



# **Grocery retailers & wholesalers: Here's what the FDA says you need to know NOW**

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[ACHESONGROUP.COM](https://www.achesongroup.com)

# Today's speakers

*Ben Miller, Ph.D., MPH*

*Executive Vice President of Scientific and Regulatory Affairs*

*The Acheson Group (TAG)*



- Epidemiologist and Foodborne Outbreak Investigation
- Led State of MN Human and Animal Food Regulatory Programs
- Served on the FDA's IFT Task Order 6 - Pilot Projects for Improving Product Tracing along the Food Supply System
- Ph.D. Thesis - The use of critical tracking events and key data elements to improve the traceability of food throughout the supply chain to reduce the burden of foodborne illnesses
- Working closely with the industry to understand and implement the Traceability Rule

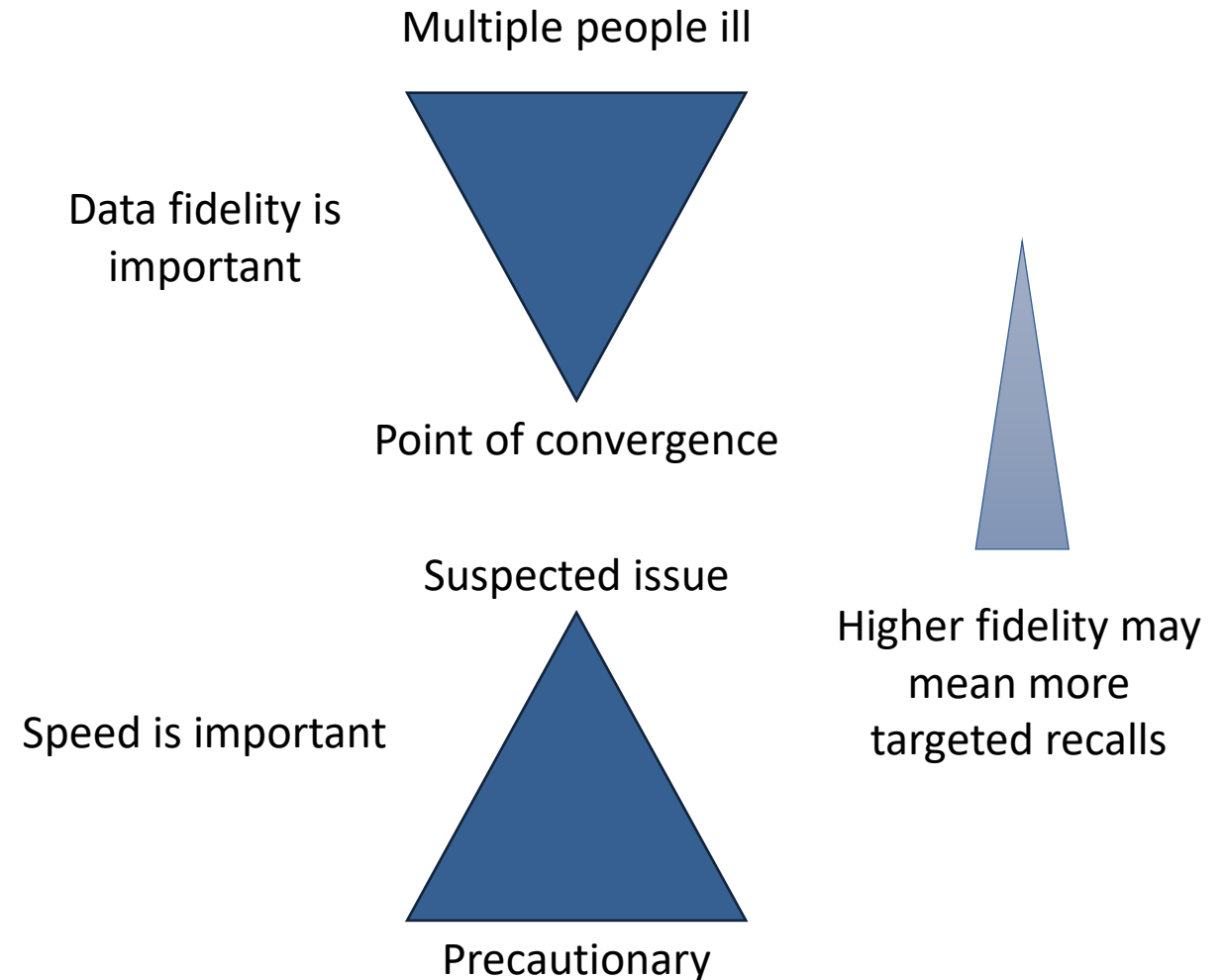
# Today's Topics

- Why are we talking about traceability and what are FTL Foods?
- Exempt? Most grocers, retail food establishments, and restaurants NEED to comply with the rule!
- Labels alone can't be the answer – you need to track other data as well
- You will need a written Traceability Plan AND can you provide a sortable spreadsheet to the FDA in 24 hours?

# Why are we talking about traceability?

Traceability = Investigation

Recall = Corrective Action



# Why are we talking about traceability?

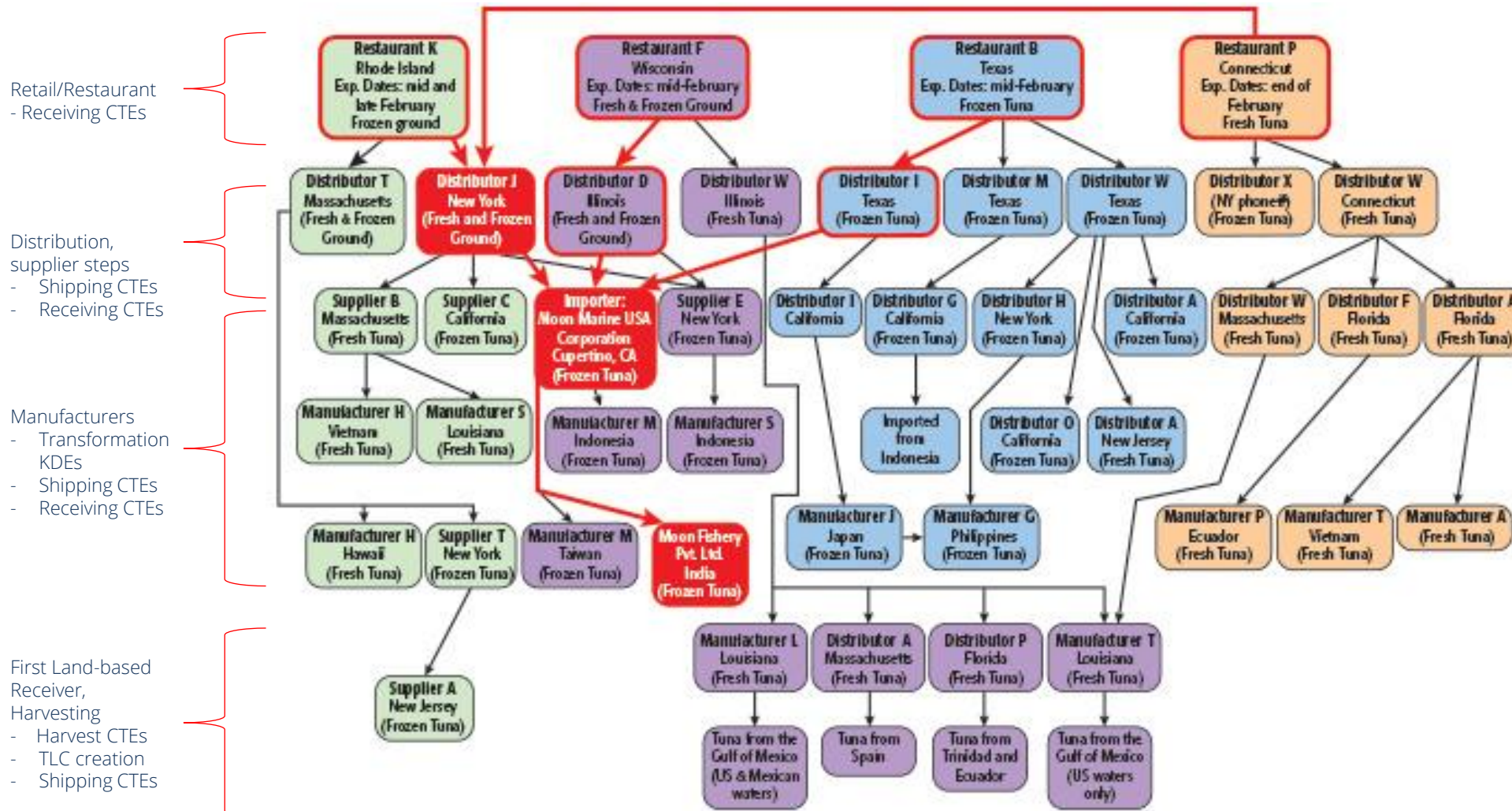
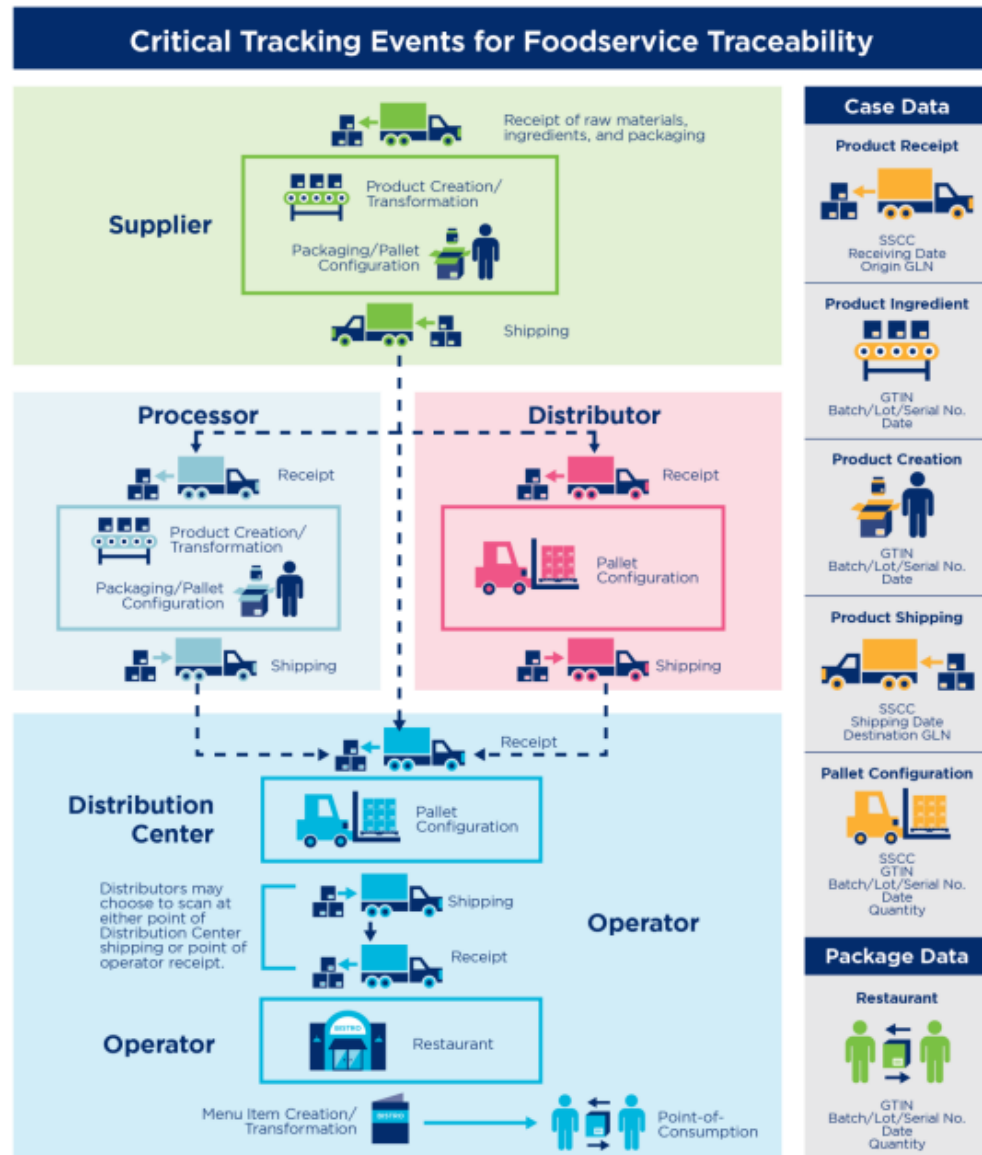


Figure 2: Salmonella Bareilly Traceback (The distribution of the contaminated tuna is outlined in red.)

# Isn't the industry already good at recalling product?



- Yes, but...we don't need to track things at the case level for recalls.
- The supply chain is DESIGNED to move in one-direction – FORWARD!
- The goal of FSMA 204 is to ensure more consistent collection of data to enable faster, more precise tracebacks.

# The FDA Traceability Rule says I need to do what?

- Exemptions for Retail Food Establishments and Restaurants are limited!

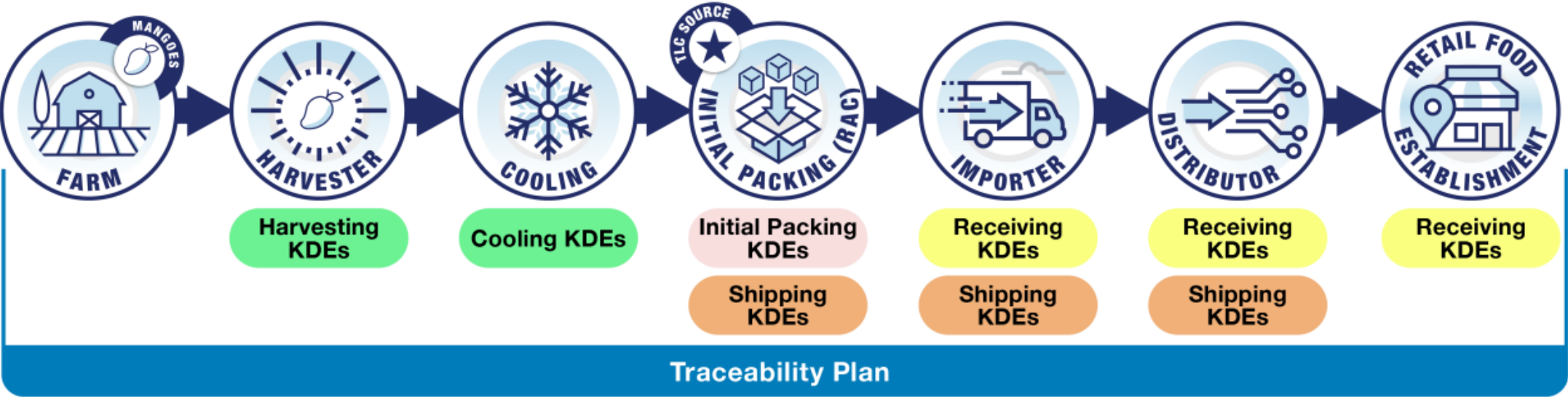
Exemption	Additional Details	Citation
Retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment		§ 1.1305(i)
Retail food establishment or restaurant with respect to a food that is produced on a farm and both sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm	The retail food establishment or restaurant must maintain a record documenting the name and address of the farm that was the source of the food for 180 days.	§ 1.1305(j)
Both entities when a purchase is made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an <i>ad hoc</i> basis outside of the buyer's usual purchasing practice (e.g., not pursuant to a contractual agreement to purchase food from the seller).	The retail food establishment or restaurant that makes the purchase must maintain a record (e.g., a sales receipt) documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase	§ 1.1305(k)

# Data complexity of shipping and receiving

## Supply Chain Example: Imported Mangoes (Importer holds the food)



In this scenario, the importer/wholesaler is importing fresh mangos. The importer takes physical possession of the mangos they are importing, so they are covered by the rule, and must maintain receiving and shipping KDEs. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs.





# Shipping and Receiving KDEs

Shipping KDEs	Receiving KDEs
Traceability lot code for the food	Traceability lot code for the food
Quantity and unit of measure of the food	Quantity and unit of measure of the food
Product description for the food	Product description for the food
Location description for the immediate subsequent recipient (other than a transporter) of the food	Location description for the immediate previous source (other than a transporter) for the food
Location description for the location from which you shipped the food	Location description for where the food was received
Date you shipped the food	Date you received the food
Location description for the traceability lot code source or the traceability lot code source reference	Location description for the traceability lot code source or the traceability lot code source reference
Reference document type and reference document number (maintain only)	Reference document type and reference document number



# Challenges for Implementation

- Case-level traceability (traceability lot codes)
- Change in operations
- Data management systems
- Data standards
- Error rates
- Do you trace everything, not just FTL foods?
- Not "just" a food safety problem – requires a multidisciplinary approach
  - FSQA, IT, Supply Chain, Logistics, etc.

# Challenges for Implementation

Your suppliers will want you to deliver FSMA 204 information in their preferred format - NOT in the way that's easiest for you.

- How do you receive information?
- How do you store it?
- How do you track and query it?

# What tools are needed?

- Training
  - PCQI approach to traceability
- How to map your supply chain (internally and externally)
- Checklist of questions and processes for a multidisciplinary team
- Traceability Plan templates
- Education and outreach to your suppliers

# As the final receiver in the supply chain what do I need to be able to do?

- Determine if you're exempt (unlikely)
  - If you sell less than \$250,000 of food annually during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation
  - You don't sell or hold any FTL food
- Determine your Receiving KDEs
  - Where is this data currently stored? How will you create a sortable spreadsheet for the FDA if requested?
  - Are there operational or IT changes needed to capture or query these data?
  - Have you talked with your suppliers? How will they be sending you the data?
- Write your Traceability Plan
- Test your system!
  - Can I identify all of the Traceability Lot Codes available for sale in the last two weeks?

# What resources are available?

- FDA
  - Small entity compliance guide (<https://www.fda.gov/media/168142/download>)
- GS1
  - <https://www.gs1us.org/industries-and-insights/by-industry/foodservice/standards-in-use/food-safety#fsma>
  - Guidance documents
  - Sector-specific case studies
- IFT Global Food Traceability Center
  - <https://www.ift.org/gftc/research-and-resources>
  - Food Traceability Library
  - [A Guidance Document on the Best Practices in Food Traceability](#)
- TAG
  - [www.achesongroup.com/traceability](http://www.achesongroup.com/traceability)
  - Traceability Toolkit

# What IT tools are available?

- IT Tools
  - Integration in existing IT systems?
  - Are new systems needed?
  - CTEs and KDEs describe when and what needs to be collected – not the data format

# What's Next?

- How do you know if you're impacted by FSMA 204?
- Do you need help producing your Traceability Plan?
- Are other functional areas of your business AWARE that FSMA 204 is coming and know what they need to do? (Legal, supply chain, IT, food safety)
- What do you need to do NOW to meet the enforcement deadline (January 20, 2026)?



# Schedule a Traceability Assessment

*Learn how the FSMA 204 food traceability rule applies to you.*

- TAG is providing an assessment to help you determine what CTEs and KDEs apply to you
- Zoom call and initial written assessment
- \$500

*Email "Traceability Rule Assessment": [info@achesongroup.com](mailto:info@achesongroup.com)*

# Questions?



# Contact Us



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