

ALERT

Farm-to-Table Traceability Is on Its Way: FDA Issues Proposed Rule

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On September 23, the U.S. Food and Drug Administration (FDA) published a proposed rule to establish additional traceability recordkeeping requirements for companies that manufacture, process, pack, or hold certain high-risk foods listed on a newly formulated proposed Food Traceability List (FTL). You can find the proposed rule [here](#).

At the core of this proposed rule is the requirement that those companies that “manufacture, process, pack, or hold foods on the FTL would be required to establish and maintain records containing Key Data Elements (KDEs) associated with different Critical Tracking Events (CTEs) ...”

That is a mouthful of acronyms – but it is easy to determine if the proposed rule may apply to your company and expected requirements by focusing on the definitions of FTLs, CTEs, and KDEs:

- **Food Traceability List (FTL)** – This is the list of foods that the proposed rule applies to. We have included the proposed FTL in the table below.
- **Critical Tracking Events (CTEs)** – If your company manufactures, processes, packs, or holds a food on the FTL, then the proposed rule requires your company to maintain additional records depending on the type of supply chain activity. CTEs cover all events in the supply chain – including, for example, the “growing, receiving (including receipt by a first receiver), transforming, creating, or shipping of the food.”

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- **Key Data Elements (KDEs)** – A KDE is information a company must keep and maintain in a record based on the type of supply chain activity performed (i.e., the CTE identified above). FDA identified which KDEs would be necessary to effectively trace a product based on the CTEs performed in the proposed rule.

Ultimately, the purpose of the proposed recordkeeping requirement for those “high risk” foods on the FTL is to allow for rapid FDA action to identify recipients of food in order to prevent or mitigate serious adverse health consequences caused by adulterated or misbranded foods.

1. Proposed Food Traceability List (FTL):

In developing the proposed rule, FDA employed a risk-ranking model consistent with the factors set forth in Section 204(d)(2) of the Food Safety Modernization Act (FSMA) to develop the FTL. This risk-ranking model will apply to those foods listed in the FTL as well as those foods that contain the FTL-listed foods. At this time, the FTL is limited to foods intended for human consumption, but FDA may consider application to animal foods in future reassessments using the risk-ranking model. FDA proposes that any future deletions it makes to the list will become effective immediately and future additions will become effective a year after the date of publication in the Federal Register.

Here is the proposed FTL:

Foods

Description

Cheeses, other than hard cheeses

Includes all soft ripened or semi-soft cheeses, and fresh soft cheeses that are made with pasteurized or unpasteurized milk

Shell eggs

Shell egg means the egg of the domesticated chicken

Nut butter

Includes all types of tree nut and peanut butters; does not include soy or seed butters

Cucumbers

Includes all varieties of cucumbers

Herbs (fresh)

Includes all types of herbs, such as parsley, cilantro, basil

Leafy greens, including fresh-cut leafy greens

Includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and Romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, collards, and endive

Melons

Includes all types of melons, such as cantaloupe, honeydew, and watermelon

Peppers

Includes all varieties of peppers

Sprouts

Includes all varieties of sprouts

Tomatoes

Includes all varieties of tomatoes

Tropical tree fruits

Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit

Fruits and Vegetables (fresh-cut)

Includes all types of fresh-cut fruits and vegetables

Finfish, including smoked finfish

Includes all finfish species, such as cod, haddock, Alaska pollack, tuna, mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish which are regulated by the USDA

Crustaceans

Includes all crustacean species, such as shrimp, crab, lobster, and crayfish

Mollusks, bivalves

Includes all species of bivalve mollusks, such as oysters, clams, and mussels; does not include scallop adductor muscle.

Ready-to-eat deli salads

Includes all types of ready-to-eat deli salads, such as egg salad, potato salad, pasta salad, and seafood salad; does not include meat salads

2. Important Points for Companies Subject to the Proposed Rule:

- Establishment of traceability lot codes: Food facilities must establish traceability lot codes for foods subject to the FTL at the time the facility originates, transforms, or creates the food.
- Development of Traceability Program: Those food facilities subject to the traceability requirements must develop a traceability program for the foods they manufacture, process, pack, or hold. The type of records that must be established and maintained will depend on the activities undertaken by the food establishment, with each activity (growing, receiving, transforming, creating, and shipping) subject to unique requirements. However, all such entities must establish and maintain the following information:
 1. A description of the reference records maintained, where they are, and how the referenced records for different tracing events are linked
 2. A list of foods on the traceability list that the food establishment ships, including the traceability product identifier and traceability product description for each food
 3. A description of how traceability lot codes are established and assigned
 4. Any other information necessary to understand the data within any required record (e.g., coding systems, glossaries, abbreviations)
- Complete Supply Chain: In addition to establishing and maintaining the required records, receivers and shippers must assure that certain records are received and sent respectively in order to assure a complete supply chain.
- Record Maintenance and Availability: Records must be maintained for two (2) years unless specified elsewhere (for example, records that must be retained by retail food establishments and institutions operating farm to school programs are required to establish and retain records regarding the name and address of the farm that was the source of the food for 180 days). To the extent that existing records satisfy the records requirement, such as those maintained in the ordinary course of business, there is no need to duplicate such records. Such records must be made available within 24 hours after an FDA request.
- Failure to Comply: Failure to comply with these requirements, once finalized, is a prohibited act under Section 301(e) of the FFDCa unless committed by a farm. Such food can be refused admission when offered for import.

3. Foods and Facilities Excluded or Partially Excluded:

There are a number of important proposed exclusions or partial exclusions from the traceability requirements, many of which track similar exclusions set forth in other FSMA requirements.

- Foods excluded:

1. Processed food: food that receives commercial processing that reduces the presence of microorganisms of public health consequences as long as they meet the requirements for exclusion from the Produce Safety Rule under 21 C.F.R. 112.2(b)
2. Shell eggs that receive “treatments” as that term is defined in the Egg Safety Rule to reduce the risk of Salmonella enteritidis, and that comply with 21 C.F.R. 118.1(a)(2)
3. Foods rarely consumed raw as set forth in 21 C.F.R. 112.2(a)(1)
4. Certain foods produced and packaged and properly labeled on a farm when the packaging remains intact and prevents contamination or alteration of the food until the food reaches the consumer
5. Foods sold directly to consumers from the farm on which it is grown

- Foods subject to partial exclusions:

1. Certain raw agriculture commingled after harvesting, but before processing
2. Food produced through the use of a fishing vessel

- Establishments excluded:

1. Farms that are not covered under the Produce Safety Rule
2. Egg producers with fewer than 3,000 laying hens
3. Originators (persons who grow, raise, or catch food, or harvest a non-produce commodity) with an annual monetary value of food sold in the last three years of now more than \$25,000 (to be adjusted for inflation)
4. Small retail food establishments with no more than 10 FTE employees (FDA is considering whether this will be a full exclusion or a partial exclusion.)
5. Transporters
6. Nonprofit food establishments
7. Persons producing food for personal consumption, or
8. Persons who are not food distributors that are holding food for particular consumers, but are not parties to the food transaction

- Establishments subject to partial exclusions:

1. Retail food establishments that receive food directly from the producing farm
2. Institutions operating farm to school or institution programs when the food is received directly from the producing farms
3. Food produced through the use of fishing vessels

- Petitions for Exemption, Modification, or Waiver: The proposed rule provides for a petition process to seek additional exemptions or modifications for a particular food or type of entity, as well as a petition process to seek a waiver for an individual entity or type of entity.

The proposed rule, when finalized, will sit in a new Subpart S within 21 C.F.R. Part 1. **Comments on this proposed rule are due on February 22, 2021.**

Please do not hesitate to contact Ann Begley, Ryan Michael Fournier, or Bob Hibbert on any of the issues discussed in this article.