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STANDARDS & GUIDANCE BRIEF · UNITED STATES · REGULATION

FSMA 204 · 21 CFR Part 1, Subpart S

Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule)

DOCUMENT	QES-WP-171, Rev B	DATE	November 7, 2026
ISSUED BY	US Food and Drug Administration	PREPARED BY	Conner Davidson
EDITION	Final rule 2022; compliance date July 20, 2028	STATUS CHECKED	October 24, 2026
INDUSTRIES	General Manufacturing	ONLINE	qesisbest.com/standard-fsma-204.html

ADOPTED, APPLIES LATER The compliance date was extended from January 20, 2026, to July 20, 2028. **Next:** July 20, 2028: Key Data Elements for each Critical Tracking Event become enforceable.

What It Covers

Additional traceability records for foods on the Food Traceability List, so that FDA can trace contaminated food quickly.

Who It Applies To

Persons who manufacture, process, pack or hold foods on the Food Traceability List, with exemptions set out in the rule.

Key Requirements

- A traceability plan describing procedures, the traceability lot codes, and a point of contact.
- Key Data Elements recorded for each Critical Tracking Event, such as harvesting, receiving, transformation, and shipping.
- Traceability lot codes assigned at defined events.
- An electronic sortable spreadsheet provided to FDA within 24 hours on request.

What an Auditor Asks to See

- The traceability plan, and the records for a lot from receipt to shipment.

Where Systems Fall Short

- Lot codes that change at each step with no link to the previous one.

How QES helps. Traceability plans and record systems ready well before July 2028. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. US FDA — FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods — www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods; eCFR — 21 CFR Part 1 — www.ecfr.gov/current/title-21/part-1.

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