

Food Traceability Rule (FSMA 204) Information and Resources

Q: What is FSMA 204?

A: The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). The final rule is a key component of FDA's New Era of Smarter Food Safety Blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The new requirements identified in the final rule will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths. *Source: [FDA.gov](https://www.fda.gov)*

- ▶ Learn more about how to read the rule: [Read eBook](#)
- ▶ Review the [FDA's FAQs on FSMA 204](#)

Q: What are Critical Tracking Events (CTEs) and Key Data Elements (KDEs)?

A: The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners with key data elements (KDEs) for certain critical tracking events (CTEs) in the food's supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes (TLCs) for FTL foods, as well as linking these TLCs to other information identifying the foods as they move through the supply chain. *Source: [FDA.gov](https://www.fda.gov)*

- ▶ Learn the [KDEs required for each CTE performed here](#)

Q: What is a Traceability Lot Code?

A: The traceability lot code (TLC) is an integral component of the rule's requirements. It links to the other KDEs required, including the TLC Source, which provides the physical location where the traceability lot code for an FTL food was assigned. *Source:* [FDA.gov](https://www.fda.gov/food/traceability-rule)

- ▶ [Read more about the TLC on FDA's website](#)
- ▶ **Article:** [What You Need to Know About Traceability Lot Codes](#)

Q: What is the Food Traceability List (FTL)?

A: Section 204 of the [FDA Food Safety Modernization Act \(FSMA\)](#) requires the FDA to designate foods for which additional recordkeeping requirements are appropriate and necessary to protect public health. Additional recordkeeping requirements are outlined in the [Food Traceability Final Rule](#) and are intended to allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths. *Source:* [FDA.gov](https://www.fda.gov/food/traceability-rule)

- ▶ View the [Food Traceability List \(FTL\) here](#)
- ▶ View our [FTL in Pictures eBook here](#)

Q: What is an Electronic Sortable Spreadsheet?

A: In accordance with the Food Safety Modernization Act (FSMA) § 204(d)(1)(C), the final rule does not prescribe specific technologies for the maintenance of records. Records may be kept as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Records must be legible and stored to prevent deterioration or loss. Electronic records may include valid, working electronic links to the information required to be maintained under the final rule.

In certain circumstances when the public health is threatened, FDA may request that information about specific foods and specific date ranges (or traceability lot code ranges) be provided to FDA in an electronic sortable spreadsheet in accordance with § 1.1455(c)(3)(ii), along with any other information needed to understand the information in the spreadsheet. *Source:* [FDA.gov](https://www.fda.gov/food/traceability-rule)

- ▶ **Article:** [Learn more about creating an Electronic Sortable Spreadsheet](#)
- ▶ [Review FDA's electronic sortable spreadsheet example and other resources here](#)

Q:

What are shipping KDEs and why do I need to share them with my customers?

A:

The rule stipulates that shippers covered under the rule must maintain records (KDEs) containing the following information about the food, as well as send them to the next recipient in the supply chain (the entity they are shipping to, i.e. their customer):

- The traceability lot code for the food;
- The quantity and unit of measure of the food;
- The product description for the food;
- Location description for the immediate subsequent recipient (other than a transporter) of the food;
- Location description for the location from which you shipped the food;
- The date you shipped the food;
- The location description for the traceability lot code source, or the traceability lot code source reference;
- The reference document type and reference document number (maintain only).

You will need to share your shipping KDEs with all entities (customers) you ship FTL foods to. Even if your customers have not yet asked you to share your shipping KDEs with them, you will be required to do so by the enforcement deadline. *Source: [FDA.gov](https://www.fda.gov)*

Q:

What is Master Data?

A:

Master Location data are the attributes of defining location, such as a location name, physical address, DUNS, GLN, and/or GPS coordinates.

Master Product data are the attributes of defining a product such as the product/item ID, product description, UOM, GTIN, FTL Category, Commodity, Variety (or common species for seafood).

Master Location Data references the addresses of all your organization's locations. Master Product Data references the information about each of the products you manufacture, process, pack, or hold.

Q:

What is Event Data?

A:

Event data references the data, or Key Data Elements (KDEs) associated with the Critical Tracking Events your organization participates in. The FSMA 204 Critical Tracking Events include:

- Harvesting
- Cooling
- Initial Packing (RAC)
- First Land-Based Receiver (food obtained from a fishing vessel)
- Shipping
- Receiving
- Transformation

Source: [FDA.gov](https://www.fda.gov)

Looking for more information?

Check out these additional resources from iFoodDS and New Era Partners.

Key Milestones to Achieving FSMA 204 Compliance for Suppliers and Enterprise Organizations

The FDA's Food Traceability Rule, FSMA 204, may not be enforced until 2028, but waiting to act could put your business at risk. With complex supply chains, evolving customer requirements, large supplier networks to onboard, and the need to optimize and/or revise internal processes, achieving full compliance takes time.

Review these milestones to help your business stay on track and fully comply by the enforcement date.

- ▶ [Milestones for suppliers](#)
- ▶ [Milestones for enterprise organizations](#)

The Traceability Plan is a Key Requirement of FSMA 204

This rule requires that companies manufacturing, processing, packing, or holding foods on the Food Traceability List (FTL) have a plan that outlines how they will meet additional recordkeeping requirements.

- ▶ **Article:** [How to Get Started Creating Your Own Traceability Plan](#)

Finding the Right Traceability Solution Partner

Putting the right technology in place to manage your data and meet your organization's unique requirements is critical to success.

- ▶ [View our solution provider checklist for suppliers](#)
- ▶ [View our solution provider checklist for retailers and distributors](#)

Looking for more information?

Check out these additional resources from FDA and industry associations.

Additional Resources Developed by GS1

What is the Food Safety Modernization Act (FSMA)? In this article, GS1 reviews FSMA 204, its requirements, and provides additional resources and guidance, including a valuable implementation toolkit.

- ▶ [Review toolkit](#)
- ▶ [Read article and view all resources](#)

Additional Resources Developed by Produce Traceability Initiative (PTI)

PTI has long been an advocate of data standardization to better handle the massive amounts of data flowing through the supply chain. Check out these valuable PTI resources, including Critical Tracking Event/market role-specific examples of the Electronic Sortable Spreadsheet and a FSMA 204 implementation guide.

- ▶ [View Resources](#)
- ▶ [View implementation guide](#)

Additional Resources Developed by Food Industry Association (FMI)

With a focus on awareness, education advocacy, and leveraging data standards to help meet the requirements of the traceability rule FMI has developed a number of tools and resources to support the industry as they diligently work toward achieving the goal of compliance.

- ▶ [Traceability Compliance Guide](#)
- ▶ [Traceability Implementation Guide](#)
- ▶ [Additional FSMA 204 Resources](#) (*members must be logged in*)

- ▶ *Additional FSMA 204 resources from iFoodDS can be found [here](#)*
- ▶ *Additional insights from iFoodDS' consulting arm, New Era Partners, can be found [here](#)*