How Traceable Are Your Products … Really?

Today's Presenters:

Dr. Ben Miller
COO & EVP of Regulatory & Scientific Affairs,
The Acheson Group

Eric Marshall
Executive Director,
Partnership for Food Traceability

FSMA FRIDAY

Monthly Industry News, Updates & Trends for Food, Beverage, & CPG Manufacturers

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What is FSMA Fridays?

- ✔ Monthly FSMA Related News
- ✔ Regulation Changes & Updates
- ✔ Industry Trends
- ✔ Q&A with TAG

FDA FOOD SAFETY MODERNIZATION ACT

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A global food safety and public health consulting group made up of seasoned industry experts.

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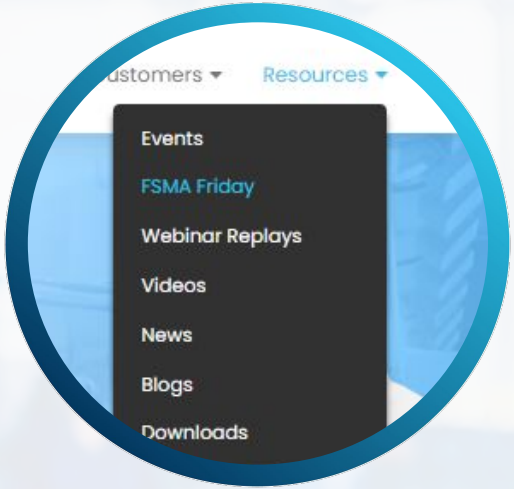
Before We Get Started...

- ✔ Only panelist microphones are on
- ✔ Ask questions! (Q&A at end)
- ✔ Recording link will be shared
- ✔ Audio issues: use call-in number



Watch prior FSMA Friday recordings at
safetychain.com > Resources > FSMA Friday

Meet Your FSMA Friday Speakers

Dr. Ben Miller

COO & EVP of Regulatory & Scientific Affairs

Dr. Miller has twenty-five years of experience in food safety, public health, epidemiology, and infectious disease outbreak investigations. Ben earned his Ph.D. in Environmental Health with a background in infectious diseases and his Master of Public Health in Epidemiology.

He currently serves as the Executive Vice President of Regulatory and Scientific Affairs at the Acheson Group where he works across multiple sectors advising on food safety, food safety culture, traceability, public health, outbreak-related and regulatory issues.

Dr. Miller also has extensive food regulatory experience and, as previous Division Director at the Minnesota Department of Agriculture, led the State of Minnesota's Human and Animal Food regulatory work. In his role as a state regulator, Dr. Miller developed experience implementing legislative reforms on topics related to food safety and is an expert in FDA traceability requirements. He is currently a member of the International Association of Food Protection Program Committee.

Meet Your FSMA Friday Speakers

Eric Marshall
Executive Director

PARTNERSHIP FOR FOOD TRACEABILITY

Eric Marshall is a principal based in Washington, D.C. of Leavitt Partners and leads the firm's life science services. Eric advises complex health care coalitions on health policy and provides consulting services to drug and device companies. A regulatory lawyer by training, Eric is an industry specialist in FDA regulation with an emphasis on domestic and international supply chain security. Eric also serves as the Executive Director of the Partnership for DSCSA Governance, a public-private partnership between industry and FDA that is committed to implementing supply chain security protections in the U.S.

A seasoned facilitator and consensus-builder, Eric leads Leavitt Partners' robust alliance practice, helping the firm and clients build, convene, manage, and advise numerous industry collaboratives committed to advancing sound health policy initiatives.

Eric graduated Order of the Coif from the University of Minnesota Law School and has a bachelor's degree in economics and finance from the University of Northern Iowa.

Agenda

01. Regulatory Review and Updates

Recent regulatory updates from FDA and USDA

02. How traceable are your products...?

Updates on FSMA 204 and challenges for the industry

03. Partnership for Food Traceability

What is the PFT and what are we working on?

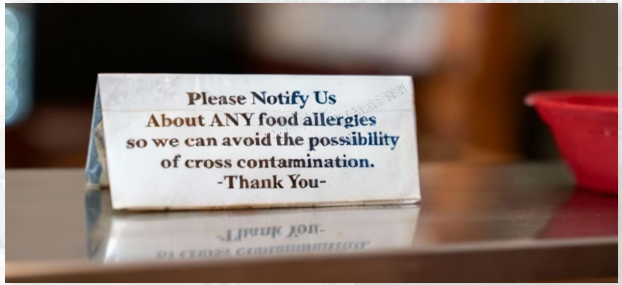
Recent Regulatory Updates Overview

Continuing Appropriations and Extensions Act, 2026

Formally delayed FSMA 204 implementation until July 20, 2028. Also included some additional exemptions for the Ag Water Rule.

FSIS - Delayed Verification Sampling of Not Ready-to-Eat Breaded Stuffed Chicken Products

FSIS is delaying the implementation of its verification activities related to Salmonella in not ready-to-eat (NRTE) breaded stuffed chicken product because of current testing method limitations. The current available test methods have accuracy limitations and have resulted in findings of false positives, especially at low levels of contamination.



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How Traceable Are Your Products … Really?

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FSMA 204 Delay

No funds appropriated by this Act may be used to administer or enforce the "Requirements for Additional Traceability Records for Certain Foods", published on November 21, 2022 (87 Fed. Reg. 70910), or any other rule promulgated in accordance with section 204 of the FDA Food Safety Modernization Act (21 U.S.C. 2223), prior to July 20, 2028. Further, the U.S. Food and Drug Administration shall:

1. **Engage quarterly with the regulated entities**, including farms, restaurants, retail food establishments, and warehouses distributing to retail food establishments and restaurants, **to identify and implement, as appropriate, additional flexibilities for satisfying the rule's lot-level tracking requirement**, as appropriate, such that regulated entities can comply with the November 21, 2022, rule consistent with section 204(d)(1)(L)(iii), which **prohibits the agency from requiring product tracking to the case level**.

2. **Within 180 days *(May 9, 2026)* of enactment of this Act**, the Food and Drug Administration is directed to **provide industry stakeholders with recommendations for these additional flexibilities satisfying the rule's lot-level tracking requirement**, as appropriate.

3. The FDA shall provide assistance to industry regarding how to handle food waste recovery, reclamation, intra-company transfers, customer returns under the rule and **initiate a series of hypothetical data intake exercises to test the capabilities of the FDA's Product Tracing System** and, upon request and as resources allow, the covered entity systems and identify any technical difficulties prior to full implementation.

Joint Explanatory Statement Language

The agreement directs:

1. **FDA to submit a report to the Committees within 60 days *(January 9, 2026)*** of enactment of this act detailing its **strategies to support industry implementation** and a timeline to complete the requirements within 18 months of enactment of this act in order to prepare for FDA's implementation of the Food Traceability Final Rule by July 20, 2028.
    - **The report shall include specific performance milestones (including progress toward operationalization of FDA's internal Product Tracing System) and an inspections and compliance roadmap** and shall describe technical assistance provided to industry.
    - FDA shall submit progress updates every 90 days thereafter until the rule is in effect.
2. **Not later than 120 days *(March 10, 2026)* after enactment of this act, FDA shall convene a tabletop exercise with participation from producers, processors, distributors, retailers, technology providers, and other covered entities.**
    - In addition, the Commissioner shall publicly post summaries of such exercises not later than 90 days after completion of the exercise.

Summary of Requirement

- Quarterly stakeholder engagements
- Tabletop exercise with stakeholders by March 10, 2026
- Recommendations to stakeholders for additional compliance flexibilities by May 9, 2026
- Test FDA's Product Tracing System through hypothetical data intake exercises
- Report to Congress outlining implementation support for industry, including an inspections and compliance roadmap, by January 9, 2026; additional reports required every 90 days thereafter

Partnership for Food Traceability

Public-Private Partnership formed with the FDA in 2024

A shared, overarching vision for food traceability across the supply chain

- Public-private partnership
- Industry-led decision making
- Drive electronic interoperability across the supply chain through mutual accountability
- Simplify FSMA 204 compliance

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Partnership for Food Traceability

Current Work

Traceability Committee

- Blueprint for Interoperability

Pilot Committee

- Simulated Supply Chain and Solution Provider Interoperability Pilot
- Whitepaper

Partnership for Food Traceability

Future Work

Traceability Committee

- Probabilistic or "Calculated" Lot Code Model

Pilot Committee

- Probabilistic Pilots
- Pilot "Code-a-thon"

Regulator Committee

- Industry challenges & alignment of regulatory approach

Parameters of a probabilistic model meets the goals and requirements of the Traceability Rule

1. In what distribution models is a probabilistic model appropriate (e.g., DSD vs. all distribution models)?
2. In what parts of the supply chain is a probabilistic model appropriate (e.g., last mile vs. full supply chain)?
3. How concentrated must your range of TLCs be and how high must your confidence be (e.g., there's a 90% chance it is TLC A and 10% it is TLC B, C, or D vs. there's a 20% chance it is TLC A, B, C, D, or E)?
4. How can/should probabilities be calculated?
5. What is the role of reliable pallet-level tracking business processes?

(cont. on next slide)

Parameters of a probabilistic model meets the goals and requirements of the Traceability Rule

6. What is the role of robust FIFO processes?
7. Are there further implications for how these apply to TLC Source/Reference KDEs?
8. What is the role of periodic testing and validation?
9. Does the model vary by use case (providing to next trading partner vs. response to FDA request)?
10. Is it essential that the next entity in the supply chain knows whether it is a definitive TLC vs Probabilistic?

What are the current challenges?

- Compliance Delay - lost sense of urgency
- Lot code traceability between distribution and retail/restaurant
  - Lot-level case scanning
- Overconfidence in data systems
- Interoperability!

What should you do?

Take the homework extension!

Don’t assume your systems are fully compliant until:

- Done an in-depth gap assessment
- Talked with your suppliers and customers about tactical-level data sharing
- Conducted data sharing pilots between your suppliers and customers
- Conducted a mock traceback (not traceability!) exercise

Wrap up

- Time is on your side (for the moment)
  - Complexity is not on your side (ever)
- If you want to get involved with industry or participate in pilot activities
  - www.pftraceability.org

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Questions?

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Food & Beverage Manufacturing

Benchmark Survey & Report

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Join us in January

Friday
Jan 30

9:00 AM PT
12:00 PM ET

Register Now

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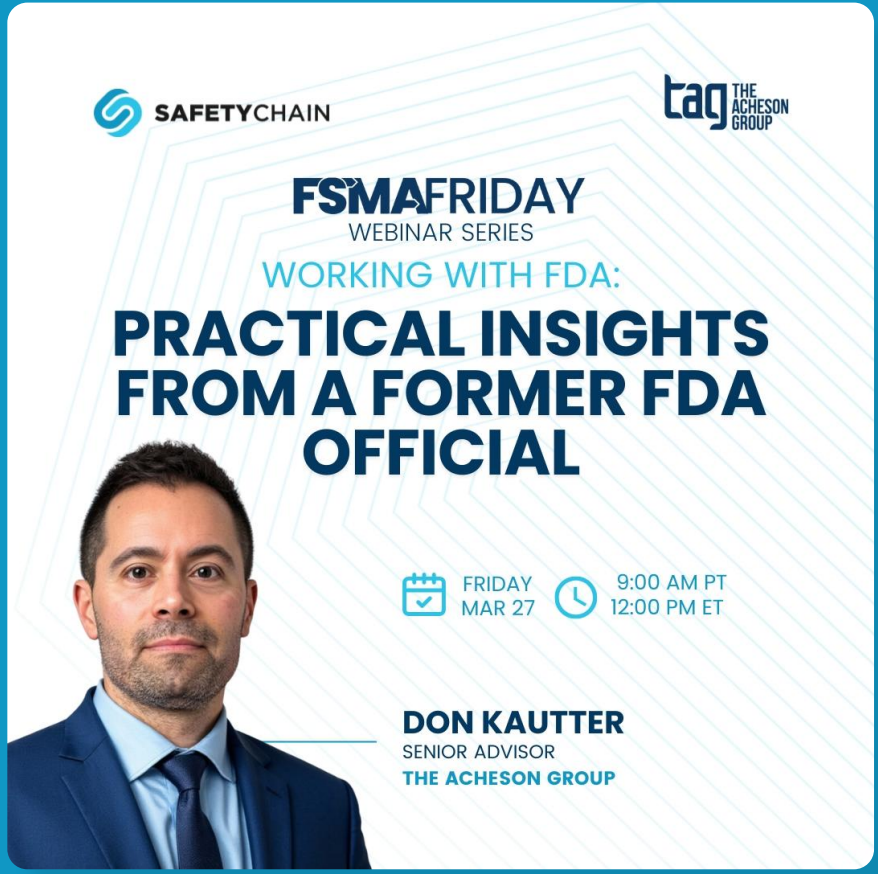

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More Resources

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- Success Stories
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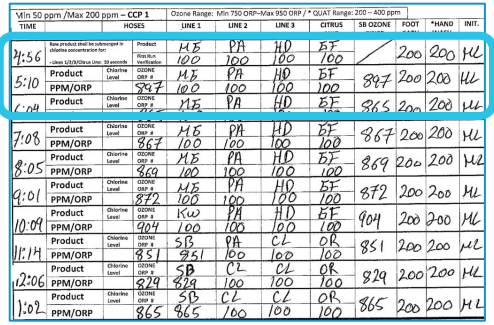
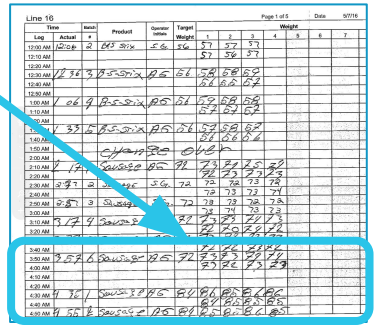
More On Boosting Food Safety

What Traceability Really Looks Like on the Floor Today

Critical traceability data exists, however, it's fragmented, manual, and slow to access



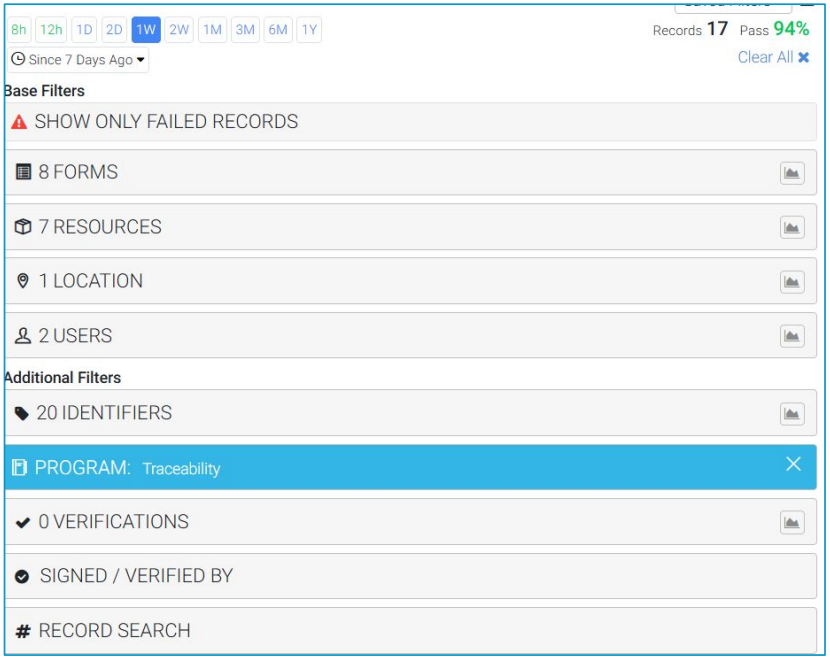


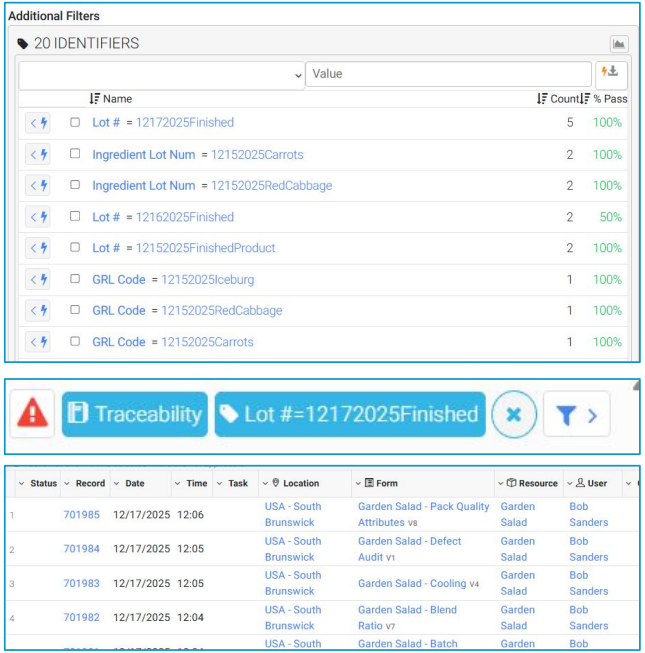
- Manual tracebacks under pressure
- High cost of time and resources
- Heavy reliance on tribal knowledge
- Error-prone root cause analysis
- Reactive compliance instead of recall readiness

The Result

- Unnecessary recall volume and margin loss
- Delayed decision making during critical events
- Erosion of customer and regulator trust

Demo Scenario: Customer Complaint Traceback Done in Minutes, Not Days





- Data collected in minutes, not days, and done with confidence
- Specific lots analyzed, not entire lines
- Controlled response for anyone, not fire drills for a limited set of individuals

This enables faster decisions, narrower recalls, and lower financial and brand risk during quality events