegulationCompliant = **TRUE**

Two other field to specify why it's not subject to the rule:
IsTradeItemRegulationCompliant=**NOT_APPLICABLE**, then
RegulationRestrictionsAndDescriptors =
KILL_STEP_APPLIED OR NOT COVERED BY FTL

**For more information on this Local Code Value, please visit: <https://www.gs1.org/standards/gdsn/3-x>*

Product Description KDEs

Section 4.3 of the GS1 FSMA Rule 204 Guideline specifies mappings between the product description KDEs required by the Final Rule and attributes in GDSN.

Example of GTINs for Traceability Product Descriptions and Traceability Product Identifiers

GTIN OR OTHER PRODUCT IDENTIFIER	BRAND NAME	COMMODITY	VARIETY	PRODUCT NAME	PACKAGING SIZE	PACKAGING STYLE
00614141007349	Brand ABC	Tomatoes	Cherry	n/a	25 LB	Carton
00614141004366	Brand ABC	n/a	n/a	Sprout Mix	4 oz	Clamshell
10012345000055	Brand 123	Tuna	Atlantic Bluefin	n/a	10 KG	Bin
80498265800736	Brand XYZ	N/A	N/A	Queso Fresco	12 x 8 oz	Vac Pack
105146287231822	Brand 999	N/A	N/A	Small Vegetable Tray w/ dip	6 oz	Tray
107483945748382	Brand 111	N/A	N/A	Peanut Butter Sandwich Cracker	12 oz	Box

[View GS1 US FSMA Guideline Sections 3.3.3 and 4.3 ▶](#)

[View 3 Steps to use GDSN for FSMA 204 ▶](#)

FSMA RULE 204: TOOLKIT CENTRAL

GLN and GS1 US Data Hub 1 OF 2

- **GLNs (Global Location Numbers)** can be used to identify physical locations and streamline the sharing of Ship to, Ship From, and Traceability Lot Code Source Location Description KDEs required by FSMA Rule 204.
 - GLNs can be included in the transactional (ASNs) and event (EPCIS) data to point to the rest of the location information in a Master Data System.
 - See [“Connecting Master Data to Transactional and Event Data”](#) for more info.
- **GS1 US Data Hub | Location** can be used as a centralized source of truth for Location Description KDEs required by FSMA Rule 204.
 - Access can be given to trading partners and/or U.S. FDA as needed.

FSMA RULE 204: TOOLKIT CENTRAL

Using GLN and GS1 US Data Hub 2 OF 2

GS1 US Data Hub | Location

[Click for more information on using GS1 US Data Hub | Location.](#) Location information can be shared with U.S. FDA and/or trading partners.



Location Description KDEs

The **GS1 US Global Location Number Recommendations for FSMA Rule 204** specifies mappings between the location description KDEs defined by the U.S. FDA in the Final Rule and attributes in GLN Data Model (and GS1 US Data Hub).

Data Attributes for Location Description KDEs

DATA ATTRIBUTES OF LOCATION DESCRIPTION	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

[View GS1 US FSMA Guideline Sections 3.1.3 and 4.4 ▶](#)[View GS1 US GLN Recommendations for FSMA Rule 204 ▶](#)

FSMA RULE 204: TOOLKIT CENTRAL

Advance Ship Notice (EDI 856) 1 OF 2

The **EDI 856** or **ASN** can be used to capture and share the Shipping KDEs required by FSMA Rule 204 efficiently, regardless of the Electronic Data Interchange (EDI) version a company's system is on.

- ASNs should be used in conjunction with the Serial Shipping Container Code (SSCC) encoded in a GS1 Logistics Label for each pallet or logistics unit being delivered.
- ASNs should arrive prior to the physical pallets so the system can recognize them once that pallet SSCC is scanned.

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

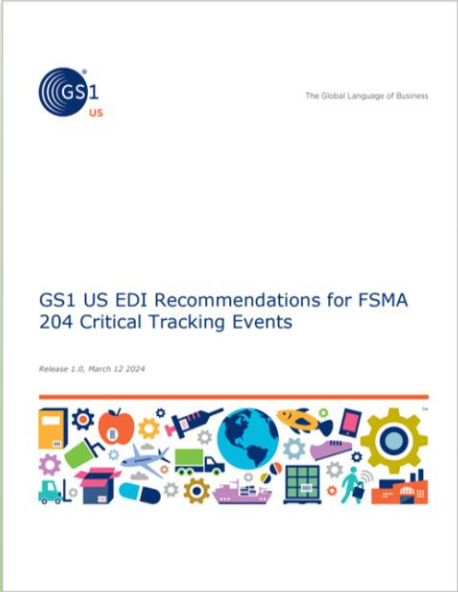
Streamline Your Logistic Unit Identification



For more information, search our Resource Library at www.gs1us.org/resource-library.

FSMA RULE 204: TOOLKIT CENTRAL

Using ASNs 2 OF 2



3

Shipping CTE and the Advance Ship Notice

3.1

Traceability Lot Code = GTIN+Batch/Lot

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

The GTIN/Lot information is submitted on the Pack level.

Ref	Id	Element Name	Req	Type	Min/Max	Usage
LIN02	235	Product/Service ID Qualifier	M	ID	2/2	Must use
<p>Description: Code identifying the type/source of the descriptive number used in Product/Service ID (234)</p> <p>Code List Summary</p> <p>Code Name</p> <p>UK GTIN-14</p> <p>Description: A 14-digit GS1 Identification Key composed of an Indicator Digit, GS1 Company Prefix, Item Reference, and Check Digit used to identify trade items.</p>						
LIN03	234	Product/Service ID	M	AN	1/80	Must use
<p>Description: Identifying number for a product or service</p>						
LIN04	235	Product/Service ID Qualifier	M	ID	2/2	Must use
<p>Description: Code identifying the type/source of the descriptive number used in Product/Service ID (234)</p> <p>Code List Summary</p> <p>Code Name</p> <p>LT Lot Number</p>						
LIN05	234	Product/Service ID	M	AN	1/80	Must use
<p>Description: Identifying number for a product or service</p>						
<p>✔ Example: LIN*01*UK*10614141000002*LT*ABCDE12345-- This pack is identified by a GTIN-14 (10614141000002) and lot # ABCDE12345</p>						

3.2

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.

The quantity is submitted on the pack level. For each different lot the quantity of packs associated with the lot number will need to be identified.

SN102	382	Number of Units Shipped	M	R	1/10	Must use
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ASNs are commonly used to share shipping KDEs between trading partners.

View GS1 US EDI* Recommendations for FSMA Rule 204 CTEs ▶

View Food Industry Guidance for Streamlining Your Logistics Labels ▶

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

FSMA RULE 204: TOOLKIT CENTRAL

EPCIS ^{1 OF 2}

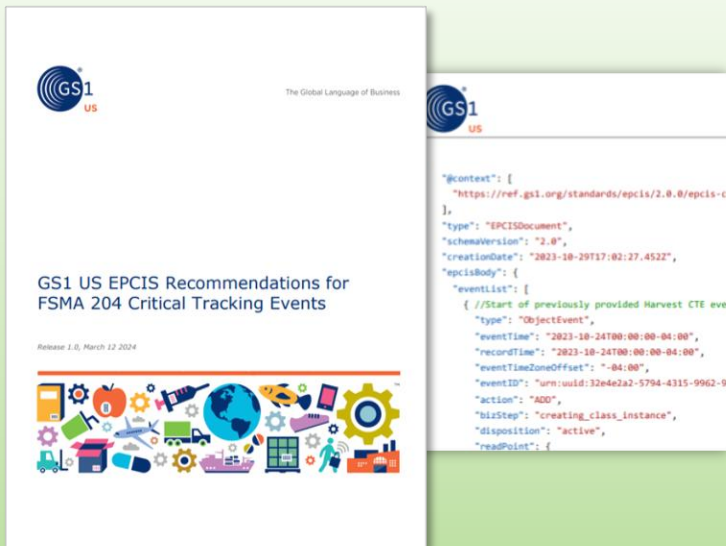
Electronic Product Code Information Services (EPCIS) can be used to capture and share all the FSMA Rule 204 required Critical Tracking Events (CTEs).

- The food industry determined the best practice is to use EPCIS for all CTEs required by FSMA Rule 204 except the Shipping event for which ASNs are most commonly used.



FSMA RULE 204: TOOLKIT CENTRAL

Using EPCIS ^{2 OF 2}



EPCIS is commonly used to share “event data” between trading partners.

[View Demystifying EPCIS Video ▶](#)

[View EPCIS Mapping Examples for FSMA Rule 204 CTEs ▶](#)

[View GS1 US EPCIS Recommendations for FSMA Rule 204 CTEs ▶](#)

[View EPCIS Sandbox* ▶](#)

**Tool owned by GS1 AISBL.*

FSMA RULE 204: TOOLKIT CENTRAL

Data Carriers, ASNs, EPCIS 1 OF 2

- The **GTIN + Lot** can be used to determine the **Traceability Lot Code** required by FSMA Rule 204. This information can be encoded in a Data Carrier such as a barcode or Radio Frequency Identification (RFID) tag.
- A **GLN** can be used to determine the **Traceability Lot Code (TLC) Source Reference**.
- The **TLC** and **TLC Source** are critical KDEs to be able to link all other CTEs together.
 - These can be included in the EPCIS events and ASN transactions, as well as in data carriers such as barcodes or RFID tags.
- Barcodes approved for use and implemented in current general food distribution environments are largely 1D (e.g., ITF-14, GS1-128). Most scanning systems and processes are currently optimized for 1D barcodes, though 2D barcodes may offer advantages in certain scenarios.



GS1-128 Barcode

Allows for 48 characters. Linear barcode scanners are needed to capture this information. Uses GS1 element string syntax. **GTIN + date + lot** information can be included.



GS1 DataMatrix

Allows for up to 2,335 encoded characters. Uses less space and has error correction. Image-based scanners are needed to capture this information. Uses GS1 element string syntax (same as GS1-128). **GTIN + date + lot** information can be included plus the **TLC Source Reference GLN**.



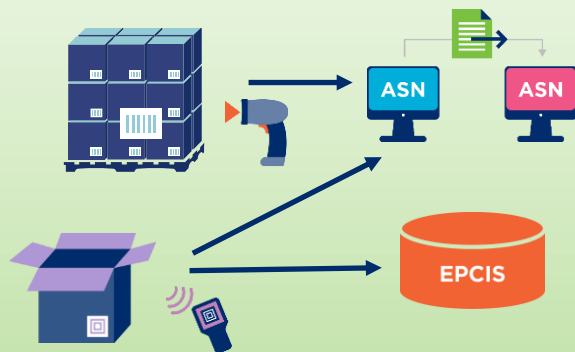
RFID

Industry participants have recently taken steps to aggressively investigate and pilot the use of the **Electronic Product Code (EPC) in RAIN RFID** tags for carton-level tracking. Such solutions provide high-speed inventory visibility without line-of-sight scanning.

FSMA RULE 204: TOOLKIT CENTRAL

Using Data Carriers, ASNs, EPCIS 2 OF 2

TLC (GTIN + lot) & TLC Source Reference (GLN) are incorporated in the ASN and EPCIS events.



- They can be encoded in data carriers such as GS1 Data Matrix, RFID tags.
- GS1-128 best practice: encode GTIN, date, lot.

Sections 2.2-2.3 of the GS1 FSMA Rule 204 Guideline explain best practice to capture TLC and TLC source throughout the supply chain.

Section 3.2.2 of the GS1 FSMA Rule 204 Guideline explains the different data carriers that could be used, such as GS1-128 barcodes, 2D barcodes, and RFID tags.

[View sections 2.2-2.3 and 3.2.2 of the GS1 US FSMA Rule 204 Guideline ▶](#)

[View North American Case Labeling Guideline for GS1-128 information ▶](#)

[View 2D Barcode Overview in General Distribution ▶](#)

[View RFID Foodservice Implementation Guideline ▶](#)

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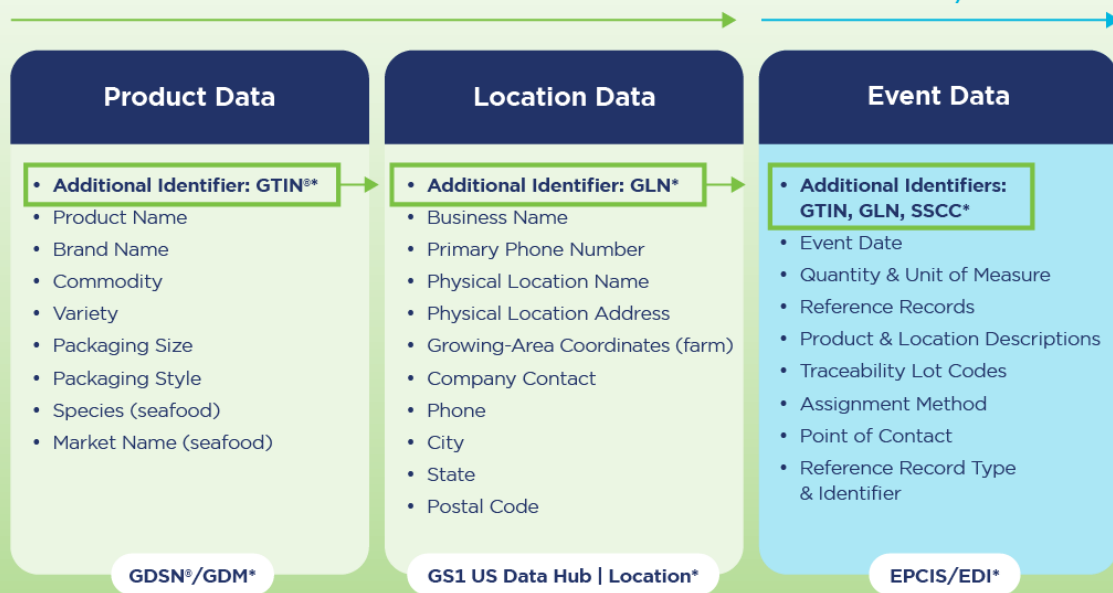
Connecting Master Data to Transactional and Event Data 1 OF 3

- **GS1 Identifiers act as the points connecting** transactional and event data that relies on master data for context and accuracy.
- When recording a shipping transaction, transactional and event data both reference master data elements such as **customer location information** and **product details** to ensure the correctness of the transaction.

Data Framework Example

MASTER DATA

TRANSACTIONAL/EVENT DATA



*Denotes possible use of GS1 Standards for FSMA 204

FSMA RULE 204: TOOLKIT CENTRAL

Connecting Master Data to Transactional and Event Data 2 OF 3

Integrate the EDI 856 with your master data systems to enhance visibility and accuracy and ensure that the relevant master data (e.g., product codes, quantities, units of measure) aligns with the shipment details in the EDI 856.

Key Steps to Master Data Integration With EDI

- 1. Mapping:** Map the GS1 Identification Keys in the EDI 856 to corresponding fields in your master data system for both recipient and sender of the ASN.
 - 2. Sender—ASN Creation:** Generate the EDI 856 based on the actual shipment.
 - 3. Receiver—Validation:** Validate the EDI 856 against master data rules (e.g., product GTINs, packaging).
 - 4. Receiver—Integration:** Integrate the EDI 856 with your enterprise resource planning (ERP) or warehouse management system (WMS).
 - 5. Real-Time Updates:** Ensure real-time updates between the EDI 856 and master data as shipments progress.
- IMPORTANT:** The order of the identifiers should be GTIN + batch/lot, followed by proprietary numbers.

FSMA RULE 204: TOOLKIT CENTRAL

Connecting Master Data to Transactional and Event Data 3 OF 3

Integrate EPCIS events with your master data systems to enhance visibility and accuracy and ensure that the relevant master data (e.g., product identifiers and descriptions) aligns with the details in the EPCIS event.

Key Steps to Master Data Integration With EPCIS

- 1. Identifier Capture:** Obtain TLC and TLC Source Reference identifiers (GTIN + Batch/Lot and GLN) during supply chain process.
- 2. Construct Event Data:** Insert TLC and TLC Source Reference identifiers into EPCIS event data, along with date/time and other KDEs, such as source/destination GLNs.
- 3. Extract Identifiers:** Obtain GS1 Identification Keys from EPCIS data exchange or internal query. Fields to extract data from include epcClass fields, readPoint fields, source/destinationList fields.
- 4. Cross Reference:** For needed master data, cross-reference extracted identifiers from EPCIS event data to trade item and location master data management systems or other sources (GS1 US Data Hub, GDSN, etc).



FSMA RULE 204

Additional Resources

FSMA RULE 204: ADDITIONAL RESOURCES

Beginner and Advanced Education Options

GS1 Standards Beginner Resources



GS1 US FSMA Rule 204 Resources and Education



Industry Resources



Investment Considerations



GS1 US Channel Partner Program



FSMA RULE 204: ADDITIONAL RESOURCES

GS1 Standards Beginner Resources



[View A Guide to GS1 Standards Adoption for Supply Chain Visibility ▶](#)

[View the GS1 US Learning Management System for training on GS1 Company Prefixes, GTINS, RFID, and more! ▶](#)

[View Quick Start Guide on GS1 Company Prefix Video ▶](#)

[View Introduction to GTIN Guideline ▶](#)

[View How RFID Benefits the Supply Chain Video ▶](#)

[View Using EPCIS for Supply Chain Visibility Webinar \(fee\) ▶](#)

FSMA RULE 204: ADDITIONAL RESOURCES

GS1 US FSMA Rule 204 Resources and Education

FREE

GS1 Standards for FSMA Rule 204 Microlearning ▸

Informational module on GS1 Standards that can help you prepare to meet the requirements.

FREE

Readiness Checklist for FSMA Rule 204 ▸

Understand who in your organization to involve, what steps are needed, and what resources are available.

FREE

Frequently Asked Questions on FSMA Rule 204 ▸

These FAQs provide an overview of the final Food Safety Modernization Act (FSMA), Section 204(d), and information on how GS1 Standards can help your company meet the requirements.

FREE

GS1 Standards for FSMA Rule 204 Guidance ▸

- Application of GS1 Standards for FSMA Rule 204 Guideline
- EDI Recommendations for FSMA Rule 204
- EPCIS Recommendations for FSMA Rule 204

FOR FEE

FSMA Rule 204 E-Learning Course ▸

For those **familiar with GS1 Standards**, this self-paced on-demand module walks you through an example of how a company uses GS1 Standards to help meet FSMA Rule 204 requirements.

FOR FEE

GS1 Standards for Traceability Certificate Course ▸

For those **new to GS1 Standards**, learn best practices for case-level traceability and how to implement them. Receive professional credential upon completion. *Bonus content included: FSMA Rule 204 & EPCIS e-Learning Module.*

To get more information on X12 licensing, visit: <https://x12.org/products/licensing-program>

FSMA RULE 204: ADDITIONAL RESOURCES

Industry Resources

U.S. FDA Resources

- [Final Rule](#)
- [Supply Chain Examples](#)

Partners

- [PTI FSMA Rule 204 Electronic Sortable Spreadsheet Templates \(2024\)](#)
- [FMI Traceability Resources](#)
 - [Implementation Guide](#)
- [NFI Resources](#)

Traceability Case Studies

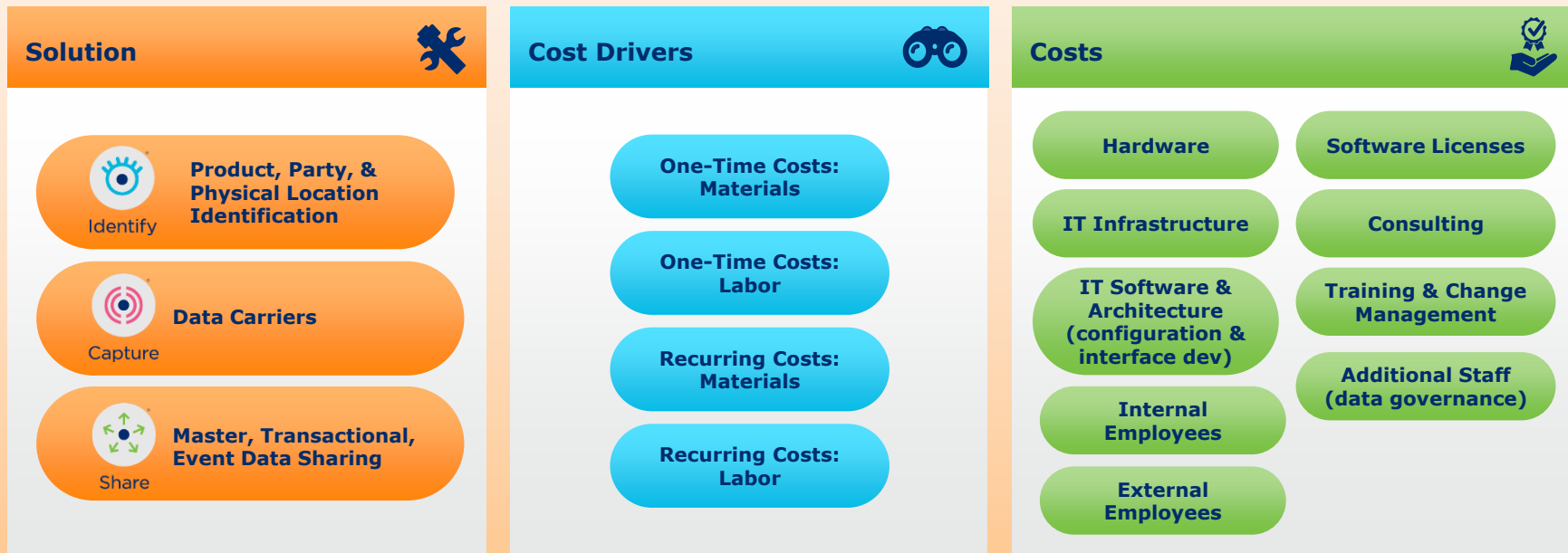
- [Fish Mongers Achieves Traceability & Empowers Farmers Using GS1 Standards Based-Solution](#)
- [Culinary Collaborations Tracks an Ocean of Data While Preparing for FSMA 204](#)
- [CKE Restaurants Trace Food from Farm to Drive-Thru](#)
- [IPC/Subway Delivers the Promise of End-to-End Traceability Throughout the Subway System](#)

Investment Considerations

The food industry compiled key investments to be considered for your customers' traceability program implementation.

FSMA RULE 204: ADDITIONAL RESOURCES

Investment Considerations



FSMA RULE 204: ADDITIONAL RESOURCES

GS1 US Channel Partner Program

- Give customers direct access to Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs) at the most critical point of implementation to meet the requirements of new regulations.
- Support smaller operations that are unsure with how to comply with FSMA, are new to traceability, and/or are concerned about money and manpower to comply.
- Collect reward fees on single GTINs/GLNs or GS1 Company Prefixes of up to 1,000 capacity that were sourced within your environment.



FSMA RULE 204: ADDITIONAL RESOURCES

How It Works

- **GS1 US Channel Partner Program** gives customers **direct access to GS1 identifiers** in your environment through URL links or API integration
- Add links to **meet the customer where they are** (landing page, blogs, resource pages, etc.)
- All identifiers licensed through program are **added to GS1 Database**

[View More Information on the GS1 US Channel Partner Program ▸](#)



FSMA RULE 204: ADDITIONAL RESOURCES

GS1 Glossary

- **EDI 856/ASN:** Electronic Data Interchange 856/Advance Ship Notice
- **EPCIS:** Electronic Product Code Information Services
- **GDSN®:** Global Data Synchronization Network™
- **GLN:** Global Location Number
- **GTIN®:** Global Trade Item Number®
- **Logistic Units:** 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](#).
- **SSCC:** Serial Shipping Container Code
- **Trade Items:** Any product or service where there is a need to retrieve predefined information about it and it may be priced, ordered, or invoiced at any point in the supply chain.

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Main Menu

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*If applicable



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