



REGULATORY REFERENCE

FDA Regulation · FSMA-204

Food Traceability Final Rule (21 CFR Part 1, Subpart S)

USA · UNITED STATES · FDA (FOOD AND DRUG ADMINISTRATION)

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JURISDICTION	TYPE	CATEGORY
United States · FDA (Food and Drug Administration)	Regulation	Traceability
DARWIN PRODUCTS	LAST OFFICIAL UPDATE	DOCUMENT VERSION
Captia · Tracium	November 15, 2025	v1.0.0 · 13/05/2026

1. What is it?

The **Food Safety Modernization Act §204(d)**, known as **FSMA-204** or the "Food Traceability Final Rule," is the U.S. federal regulation that requires extended traceability recordkeeping for high-risk foods. The rule was published by the **FDA** in November 2022. Its original compliance date was January 20, 2026, but it was extended by 30 months following the FDA's proposed extension of August 7, 2025 and a Congressional directive via the Continuing Appropriations Act 2026. The **current compliance date is July 20, 2028**. The rule applies to every actor that produces, processes, transports or receives foods on the **Food Traceability List (FTL)**, whether domestic or as importers shipping into the United States.

2. Who does it apply to?

Covered actors along the supply chain:

- Agricultural producers (harvest and cooling).
- Packers (Initial Packing CTE).
- Processors and transformers.
- Transporters when they take custody of the product.
- Wholesalers and distributors (Shipping and Receiving CTEs).
- Retailers and food service operators (Receiving CTE).

Covered products: those listed on the **Food Traceability List (FTL)**, which the FDA updates periodically. Covered categories include:

- Fresh and fresh-cut leafy greens (lettuce, spinach, kale).
- Fresh herbs (cilantro, parsley, basil).
- Cucumbers.
- Bell peppers.
- Tomatoes.
- Melons.
- Sprouts (alfalfa, mung, etc.).
- Tropical tree fruits: mango, papaya, guava, lychee, jackfruit, mamey, starfruit.
- Fresh-cut fruits and vegetables.
- Finfish, including smoked (fresh and frozen).
- Crustaceans (shrimp, lobster, crab).
- Bivalve mollusks (oysters, mussels, clams, scallops).
- Soft cheeses, semi-soft cheeses and cheeses with soft ripened rind (excluding hard cheeses).
- Shell eggs (chicken).
- Nut butters.
- Ready-to-eat refrigerated deli salads.

Common clarification: *avocado is **NOT** on the FTL. The "tropical tree fruits" category explicitly excludes pit fruits. Bananas, pineapple, dates and coconut are also not on the FTL.*

Markets: the rule applies to any FTL food **commercialized in the United States**, regardless of country of origin. LATAM exporters (Peru, Mexico, Chile, Colombia, Argentina) shipping to the U.S. are therefore subject to the rule de facto.

Common exemptions:

- Farms with average annual produce sales below **USD 25,000** (3-year rolling average, inflation-adjusted from a 2020 baseline).
- Foods produced and consumed on the same farm.
- Foods that have already been processed and are now an ingredient in another food no longer on the FTL.

- Restaurants and food service that receive FTL items only for immediate local consumption (with exceptions).
- Pharmaceutical products and dietary supplements.

3. Key requirements

The rule requires capturing **Key Data Elements (KDEs)** at each **Critical Tracking Event (CTE)**, linked by a unique **Traceability Lot Code (TLC)**. The covered CTEs are: Harvesting, Cooling, Initial Packing, Shipping, Receiving, Transformation.

Harvesting CTE (§1.1330)

ID	KDE	Description
K-H-01	Traceability Lot Code	Unique code assigned at the originating event.
K-H-02	Location identifier of harvest location	Field/orchard identifier (address or GPS coordinates).
K-H-03	Location description of harvest location	Readable description of the orchard or field.
K-H-04	Date of harvesting	Calendar date of the harvest.
K-H-05	Quantity and unit of measure	Harvested quantity in a standard unit.
K-H-06	Commodity and variety	Food and variety (e.g. mango Tommy Atkins).
K-H-07	Reference document type + number	Reference document (manifest or receipt).
K-H-08	Location of immediate subsequent recipient	Next destination (not counting the transporter).

Cooling CTE (§1.1335)

ID	KDE	Description
K-C-01	Traceability Lot Code (link)	Same TLC as the linked Harvest event.
K-C-02	Location identifier of cooling location	Identifier of the cooling facility.
K-C-03	Location description of cooling location	Readable description of the facility.
K-C-04	Date of cooling	Date cooling started.
K-C-05	Quantity and unit of measure (if different)	Quantity if it differs from Harvest.
K-C-06	Reference document type + number	Reference document.
K-C-07	Location of immediate subsequent recipient	Next destination.

Record keeping (§1.1455)

- Records must be retained for **at least 2 years**.
- They must be **provided to the FDA within 24 hours** upon formal request (recall, outbreak investigation or audit).
- Format: paper or electronic, with verifiable data integrity.

4. How does Darwin cover it?

Captia is the CTE event capture layer in the field and at the plant. **Tracium** anchors the records to the immutable ledger. Together they cover the KDEs as follows.

- **K-H-01 / K-C-01 (TLC): Captia** auto-generates Traceability Lot Codes per CTE event; **Tracium** persists and signs each TLC on-chain, ensuring uniqueness and temporal integrity.
- **K-H-02 and K-H-03 (location): Captia** resolves orchard or field identifiers against the tenant knowledge base (configured at onboarding) and persists them with approximate GPS coordinates.
- **K-H-04 / K-C-04 (date): Captia** captures the event timestamp automatically; **Captia Field** (voice, on the PoC roadmap) captures retroactively reported dates.

- **K-H-05 / K-C-05 (quantity): Captia** converts vernacular units (crates, boxes, sacks) to a standard unit via the tenant vocabulary.
- **K-H-06 (commodity + variety): Captia** infers the default variety from the tenant scope (configured at onboarding), with manual override available.
- **K-H-07 / K-C-06 (reference documents): Captia** auto-generates reference document numbers tied to the TLC.
- **K-H-08 / K-C-07 (subsequent recipient): Captia** captures the next destination from the knowledge base of inter-facility relationships.
- **§1.1455 (24h availability): Tracium** exposes a TLC-keyed query API with sub-second SLA; the **Captia** web portal allows CSV or JSON exports ready to submit to the FDA.

Areas not yet covered in V1 (transparent):

- The Initial Packing, Shipping, Receiving and Transformation CTEs are on the roadmap; full coverage of the 6 CTEs is within the MVP scope.
- Chain-of-custody integrity (TLC chain integrity) between upstream and downstream actors requires the receiver to also use **Captia** or an interoperable system.

5. Sanctions and consequences of non-compliance

Regulatory sanctions (FDA enforcement):

- The FDA can issue public **Warning Letters**, which damage commercial reputation and are read by importers.
- Shipment rejection at U.S. ports of entry (cargo returns to origin or is destroyed at the importer's cost).
- **Detention without physical examination (DWPE)**: the FDA can blacklist the exporter until compliance is demonstrated.
- For serious violations: **federal judicial action** with variable fines and possible criminal charges in extreme cases.

Commercial risk:

- U.S. importers and large retailers (Walmart, Costco, Kroger) are already requiring evidence of FSMA-204 compliance well ahead of the July 2028 legal deadline. The supply chain transition takes time and buyers will not wait until the last day. No records, no deal.
- Large chains require TLCs traceable back to origin as part of their supplier due diligence.

- A recall forces identifying the affected lot in hours; an exporter without traceability suffers expanded recalls (entire brand vs. specific lot).

Operational risk:

- Without a traceability system, a recall can demand **days or weeks** of manual investigation when the rule requires the information within 24 hours.

6. Timeline

- **September 2020:** the FDA publishes the proposed rule.
- **November 2022:** the FDA publishes the final rule (21 CFR Part 1, Subpart S).
- **January 2023:** the rule becomes technically effective; original compliance date set for January 20, 2026.
- **March 2024:** the FDA issues preliminary guidance.
- **August 7, 2025:** the FDA publishes a proposal in the Federal Register to extend the compliance date by 30 months, moving it to July 20, 2028. Public comment period open until September 8, 2025.
- **November 2025:** Congress passes the *Continuing Appropriations Act 2026*, which includes an express directive instructing the FDA not to enforce the rule before July 20, 2028. The FDA confirms it will comply with the directive.
- **July 20, 2028: current compliance date (post-extension).** From this day forward, any FTL food imported or commercialized in the U.S. requires the KDEs.
- **2029 to 2030 (expected):** the FDA begins systematic audits and formal enforcement of importers and domestic retailers.

7. Official source and updates

- **Primary source:** [FDA · FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods](#)
- **Full regulatory text:** [21 CFR Part 1, Subpart S · eCFR](#)
- **Food Traceability List (FTL):** [FDA · Food Traceability List](#)
- **Extension proposal (Federal Register):** [Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension \(Aug 7, 2025\)](#)
- **Last official update verified:** November 15, 2025 (Congressional directive).

- **Darwin doc version:** 1.0.0.
- **Darwin doc date:** May 13, 2026.

Legal notice

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All-in-One Digital Product Platform

Traceability, compliance and operational efficiency for food and agro-industrial supply chains.

From origin to market. From traceability to trust.

Traceability is now market-access infrastructure

Food supply chains must demonstrate origin, process, compliance and evidence. Pressure converges from regulators, global buyers, consumers, brands and higher-value markets.

Regulators

FSMA 204 / EUDR

Buyers

visibility and response

Consumers

trust with evidence

Markets

origin, quality and access

Darwin covers the full traceability cycle



AI LAYER Intelligence applied over traceable data: inconsistencies, gaps, risks, alerts, queries and audits.

What it solves

- Fragmented data across field, plant, logistics and customers.
- Slow audits and traceability rebuilt after the fact.
- Gap between market requirements and operational reality.
- Low digitalization at producers and rural areas.

What it enables

- **Comply better:** structured, auditable and verifiable data.
- **Operate better:** fewer errors, rework and manual load.
- **Sell better:** demonstrable origin, quality and sustainability.
- **Include better:** producers connected to higher-value chains.

Multi-standard compliance

Capture once, structure correctly and reuse the data for regulatory, commercial and operational purposes.

FSMA 204

CTEs / KDEs

EUDR

DDS and deforestation

Certifications

GlobalGAP, BRC, organic

Private standards

retailers and buyers

One platform, different value cases

● Producers

evidence and market access

● Exporters

control and compliance

● Retailers and brands

risk, recalls and claims

● Certifiers

audit-ready evidence

● Industry bodies

sectoral standardization

● Governments

inclusion and markets

Rollout: Discovery, Pilot and Go-live

Differentiators: traceability at the core · capture at origin · interoperability · verifiable evidence · all-in-one modular · AI on top of real traceability.

01 Discovery

02 Pilot

03 Go-live