



## Food Safety Modernization Act (FSMA) Section 204: Leveraging compliance to unlock value

How food organizations can move from 'cost to comply' to 'invest to sustain'

# FSMA Section 204 – Accelerating food industry shifts

In response to the growing food safety challenges occurring within the food system, the Obama administration signed into law the Food Safety Modernization Act (FSMA) in 2011.<sup>1</sup> On November 15, 2022, the Food and Drug Administration (FDA) published the highly anticipated and long-awaited finalized Food Traceability Rule, implementing Section 204 of FSMA (FSMA Section 204).<sup>2</sup>

A component of the FDA’s “New Era of Smarter Food Safety” blueprint, the rule encourages more investment in digital technology and traceability.<sup>3</sup> By creating a “digital twin” of their supply chain, combining traceability and digitalization, companies can play a crucial role in increasing the effectiveness of recalls through the swift identification and removal of contaminated foods from the market.

Figure 1. Overview of FSMA Section 204

**FSMA Section 204**  
Establishes a foundation for end-to-end food traceability

The FDA’s Food Traceability Rule will take effect in **January 2023** and compliance with the rule will be enforced by **January 2026**<sup>1</sup>

Regulators aim to increase the **speed of recalls** and **conduct tracebacks** more swiftly<sup>2</sup>

**Traceability use cases**

- ✓ Product certification
- ✓ Supply chain risk monitoring
- ✓ **Recall capabilities**
- ✓ GHG emissions disclosures

1. Food and Drug Administration (FDA), "Requirements for additional traceability records for certain foods," 2022.  
2. Ibid.

## What are the core requirements of FSMA Section 204?

FSMA Section 204 requires the FDA to:

- Establish and publish a Food Traceability List (FTL) identifying high-risk foods to human health.
- Set additional traceability recordkeeping requirements for “persons” who manufacture, process, pack, or hold foods on the FTL.<sup>4</sup>

## Which types of foods are on the Food Traceability List?

The FTL includes food products such as non-pasteurized cheeses, nut butters, many categories of fresh produce, fresh seafood, and ready-to-eat deli salads.<sup>5</sup>

The recordkeeping requirements detailed within the rule apply to single and multi-ingredient products. However, there are provisions within the rule that would cease traceability requirements after products undergo “kill steps,” whereby dangerous pathogens are removed. Additionally, the rule establishes that if a food is

characterized as “fresh” on the FTL, the food product should not have recordkeeping requirements once changed to a frozen or dried state.

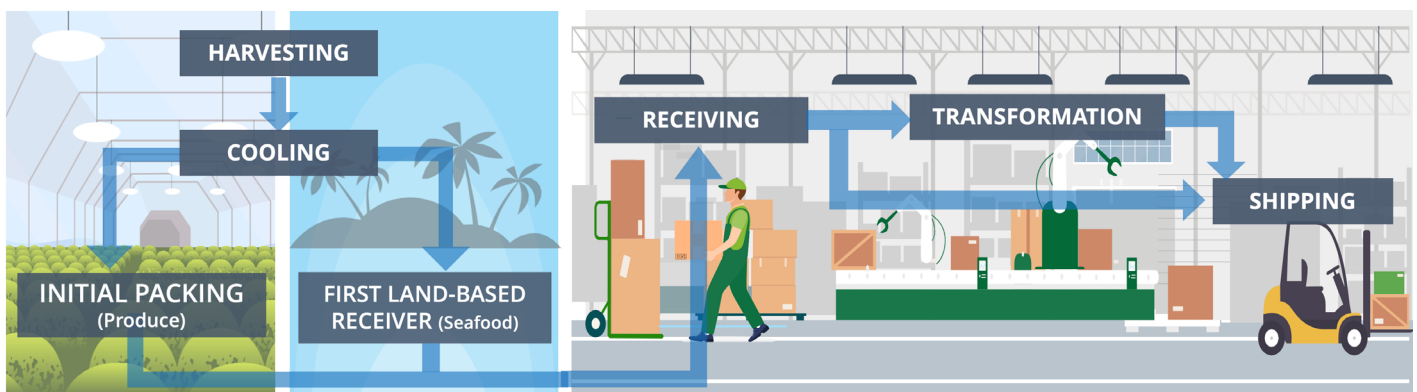
Additionally, the rule highlights the FDA’s intention to update the FTL every five years, meaning food companies should be prepared to expand their traceability program, if needed.<sup>6</sup>

## What are the additional recordkeeping requirements?

Food companies are required to establish and maintain records containing key data elements (KDEs) for critical tracking events (CTEs) occurring within their supply chain. CTEs are events in the supply chain involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity (RAC), first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of foods on the FTL.<sup>7</sup>

The traceability data (KDEs) and their associated referenced documents (e.g., purchase orders, advanced shipping notifications) should be retained for a minimum of two years. Companies should be able to collect and send the implicated lot codes with their relevant traceability data to the FDA in an electronic sortable spreadsheet within 24 hours of a request.<sup>8</sup>

**Figure 2. Critical tracking events**



*Unique identifiers (i.e., Traceability Lot Codes) should be established and linked to the KDEs across the supply chain’s CTEs.*

## Who is impacted and how?

The FDA’s use of the word “persons” within the regulation can apply to anyone from a small food truck owner to a large global food distributor. While specific exemptions exist for small farms and retail food establishments, the concept of a “retail food

establishment” further expands the scope of impacted companies. Some of the examples of “retail food establishments” provided include, but are not limited to, grocery stores, restaurants, online food retailers, foods sold directly to consumers on farms, community-supported agriculture (CSA) programs, catalog sales, and meal-kit delivery organizations.<sup>9</sup>

# Challenges for companies in the food value chain

When complying with the FDA's Food Traceability Rule, companies may face four types of challenges across the following areas: data, processes, stakeholders, and technology.



## 1. Data challenges:

**Data governance and privacy:** Existing data-sharing processes need to be supplemented with additional traceability data and should be assessed for privacy considerations. Additionally, companies may incur increased compliance costs and risk without transparent governance over the traceability data or insight into its integrity.

**Data architecture and capture:** The critical tracking events may require architectural data changes to facilitate data capture. Additionally, the state of existing data may vary (e.g., paper-based versus digital) and may require widespread effort and coordination across supply chain participants to begin capturing and sharing this data in a digital state.

**Data processing:** Processes needed to validate, enrich, and transform the traceability data can be resource intensive and pose risks to existing critical business processes within supply chain technologies (e.g., enterprise resource planning systems).

**Data standardization and interoperability:** The transfer of data across supply chain participants may result in data being shared in different formats preventing interoperability between supply chain participants.

## 2. Process challenges:

**Lot-level traceability:** Many suppliers and producers do not currently adhere to a standardized system that enables the provision of globally unique identifiers. Therefore, many inbound products may not have or receive scannable labels that include lot codes, resulting in lost lot-level traceability.

**Labeling strategies:** Today, many suppliers perform labeling at the pallet level and practice lot mixing within a single pallet. Neither practice may provide the granularity needed for compliance with the Food Traceability Rule.

## 3. Stakeholder challenges:

**Supplier considerations:** The transfer of KDEs across supply chain partners can increase a company's compliance risk if upstream partners do not send the traceability data required for their own compliance (e.g., Traceability Lot Code). Also, there is an increased dependency on suppliers to provide ingredient details, which may be considered intellectual property.

**Traceability culture and training:** Supply chain partners and employees may likely need training on how the new culture of traceability will impact their day-to-day responsibilities.

## 4. Technology challenges:

**Legacy supply chain systems:** Organizations may need to implement processes to validate and capture traceability data throughout the supply chain. Some of these processes may need to be event-driven, which can add complexity to legacy systems.

**Centralization of traceability data:** Existing traceability data is spread across different source systems, and companies may need to centralize and optimize their data for reporting to provide an electronic sortable document to the FDA within 24 hours of their request.

**Data sharing:** Organizations may need to develop data-sharing mechanisms that account for stakeholders with different levels of technological maturity.

# How to get started

## Four steps that can help companies get ready for the FDA's Food Traceability Rule

To understand the impact from the FDA's Food Traceability Rule, companies should consider taking four deliberate steps toward compliance:



### Data readiness:

Unlocking value with traceability should start with a systemwide focus on standardization, digitization, and unique identification. Since data becomes less reliable and more expensive to maintain the further it moves from its source, standardization practices should begin in the first mile. Consider:

- Do you currently use standards or frameworks to manage your supply chain data?
- Do you understand the source of existing data and where it is stored? Is it in a central repository or scattered across multiple source systems?
- Which KDEs are not captured to date? How will you begin capturing this data?

### Processes readiness:

The physical-to-digital link established by the unique lot code should be maintained for each product as it moves through the value chain. Companies should assess current processes to identify areas where traceability may be compromised. Consider:

- Do you currently capture lot codes for food products?
- Where is the traceability of products lost within physical processes (e.g., transformation)?
- Where are the gaps within your existing physical-to-digital link?

Maintaining labeling at the most granular product level of handling (e.g., case, item) is a helpful tool for maintaining traceability in many instances.

### Stakeholder readiness:

Compliance with the FDA's Food Traceability Rule requires widespread effort and coordination across a company's supply chain. Mechanisms to share traceability data may likely need to be agreed upon between supply chain partners to promote the digitalization of traceability data. Consider:

- How will you promote supplier and customer compliance with traceability requirements?
- How will you manage exempt suppliers?
- How will you send traceability data to customers?

### Technology readiness:

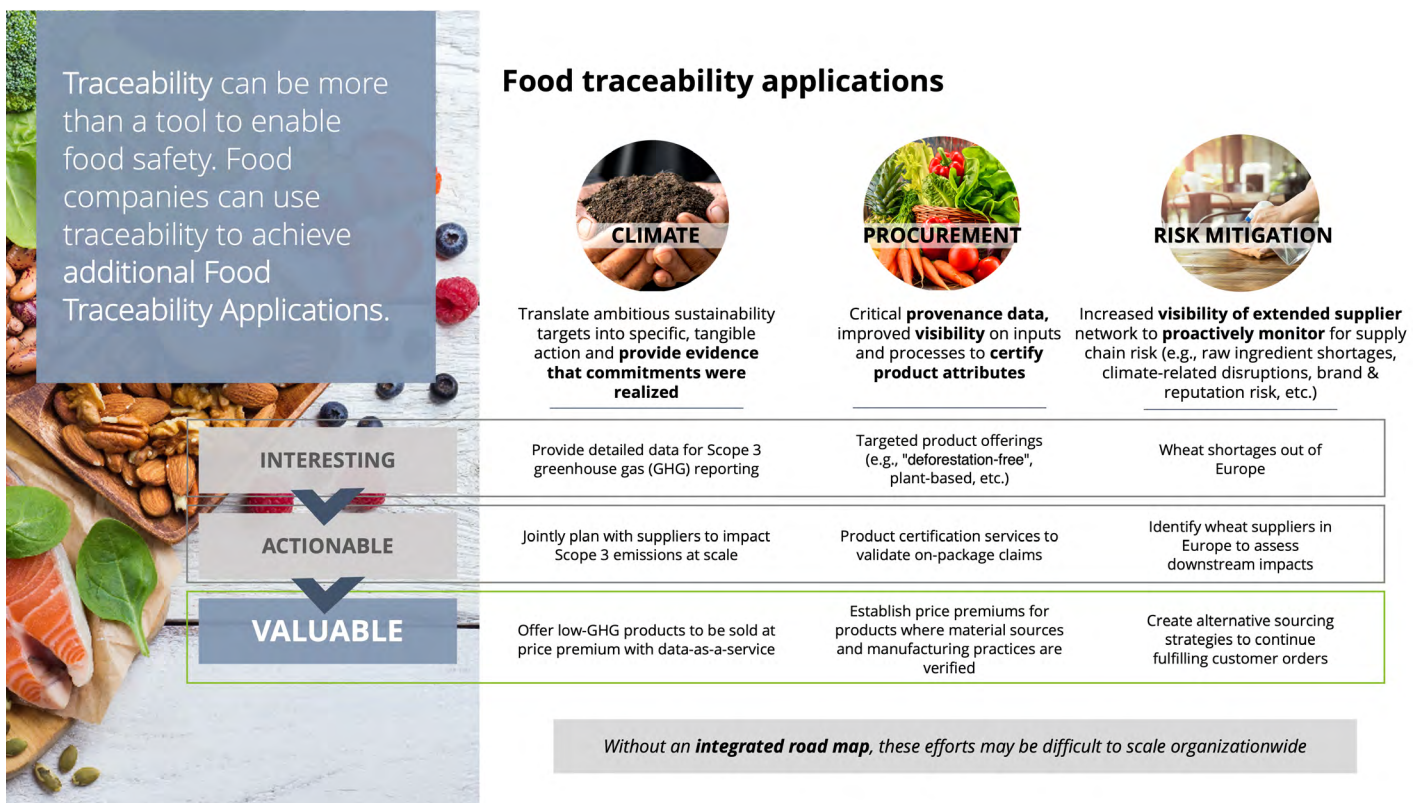
The FDA's Food Traceability Rule does not stipulate the use of any particular digital technologies.<sup>10</sup> However, the sheer volume of data required to maintain the needed granular level of traceability will be challenging to manage without digital records. While implementing digital systems to achieve lot-level traceability might seem costly, improving current recall processes can have a significant upside. Consider:

- Which supply chain technologies require changes or enhancements to support data capture?
- How will you account for the growing volume of traceability data required to be retained?
- Will you manage the traceability data yourself or outsource to third parties?

# Using the cost to comply to unlock additional value across the supply chain

While the FDA's Food Traceability Rule primarily focuses on preventing illness from foodborne pathogens to facilitate proactive food safety recalls, establishing traceability is an essential step to digitizing the food system and addressing growing concerns around environmental impact and supply chain logistics.

Figure 3. Additional use cases for traceability



Through the Food Traceability Rule, and the digitization of the food system, companies can be better positioned to unlock additional value in three specific areas:

## 1. ESG Scope 3 emissions validation

To truly understand the carbon footprint of a product, it is critical to maintain a reliable record of the emissions involved

across sourcing, production, logistics, and operations. Gaining visibility into first-mile emissions data not only can enable supply chain partners to more accurately estimate their Scope 3 emissions, but could introduce a viable new revenue stream. Regenerative farming techniques have the potential to return atmospheric carbon to the soil, making it a potential untapped source of revenue in the carbon credits market.

**2. Claims certification and price premiums**

Due to shifting consumer expectations, it's important to provide accurate information about the sustainability impacts of the food being sold. Leveraging the foundation of traceability, food companies can maintain the integrity of sustainability data attributes collected throughout the supply chain. Food companies can couple price premiums with the sustainable product claims being made if they can provide evidence of the various actors involved throughout the different stages of the food value chain and confirm the origins of ingredients used in production.

**3. Supply chain visibility and risk mitigation**

Providing visibility into the originator or producer of food products (e.g., Lot Code Generators) enables companies to illuminate their extended supplier network to proactively monitor for supply chain disruptions (e.g., recalls, climate-related disruptions, raw ingredient shortages) and conduct more targeted recalls to prevent food loss and illness.



The time for action is now

Consumers demand more transparency about the safety, quality, and sustainability of the food they eat. One survey found 71% of consumers feel traceability is important and may likely even pay a premium for traceable products.<sup>11</sup> Food companies have responded by proactively offering more information and making claims on their labels and packaging. Still, in the absence of adequate traceability, the industry has been unable to demonstrate real progress, leading consumers to question

the authenticity of these claims. While not all misleading claims are intentional, they equally contribute to the continued deterioration of public trust in the food system.

The creation of a digital twin of the supply chain, combining traceability and digitalization, is an effective strategy that can expose and help correct the imbalances perpetuated by pervasive gaps in information, if implemented correctly. A lack of preparation may expose companies to significant risks, including noncompliance, loss of consumer trust, and limited supply chain visibility that hinders product quality and safety.

# Endnotes

1. [Food and Drug Administration \(FDA\), "Full text of the Food Safety Modernization Act \(FSMA\)," Pub. L. No. 353, 111th Cong., 2017.](#)
2. [FDA and Department of Health and Human Services \(HHS\), "Requirements for additional traceability records for certain foods," 21 C.F.R. Part 1, 2022.](#)
3. [FDA, "New era of smarter food safety: FDA's blueprint for the future," July 2020.](#)
4. [FDA and HHS, "Requirements for additional traceability records for certain foods."](#)
5. Ibid.
6. Ibid.
7. Ibid.
8. Ibid.
9. Ibid.
10. Ibid.
11. [International Food Information Council, 2022 Food and Health Survey, May 18, 2021.](#)



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