



# Beyond Compliance: Establishing the Right Foundation for a Transparent Supply Chain



Liz Sertl, Sr Director Supply Chain Visibility GS1 US Lucy Angarita, Director Supply Chain Visibility GS1 US

*IDDBA Member exclusive access!*

View recording and download slide deck at [iddba.org](http://iddba.org). (Available in 24-48 hours)



# 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<sup>®</sup> 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>

# Legal Disclosure

GS1 US, Inc. is providing this presentation, as is, as a service to interested parties. GS1 US MAKES NO REPRESENTATIONS IN THIS REGARD AND DISCLAIMS ALL WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF ACCURACY OR RELIABILITY OF ANY CONTENT, NONINFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

GS1 US shall not be liable for any consequential, special, indirect, incidental, liquidated, exemplary, or punitive damages of any kind or nature whatsoever, or any lost income or profits, under any theory of liability, arising out of the use of this presentation or any content herein, even if advised of the possibility of such loss or damage or if such loss or damage could have been reasonably foreseen.

GS1 US recommends that any organization developing an implementation designed to be in conformance with any GS1 Specification, Guideline or Recommendation, should consult with their own counsel to determine the compliance of such an implementation with any relevant intellectual property or other rights of third parties.

Portions of the following presentation may have been generated using AI. GS1 US does not provide any warranty or guarantee regarding the reliability or accuracy of its content, nor does it assume legal liability or responsibility regarding the same. Instead, we encourage participants to independently verify and cross-reference the content provided with other reliable sources before making any decisions or taking any actions based on the information presented.

The views and opinions expressed in this presentation by Companies are theirs alone, and do not reflect the opinions of GS1 US, Inc. GS1 US is providing this presentation, as is, as a service to interested parties and does not constitute or imply an endorsement, recommendation, or favoring by GS1 US of any of the identified companies, products, or services. GS1 US does not warrant or guarantee any of the products or services identified here, nor does it assume any legal liability or responsibility with respect to them.

\*GS1 US employees are not representatives or agents of the U.S. FDA, and the content of this presentation has not been reviewed, approved, or authorized by the U.S. FDA.

\*If applicable

# Agenda

|           |                                                        |
|-----------|--------------------------------------------------------|
| <b>01</b> | FSMA 204 Overview & Compliance Extension               |
| <b>02</b> | Industry's Reaction: Extension = Strategic Opportunity |
| <b>03</b> | Supply Chain Visibility is Critical                    |
| <b>04</b> | How GS1 Standards Can Help                             |
| <b>05</b> | Beyond Regulation: What does the Future Hold?          |

# FSMA 204 Overview

## What is it and who is impacted?

- Establishes Requirements for Additional Traceability Records for high-risk products outlined in the **Food Traceability List (FTL)**
- Anyone who manufactures, processes, packs, or holds foods
- Full and partial **exemptions may apply**

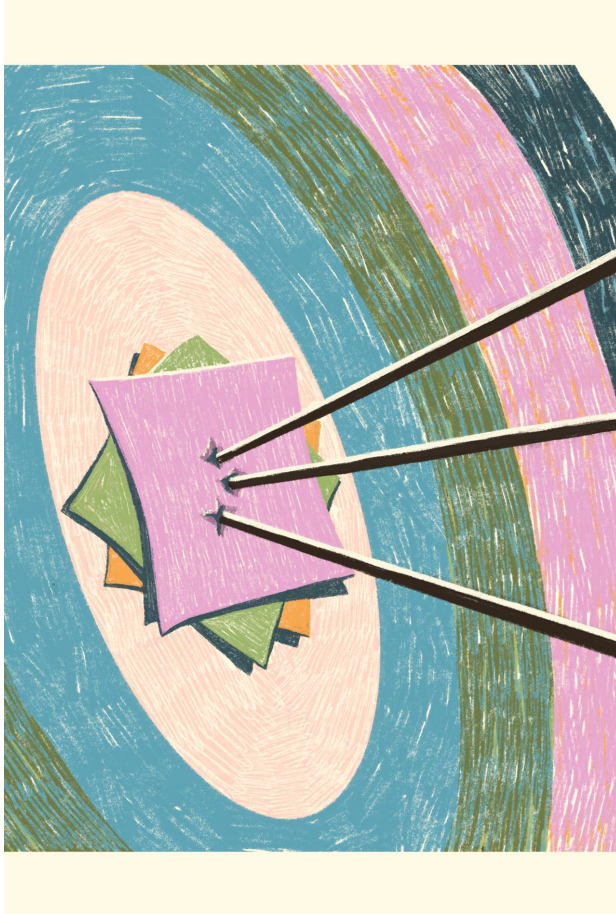
## What is required?

- 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
- Compliance Date: FDA announced it's intend to extend 30 months to **July 2028**
- Records should be maintained for 2 years

# What is Industry's Reaction?



- Continue the effort
  - Extended preparation time
- Focus on laying the right foundation:
  - Master Data Accuracy
  - Current System Assessment and Improvement
  - Internal and External Education
  - Use of a Common Language: Standards
- Enhance Supply Chain Visibility while meeting FSMA 204 requirements
  - Develop a clear compliance roadmap aligning FSMA 204 requirements with strategic business goals.

# Supply Chain Visibility is Critical



**Keep up with  
consumer  
demands**



**Streamline  
trading partner  
communication**



**Enhance  
interoperability**



**Offer real-time  
inventory data  
across channels**



**Meet regulatory  
compliance & ensure  
customer safety**

# 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.

**45 million**

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

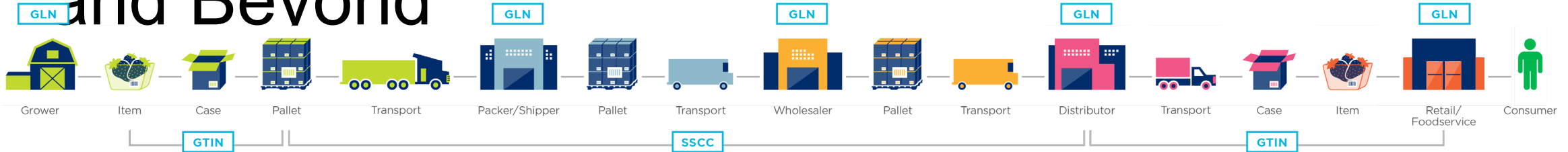
**2 million**

companies around the world use  
GS1 Standards.

**More than 40 million**

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

# How GS1 Standards Work for FSMA 204... and Beyond



## Identify

- **Product**  
Global Trade Item Number® (GTIN®)
- **Pallet**  
Serial Shipping Container Code (SSCC)
- **Location/Party**  
Global Location Number (GLN)



## Capture

Data carriers that allow for the addition of lot codes:

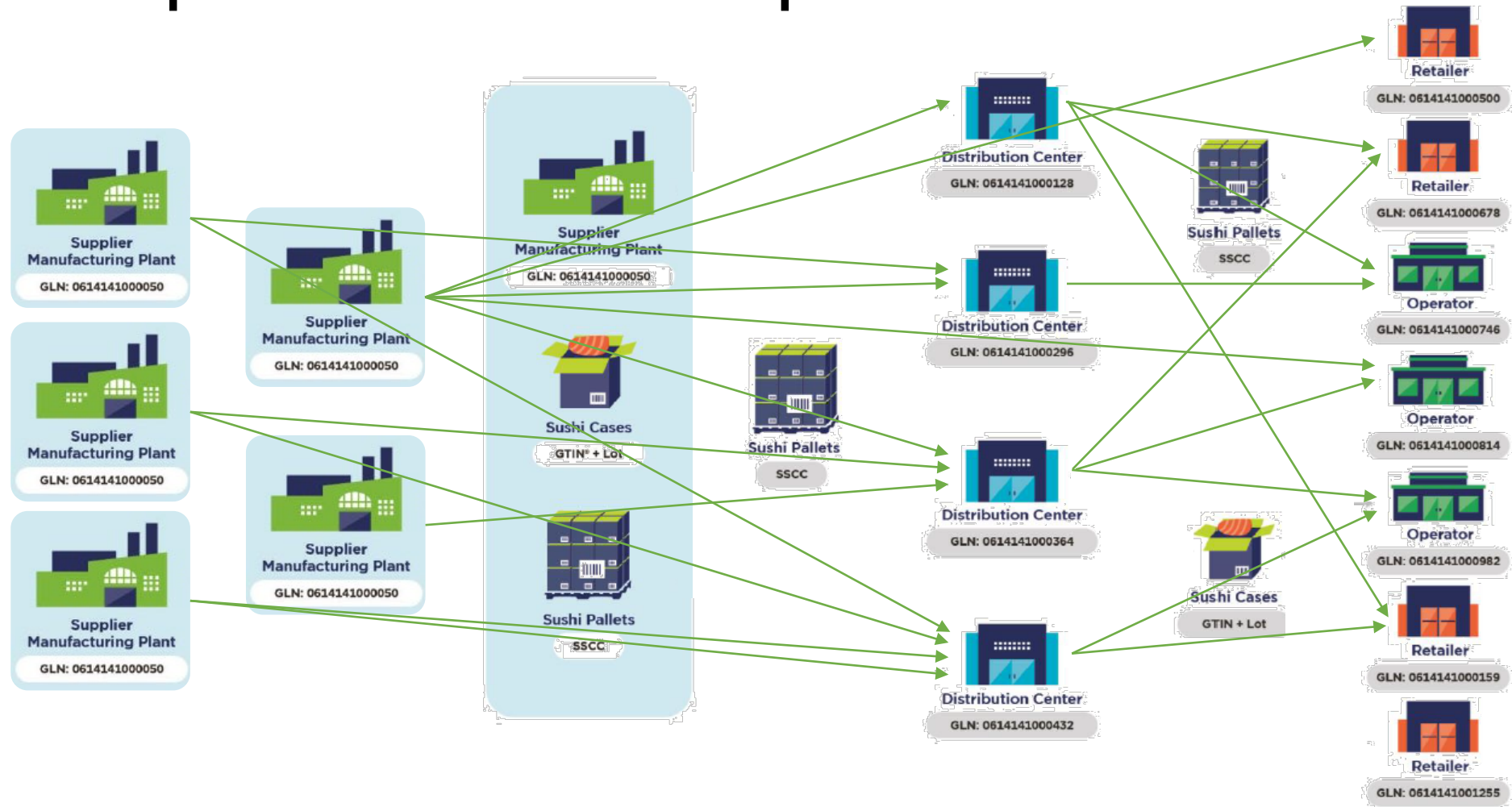
- **Barcodes**
  - GS1-128 ,
  - GS1 Data Matrix
- **RFID Tags**
  - RAIN radio frequency identification (RAIN RFID)



## Share

- **Product Data Exchange**  
GDSN
- **Location Data Exchange**  
GS1 US Data Hub | Location - View/Use
- **Event Data Exchange**  
Electronic data interchange (EDI), Electronic Product Code Information Services (EPCIS)

# The Importance of Unique Identification



# Beyond Regulation: What Does the Future Hold?





# The Critical Role of Data in Today's Business landscape

## **Importance of Data Accuracy**

Accurate data helps track products, respond quickly, and maintain compliance effectively.

## **Interoperability Benefits**

Seamless system communication reduces errors and improves supply chain efficiency.

## **Strategies for Data Quality**

Implement monitoring, validation, staff training, and standardized formats to ensure data quality.

Focusing on data accuracy and interoperability builds trust and reduces risks.





# Meeting Consumer Demands for Transparency

## **Consumer Expectations**

Consumers demand transparency about food origin, production, and safety standards.

## **Traceability Systems**

Robust traceability systems provide accurate, timely information to meet consumer demands.

## **Building Trust and Loyalty**

Transparency and responsiveness build consumer trust and long-term brand loyalty.

## **Driving Growth**

Leveraging traceability data supports marketing and differentiates products to drive growth.





# Do's and Don'ts

- **DON'T** - Stop or waste time reinventing the wheel...the path has been laid out for you.
- **DO** - Standardize to ensure interoperability with your network.
- **DO** - Prioritize the trading partners you need to focus on.
- **DON'T** - Expect perfection, look for progress- but always aim for continuous improvement.
- **DO** - Find the ROI in the simple achievements.
- **DON'T** - Get bogged down with exceptions and issues.
- **DO** - bring in the different teams, this is not just a food safety team effort.
- **DO** - Start with cleaning up master data, otherwise your data will be exponentially wrong.

# Questions?

[gs1us.org/fsma](https://gs1us.org/fsma)

Lucy Angarita [LAngarita@gs1us.org](mailto:LAngarita@gs1us.org)

Liz Sertl [ESertl@gs1us.org](mailto:ESertl@gs1us.org)

