



Frequently Asked Questions: FSMA 204

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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.

What resources does GS1 have for learning more about traceability?

By implementing standards-based traceability, products can be more reliably tracked through supply chains to help ensure consumer safety. GS1 US has created a guide that outlines information on the various Standards and how they support Supply Chain Visibility. Please review the **Guide to GS1 Standards Adoption for Supply Chain Visibility** in the [Resources](#) section of this document for more information.

General Background

What is FSMA 204?

On November 21, 2022, the United States Food and Drug Administration (FDA) published a Final Rule titled **Requirements for Additional Traceability Records for Certain Foods** which implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA). This rule is commonly referred to as the “Final Rule”. The Final Rule requires companies to keep additional records for designated foods to protect public health. The additional recordkeeping requirements that the FDA has established are outlined in the [Federal Register Notice](#). The rule was finalized in November 2022 and businesses will have until January 20, 2026, to comply.

Why is FSMA 204 important?

The Final Rule establishes the framework for end-to-end traceability throughout the food industry. The requirements would assist the FDA in more rapidly and effectively tracking the movement of a food to prevent or mitigate a foodborne illness outbreak and to address potential recalls.

What is the Food Traceability List?

The [Food Traceability List \(FTL\)](#) is a list of foods that are subject to additional recordkeeping requirements under FSMA Rule 204. The FTL includes but is not limited to:

- Many fresh fruits and vegetables, including all leafy greens, melons, sprouts, cucumbers, tomatoes, peppers, herbs, tropical tree fruits, and all fresh-cut items.
- Cheeses, other than hard cheeses
- Shell eggs
- Nut butter
- Some categories of seafood
- Ready-to-eat deli salads (refrigerated)

What are the FDA Food Traceability Requirements?

If you manufacture, process, pack, or hold any of the foods on the Food Traceability List, you are required to keep additional records on these items as per the FDA. The FDA has defined a set of metrics called Key Data Elements (KDEs) that correspond to different events in the supply chain known as [Critical Tracking Events \(CTEs\)](#). **The CTEs are:**

- Harvesting
- Cooling
- Initial Packing
- First Land-Based Receiver
- Shipping
- Receiving
- Transformation

The Final Rule outlines cases under which certain foods or persons may be exempt or partially exempt from the requirements in the Final Rule. The [Traceability Exemptions Flowchart](#) can assist in determining whether certain foods or persons are exempt from the Final Rule. Please review the appropriate section of the Final Rule for complete information on the [exemptions](#).

- Certain small farms.
- Certain small retail food establishments and restaurants.
- Foods not listed on the FTL or that have gone through a kill step.
- Certain bivalves and mollusks that are covered by the Seafood Sanitation Program.

What are the requirements for record keeping?

The FDA has outlined these requirements for recordkeeping:

- Keep records as original paper records, electronic records, or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Electronic records may include valid, working electronic links to the information required to be maintained under this subpart.
- The required records must be made available to an authorized FDA representative, upon request, within [24 hours](#) of such request. (or within some reasonable time to which FDA has agreed), along with any information needed to understand these records.

Please review the appropriate section of the Final Rule for complete information on [Records Maintenance and Availability](#).

Do companies outside of the U.S. have to comply with the requirements in the Final Rule?

The [requirements](#) of the Final Rule apply to all persons or companies who manufacture, process, pack, or hold foods on the FTL (unless an exemption applies), regardless of whether the person/company is in the United States or a foreign country. For complete information, please reference the following section of the Final Rule: [Application of the Rule to Imported Foods](#).

What is the difference between FSMA 204 Final Rule and the FDA New Era for Smarter Food Safety Blueprint (New Era)?

The FSMA 204 Final Rule is a food safety law that industry must follow, while New Era is a strategy that outlines the approach FDA will take to create a safer and more digital, traceable food system. The [New Era Blueprint](#) centers around four core elements: (1) Tech-enabled Traceability (2) Smarter Tools and Approaches for Prevention and Outbreak Response (3) New Business Models and Retail Modernization, and (4) Food Safety Culture. The Final Rule is a component of the initiatives under the first core element, [Tech-enabled Traceability](#). Under New Era, the FDA and industry can work collaboratively in a voluntary manner to address food safety challenges. Tools and resources tested and developed in New Era can help support compliance with FSMA 204 and are voluntary measures industry can follow.

What are some of the potential benefits of FSMA 204?

Despite being limited to certain foods, the Final Rule would establish a first-of-its-kind standardized approach to traceability recordkeeping, paving the way for industry to adopt and use more digital, tech-enabled traceability systems both in the near term and the future. This helps protect consumers by more quickly identifying the source of contaminated products, limiting the scope of recalls, and reducing the risk of illness or death. Advancing

traceability will make it easier to conduct timely root-cause investigations to understand how contamination happens to prevent outbreaks in the future.

Some benefits of the Final Rule include:

- Fewer foodborne illnesses/deaths
- Faster identification of source of contamination
- Rapid removal of contaminated food from market
- Limit the scope of recalls
- Harmonized information
- Establish linkages along supply chain more quickly
- Aligns with current industry approaches
- Enhances ability to conduct root cause investigations to identify and apply lessons learned from outbreaks

How GS1 US is helping with FSMA 204 Compliance

How is GS1 US Involved with FSMA 204?

In September 2020, the US FDA published the proposed rule for the Food Safety Modernization Act (FSMA) Section 204, to which [GS1 US issued comments](#). The GS1 US FSMA 204 Workgroup was created to bring together industry leaders, to create a guideline on how to use GS1 Standards to help meet the Final Rule requirements. This guidance document, [GS1 US Application of GS1 System of Standards to Support FSMA 204](#), outlines best practices on how GS1 Standards can be adopted to make traceability programs more scalable, accurate and interoperable while helping to meet FSMA 204 requirements. The document excludes the point of consumption and is limited to batch/lot traceability. GS1 US will also continue to engage with the FDA to support the communication and education of how GS1 Standards can be leveraged to help with FSMA 204 compliance.

How do the new FSMA 204 Final Rule requirements relate to GS1 Standards?

The Final Rule calls for the adoption of Key Data Elements (KDEs) and Critical Tracking Events (CTEs) for supply chain visibility, which map directly to several GS1 Standards. GS1 US in collaboration with Industry, has created guidance to provide companies with tools that can be used to help track the different events that occur during a product's lifecycle. The [GS1 US Application of the GS1 System of Standards to Support FSMA 204](#) illustrates mappings between the Final Rule's CTEs/KDEs and attributes from applicable GS1 Standards. It summarizes how the Global Location Number (GLN), Global Data Synchronization Network (GDSN), Global Data Model (GDM), Electronic Data Interchange (EDI) with Advanced Ship Notice (ASN)*, and Electronic Product Code Information Services (EPCIS) may be leveraged to help meet the Final Rule requirements. Please see the [Resources](#) section of this document for links to these materials.

Sharing these data-use standards are exponentially more important today, not only to meet FDA requirements, but to also help enable the traceability promised by so many emerging technology solutions. Solution developers are designing cutting-edge traceability systems using EPCIS because it helps to describe CTEs that occur from the harvest to the sale of the finished goods. It helps enable companies to rely on a single version of the truth about supply chain and logistics events by simplifying the capture and description of events and removing barriers caused by disparate entries and proprietary systems.

** 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*



Basic elements of food traceability



Identify

Products need to be uniquely identified with Global Trade Item Numbers and Batch/Lot information for effective traceability.

Locations need to be uniquely identified with Global Location Numbers to be able to tie Key Data Elements to Critical Tracking Events along the supply chain.



Capture

Product data needs to be captured via barcodes and shared between trading partners for traceability and food safety.



Share

Product master data and location information can be shared with:

- GS1 US Data Hub*
- Global Data Synchronization Network™ (GDSN*)

Critical Tracking Events (CTEs) and Key Data Elements (KDEs) that describe what's happening to products as they travel from source to consumer can be shared with:

- Electronic Product Code Information Services (EPCIS)
- Electronic Data Interchange (EDI) transaction sets/reference documents (e.g. Advance Ship Notice)

How to get started with GS1 Standards for FSMA 204 Compliance

How can GS1 US help my company prepare for the FSMA 204 requirements?

The [GS1 US Application of GS1 System of Standards to Support FSMA 204](#) outlines how to use GS1 Standards to help meet the Final Rule requirements and was created in close collaboration with the GS1 US FSMA 204 Workgroup. If you are interested in joining this workgroup, please reach out to mpradhan@gs1us.org for information. The [GS1 Standards for Food Traceability Online Certificate Course](#) provides expert guidance on establishing or enhancing your traceability program. For a more personalized approach, the [GS1 US Advisory Services](#) can offer a combination of technical and business expertise to address specific challenges your organization may face in integrating the GS1 System of Standards into your operations.

Additional Support & Resources

Who should I contact for questions regarding FSMA 204?

Please contact: foodsafety@gs1us.org

Resources

GS1 US

- [GS1 US Application of the GS1 System of Standards to Support FSMA 204](#)
- [Guide to GS1 Standards Adoption for Supply Chain Visibility](#)
- [How Do GS1 Standards Enable Traceability for Enhanced Food Safety?](#)
- [Fresh Foods Management Solution: Explore Critical Tracking Events \(CTEs\) and Key Data Elements \(KDEs\)](#)
- [EDI 856 Foodservice Ship Notice - Explained](#)

Federal Register

- [Final Rule in the Federal Register](#)

FDA

- [FSMA Final Rule for Food Traceability](#)
- [Food Traceability List](#)
- [Traceability Exemptions Flowchart](#)
- [Tracking and Tracing of Food](#)
- [New Era of Smarter Food Safety](#)
- [New Era of Smarter Food Safety Blueprint](#)
- [FDA Stakeholder Webinar on the Food Traceability Final Rule](#)



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