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ROADMAP TO PREPARE FOR FSMA 204

ENHANCING TRACKING AND TRACING OF
FOOD AND RECORDKEEPING

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Are food recalls, compliance, and meeting customer demand for provenance on your radar?

If not, they should be...

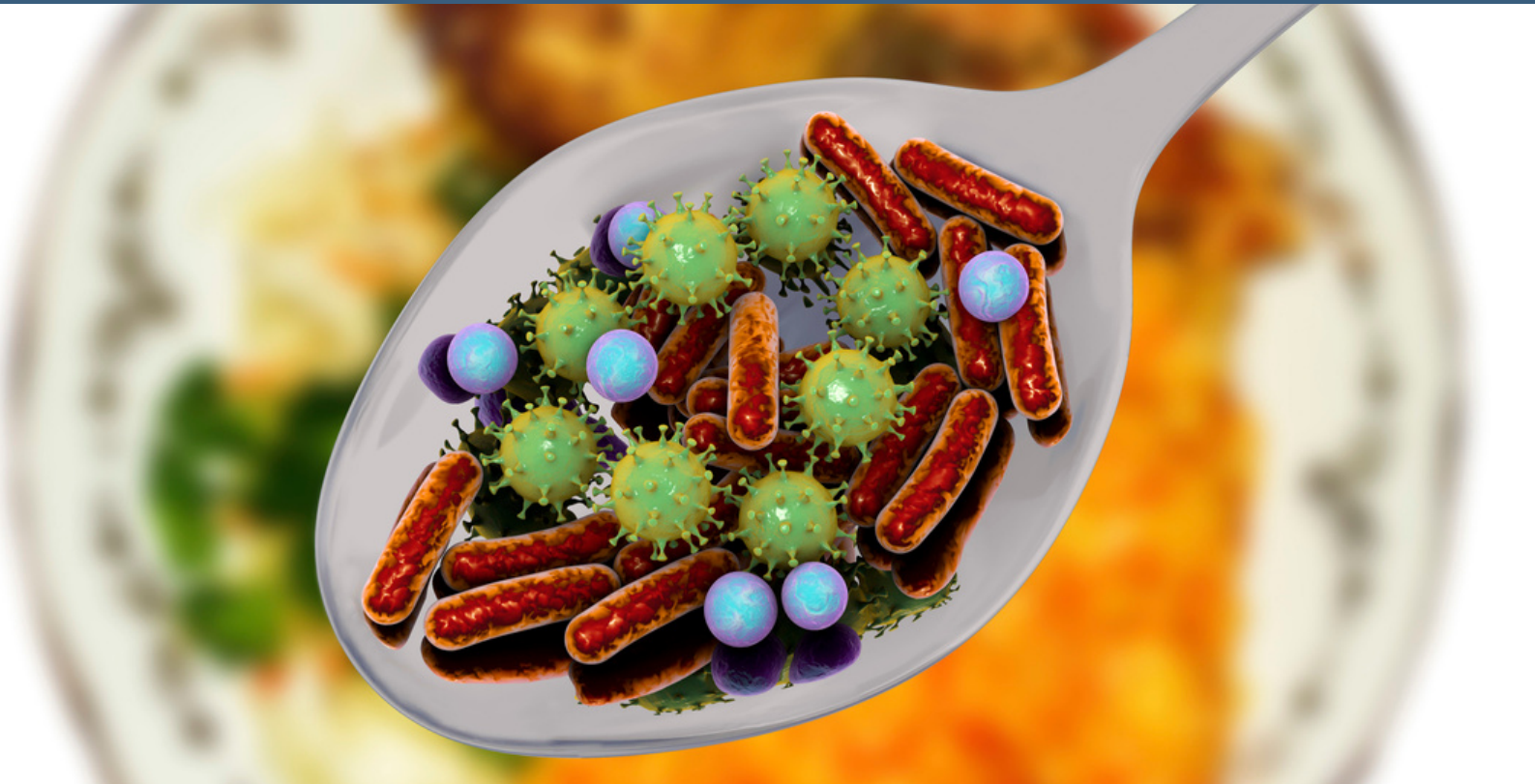# What Is FSMA?

FSMA (The Food Safety Modernization Act) is the FDA's solution for implementing legislation to reduce outbreaks of foodborne illnesses. To combat the rising number of foodborne illnesses, the United States government signed the FSMA regulations into law in 2011.

Starting January 20, 2026, the FSMA regulations will require certain types of foods to comply with FSMA Rule #204, which includes detailed, digital data from all supply chain contributors through to public consumption (including imports).

The goal of FSMA laws is to encourage food handlers and producers to put more effort into averting food safety problems at an early stage. As a result of the FSMA laws, the FDA now has increased power to enforce food safety standards.

WHAT IS THE IMPACT OF FSMA LAW?

The whole food safety system's perspective on handling food safety issues was transformed. The food safety law emphasizes preventing foodborne illnesses via proper food safety procedures and regulations rather than reacting to problems after they occur.

The number of foodborne illnesses worldwide cannot overstate the significance of the FSMA laws. The FDA FSMA aimed to provide guidelines to food enterprises along the whole food supply chain since some of the most prevalent causes of these foodborne illnesses are rooted in inappropriate food handling.

Does FSMA Fall Under The Purview Of The FDA?

FDA | U.S. FOOD & DRUG ADMINISTRATION

The FSMA law's implementation regulating body is the FDA. The FDA FSMA laws, which apply to at least 70-75% of the food sector, must be followed by all businesses under its purview.

Over the 70 years, FDA's found that the FSMA regulations are the most significant and prominent reforms. The FDA introduced this rule to protect public health more effectively by strengthening and modernizing the food safety system.

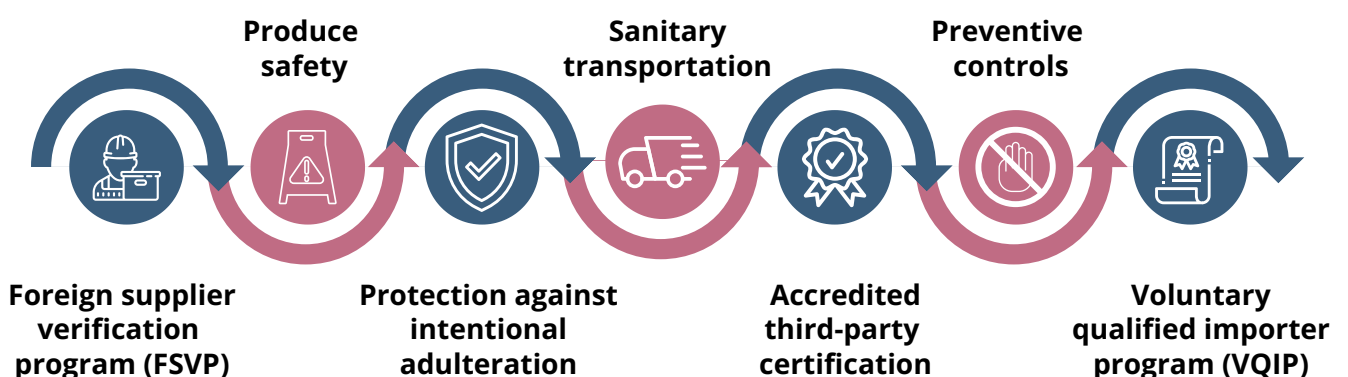The FDA gets a tremendous implementation capability under the FSMA law to achieve improved compliance rates. Additionally, it has improved the FDA's ability to take action against possible food safety problems, such as recalls and investigations.

Seven rules were established under the FSMA law to keep pace with the food industry's impulsive globalization and the rising risks of foodborne illnesses.

Each rule requires different levels of compliance depending on the size of your food business. Businesses are divided into three categories under the FSMA regulations:
- Small companies,
- Very small companies, and
- other companies.

The 7 FSMA Rules

	Produce safety		Sanitary transportation		Preventive controls	

Foreign supplier verification program (FSVP) | **Protection against intentional adulteration** | **Accredited third-party certification** | **Voluntary qualified importer program (VQIP)**

FSMA 204
REGULATION

The food agency has strengthened its food safety control element by amending several current rules and the seven core FDA FSMA regulations. The relevant government departments have discussed and presented a new federal food safety rule, Section 204 of the FDA Food Safety Modernization Act (FSMA).

Rule #204 has now been accepted and will go into effect in January 2026. In addition to the FDA's existing traceability programs, this FSMA regulation adds new requirements. According to the FDA's New Era of Smarter Food Safety Blueprint, this addition is considered one of the most important needs. To successfully reduce the impact of an outbreak, it intends to create a system for quickly locating receivers of contaminated products.

The requirement to create records with Key Data Elements (KDEs) connected to various Critical Tracking Events (CTEs) examined by the FDA is at the core of this amendment. This regulation applies to manufacturers who handle and process food included on the Food Traceability List (FTL).

The FDA used a risk-ranking model that produced the FTL, a peer-reviewed list of high-risk foods. Which counted:

- Outbreak frequency
- Severity of potential illnesses
- Contamination risk, and
- Other risk-based factors.

Your Business May Be Impacted

Collaboration is necessary if the industry is to solve significant food safety issues. FSMA Rule 204 is a collaborative effort to bring the food industry's view of traceability by connecting all levels of the supply chain.

Foodborne illness outbreaks harm the public's health, diminish trust, and cost businesses millions of dollars. The industry's top companies are moving toward adopting supply chain visibility across the board.

DIGITALIZE YOUR FOOD SAFETY SYSTEM

Using manual processes to comply with the new rule would be very challenging and expensive, especially in today's labor market. Companies must respond to FDA requests for data in a sortable electronic spreadsheet within 24 hours.

Digital traceability among suppliers and customers will provide visibility throughout the supply chain. It matters the most during an outbreak investigation when you need to trace the product back to the lot level.

In many cases, the ability to quickly access and provide this information directly impacts lives saved or lost.

COMPETITIVE ADVANTAGE BY EMBRACING TRACEABILITY

Traceability is essential to consumers' expectations of the food products they purchase. They would like the information pertaining to the products they purchase to be available and transparent. They demand assurance that their food is fresh, safe, and meets their social value structure.

Brand owners are strengthening their standards to secure their position in response to rising customer demands. Be cautious about the cost of regaining market share should a competitor present this value to the marketplace first.

CONTACT US FOR DETAILED INFORMATION.

THINK BEFORE CHOOSING A SOLUTION

You must pick the appropriate technologies that fit this rule's demands. The fragmentation of the supply chain has been the main barrier to better outbreak response. Even though the technology exists for complete supply chain traceability, it is practically hard to get all parties to agree on a single supplier.

Farm to Plate offers a Blockchain-based Traceability solution that benefits you, your suppliers, and your customers. With Farm to Plate, you will never need to worry about traceability issues.

- Protects your brand
- Limits your recall exposure
- Establish a digital connection with your trading partners to reduce transaction costs
- Enable more efficient communication with trading partners.

You need to start as soon as possible because if you wait, you may find it challenging to meet the 2026 deadline.

IS YOUR BUSINESS READY FOR
FSMA 204?

Companies that are just concerned with compliance and have limited links in the supply chain are losing a chance to be part of the future of food commerce. They risk their business by not looking "customer-in" and understanding that to respond to consumers' demand for product information. There must be a connection back through the supply chain to show product origins and support brands.

PREREQUISITES FOR FSMA 204.

FSMA Rule 204 will go into effect in January 2026. Here are a few steps you can take initially to start preparing for FSMA Rule 204:

1 Check the revised Food Traceability List

2 Discover the critical tracking events and key data elements you need

3 Find a traceability solutions that can solve your purpose.

4 Record and keep these key data elements in an easily accessible manner.
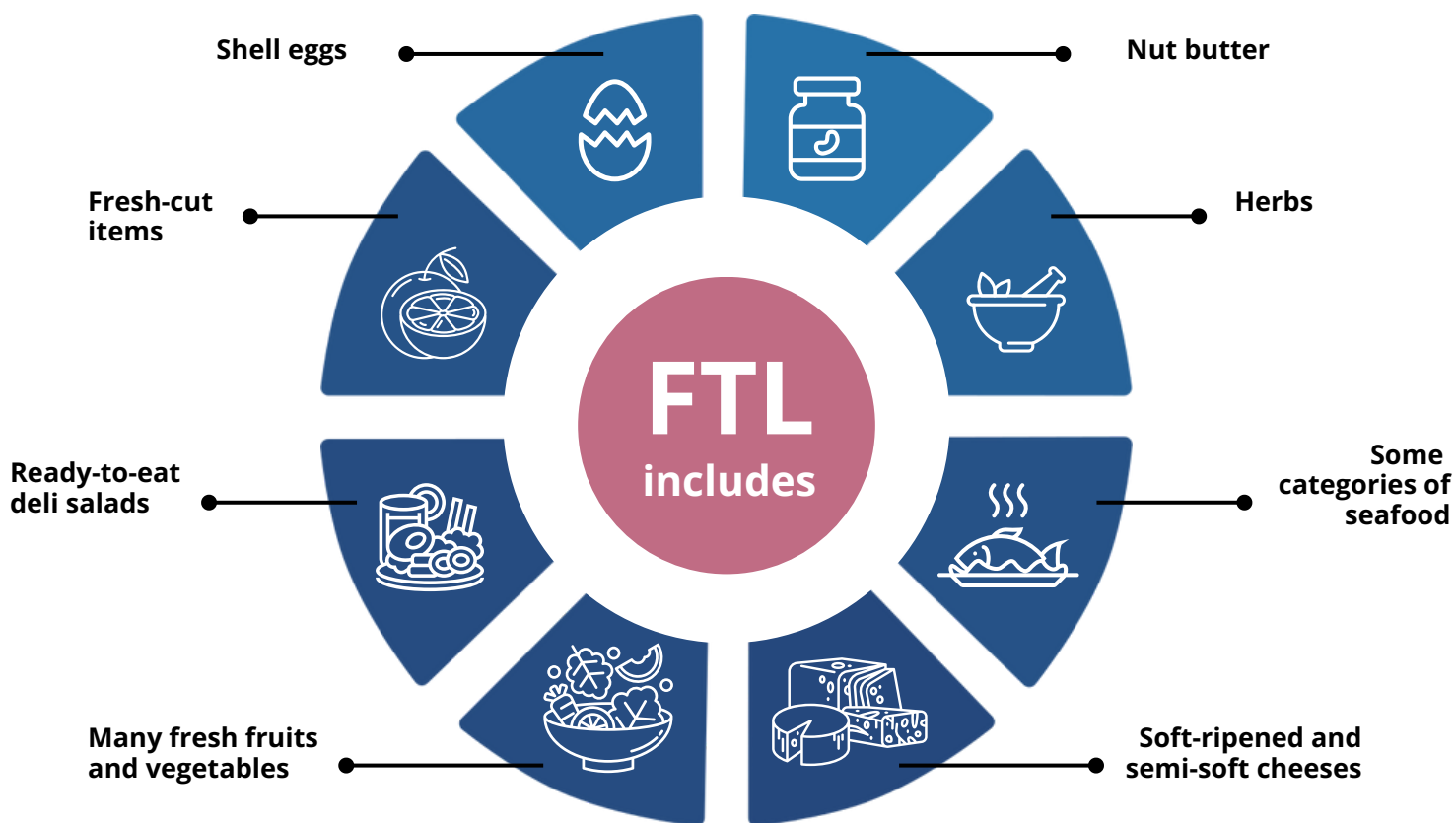
With the new rule, additional recordkeeping requirements will be mandatory. You must keep these additional records if you grow, ship, pack, process, manufacture, or sell foods on the Food Traceability List.

FOOD TRACEABILITY LIST(FTL)

A list of foods subject to additional recordkeeping requirements under FSMA Rule 204. The FDA released a draft list in 2014, which is now updated.
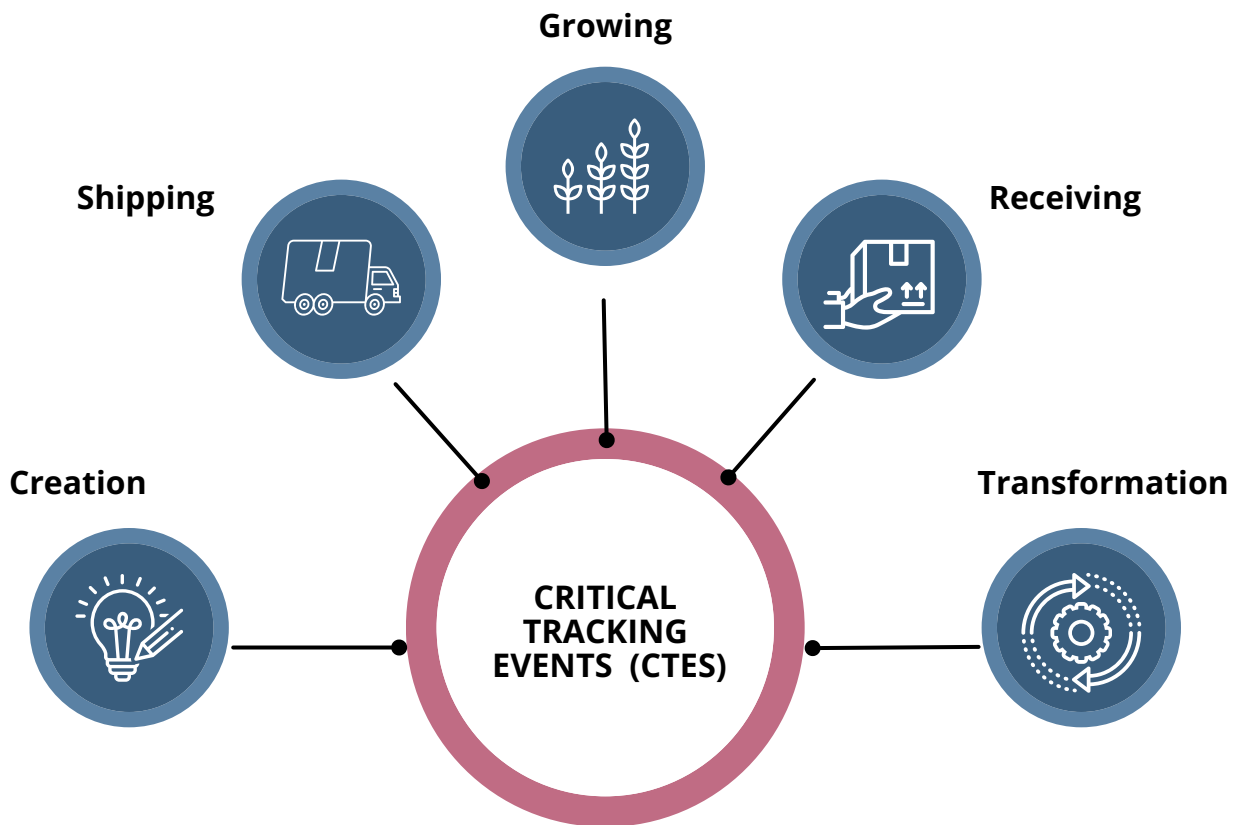
According to the new rule, companies must provide documentation for specific Key Data Elements (KDEs) for Critical Tracking Events (CTEs). You may be required to collect numerous sets of KDEs depending on the type of your business functions.

Shell eggs

Nut butter

Fresh-cut items

Herbs

Ready-to-eat deli salads

Some categories of seafood

Many fresh fruits and vegetables

Soft-ripened and semi-soft cheeses

FTL includes

KEY DATA ELEMENTS (KDES)

The FDA has established a set of metrics known as Key Data Elements (KDEs) that relate to various supply chain events known as Critical Tracking Events (CTEs).

We had included some type of chart on KDE. It's the KDEs that F2P will accept, record, add to and transmit. We also put the information about KDE after the CTEs.

Growing

Shipping

Receiving

Creation

Transformation

CRITICAL TRACKING EVENTS (CTES)

Please check the FDA resource guide to determine what KDEs and CTEs relate to your company.

GET READY BEFORE IT'S TOO LATE.

According to this rule, companies must provide documentation within 24 hours of request and in a sortable electronic format.

Farm to Plate is a digital traceability solution that automates KDE collection and securely stores data. With Farm to Plate, you will never need to worry about traceability issues.

CONTACT US FOR CONSULTATION

www.farmtoplate.io

Thank You

>>> Additional Resources <<<

A Guide to GS1 Standards Adoption for Supply Chain Visibility
https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/partners/GS1-US-Solution-Partner-Supply-Chain-Visibility-Implementation-Guide.pdf

FMI.org Food Safety Resources
https://www.fmi.org/food-safety/food-safety-resources

To learn more about the FDA Final Rule on Requirements, please click on the link below:
https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods

GS1 US FAQ FSMA 204
https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/food/guideline-toolkit/GS1-FSMA-204-FAQs.pdf