

# From Traceability to Transparency

## Preparing for FSMA 204

Compliance Deadline: **July 20, 2028** | The Time to Start is **NOW**

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# WHAT IS FSMA 204?

## THE RULE

**Section 204(d) of FSMA** — Enacted 2011

**Final Rule Published:** November 21, 2022

**Governing Body:** U.S. FDA

**Part of:** FDA's New Era of Smarter Food Safety Blueprint

**Codified in:** 21 CFR Part 1, Subpart S

**Goal:** Enhance traceability so FDA can identify & remove contaminated food in 24 hours

## KEY DATES

2011 FSMA signed into law

2022 FSMA 204 Final Rule published

Jan 2026 **Original compliance deadline (MISSED)**

Mar 2025 FDA proposes 30-month extension

Jul 2028 **FINAL compliance deadline — NO extensions expected**

# FSMA 204 Were You Ready January 20, 2026 ?



YES



NO

## Will You Be Ready July 20, 2028 ?

# Why This Matters

**48M**

Americans sick from foodborne illness each year

**128K**

Hospitalizations annually

**3,000**

Deaths annually

**21+ days**

Average outbreak-to-recall time without FSMA 204

**FSMA 204 Goal: Reduce outbreak-to-recall from weeks to 24 HOURS**

Outbreak Reported



Investigation Begins



Source Identified



Recall Issued

Today: 14–21+ days

FSMA 204 Target: 24 hours

# The Food Traceability List (FTL)

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What Foods Are Covered?

- + Fresh-cut fruits and vegetables
- + Leafy greens (fresh and fresh-cut): romaine, spinach, cabbage, arugula, endive, etc.
- + Shell eggs
- + Nut butters (peanut, almond, etc.)
- + Cheeses (other than hard cheeses)
- + Seafood: finfish, smoked fish, crustaceans, mollusks
- + Ready-to-eat deli salads
- + Fresh herbs: basil, fresh ginger, parsley, etc.
- + Cucumbers, peppers, tomatoes, tropical tree fruits, melons
- + **IMPORTANT:** Foods containing FTL items as ingredients (in the same form) are also covered
- + FDA can update the FTL at any time — monitor regularly

# Who Must Comply?

## DOMESTIC

- + Manufacturers processing FTL foods
- + Packers & co-packers
- + Holders / warehouses / cold storage
- + Distributors handling FTL items
- + Importers of FTL foods

## FOREIGN

- + ANY company exporting FTL foods to the U.S.
- + Canadian exporters — SFCR ≠ FSMA 204
- + No foreign authority verifies compliance for you
- + Must provide KDEs electronically within 24 hrs
- + U.S. importers bear responsibility for supplier compliance

## EXEMPTIONS

- + Very small businesses (below sales threshold)
- + Farms with <\$25K avg annual sales of that food
- + Certain direct farm-to-consumer sales
- + Shell egg producers covered by other rules
- + Always verify — exemptions are narrow

# CTEs & KDEs — The Heart Of Compliance

**Critical Tracking Events (CTEs)** = moments in the supply chain that must be recorded

**Key Data Elements (KDEs)** = the data captured at each CTE



CTE

## Harvesting

**KDEs:** Commodity, farm ID, quantity, date, GPS coords



CTE

## Shipping

**KDEs:** TLC, quantity, location shipped from/to, date



CTE

## Initial Packing

**KDEs:** TLC assigned, commodity, farm source, date, quantity, location



CTE

## Receiving

**KDEs:** TLC, product description, quantity, location from, date



CTE

## 1st Land Receiving (seafood)

**KDEs:** Vessel name, port, date, quantity, TLC



CTE

## Transformation

**KDEs:** New TLC, all input TLCs, date, location, descriptions

All records must be provided to FDA within 24 hours of request in electronic, sortable format

**July 2028  
Seems  
Far Away.  
*It is not.***

Supplier Onboarding	<b>6–12 months</b>
System Implementation (ERP/QMS/SRM)	<b>12–18 months</b>
Process Redesign + SOPs	<b>6–9 months</b>
Staff Training	<b>3–6 months</b>
Testing & Validation (mock FDA drills)	<b>3–6 months</b>

**Add it all up:  
Companies starting today are already cutting it close.  
Companies not yet started are behind.**

# FSMA 204 Impacts: People · Process · Systems

## PEOPLE

- + FSMA 204 Compliance Owner
- + Cross-functional team
- + Supplier relationship managers
- + Staff training at every CTE
- + Named Traceability Contact

## PROCESS

- + Lot code assignment SOPs
- + KDE capture
- + Traceability lot linkage
- + Recall simulation / mock FDA drills
- + Supplier data exchange protocols
- + Traceability Plan maintenance

## SYSTEMS

- + ERP: lot/batch tracking across all transactions
- + WMS: lot-level movements & locations
- + EQMS: CAPA, supplier quality, audits
- + SRM: supplier portal and KDE exchange
- + AI: pattern detection & compliance monitoring

# The Hard Truth — Where Most Companies Stand Today



The original 2026 deadline was MISSED by a majority of industry — that is WHY the extension was granted



Reagan-Udall Foundation industry roundtables (Sept 2024) found: most companies have not completed CTE/KDE mapping



Top reasons companies aren't ready: siloed systems, paper-based records, supplier data gaps, lack of awareness



Most at risk: mid-market manufacturers who process FTL foods but haven't assessed exposure

# FSMA 204 Readiness Assessment – 5 Pillars

1

Scope

*Do we handle FTL foods?*

2

Supply Chain

*Can we trace every FTL item?*

3

Data & Records

*Are we capturing all KDEs?*

4

Systems

*Can our ERP/WMS/QMS support traceability?*

5

Traceability Plan

*Is it written and current?*

# Recommended Readiness Roadmap

PHASE 1  
(NOW – 3 MONTHS)

## Assess & Scope

Form compliance team, complete FTL product audit, map supply chain CTEs

PHASE 3  
(9–18 MONTHS)

## System Implementation & Process Redesign

Implement/configure ERP, WMS, EQMS; redesign processes; develop Traceability Plan

PHASE 2  
(3–9 MONTHS)

## Gap Analysis & Supplier Engagement

Identify KDE gaps, begin supplier outreach, assess system capabilities

PHASE 4  
(18–24 MONTHS)

## Testing, Training & Validation

Mock FDA requests, train staff, validate 24-hour response capability

# 10 Questions To Judge Your Readiness

1. Have we audited our full product catalog?
2. Have we mapped every CTE in our supply chain?
3. Are we capturing ALL required KDEs at every CTE  
— in electronic, sortable format?
4. Have we assessed our suppliers?
5. Have we tested our traceability?
6. Do we have a current Traceability Plan?
7. Do our foreign suppliers know they must independently comply with FSMA 204?
8. Does our ERP link lot codes across all transactions?
9. Who **owns** FSMA 204 compliance?
10. Do we have a plan and timeline?

# The QAD Ecosystem: Your Complete Answer to FSMA 204

## FSMA 204 Requirement









## QAD Solution

Lot tracking across entire supply chain	→	<b>QAD Adaptive ERP</b>
24-hour electronic records response to FDA	→	<b>QAD Adaptive ERP + EQMS</b>
Traceability Lot Code (TLC) assignment	→	<b>QAD Adaptive ERP</b>
Written Traceability Plan — document control	→	<b>QAD EQMS</b>
Supplier qualification & KDE data exchange	→	<b>QAD SRM</b>
CAPA & non-conformance management	→	<b>QAD EQMS</b>
Proactive compliance & data quality monitoring	→	<b>QAD Adaptive ERP</b>
Recall simulation & mock FDA drills	→	<b>QAD Adaptive ERP + EQMS + ChampionAI</b>

# The Cost Of Doing Nothing VS. The QAD Path

## WITHOUT QAD — TODAY'S REALITY

## WITH QAD — THE COMPLIANT OPERATION

Can you respond immediately?		<b>FDA records request arrives</b>		Trace report created in minutes
Can you get immediate data on the incident?		<b>Contaminated lot is discovered</b>		Adaptive ERP's recall workbench responds immediately
Do you have instant access to this data?		<b>Supplier KDE data</b>		SRM portal auto-collects compliant KDE Data
Are you ready?		<b>July 20, 2028 arrives</b>		You have met the requirements
Can you manage a recall responsibly?		<b>Recall</b>		Recalls are precise with customer trust and reputation intact

# What To Do Monday Morning

**01**

## **Pull your product catalog**

Identify every FTL food you manufacture, process, pack, or hold — including ingredients

**02**

## **Schedule a cross-functional meeting**

Bring together QA, Operations, IT, Procurement, and Logistics leadership

**03**

## **Audit your ERP lot tracking**

Does it cover all CTEs? Can you pull a full trace report? Can you export it in sortable format?

**04**

## **Contact your top 10 suppliers**

Ask them directly: 'Are you preparing for FSMA 204? Can you provide KDEs electronically?'

**05**

## **Request a QAD FSMA 204 Assessment**

Let QAD help you understand exactly where you stand and what it takes to get compliant

# Next Steps: Getting Ahead of FSMA 204



Revisit the presentation's key takeaways



Ask the 10 critical questions



Review the FSMA Readiness Checklist



conduct a systems review



**Act now.** Contact QAD to schedule your FSMA 204 readiness assessment.

# Questions?

*Let's Talk About Your FSMA 204 Readiness*

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FDA FSMA 204 Resources: [fda.gov/food](http://fda.gov/food) | GS1 US: [gs1us.org/fsma](http://gs1us.org/fsma)