



Fate or FSMA 204? You are likely NOT prepared.

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ACHESONGROUP.COM

Today's speakers

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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?
- Isn't traceability just a food safety issue?
- Exempt? Most grocers, retail food establishments, and restaurants NEED to comply with the rule!
- You will need a written Traceability Plan AND can you provide a sortable spreadsheet to the FDA in 24 hours?

FTL Foods

TABLE 1—FOOD TRACEABILITY LIST

Food traceability list	Description
<p>Cheeses, other than hard cheeses, specifically:</p> <ul style="list-style-type: none"> • Cheese (made from pasteurized milk), fresh soft or soft unripened. • Cheese (made from pasteurized milk), soft ripened or semi-soft. • Cheese (made from unpasteurized milk), other than hard cheese¹. 	<p>Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.</p> <p>Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.</p> <p>Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.</p>
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.
Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e).
Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.
Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Vegetables other than leafy greens (fresh-cut).	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
<p>Finfish (fresh and frozen), specifically:</p> <ul style="list-style-type: none"> • Finfish, histamine-producing species. • Finfish, species potentially contaminated with ciguatoxin. • Finfish, species not associated with histamine or ciguatoxin. 	<p>Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.</p> <p>Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.</p> <p>Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.² Siluriformes fish, such as catfish, are not included.³</p>

Key Takeaway!

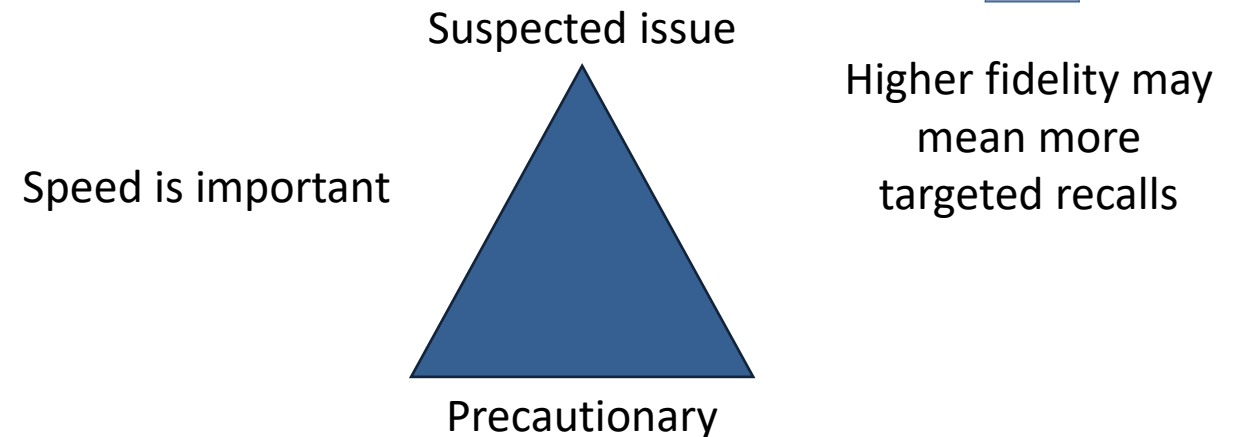
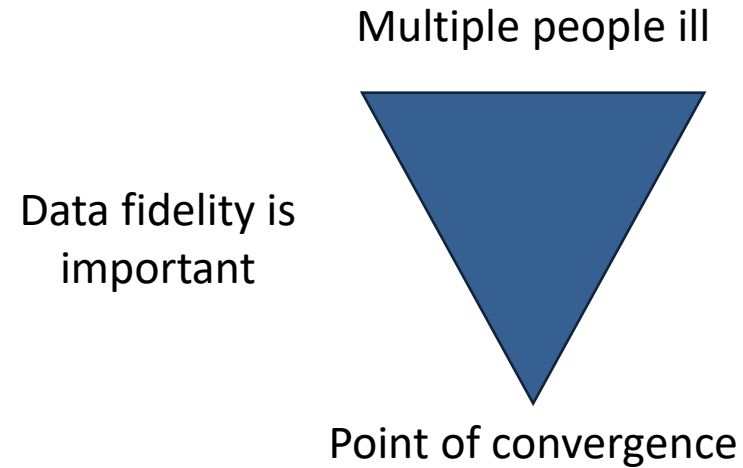
If an FLT Food is used in its listed form as part of a multi-ingredient food, then the multi-ingredient food would be covered under the final rule.



Why are we talking about traceability (and why isn't it a food safety issue)?

Traceability = Investigation

Recall = Corrective Action



Why are we talking about traceability?

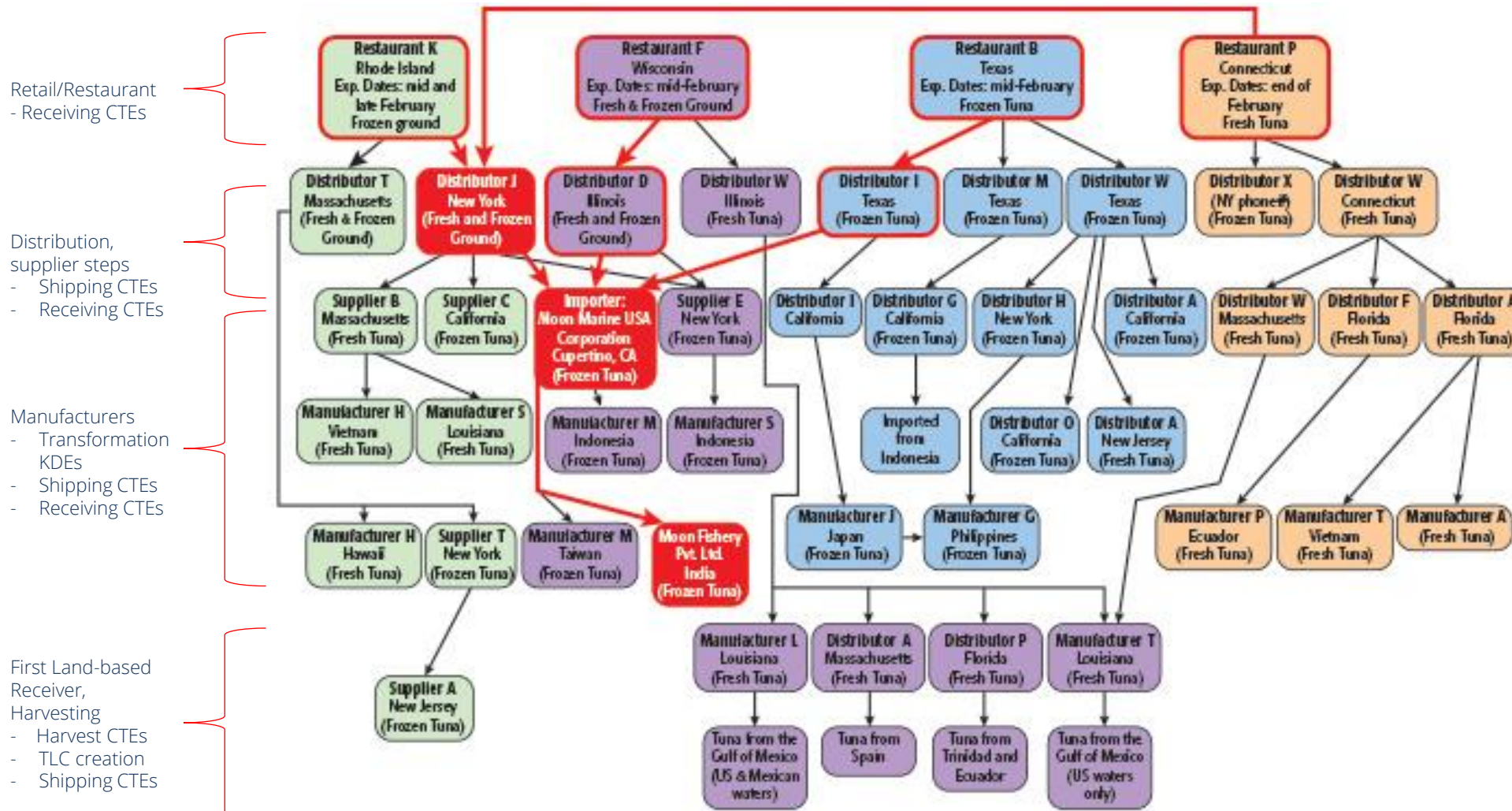
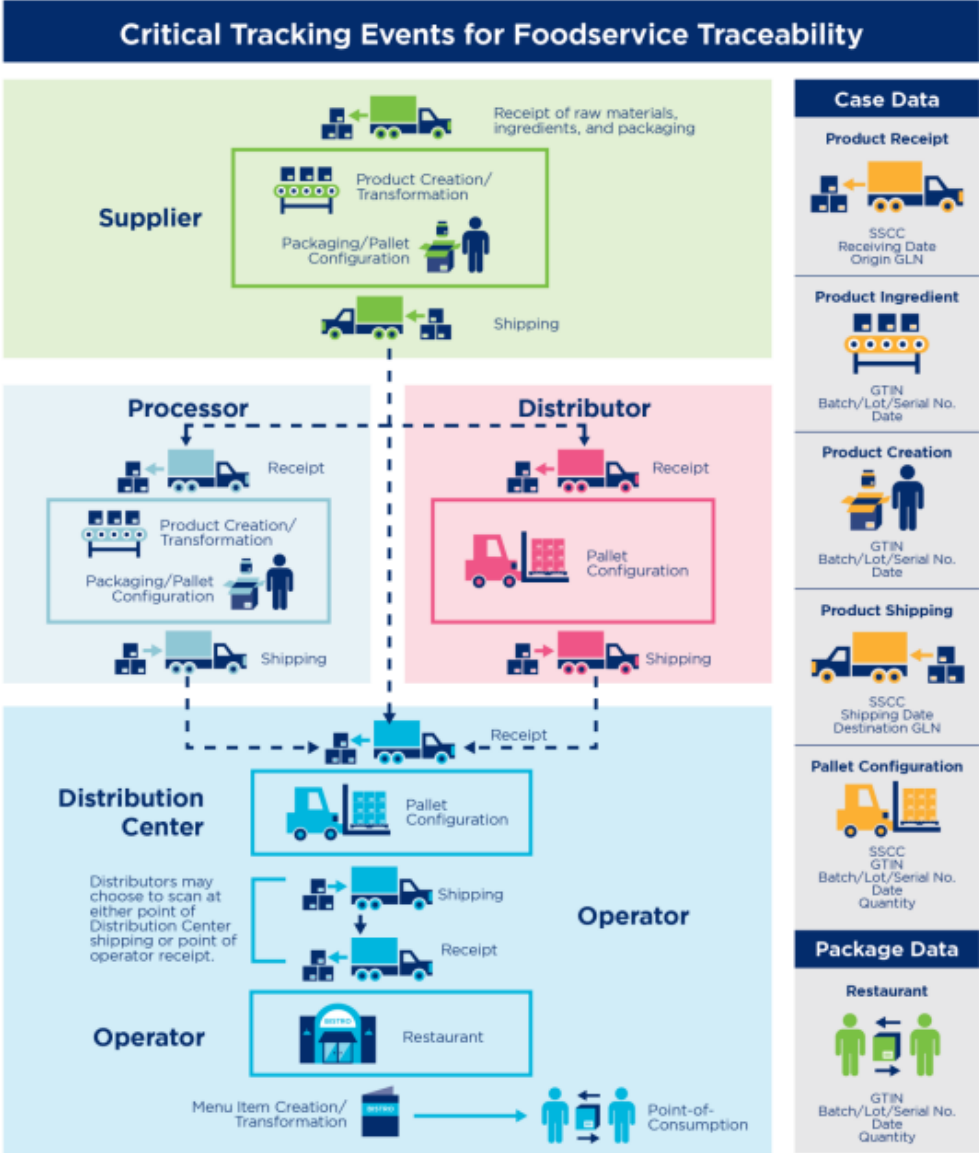


Figure 2: Salmonella Bareilly Traceback (The distribution of the contaminated tuna is outlined in red.)

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.

<https://www.gs1us.org/content/dam/g1us/documents/industries-insights/by-industry/food/guideline-toolkit/Guideline-Foodservice-Implementation-Guideline-for-Case-Level-Traceability-Using-GS1-Standards.pdf>

The FDA Traceability Rule says I need to do what?

- Exemptions for Retail Food Establishments and Restaurants are limited!

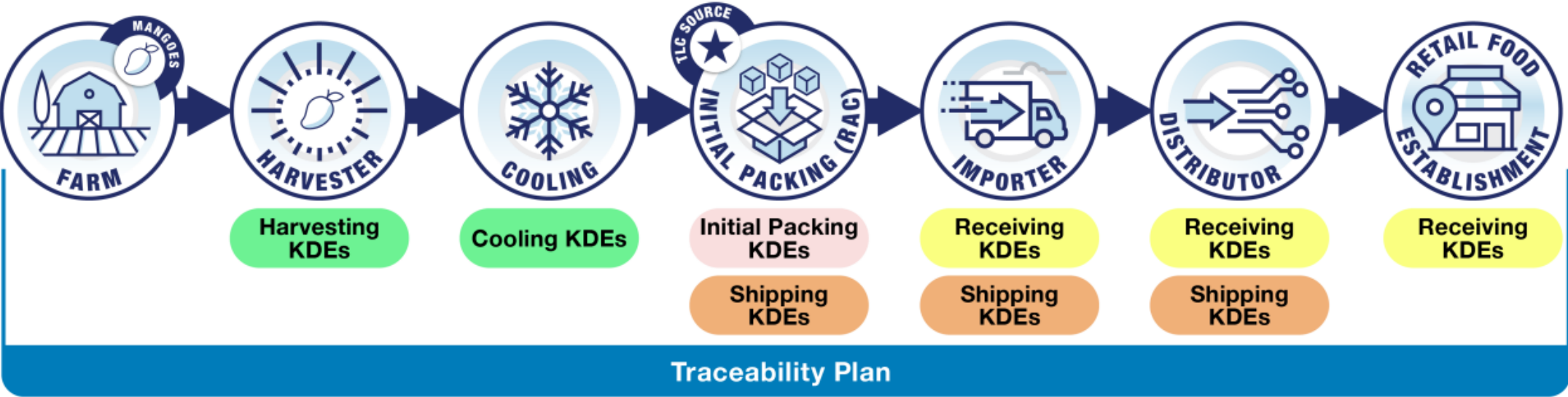
Exemption	Additional Details	Citation
Retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the 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)
- Direct Store Deliveries
 - Can't rely solely on distributors to solve the problem for you
- Exemptions = accepting someone else's risk!
 - How are you verifying that someone is exempt?
- 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.

What do I need to do next?

- Do an assessment – figure out your CTEs and KDEs and how you'll track and store this data
 - 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?
- Get Management Buy-In – you're going to need a team and resources to solve this problem
- Write your Traceability Plan
- Test your system!
 - Can I identify all of the Traceability Lot Codes available for sale in the last two weeks?
- Full Supply Chain needs to be ready by January 2026!

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
 - Traceability Toolkit

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

Questions?



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