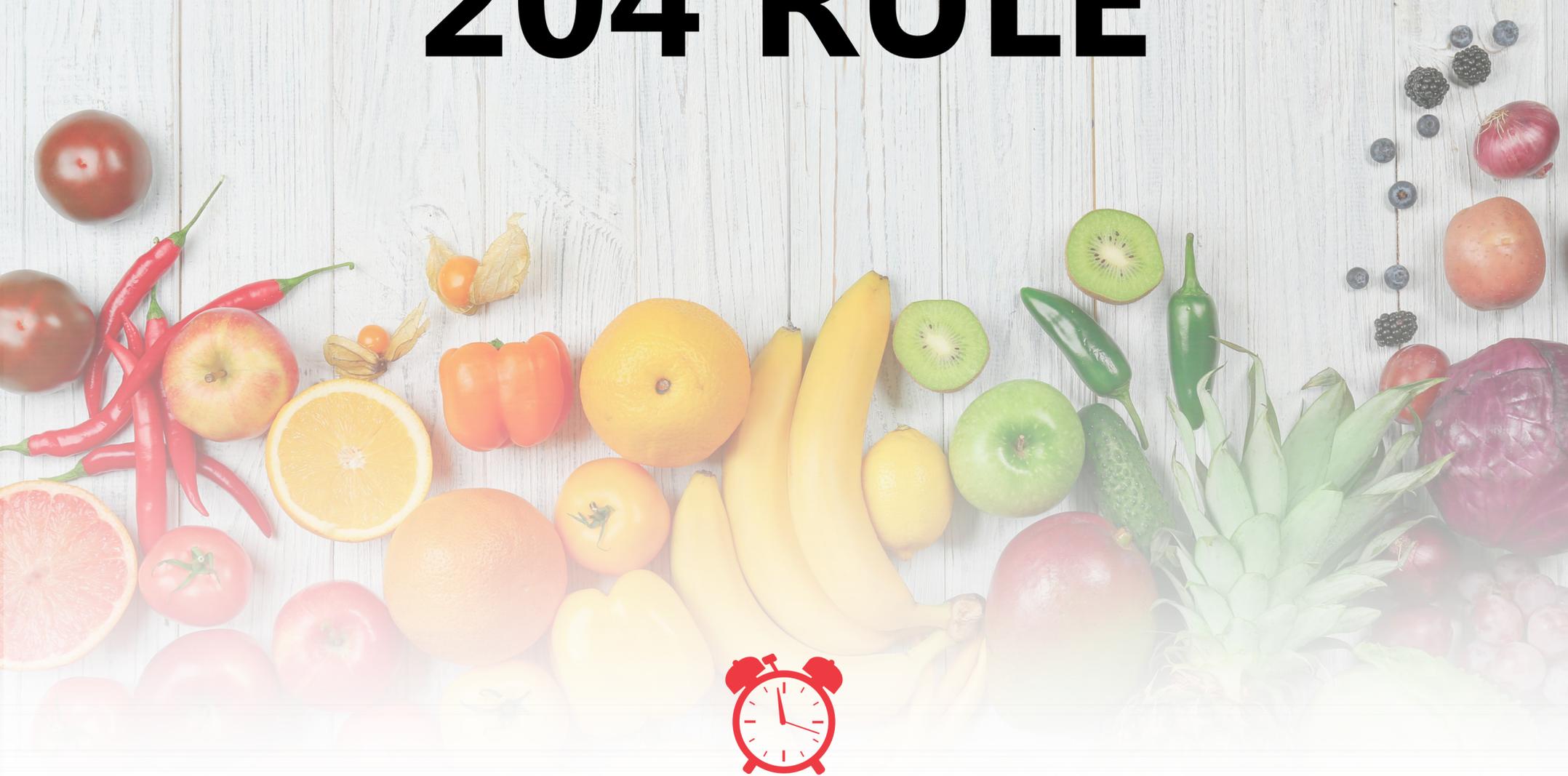




FDA FSMA 204 RULE



Deadline: January 20, 2026

The FDA's Food Traceability Final Rule establishes advanced recordkeeping requirements for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). Those subject to the rule must maintain and provide to their supply chain partners Key Data Elements (KDEs) for Critical Tracking Events (CTEs). Companies must provide this information to the FDA within 24 hours, upon request.



**Build Traceability
Roadmap**



**Integrate Software &
Technology**



**Track KDEs &
CTEs**



**Share with Trading
Partners**



**Report
to FDA**

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START
HERE

Contact the PLM TrustLink™ Team

Talk to our experts to start your FSMA 204 Roadmap today.



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1

Build Traceability Roadmap

Building a Traceability Roadmap for your company includes creating and maintaining a Traceability Plan. Requirements for the Plan are stipulated in the full regulations, and include such things as:

- Procedures and responsibilities your company use to identify and track foods on the FTL
- How you assign or capture traceability lot codes
- How you maintain required records for tracking the KDEs of FTL items through your CTEs including the data definitions, format, retention, and availability policies

2

Integrate Traceability Software & Technology

Implement solutions like PLM TrustLink™ that can improve your operational capabilities to track & trace product in your food chain, plus enable FDA FSMA 204 compliance and reporting at the touch of a button.

3

Track KDEs & CTEs

The final rule identifies the CTEs and KDEs, including traceability lot codes that must be tracked. The KDEs required will vary by the CTE. The CTEs include:

- Harvesting
- Cooling
- Initial Packing
- First Land Based Receiver
- Shipping
- Receiving
- Transformation

4

Share with Trading Partners

The final rule requires the traceability information to be transferred up and down the supply chain and allows third parties to maintain that data. PLM TrustLink™ solutions can be the trusted data bridge between you, your customers, and your suppliers to enable compliance.

5

Report to FDA

The final rule requires electronic data to be made available to FDA within 24 hours upon request and maintained for two years. PLM TrustLink™ solutions can consolidate the data report in the event of an FDA request.

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