



Starting Your New Food Traceability Journey

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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



Today's Webinar

- Section 204 – “Traceability Rule” Overview
- Questions we're getting about “The Rule”
- Q&A from you



How is the new traceability rule different than the 2002 Bioterrorism Rule?

PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

“(b) REGULATIONS CONCERNING RECORDKEEPING.—The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

One Forward – One Back

TRACEABILITY PLAN

§ 1.1315 What traceability plan must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

- (a) If you are subject to the requirements in this subpart, you must establish and maintain a traceability plan containing the following information:
 - (1) A description of the procedures you use to maintain the records you are required to keep under this subpart, including the format and location of these records.
 - (2) A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;
 - (3) A description of how you assign traceability lot codes to foods on the Food Traceability List in accordance with [§ 1.1320](#), if applicable;
 - (4) A statement identifying a point of contact for questions regarding your traceability plan and records; and
 - (5) If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.
 - (i) Except as specified in [paragraph \(a\)\(5\)\(ii\)](#) of this section, the farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area.
 - (ii) For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each container.
- (b) You must update your traceability plan as needed to ensure that the information provided reflects your current practices and to ensure that you are in compliance with the requirements of this subpart. You must retain your previous traceability plan for 2 years after you update the plan.

Case-Level Traceability

What foods are covered by the new traceability rule?

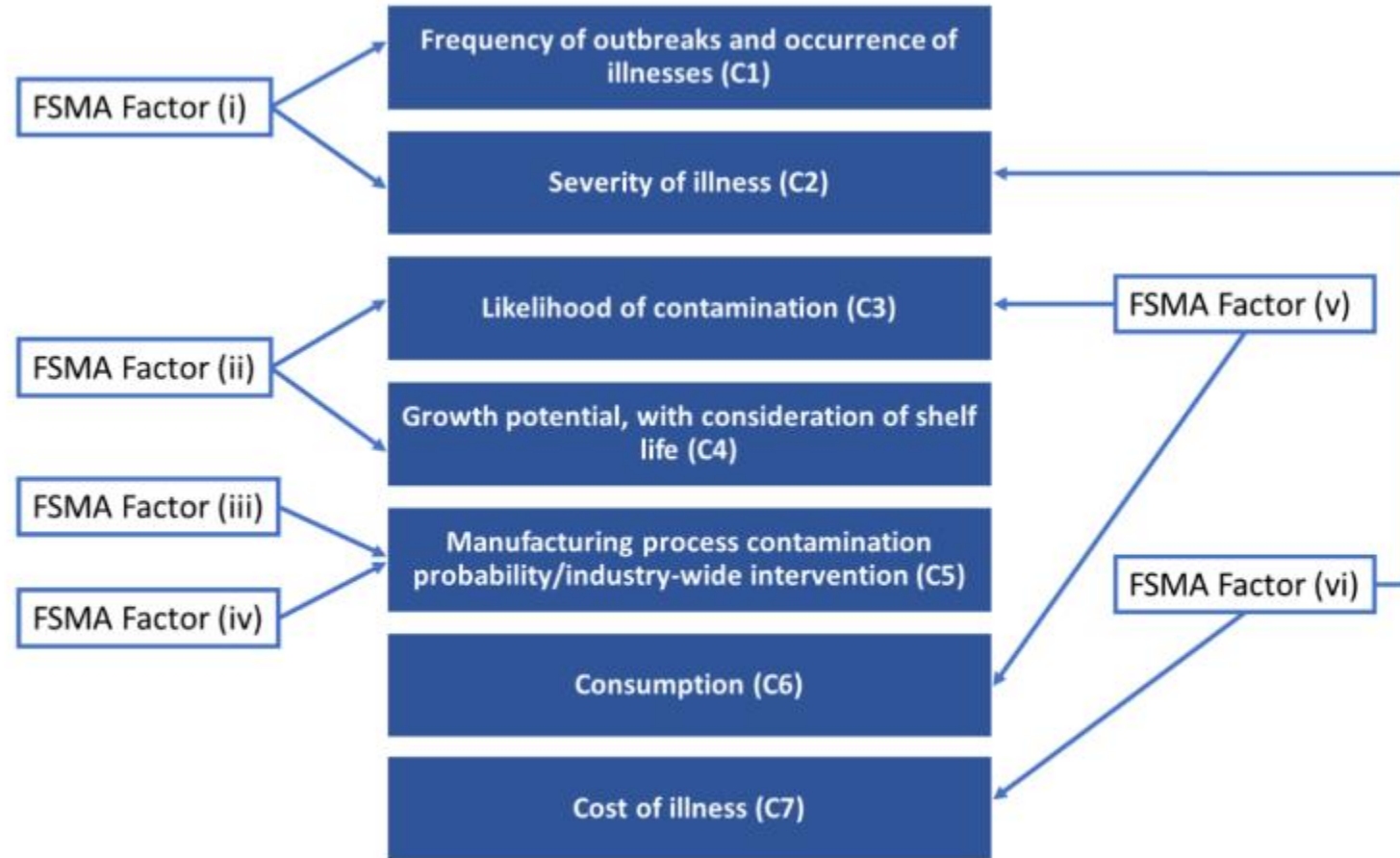


Figure 2-1. Relationship between Criteria in RRM-FT and Factors Required by FSMA

What foods are covered by the new traceability rule?

The Food Traceability List

| Food Traceability List | Description |
|---|--|
| Cheeses, other than hard cheeses, specifically: | |
| <ul style="list-style-type: none">Cheese (made from pasteurized milk), fresh soft or soft unripened | 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. |
| <ul style="list-style-type: none">Cheese (made from pasteurized milk), soft ripened or semi-soft | 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. |
| <ul style="list-style-type: none">Cheese (made from unpasteurized milk), other than hard cheese[1] | 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. |
| 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. |

<https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>

What foods are covered by the new traceability rule?

| | |
|------------------------------|--|
| 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/bok 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). |

What foods are covered by the new traceability rule?

| | |
|--|---|
| 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). |
| Finfish (fresh and frozen), specifically: | |
| <ul style="list-style-type: none"> Finfish, histamine-producing species | Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail. |
| <ul style="list-style-type: none"> Finfish, species potentially contaminated with ciguatoxin | Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper. |
| <ul style="list-style-type: none"> Finfish, species not associated with histamine or ciguatoxin | 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] |
| Smoked finfish (refrigerated and frozen) | Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.[4] |
| Crustaceans (fresh and frozen) | Includes all crustacean species. Examples include but are not limited to shrimp, crab, lobster, and crayfish. |
| Molluscan shellfish, bivalves (fresh and frozen)[5] | Includes all species of bivalve mollusks. Examples include, but are not limited to, oysters, clams, and mussels. Does not include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 CFR part 123, subpart C, and 21 CFR 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish are exempt from the requirements of the rule under § 1.1305(f). |
| Ready-to-eat deli salads (refrigerated) | Includes all types of refrigerated ready-to-eat deli salads. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. Does not include meat salads. |

Who is covered by the traceability rule?

You are subject to the Food Traceability final rule, unless an exemption applies.
To determine whether you may be exempt, please click on any of the following categories that may apply to you:

Farms

Certain types of processing

Commingled raw agricultural
commodities (RACs)

Personal consumption, holding
food for specific consumers

Fishing vessels, molluscan shellfish


Other

Retail food establishments (RFEs),
restaurants



How do I know what KDEs I need to create?

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



| Harvesting | Cooling (before Initial Packing) | Initial Packing (RAC) | First Land-Based Receiver | Shipping | Receiving | Transformation | Traceability Plan |
|---|-------------------------------------|--------------------------|---------------------------|----------|-----------|----------------|---|
| <p>Harvesting KDEs (Raw agricultural commodities (RACs) not obtained from a fishing vessel)</p> <ul style="list-style-type: none">• Location description for the immediate subsequent recipient (other than a transporter) of the food• Commodity and, if applicable, variety of the food• Quantity and unit of measure of the food• Location description for the farm where the food was harvested• For produce:<ul style="list-style-type: none">- Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or- Other information identifying the harvest location at least as precisely as field or growing area name• For aquacultured food:<ul style="list-style-type: none">- Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or- Other information identifying the harvest location at least as precisely as the container name• Date of harvesting• Reference document type and reference document number | | | | | | | <p>Provide to the Initial Packer</p> <ul style="list-style-type: none">• Business name• Phone number• Harvesting KDEs (except the reference document type and reference document number) |

Can't we just maintain the records rather than send the KDEs to our customers, and provide them when and/if they need them?

- The traceability rule isn't just an expansion of the 2002 Bioterrorism Rule (one up and one back)
- During an investigation need to provide records to FDA in 24 hours
 - If records haven't been sent, you're relying on others in the supply chain for your legal compliance timeframes (you don't have information you should have)

What if I have a kill step in my processing; do I need to track the FTL products that I receive?

- Must maintain records of kill step. No records need to be maintained from shipment forward
- For FTL foods prior to the kill step, records must be maintained or have written agreements stating that a kill step will be applied between shippers and receivers throughout the supply chain (from harvesting or first land-based receiving) until the kill step is applied



Can I create a new lot code when I send product to my customer and not use the one generated by the farm?

- Traceability Lot Codes (TLCs) can only be created for specific CTEs:
 - Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel
 - Perform the first land-based receiving of a food obtained from a fishing vessel
 - Transform a food
- TLC source reference is a method for giving FDA access to the TLC source location description required under subpart S without providing the TLC source location information directly to subsequent recipients



Does this rule apply to products grown/produced outside the US?

- Yes! – but recordkeeping does not apply to those who don't “physically hold” a FTL food (importer, broker, etc.)
- Broker or importer can be designated to maintain records
- “Covered entity” needs to ensure that designee is meeting recordkeeping requirements

As a distributor, do I
need to track case-
level shipments to my
retail and restaurant
customers?

- Yes, for FTL Foods!

Shipping KDEs (maintain and provide)

KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of 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 location from which you shipped the food
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)



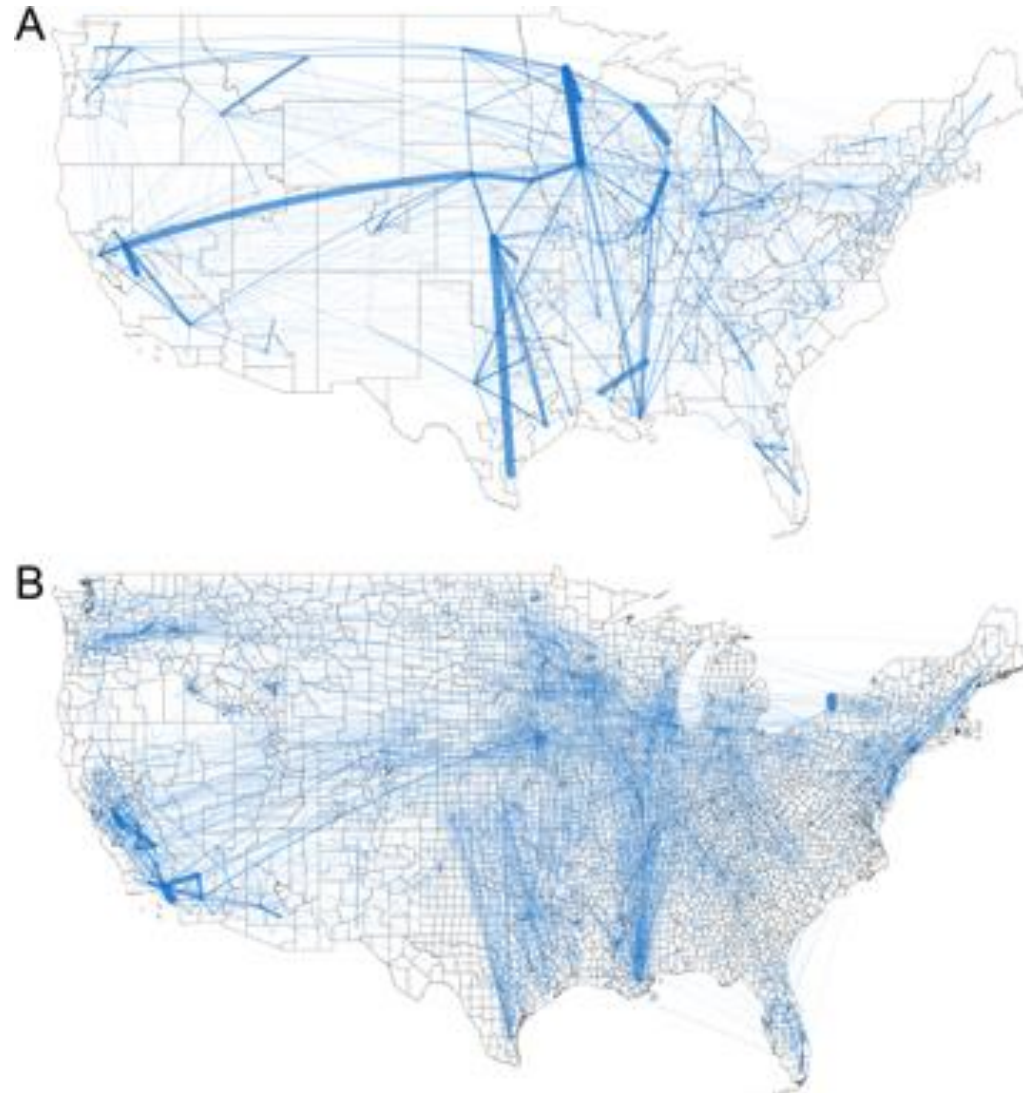
As a retailer or restaurant, what KDEs do I need to track in general, and at the case-level?

Receiving KDEs

KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

What if I don't
have a system to
generate the
KDEs today?



Lin, X., Ruess, P. J., Marston, L., & Konar, M. (2019). [Food flows between counties in the United States](#). *Environmental Research Letters*, 14(8), 084011.

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How does the rule apply 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

Get FSMA 204 Compliant with ReposiTrak

- FSMA 204 brings substantial new requirements and challenges
- This is not one forward – one back traceability...this requires data sharing with your customers/stores
- Your current systems do not support sharing KDEs and storing them for easy retrieval
- The ReposiTrak Traceability Network can get you FSMA 204 compliant
 - No hardware or software to buy
 - No substantial changes to your operations
 - No labels or standards required
 - Guaranteed to be the low cost solution for suppliers, distributors and retailers



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