AEROZ

US FOOD · FSMA 204 · READINESS CHECKLIST

FSMA 204 Food Traceability Rule Readiness Checklist

Critical Tracking Events, Key Data Elements and 24-hour records to FDA — ahead of the deadline.

WHO MUST COMPLY

Firms that manufacture, process, pack or hold foods on the FDA Food Traceability List (FTL) — and their upstream and downstream trading partners.

THE DEADLINE

The compliance date was extended by 30 months to **20 July 2028** (FDA, Aug 2025; made binding by Congress in Nov 2025). The extra runway is for building the data plumbing across thousands of partners — starting now leaves time to finish.

1 · Scope & traceability plan

- [ ] Determine whether you handle any Food Traceability List (FTL) foods.
- [ ] Assess exemptions (certain small producers, specific retail and food-service cases).
- [ ] Create and maintain a written Traceability Plan: procedures, a point of contact, how you assign Traceability Lot Codes, and farm maps where applicable.

2 · Critical Tracking Events & KDEs

- [ ] Identify your Critical Tracking Events (CTEs): harvesting, cooling, initial packing, shipping, receiving, and transformation.
- [ ] Capture the Key Data Elements (KDEs) required for each CTE you perform.
- [ ] Assign and preserve the Traceability Lot Code (TLC) and record where the lot was established or transformed.

3 · Data systems & retention

- [ ] Put in place a system to record and retain traceability records for 2 years.
- [ ] Link KDEs across CTEs so a single lot can be followed end to end.
- [ ] Standardise identifiers (GTIN / GLN) with your trading partners.

4 · FDA response readiness

- [ ] Be able to produce a sortable electronic spreadsheet of the required records within 24 hours of an FDA request.
- [ ] Run a mock recall / traceback drill and time it.

5 · Trading-partner coordination

- [ ] Confirm upstream partners pass you the KDEs you need, and that you pass required KDEs downstream.
- [ ] Agree an interoperable data-exchange format (GS1, EPCIS optional) with partners.

WHERE AEROZ FITS

FSMA 204 is a data-linkage problem: the same lot has to stay identifiable and connected across every handoff. Aeroz assigns item- and lot-level identity, records custody events at each CTE, and can export the sortable traceback FDA asks for — turning a 24-hour scramble into a query.

Book a fixed-fee, 14-day Aeroz Readiness Audit — a written gap analysis, no commitment to proceed. **aeroz.io/contact**

Sources: 21 CFR Part 1, Subpart S (Food Traceability Rule); FDA compliance-date extension, 90 FR (7 Aug 2025); Pub. L. extension (Nov 2025).

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