BEST PRACTICE GUIDE

3 Steps to Use GDSN for FSMA Rule 204

For Global Data Synchronization Network™ (GDSN®) users to share product information, specific data fields are recommended for FSMA Rule 204 compliance. These attributes should notify recipients of the compliance or exemption of the final product or ingredient but do not replace formal notifications or additional dialogue. The use of these attributes is also advisable for imported products.

GS1 US

The Global Language of Business

3 Steps to Use GDSN for FSMA Rule 204

01 Confirm if supplier/processor exemptions are applicable.

- Check if your organization qualifies for U.S. Food & Drug Administration (U.S. FDA) partial or full product exemptions in section 1.1305 of the final rule. Use the **U.S. FDA tool** to verify.
- If applicable, a written agreement between entities may be required for product setup. This must include the effective date, printed names, signatures, and substance of the agreement. Additional records may apply. Consult legal counsel and internal teams for the next steps.

02 Determine if the final product or ingredient is subject to FSMA Rule 204.

- The brand owner can confirm to the recipient whether the final product or ingredient is subject to FSMA Rule 204.
- The brand owner can inform the recipient if the final product or ingredient is exempt from FSMA Rule 204.

03 Use recommended GDSN attributes.

03A   The product is subject to the rule.

Attribute	Selections
RegulationTypeCode	**TRACEABILITY_REGULATION**
RegulatoryAct (U.S. LCL)	**FSMA204**
IsTradeItemRegulationCompliant	**TRUE** NOT_APPLICABLE

A Few Notes to Keep in Mind:

- U.S. Local Code List (U.S. LCL) code values are subject to change based on GS1 US FSMA 204 workgroup recommendations. See **U.S. LCL** for the most up-to-date list of code values.
- Data pool descriptive names may differ from code values.
- Data pool capabilities for the U.S. LCLs will vary. Most U.S. LCLs will be in open text format, but validation rules, min/max character limitations, drop-downs, or examples of code values could be implemented by the data pool to optimize the user experience and limit code value error input.
- To ensure no Catalogue Item Confirmation (CIC) synchronization errors from your recipient, ensure code values are spelled exactly as listed. (Code values MUST be written in CAPS LOCK, with underscores and no spaces.)
- To ensure attributes function collaboratively for optimal performance, the following GDSN rule can be implemented as a recipient requirement:
  If IsTradeItemRegulationCompliant = Not Applicable and regulatoryAct = FSMA204, then the code value for U.S. LCL RegulationRestrictionsAndDescriptors must be provided.

03B   The product is not subject to the rule.

Attribute	Selections
RegulationTypeCode	**TRACEABILITY_REGULATION**
RegulatoryAct (U.S. LCL)	**FSMA204**
IsTradeItemRegulationCompliant	TRUE **NOT_APPLICABLE**
RegulationRestrictionsAndDescriptors Code Values (U.S. LCL)	**NOT_COVERED_BY_FTL**

03C   The product may contain a U.S. FDA Food Traceability List (FTL) ingredient, but Is not subject to the rule.

Attribute	Selections
RegulationTypeCode	**TRACEABILITY_REGULATION**
RegulatoryAct (U.S. LCL)	**FSMA204**
IsTradeItemRegulationCompliant	TRUE **NOT_APPLICABLE**
RegulationRestrictionsAndDescriptors Code Values (U.S. LCL)	**KILL_STEP_APPLIED** OR **NOT_COVERED_BY_FTL**

Code Values With Definitions:

- **KILL_STEP_APPLIED:** The Product or ingredient is on the FTL but underwent a kill step or other critical control point.
- **NOT_COVERED_BY_FTL:** The final product or ingredient is not subject to the rule because it is either not included in the U.S. FDA FTL or has undergone a processing step other than a kill step or critical control point that exempts it from the rule.

Additional guidance can be found here: Retail Grocery and Foodservice Application of GS1 System of Standards to Support FSMA 204