

**FSMA 204 – AI-NATIVE TRACEABILITY INTELLIGENCE**

# Transforming Food Safety for 24-Hour Recall Readiness

Turning FSMA 204 compliance into a risk management advantage, Unframe converts fragmented lot-level data across documents and systems into audit-ready traceability intelligence, delivering automated compliance and 24-hour recall confidence in days, not months.

**THE PROBLEM: The Enterprise Reality: Where FSMA 204 Breaks Down**

By July 2028, companies handling foods on the FDA Traceability List must capture Key Data Elements at every Critical Tracking Event, maintain sortable digital records, produce complete lot-level traceability files within 24 hours, and sustain a documented, auditable traceability plan. FSMA 204 forces companies to:

- Digitize traceability
- Structure lot-level data
- Deliver 24-hour response capability
- Maintain governed, auditable records

Most companies are patching this together with spreadsheets, middleware, and incremental IT builds. This approach increases complexity.

**LOT-LEVEL DATA TRAPPED IN UNSTRUCTURED DOCUMENTS**

- COAs, BOLs, invoices, logs in PDFs & emails
- Non-standard spreadsheets, scanned files
- Manual entry

**Results:**

- Missing KDEs
- Lot mismatches
- Data gaps
- Recall risk

**SYSTEMS NOT DESIGNED FOR END-TO-END TRACEABILITY**

- ERP, WMS, QA operate in silos
- Supplier data outside core systems
- No unified lot genealogy

**During recall:**

- Query multiple systems
- Normalize lot codes
- Rebuild chains manually
- Validate under pressure

**24-HOUR RESPONSE IS A BOARD-LEVEL RISK**

If the FDA requests digital traceability records tomorrow:

- Can you generate a sortable spreadsheet immediately?
- Can you guarantee no missing KDEs?
- Can you prove source traceability?
- Can you show the full upstream and downstream lot linkage?

**THE SOLUTION: AI-Native Traceability Intelligence tailored to your workflows, deployed in Weeks**

Unframe's AI-native intelligence layer works across existing systems, operationalizing FSMA 204 at enterprise scale without replacing your ERP.

## Intelligent KDE Extraction & Lot Normalization

→ **AI-powered extraction across:**

- Supplier COAs
- Bills of lading
- Invoices
- Shipping documents
- Transformation records
- QA reports

→ **Then:**

- Normalizes across inconsistent supplier formats
- Flags missing or low-confidence KDEs
- Detects lot chain gaps
- Maintains full source traceability and audit logs

→ **Automatically extracts:**

- Lot codes
- Product identifiers
- Origin
- Dates
- Quantities
- Critical Tracking Events

→ **Result:**

- **70–90% reduction** in manual lot data entry
  - Structured, validated KDE capture
  - Reduced recall simulation time
- Higher data confidence before audits

## Context-Aware Enterprise Traceability Intelligence

**Unframe unifies traceability intelligence across:**

- ERP
- WMS
- QA systems
- Supplier portals
- Email
- Shared drives

**Now leadership can ask:**

- “Trace finished product X back to farm origin.”
- “Show all downstream customers impacted by lot 4589.”
- “Identify transformation events linked to supplier Y.”
- “Generate recall file for shipments between May–July.”

**Answers are:**

- Cross-system
- Role-based secure
- Source-linked
- Audit-ready

Recall analysis shifts from days to minutes.

## Automated 24-Hour FDA Response Readiness

Unframe enables:

- Pre-configured traceability dashboards
- Automated generation of FDA-ready spreadsheet files
- Continuous KDE completeness monitoring
- Lot genealogy validation
- Proactive compliance gap detection

Instead of scrambling during a recall event, compliance becomes continuously verifiable.

## AI-Generated, Living Traceability Plans

FSMA requires documented traceability plans. Unframe helps generate and maintain:

- CTE mapping to internal systems
- KDE governance logic
- Supplier documentation standards
- Record retention frameworks
- Exception handling procedures

Updated dynamically as systems evolve.

## WHY ENTERPRISE LEADERS CHOOSE UNFRAME

→ **No Rip-and-Replace Required**

Operates across existing ERP, WMS, QA, and supplier systems, without costly system overhauls.

→ **No Manual Data Preparation to Get Started**

Handles inconsistent supplier formats, PDFs, emails, and legacy data without template building, preprocessing, or custom rule scripting.

→ **High-Accuracy, Audit-Grade Outputs**

Combines AI intelligence with deterministic validation to deliver 98%+ extraction accuracy, confidence scoring, and full source traceability, reducing exception handling and audit risk.

→ **Supplier-Format Agnostic**

Works across global suppliers without requiring standardized document templates upfront.

→ **Enterprise Governance Built-In**

Role-based access, audit trails, policy enforcement, and traceable outputs by design.

→ **Deployed in Days, Not Months**

Custom AI solutions aligned to your SKU, supplier, and system landscape—without multi-year transformation programs.

## CUSTOM AI IN DAYS

Not a 2-year IT transformation. Rapid deployment aligned to your specific SKU, supplier, and system landscape. Unframe delivers AI-native traceability intelligence across your enterprise, transforming FSMA from a compliance burden into a risk management advantage.

## About Unframe

Unframe is the Managed AI Delivery Platform that delivers AI solutions that work — tailored to your business and delivered in days. With Unframe, organizations can turn high-value AI use cases into real outcomes, without sharing data, committing upfront costs, or compromising on results. Unframe is headquartered in Cupertino, California, with a global presence in Tel Aviv and Berlin.

