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.

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.
  ▪ 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.
  ▪ 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.
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 Identifiers 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 Streaming Your Logistics Labels
    - An Introduction to the Serial Shipping Container Code (SSCC)
    - Section 3.1.4 of the GS1 US FSMA Guideline

Important: As with all GS1 Standards and solutions, this guideline is voluntary, not mandatory. It should be noted that the use of the words "must" and "require" throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation. GS1 US recommends that any organization developing an implementation designed to be in conformance with a GS1 Specification 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. Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company’s legal counsel or compliance team (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

This Publication is provided "As-Is" And GS1 US disclaims, and you expressly release GS1 US from, all liability relating to your use of this case study. GS1 US does not represent that any methods or recommendations in the document do not violate the Intellectual Property Rights of any third party. GS1 US has not performed a search to determine what Intellectual Property may be infringed by an implementation of any strategies or suggestions included in this document. GS1 US makes no warranties of any kind relating to the suitability of the GS1 Standards and the specific content within this publication and disclaims any liability for any party's infringement of Intellectual Property Rights that arise as a result of any implementation of strategies or suggestions included in this document. Click here for GS1 US’ full disclaimer.

Visit our FSMA 204 and Food Safety resources for additional information!