



GS1 US FSMA 204 Readiness Checklist

Gain Organizational Support

Launch Support and Resources Discovery	
<input type="checkbox"/> Secure leadership buy-in and support.	<ul style="list-style-type: none"> Communicate final regulatory deadline to leadership: Jan. 2026. Assign full-time project lead.
<input type="checkbox"/> Assemble Task Force; RACI (responsible, accountable, consulted, informed).	<ul style="list-style-type: none"> 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.
<input type="checkbox"/> Map out processes, systems, and teams that capture FSMA 204 CTEs/KDEs.	<ul style="list-style-type: none"> Understand physical/digital data flows and address gaps where new data needs to be captured or shared. Estimate financial requirements.
<input type="checkbox"/> Determine trading partners need to be involved.	<ul style="list-style-type: none"> These can be suppliers, distributors, customers, third-party storage providers, etc. Keep in mind these can be domestic or international entities.
<input type="checkbox"/> Communicate FSMA 204 requirements with trading partners.	<ul style="list-style-type: none"> Align on common goals and deadlines.

Assess GS1 Standards Capabilities

Identify Product and Location, Master Data	
<input type="checkbox"/> Survey trading partner's GS1 capabilities and ensure understanding of FSMA 204 requirements.	<ul style="list-style-type: none"> Review the following documents for more information: Guide to GS1 Standards Adoption for Supply Chain Visibility GS1 Traceability Checklist Assessor's Guide v1.0
<input type="checkbox"/> Understand how GS1 Standards can help in meeting FSMA 204 requirements.	<ul style="list-style-type: none"> Review GS1 US FSMA 204 Resources
<input type="checkbox"/> Confirm if GTINs are assigned to products in the Food Traceability List (FTL) and determined how they will be identified. <i>*Note: Internal asset identifiers are different than GTINs</i>	<ul style="list-style-type: none"> 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.
<input type="checkbox"/> Determine if FSMA 204 Product Description KDEs are shared using GDSN or other share method using GDM (Global Data Model) defined attributes.	<ul style="list-style-type: none"> Review section 4.3 of the GS1 US FSMA Guideline for more details.
<input type="checkbox"/> Confirm if companies or locations – where products are processed, manufactured, packed, and held – are identified with GLNs.	<ul style="list-style-type: none"> 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.
<input type="checkbox"/> 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.	<ul style="list-style-type: none"> Review section 4.4 of the GS1 US FSMA Guideline for more information.
<input type="checkbox"/> Assess your capabilities for the sortable electronic spreadsheet that includes all FSMA-required KDEs for each product and location. <i>*Note: Examples of systems include Product Information Management Systems, Trading Partner Information Management Systems, and Master Data Management Framework.</i>	<ul style="list-style-type: none"> 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	
<input type="checkbox"/> Identify the data carrier (i.e., barcodes, RFID Tags) used (if any) for each item by the supplier and customer.	<ul style="list-style-type: none"> 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
<input type="checkbox"/> Assess customer requirements and supplier/distributor capabilities to capture this information.	
<input type="checkbox"/> 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.	<ul style="list-style-type: none"> 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
<input type="checkbox"/> Confirm if SSCCs are assigned to pallets or other logistics units and tied to an EDI 856 – ASN (Advance Ship Notice).	<ul style="list-style-type: none"> 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

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.

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Share Transaction and Physical Event Data	
<input type="checkbox"/> 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.	<ul style="list-style-type: none"> 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 <p><i>*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</i></p> <p><i>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.</i></p>
<input type="checkbox"/> Confirm if all FSMA 204 Shipping KDEs are included in ASNs. If not, determine how will they be captured/added to the ASN.	
<input type="checkbox"/> If ASNs are not used, are the ASN standard field names, formats, and definitions used and recognized in other systems?	<ul style="list-style-type: none"> Review section 4.2.2 of the GS1 US FSMA Guideline for more information
<input type="checkbox"/> Confirm if EPCIS is used to share physical event data. Consider:	<ul style="list-style-type: none"> 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
<input type="checkbox"/> Define how transactional/event data will be stored and maintained for the 2-year requirement specified in FMSA 204.	
<input type="checkbox"/> Determine how this transactional / event data will be exchanged as needed.	
<input type="checkbox"/> Determine how quickly data can be retrieved and validated (within the 24 hour window).	
<input type="checkbox"/> Review if systems need to be upgraded and/or purchased to enable data retrieval & validation. Include in fiscal planning as necessary.	

Visit our [FSMA 204](#) and [Food Safety](#) resources for additional information!

