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FDA Proposes FSMA Food Traceability Rule, Including High-Risk Food Categories

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Food, Drugs, and Devices

Yesterday, FDA released a proposed rule that, if finalized, would impose additional traceability recordkeeping requirements for certain high-risk foods. This rulemaking is required by section 204 of FSMA, and is an additional action in FDA's ongoing FSMA implementation.

FDA proposes to establish a "Food Traceability List" (FTL) that would enumerate certain foods the agency deems "high-risk." Foods on this list would be subject to the heightened traceability requirements described in more detail below. The FTL includes foods ranging from leafy greens and fresh cut fruits and vegetables to certain types of fish, shell eggs, and nut butters, among other commodities.

The new rule would build on existing recordkeeping requirements to add another layer of recordkeeping intended to help rapidly and effectively identify recipients of a high-risk food in the event of an outbreak or other safety issue. Entities 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), such as growing, receiving, creating, transforming, and shipping. While these requirements would only apply to foods on the FTL ("Listed Foods"), FDA has indicated it will recommend that others in the food industry adopt these practices voluntarily.

Origins of the Rule

Current FDA food traceability recordkeeping requirements allow FDA to identify the immediate previous sources and immediate subsequent recipients of foods (*e.g.,* one-up, one-back) when addressing credible food safety threats.

When FSMA became law in 2011, Congress directed FDA to establish additional recordkeeping requirements for "high-risk foods." Citing recent outbreak investigations, inconsistent product descriptions, and commingling of products, FDA notes its inability -- in many cases -- to quickly identify points of origin and root causes of foodborne illness, leading to expansive recalls. FDA explains that the proposed rule "will help FDA follow the movement of listed food products and ingredients both backward and forward throughout the supply chain."

The proposed regulations would standardize the required data elements and other information firms must establish and maintain for such high risk foods, as well as information firms would need to send to the next entity in the supply chain to facilitate rapid and accurate traceability. FDA explains that the proposed provisions would assist the Agency in more efficiently capturing information needed to expediently link shipments of food through each point in the supply chain.

FDA specifically notes the following significant gaps in its current food recordkeeping requirements:

- Lack of coverage of all sectors involved in food production, distribution, and sale (e.g., exemptions for farms and restaurants).
- Lack of uniform data collection (e.g., regarding the source of food ingredients used in each lot of finished product; the requirement to record a lot code or other identifier only "to the extent this information exists" (see §§ 1.337(a)(4) and 1.345(a)(4)); and
- Inability to link incoming with outgoing product within a firm and from one point in the supply chain to the next.

FDA explains, through a number of examples, that most challenges encountered during a traceback investigation often implicate one or more of the above-listed gaps.

Key Provisions of Proposed Rule

The proposed rule would require firms to establish and maintain records containing KDEs associated with various CTEs in a Listed Food's supply chain, including the growing, receiving, transforming, creating, and shipping of Listed Foods.

The following are key requirements in the proposed rule:

- **Establish and maintain certain traceability program records**. Firms would be required to establish and maintain a description of the reference records in which they maintain required information, an explanation of where on the records the required information appears, and, if applicable, a description of how reference records for different tracing events for a food (*e.g.*, receipt, transformation, shipment) are linked.
- **Establish and maintain a list of foods on the Food Traceability List shipped by a firm.** Firms would be required to establish and maintain a list of Listed Foods that they ship. This would include the traceability product identifier and traceability product description for each Listed Food. FDA notes that although this requirement would only apply to Listed Foods that a firm ships, FDA would consider it a best practice for a firm to maintain such a list of all foods it ships.
- **Establish and assign traceability lot codes to foods on the Food Traceability List**. Firms would be required to establish and assign a traceability lot code when they originate, transform, or create a Listed Food. Generally, a firm may not establish a new traceability lot code when conducting other activities (e.g., shipping, receiving) in the supply chain for a Listed Food for which another entity has already established a traceability lot code.
- **Maintain Key Data Elements for Critical Tracking Events.** FDA proposes growing, receiving, transforming, creating, and shipping activities as CTEs for which records containing KDEs would be required. The KDEs required would vary depending on the CTE that is being performed. Firms that perform multiple CTEs would be required to maintain all the KDEs that pertain to the CTEs they perform. For example, if a firm receives a Listed Food and then transforms and ships it, FDA would require the firm to keep records of KDEs relevant to the receiving, transforming, and shipping events.
- **Records access requirements**. Firms would need to make required records available to an authorized FDA representative as soon as possible but not later than 24 hours

after the request. A firm would be required to provide FDA with an electronic sortable spreadsheet containing traceability information on foods that are the focus of an FDA investigation, when necessary.

Food Traceability List

FDA has tentatively identified foods in the table below as "high-risk," and for which additional traceability records would be required. The list only contains human food at this time.[1] The new requirements would apply to Listed Foods, as well as foods that contain Listed Foods as ingredients.

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

[1] Section 204(d) of FSMA does not exclude food for animals, and FDA reserves the option to add food for animals to the list at some point in the future. However, the risk-ranking model employed by FDA in designating high-risk foods was limited in scope to account only for humans, and FDA explained this model cannot extend to other animal species.

Foods	Description
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 mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish
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

Notable Exemptions

FDA proposes several full and partial exemptions from the new requirements. Small retail food establishments, small farms, farms selling food directly to consumers, certain food produced and packaged on a farm, food that is subject to certain types of processing for safety, and transporters of food would be completely exempt.

Certain commingled raw agricultural commodities -- not including fruits and vegetables subject to the produce safety regulations -- fishing vessels, retail food establishments that receive a listed food directly from a farm, and farm to school and farm to institution programs would be exempt from certain of the requirements, depending primarily on the complexity of the supply chain.

Proposed Effective and Compliance Dates

FDA proposes that the final rule would become effective 60 days following its publication in the Federal Register, and further proposes a compliance date for all regulated entities of 2 years following the effective date of the final rule.

Comment Period

FDA will be accepting comments on the proposed rule for 120 days following its publication in the Federal Register, scheduled for September 23, 2020.

Notable issues ripe for comment, among many critical issues, include compliance costs for affected entities to establish and maintain traceability records for Listed Foods, the categories FDA has included on the Food Traceability List, and any possible alternatives that would achieve the enumerated goals of this rulemaking.

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Covington's Food Industry Group has expertise advising on all aspects of food regulation, including compliance with new requirements under FSMA. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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