



Food Safety Modernization Act (FSMA) – Section 204(d)

Enabling compliance with the
FDA Food Traceability Final Rule

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FSMA 204—road to delivering end-to-end food traceability

The US Food and Drug Administration (FDA) is driving major improvements in food safety through a new regulation called the FDA Final Rule on Requirements for Additional Traceability Records for Certain Foods. Implementing a key section of the Food Safety Modernization Act of 2011, this regulation enables the FDA to address foodborne illness outbreaks and other issues faster and with more precision.

The regulation, often called FSMA 204, expands requirements for persons and organizations that are handling certain food items. They must capture data on all key activities involved in the food supply chain and maintain a readiness to report this information to the FDA within 24 hours after being requested to do so.

The regulation has been developed in close consultation with the US food industry to avoid unnecessary bureaucracy while meeting its goals around reducing negative impacts of foodborne illnesses. The pragmatic approach can be seen, for example, in the several exemptions included in the regulation as well as the extension of the original compliance deadline of January 20, 2026 to July 2028 to allow the industry sufficient time to meet the requirements.



Ensuring FSMA compliance with OpenText

As a leading information management company, OpenText can help your business ensure FSMA 204 compliance. With emphasis on compliant data exchange across the supply chain, OpenText solutions enable seamless capture and reporting of the key data elements covered by the regulation.

FSMA 204—What is it?

To allow for faster identification and removal of potentially contaminated food from the market, the FDA Final Rule on Requirements for Additional Traceability Records for Certain Foods also known as FSMA 204 or Food Traceability Final Rule—presents new requirements for organizations involved in US food supply chains.



Compliance requirement

The **FDA Final Rule on Requirements for Additional Traceability Records for Certain Foods** (Food Traceability Final Rule)...



Mandated action

...establishes **traceability recordkeeping requirements**, beyond those in existing regulations,...



Affected parties

...for **persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL)**.



Guiding vision

The final rule is a key component of FDA's **New Era of Smarter Food Safety Blueprint**...



Legal foundation

...and **implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA)**.

Why food traceability requirements matter

Foodborne illnesses continue to be a major public health issue in the US. By improving traceability of high-risk food items, FSMA 204 aims to significantly reduce the health risks around food contamination.

800

foodborne illness **outbreaks** reported in the U.S every year¹



1 in 6 people in the US get sick from foodborne diseases each year,² out of which...

128,000

people get **hospitalized**², and...

3,000

people **die**.²



1 FDA, Requirements for Additional Traceability Records for Certain Foods, 2022;
2 CDC, Burden of Foodborne Illness: Findings, 2018

Brief history and timeline of the FSMA 204

Compliance with the FSMA 204 regulation is expected to become mandatory in July 2028 and it has been a long time in the making. The new regulation implements section 204 of The Food Safety Modernization Act, which was passed into law in 2011.



Jan 2011
The Food Safety Modernization Act (FSMA) passes into law



Feb 2014
First draft of the FDA **Food Traceability List (FTL)** published



Sep 2020
FDA announces a rule to enact **section 204** of FSMA to advance food traceability



Jan 2021
FDA makes edits to the Food Traceability List to **clarify the food products in scope**



Nov 2022
FDA announces the FSMA **Final Rule** on Requirements for Additional Traceability Records for Certain Foods



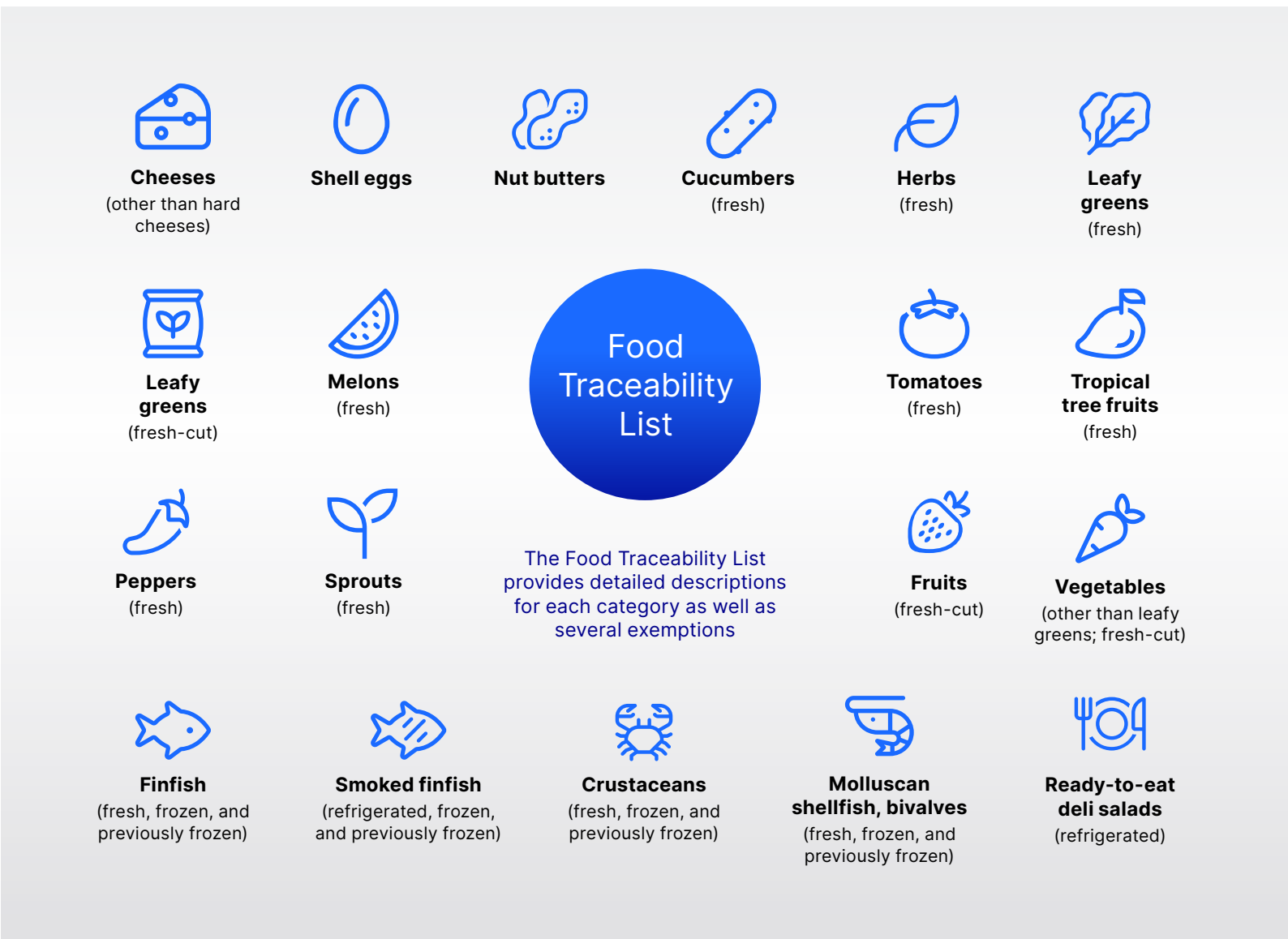
Jan 2026
Original compliance date announced for January 20, 2026 - 30-month extension announced by FDA in March 2025



Jul 2028
Compliance becomes mandatory for all persons subject to the requirements

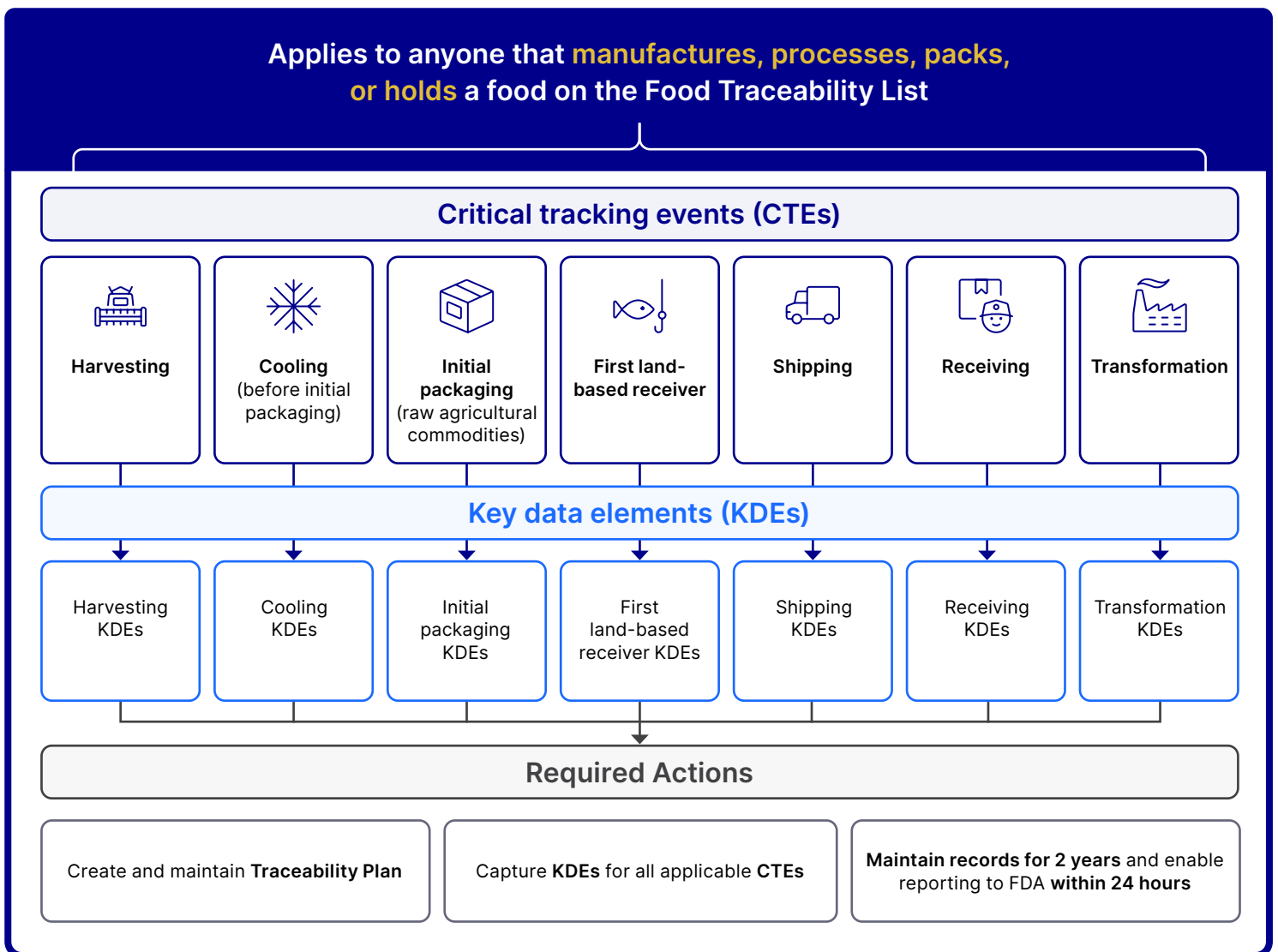
Foods in scope of the regulation: FDA Food Traceability List

To focus regulatory efforts on foods that present the highest public health risks, the FDA maintains Food Traceability List, which governs what foods are in scope for the FSMA 204 regulation. The list provides specific definitions, as well as several exemptions based on rigorous risk assessment.



Who needs to comply and what they need to do

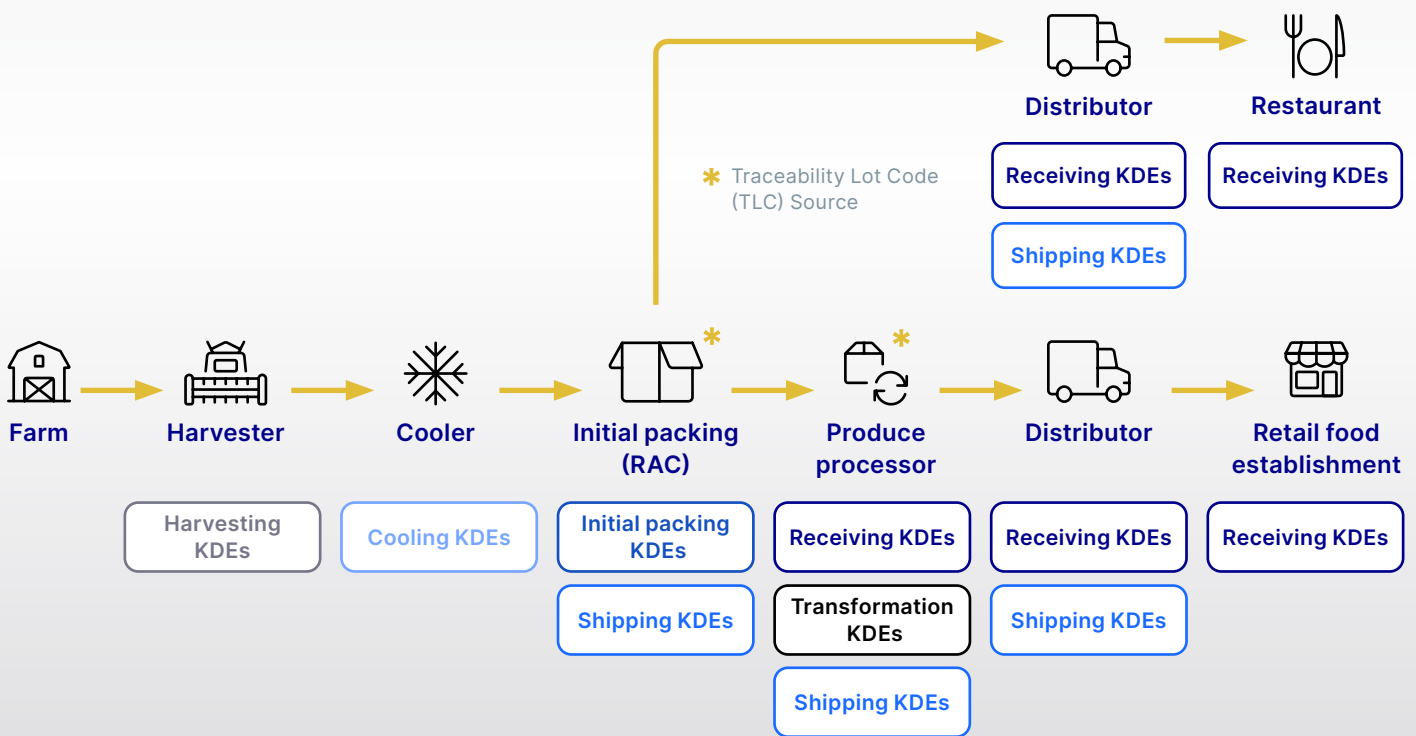
The FSMA 204 regulation identifies seven critical tracking events (CTEs) in the food supply chain. Parties performing any of these CTEs must maintain a traceability plan, capture related key data elements (KDEs) for each CTE, and enable data reporting to the FDA within 24 hours upon request.



Exemptions apply. These are listed in § 1.1305 of the final rule.

Example—responsibilities in a fresh produce supply chain

KDEs must be captured for all CTEs performed by parties involved in the supply chain. Initial packing and transformation CTEs play a special role, since these involve assigning traceability lot codes (TLCs) to food products. TLCs identify the source of the food and are passed down the supply chain.



Example—key data elements for shipping

KDEs that organizations must capture and retain vary for each CTE, but many elements are shared between them. For example, KDEs for the shipping CTE largely mirror KDEs for the receiving CTE. This data is typically passed from the supplier to the buyer using advance ship notices (ASNs).

Shipping KDEs (maintain and provide)

KDEs must be linked to the traceability lot for the food

- **Traceability lot code** for the food
- **Quantity** and **unit of measure** of the food
- **Product description** for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food (**ship to location**)
- Location description for the location from which you shipped the food (**ship from location**)
- **Date** you shipped the food
- Location description for the **traceability lot code source** or the **traceability lot code source reference**
- **Reference document type** and **reference document number** (maintain only)

Does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel)



36

Data fields

provided for shipping KDEs in the FDA electronic sortable spreadsheet template



Key impacts of the FSMA 204 regulation

FSMA 204 aims to significantly reduce the health risks around foodborne illnesses in the US, which will benefit both the general public and the food industry. To enforce compliance, the FDA can resort to a range of penalties. Non-compliance may also result in indirect consequences for organizations.

Key goals of the regulation

Benefits to the public

- Faster identification and rapid removal of potentially contaminated food from the market
- Reduction in foodborne illnesses and the resulting hospitalizations and deaths

Benefits to the organizations

- Reduced product recall risks and scope
- Enhanced supply chain visibility
- Increased consumer trust

Penalties for non-compliance

Direct penalties (depend on the nature of violation)

- Hourly re-inspection fees (\$340/hour*)
- FDA-mandated product recalls
- Suspension of facility registration
- Potential civil & criminal penalties

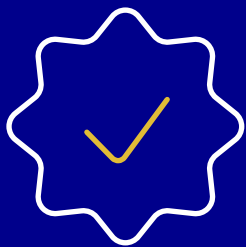
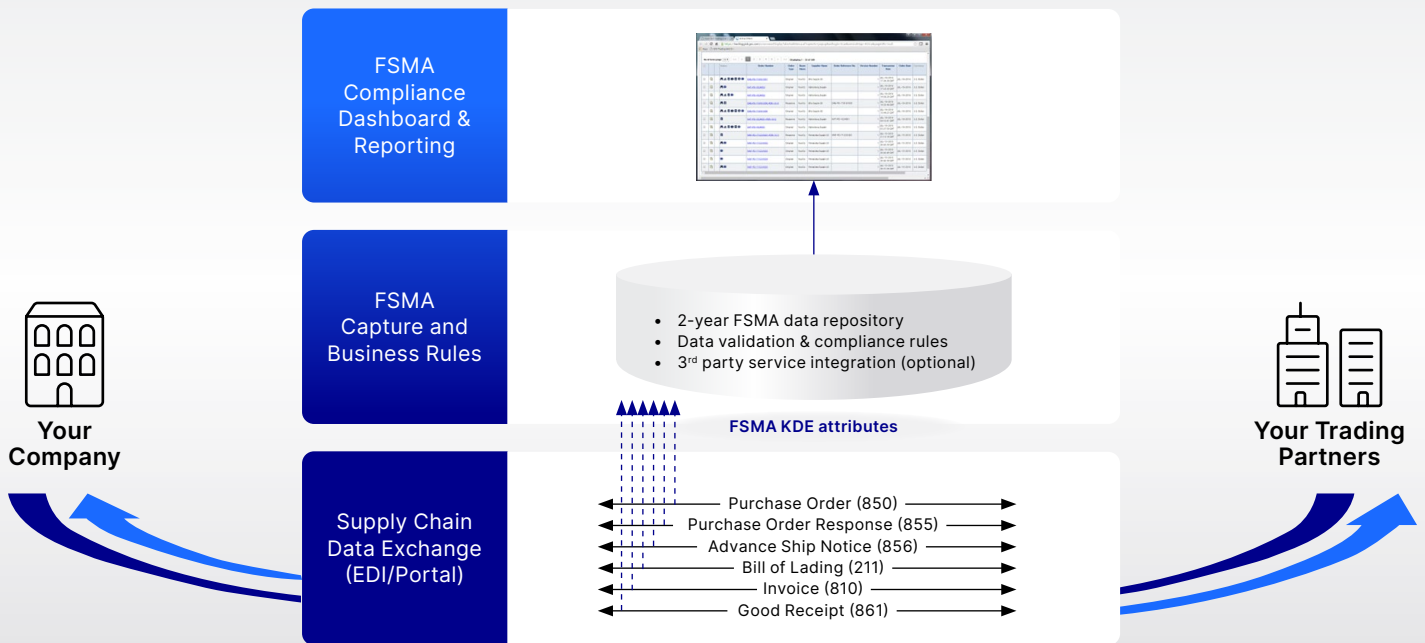
Indirect consequences

- Limited market access due to partner requirements
- Reputational damages

* Source: Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2025

Enabling FSMA 204 compliance with OpenText

To efficiently meet FSMA compliance requirements organizations should automatically capture the KDEs on all CTEs they participate in. OpenText offers highly configurable solutions for companies in the food supply chain to automate FSMA compliance while improving overall supply chain performance.



FSMA 204 adds new requirements for capturing and sharing data in the food supply chain.

Contact us to discuss how OpenText Business Network can help you enhance collaboration and ensure compliance.