

At-A-Glance

The FDA is proposing to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed rule, “Requirements for Additional Traceability Records for Certain Foods” (Food Traceability Proposed Rule) is a key component of the FDA’s New Era of Smarter Food Safety Blueprint and would implement Section 204(d) of the FDA Food Safety Modernization Act (FSMA). When finalized, the proposal would standardize the data elements and information firms must establish and maintain, and the information they would need to send to the next entity in the supply chain to facilitate rapid and accurate traceability needed to prevent or mitigate foodborne illness outbreaks.

The proposed rule will be available for public comment for 120 days from the date of publication.

At the core of this proposal is a requirement for those who manufacture, process, pack or hold foods on the **Food Traceability List (FTL)** to establish and maintain records containing **Key Data Elements (KDEs)** associated with different **Critical Tracking Events (CTEs)**. While the proposed requirements would only apply to those foods on the FTL, they were designed to be suitable for all FDA-regulated food products. FDA would encourage the voluntary adoption of these practices industry-wide.

Food Traceability List (FTL)

To determine which foods should be included on the Food Traceability List, the FDA developed a Risk-Ranking Model for Food Tracing. The risk-ranking model scores commodity-hazard pairs such as Shiga toxin-producing *E.coli* O157 and leafy greens or *Listeria Monocytogenes* and soft cheese according to data and information relevant to criteria described in a technical report, which is available to review on our website.

Using the results of the risk-ranking model, we tentatively identified foods for the Food Traceability List, as shown in **Table 1.0**. The term “Food Traceability List” (FTL) refers not only to the foods specifically listed, but also to any foods that contain listed foods as ingredients. Each proposed requirement described below therefore pertains to all such foods unless an exemption applies.

Table 1.0 Food Traceability List

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 mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish ¹
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

¹Data for catfish were excluded from the Risk-Ranking Model because siluriformes fish (such as catfish) are primarily regulated by the U.S. Department of Agriculture.

The proposed rule sets forth a process for the FDA to update the Food Traceability List if the agency concludes that updates are appropriate. Under that process, FDA would publish a notice in the *Federal Register* stating any proposed changes to the list and the reasons for the changes, and requesting information and views on the proposal. After considering any information or views submitted, the FDA would publish a second notice in the *Federal Register*, stating whether any changes are being made, and the reason for the decision. Any additions to the list would become effective one year after the date of the second *Federal Register* notice, unless otherwise stated. Any deletions from the list would become effective immediately.

KEY FEATURES

1. Critical Tracking Events

The proposed rule identifies growing, receiving, transforming, creating, and shipping as the CTEs for which records containing KDEs would be required. The KDEs required would vary depending on the CTE that is being performed. The records required at each CTE would need to contain and link the traceability lot code of the food to the relevant KDEs. Additional information regarding the KDEs we are proposing can be found in the proposed rule and at FDA.gov. Below is a brief description of each CTE.

Growing

For products such as fruits and vegetables, **growing** is generally the first step in the supply chain. In addition to the general KDEs for growing, sprout growers would be required to establish and maintain additional growing KDEs that are specific to sprouts.

Receiving

Receiving is an event in a food's supply chain in which a food is received by a customer (other than a consumer) at a defined location after being transported (e.g., by truck or ship) from another defined location. In addition to the general KDEs for receiving, "first receivers" would need to establish and maintain additional KDEs.

- **First Receiver**

A **first receiver** is the first person (other than a farm) who purchases and takes physical possession of a listed food. Only foods that are originated (i.e., grown, raised, caught, or, in the case of a non-produce commodity such as eggs, harvested) can have a first receiver. Listed foods that are created (such as a ready-to-eat deli salad that is not made from any listed ingredients) do not have a first receiver.

We introduced the category of first receiver in this proposed rule. We are proposing this category in part because on-farm activities can involve movement of a food between different entities (e.g.,

growers, harvesters, coolers) without sale of the food, and the relevant business relationships can be complex. In order to ensure that comprehensive records relating to the origination and initial handling of the food are maintained by a single person who both owns and possesses the food, the first receiver of the food was identified as the entity who would be responsible for maintaining certain KDEs relating to originated foods. First receivers are required to maintain different KDEs depending on whether the food was obtained from a fishing vessel or not.

Creating

Creating is the making or producing of a food on the Food Traceability List (e.g., through manufacturing or processing) using only ingredient(s) that are not on the Food Traceability List. Creating does not include originating or transforming a food.

Transformation

Transformation is an event in a food's supply chain that involves changing a food on the Food Traceability List, its package, and/or its label (regarding the traceability lot code or traceability product identifier), such as by combining ingredients or processing a food (e.g., by cutting, cooking, commingling, repacking, or repackaging). Transformation does not include the initial packing of a single-ingredient food or creating a food.

Shipping

Shipping is an event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from a defined location to another defined location at a different farm, a first receiver, or a subsequent receiver.

2. Traceability Program Records

In addition to requiring records of KDEs, as discussed above, the proposed rule would require persons who manufacture, process, pack or hold foods on the FTL to establish and maintain **traceability program records**. These records are intended to help regulators understand an entity's traceability program, and include:

- **A description of relevant reference records**

A firm's KDEs might be kept on various types of reference records, such as bills of lading, purchase orders, or production logs. A firm's traceability program records would need to include a description of the reference records on which the firm maintains the required KDEs. This description would explain where on the reference record the traceability information appears, and if applicable, a description of how reference records for different tracing events for a food are linked.

- **A List of foods on the FTL that are shipped**

The proposed rule would require anyone who ships food on the FTL to keep a list of which listed foods they ship, including the traceability product identifier and traceability product description for each food. This list would be part of a firm's traceability program records.

- **A description of how traceability lot codes are assigned**

The proposed rule would require traceability lot codes to be established when a food on the FTL is originated, transformed, or created. The traceability lot code allows a food to be uniquely identified throughout the supply chain. As part of a firm's traceability program records, firms would be required to describe how they establish and assign traceability lot codes. Because of the crucial role that traceability lot codes play in the proposed rule, it is important that regulators know how a firm created and assigned these codes, so that they can better understand the scope of the records they are reviewing.

- **Other information needed to understand data provided within the required records**

The proposed rule would require a firm's traceability program records to include any other information needed to understand the data within their traceability records, such as internal or external coding systems or classification schemes, glossaries, and abbreviations. This will help regulators understand the terminology, methods, and systems a firm uses in its traceability operations.

3. Additional Requirements

The proposed rule would also require that:

- records be maintained as either original paper records, electronic records, or true copies; they all must be legible and stored to prevent deterioration or loss.
- traceability records be provided to FDA as soon as possible but no later than 24 hours after a request is made.
- an electronic sortable spreadsheet containing relevant traceability information be provided to FDA within 24 hours of a request when necessary to assist FDA during an outbreak, recall or other threat to public health.

Exemptions and Modified Requirements

The proposed rule includes exemptions for certain types of foods and certain persons who manufacture, process, pack or hold foods on the Food Traceability List. Some of these exemptions were provided by Congress, while others reflect the FDA's current thinking about the application of this rule to certain foods and persons.

Additional information regarding the exemptions we

are proposing can be found in the proposed rule and on our website at FDA.gov. That said, stakeholders should take note of two proposals we are offering for how this rule would apply to small retail food establishments.

Co-proposal for Small Retail Food Establishments

Option 1 Full exemption: RFEs that employ 10 or fewer full-time equivalent employees (FTEs) would be exempt from the requirements of the rule

Option 2 Partial exemption: RFEs that employ 10 or fewer FTEs would be exempt from the requirement to provide FDA, under specified circumstances, with an electronic sortable spreadsheet containing certain traceability information; however, they would be required to comply with all other aspects of the rule.

The FDA is interested in hearing from stakeholders regarding these options during the public comment period and public meetings.

In addition to the exemptions listed above, the proposed rule would allow the FDA, on its own initiative or in response to a citizen petition, to create modified requirements or exemptions if the FDA determines that the application of the relevant requirements to a given food or type of entity is not necessary to protect the public health. The proposed rule describes the process by which such modified requirements and exemptions can be requested. The proposed rule would also establish a process for the FDA to provide waivers when the agency determines that the application of the requirements would result in economic hardship for an individual entity or type of entity, due to the entity's unique circumstances.

IMPLEMENTATION

Compliance Dates

The FDA proposes that the final rule would become effective 60 days after it is published in the *Federal Register*.

Because an effective traceability system requires all entities in a supply chain to maintain traceability records, we believe all persons subject to the rule should come into compliance by the same date. We propose that the compliance date for all persons subject to the recordkeeping requirements would be 2 years after the effective date of the final regulation.

Contact Us

The proposed rule will be available for public comment for 120 days from the date of publication. Comments should be submitted to regulations.gov.

Meeting requests related to this rule should be submitted to smarterfoodsafety@fda.hhs.gov

Additional questions related to this rule should be sent to the [FSMA Technical Assistance Network](#)