FSMA 204

Preparedness Checklist

With the finalization of the requirements of the Food Safety Modernization Act (FSMA) 204, tech-enabled supply chain visibility, traceability, and rapid recall response are at the forefront.

FSMA 204 requires enhanced lot-level record keeping, and in the case of a recall, accurate tracking around high-risk foods on the FDA Food Traceability List (FTL).

As of March 2025, the FDA has granted a 30-month compliance date extension to ensure retailers have the necessary time to fully implement a solution that maximizes food safety and transparency. Successful and reliable implementation requires receiving accurate data from supply chain partners.

Start Your Journey Here

FSMA 204 will require detailed data capture around various critical tracking events (CTEs) aligned with the required key data elements (KDEs) associated. Paving the way to compliance will require understanding regulations, food traceability lists, data standards, and much more. Dive into Upshop's FSMA Preparedness Checklist and identify areas of improvement and strength:

Regulation & Requirements

- ☐ What does compliance mean to your organization?
- ☐ Are you monitoring the changing landscape and interpretation / differences?
    - ☐ Do you have a voice in industry workgroups?
- ☐ What are the critical tracking events (CTEs) that impact your organization?
- ☐ What are the key data elements that matter to your organization?

The Food Traceability Listing (FTL)

- ☐ How do foods and categories impact your overall operations?

- ☐ How will high risk foods be identified?

- ☐ Do you understand the CTE and FTL cross overs that matter?

- ☐ How will suppliers identify high risk foods?

- ☐ How will you as a retailer identify high risk foods?

- ☐ How will you understand exemptions?

- ☐ How will items be monitored / audited / leveraged for compliance?

- ☐ How will they be maintained when suppliers and supply chain adjust?

Supplier Network Integration

- ☐ Are your stores integrated with a large supplier network like ReposiTrak?

- ☐ Can your solution identify and resolve data errors from suppliers?

- ☐ Can you automatically capture lot codes and other KDEs directly through receiving?

- ☐ Are you able to generate a compliance report for the FDA within 24 hours of a recall?

Industry Data Standards for Exchange of Data

- [ ] Have you opened discussions with suppliers around how data and technology can be used to streamline?

  - [ ] Identify – GLN, SSCC, GTIN

  - [ ] Capture – barcodes for greater capture (GS1-128, 2D, RFID)

  - [ ] Share – GDSN, EDI, EPCIS

  - [ ] How do my current technology providers plan to bridge the gap

Understand Supplier Processes for Identification, Capture and Share

- [ ] Are you having open discussions with suppliers on their approach and thoughts?
- [ ] How do you consider exceptions and edge use cases?

  - [ ] Small suppliers & local

  - [ ] FSMA exemptions (FDA); USDA traceability products and alignment

  - [ ] Missing bar codes; no GDSN data exchange

Mini Pilots: Process & Knowledge Sharing

☐ Have you scoped the CTEs that matter within your organization?

☐ Receiving

Warehouse or distribution center (DC)

☐ Supplier to DC; DC to DC transfer; backhaul

☐ Outside storage

Direct to Store Receiving (DSD)

☐ Cross dock; drop shipments; consignment; distributors; store-to-store

☐ Shipping

☐ DC to stores; store-to-store transfers; sales to non-profit

☐ Transforming

☐ Centralized production followed by shipping event (store/commissary)

☐ Third-party production (sushi, fresh cut fruit, etc.)

☐ Assigning new lot codes to transformed products

☐ How do you plan to store and capture the data elements that matter?

☐ Data capture

☐ Data storage

☐ Data maintenance

☐ Data visibility / accuracy

☐ Data accessibility (24-48 hour response)

☐ Internal data audit and monitoring

☐ Supplier audit / monitoring for compliance

- [ ] How do you consider the project beyond FSMA 204 and future ROI?

  - [ ] Review current state of data

  - [ ] Document and assess the gaps

  - [ ] Assess technology needs and requirements

- [ ] How do you plan to formulate your traceability plan?

  - [ ] Records - how and where they are kept

  - [ ] Identification - food traceability list and how indicated in process

  - [ ] Traceability lot codes - how are they assigned and stored

  - [ ] Designated owner - point of contact about plan and records

  - [ ] Growing location (farm map, location and name of field, etc.)

  - [ ] Plan maintenance - how to keep it current

  - [ ] Plan retention - retain for two years after update

Recall Readiness

- [ ] How do you think about recall readiness across all processes?

    - [ ] Sortable spreadsheet

    - [ ] 24-48 hour response time
    - [ ] Incorporate USDA products (consider chicken, FTL, etc.) – align process with FSMA?

Plan for Pilots

- [ ] Mini Supplier Pilots

    - [ ] Identify, Capture and Share

    - [ ] Technology Partners

    - [ ] Continue to test and validate process
- [ ] Mock recalls

    - [ ] Recall initiated for DSD Products and Warehouse Products

    - [ ] Recall Initiated for 'In Store Processed' FTL Ingredient Products

    - [ ] Continue to test and validate process ongoing

Watch our webinar on Traceability