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Food Safety Modernization Act Section 204: Traceability and Transparency in the Food Industry

Using Digitization to Track and Trace Foods in the Food Value Chain Enables Transparency and Drives Value Creation

The US Food and Drug Administration (FDA) published the finalized Food Traceability Rule ("Rule"), implementing Section 204 of the Food Safety Modernization Act (FSMA Section 204), with a compliance date of January 20, 2026. This Rule incorporates additional traceability and record-keeping requirements that are likely to need significant transformations in the food industry.

FSMA Section 204 – Creating an opportunity for enhanced transparency and accelerating food industry shifts

There is a growing trend among consumers looking for transparency into the safety, quality, and sustainability of the food they consume. Increased awareness of sustainability has altered purchasing habits and consumer preferences at a global level. Consumers are likely to interact with and show a strong preference, for sustainable and ethical brands (e.g., responsible sourcing). 69% of consumers stated that sustainability has become more important to them over the last two years.[1]

This demand for transparency starts at the point of origin—during production and harvesting of food products and ingredients —and extends into food processing and handling, distribution, preparation, and consumption. The method for measuring and monitoring this transparency is termed traceability—how the industry tracks the movement of food products and ingredients through the stages of the food supply chain.

Accountability, across the food supply chain

Parties within the supply chain have an essential role in identifying the origin of food products and tracking the journey those products take to reach the consumers. Traceability may also have an impact on profitability, as 65% of Gen Z and 60% of Millennials prioritize brands that provide transparency and traceability of their supply chains.[2]

Food Traceability Rule requirements

Unpacking the FDA Food Traceability Rule

In response to the growing food safety challenges occurring within the food system, in 2011 the US government signed into law the Food Safety Modernization Act (FSMA).[3] To implement FSMA, several rules were finalized including Food Traceability (implementing FSMA section 204) which was published on November 15, 2022 with a compliance date of **January 20, 2026**.[4] In this Rule, FDA has identified sixteen food categories on the Food Traceability List (FTL).

The Food Traceability List identifies **16 categories** of foods that have increased reporting standards.

Record-keeping requirements with a future-ready approach

A critical component to a company looking to scale their food traceability programs and systems for the future, the Rule requires a traceability lot code (TLC) to be assigned to a group of products made together (i.e., in the same production run, using the same materials). A traceability lot code enables bi-directional tracking, meaning that stakeholders in the supply chain can trace a product upstream to its raw materials and production processes or downstream to its distributors, wholesalers, and end customers.

Industry challenges that shape leading practices

When working to modernize systems and comply with the Rule, companies may face four types of challenges across the following areas: data, processes, stakeholders, and technology.

Data

- **Data governance and privacy:** Existing data-sharing processes need supplemental traceability data and should be assessed for privacy considerations. Additionally, companies may incur increased compliance costs and risk without transparent governance over the traceability of data or insight into its integrity.
- **Data architecture and capture:** Critical Tracking Events (CTEs) may require architectural data changes to facilitate data capture. 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 data digitally.
- **Data processing:** Processes needed to validate, enrich, and transform traceability data can be resource-intensive and pose risks to existing critical business processes within supply chain technologies (e.g., enterprise resource planning systems).

Process

- **Lot-level traceability:** Some suppliers and producers do not currently adhere to a standardized system that enables the provision of globally unique identifiers. Therefore, some inbound products may not have or receive scannable labels that include Traceability Lot Codes (TLCs), resulting in lost lot-level traceability.
- **Consistent scanning of labels:** Some companies undertake scanning of the product in an inconsistent manner, which may result in the loss of visibility into lot-level details at different stages of the supply chain. The Rule requires Key Data Elements (KDEs) to be tracked at each CTE; and while this information can be used through digital means, the physical scanning of labels at certain stages of product handling allows companies to also confirm if the digital information is accurate.
- **Labeling strategies:** Today, some 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 Rule.

Stakeholders

- **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., TLC). Also, there is an increased dependency on suppliers to provide ingredient details, which may be considered intellectual property.
- **Traceability culture and training:** A company's employees and their supply chain partners likely need training on how the new culture of traceability will impact their day-to-day responsibilities.

Technology

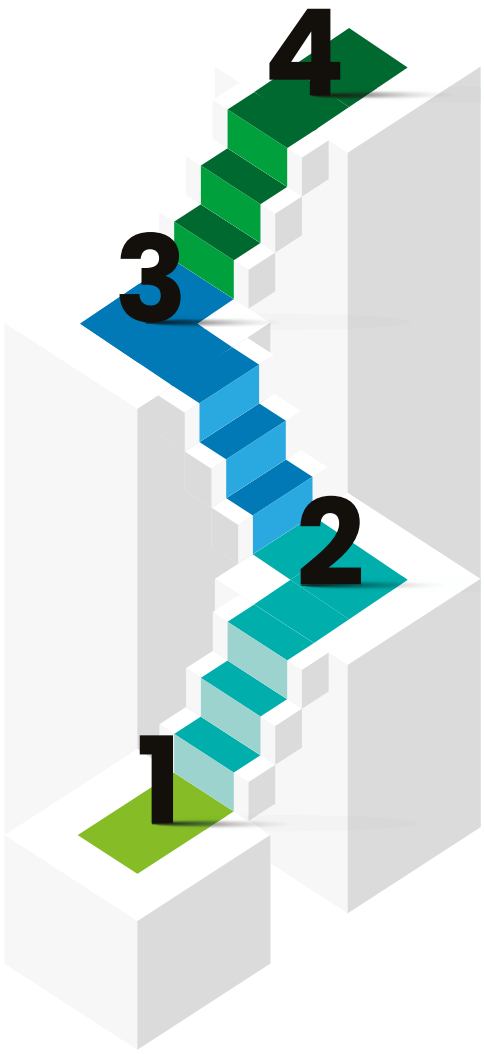
- **Legacy supply chain systems:** Companies may need to implement processes to analyze and capture traceability data throughout its supply chain. Some of these processes may need to be event-driven, which can add complexity to legacy systems.
- **Centralization of traceability data:** Existing traceability data may bespread across different source systems, and companies may need to centralize and enhance their data for reporting to provide an electronic sortable document to the FDA within 24 hours of their request.
- **Data sharing:** Companies may need to develop data-sharing mechanisms that account for stakeholders with different levels of technological maturity.

Overcoming challenges may require establishing physical-to-digital links

Companies can find their way through the above challenges by establishing dedicated links between the physical food products in their supply chain and the digital markers and identifications they create to track those products. Barcodes, labels, or RFID (radio frequency identification) can create a physical-to-digital link at the intersection of handling physical products and capturing digital data. These links support the accuracy and completeness of a company's overall food traceability data.

A next step is to identify technology that addresses your unique needs

With an understanding of what it takes to build a foundation for improved food traceability systems through physical-to-digital links, the next steps revolve around identifying the right technology considerations for reporting compliance.



Step 4: Technology readiness

The Rule does not stipulate the use of specific digital technologies.[5] However, the huge volume of data required to maintain granular levels of traceability can 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.

Step 2: Process readiness

The physical-to-digital link established by a companies' unique TLCs should be maintained for each product as it moves through the value chain. Companies should assess current processes to identify areas of possible traceability complications.

Step 3: Stakeholder readiness

Compliance with the Rule also may require widespread effort and coordination across a company's supply chain. Supply chain partners may need to agree on mechanisms to share digital traceability data.

Step 1: Data readiness

Unlocking value with traceability should start with a system-wide 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.

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

While the Rule primarily focuses on preventing illness from foodborne pathogens and to facilitate food recalls, establishing traceability is an essential step to digitizing the food system and addressing growing concerns around environmental impact and supply chain logistics. Pursuing a lot-level traceability program can also provide additional value in the areas of reducing recall cost and waste, optimizing supply and inventory management and sustainability data capture.

1 Reducing the cost of recalls

Lot-level traceability can reduce the cost of recalls by reducing recall scope and the resulting expenditures from coordination including responding to regulatory inquiries, product identification, re-shipment and destruction. A smaller scale recall can also mean reduced brand damage, loss of trust and damage to brand loyalty.

2 Reducing waste

An increase in supply chain and sourcing transparency and traceability provides the opportunity for near real-time monitoring of shelf life, temperature and product routing. This can reduce food and packaging waste expenses and enhance brand reputation due to increased freshness at the point of sale.

3 Supply and inventory optimization

Traceability data and systems can be leveraged for insights into the supply chain including supplier performance. Savings can potentially be realized from improved inventory management and operations can be streamlined for a gain in efficiency.

4 Sustainability data capture

Supply chain data collection should include technology implementation and process redesign, both of which can be leveraged to collect environmental data and facilitate sustainability progress reporting and a reduction in disclosure times. Additional value can be realized in the monetization of carbon abatement data.

The time for action has come

Consumers are demanding more transparency into the safety, quality, and sustainability of the food they eat. 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 struggled 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.

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Endnotes:

1 Nielsen IQ," The CPG sustainability report", January 19, 2019.

2 Deloitte Global, "Deloitte's 2024 Gen Z and Millennial Survey", May 18, 2024.

3 Food and Drug Administration (FDA), "Full text of the Food Safety Modernization Act (FSMA)," Pub. L. No. 353, 111th Cong., 2017.

4 FDA and Department of Health and Human Services (HHS), "Requirements for additional traceability records for certain foods," 21 C.F.R. Part 1, 2022.

5 Food and Drug Administration (FDA), "Full text of the Food Safety Modernization Act (FSMA)," Pub. L. No. 353, 111th Cong., 2017.

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