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FSMA Update: FDA issues final traceability rule for certain foods

29 November 2022

FDA published a final rule "Requirements for Additional Traceability Records for Certain Foods" designed to improve the agency's ability to rapidly track and trace food through the supply chain. The final rule maintains the primary concepts and structure of the agency's proposed rule, but has been revised in response to stakeholder feedback. Covered entities must comply with this rule by January 20, 2026.

On November 21, 2022, FDA published a final rule "Requirements for Additional Traceability Records for Certain Foods" ("the final rule").1 This regulation was mandated by Section 204 of the FDA Food Safety Modernization Act (FSMA). The final rule is aimed at improving FDA's ability to rapidly track and trace food through the supply chain through the use of traceability lot codes to link food to certain Key Data Elements (KDEs) that must be maintained at critical stages of the supply chain.

The final rule maintains the primary concepts and structure of the agency's proposed rule, issued September 2020, but has been altered in response to feedback from stakeholders, particularly regarding which entities are covered, which steps in the supply chain are considered Critical Tracking Events (CTEs), and which KDEs are required to be recorded at each CTE.2 This memorandum summarizes the final rule by providing an overview of the rule and then outlining the major changes in the final rule. The final rule has a three year compliance date of January 20, 2026 for all covered entities.

Overview of the Final Rule

The final rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to supply chain partners specific information (key data elements or KDEs) for certain critical tracking events (CTEs) in the handling of food. The CTEs for which the final rule requires recordkeeping are harvesting, cooling, initial packing, first land-based receiving from a fishing vessel, transforming, receiving, and shipping a listed food. Depending on the CTE being performed, the KDEs vary.

The recordkeeping requirements emphasize the importance of documenting the applicable traceability lot code and linking this code to other KDEs along the supply chain. If a covered entity is the "initial packer" of a raw agricultural commodity (RAC), the "first land-based receiver" for food from a fishing vessel, or transforms a food on the Food Traceability List, it is responsible for establishing and assigning a traceability lot code for the food. Creating a new traceability lot code for a food is prohibited outside of these events. [3]

In addition to the records specific to CTEs, covered entities are required to establish and maintain a traceability plan that describes their traceability procedures (maintenance of records, identification of FTL foods handled, and assignment of traceability lot codes). The traceability plan is intended to provide a roadmap of relevant information in the event FDA needs to review a firm's records during a recall or similar traceback activity.

Traceability records can be kept in paper or electronic form, although FDA strongly encourages the use of electronic records. In addition, with a few limited exceptions, covered entities will be required to provide FDA with an electronic, sortable spreadsheet for specified foods and date ranges within 24 hours when requested by FDA in certain situations, although a longer time period could be agreed to by the parties.

The final rule includes a number of exemptions and modified requirements for certain food and entities. It also establishes procedures under which persons may request modified requirements or an exemption for a specific food or entity on the grounds that the traceability records requirements are not necessary to protect the public health. The rule also establishes procedures for requesting a waiver of one or more of the requirements for an entity on the grounds that having to meet the requirements would result in an economic hardship due to the unique circumstances of the entity or type of entity.

Key Revisions in the Final Rule

Although the overall structure of the final rule is the same as the proposed rule, FDA made a number of revisions based on feedback from stakeholders. The primary substantive changes between the proposed rule and the final rule include greater clarity regarding foods covered by the FTL; additional exemptions to the rule, including foods subject to a further processing; and altering the designated critical tracking events (CTEs) and the required KDEs at each CTE. Key differences between the proposed and final rule are outlined below.

The Food Traceability List

The Food Traceability List (FTL) and its related risk-ranking model represents FDA's methodology for determining which foods represent a heightened risk of foodborne illness or contamination and thus require additional traceability records.[4] The risk-ranking model and the resulting list of high-risk foods did not change from the proposed rule; however, FDA did provide further clarity on covered foods through more detailed definitions of foods on the FTL and in discussions in the preamble to the final rule. In particular, FDA has provided additional information regarding when a food on the FTL is considered to be an ingredient in another food. The major clarifications include:

- The final FTL specifies which version of the listed commodity is on the FTL and therefore covered by the final rule. If a commodity is listed as "fresh" on the FTL, then only the fresh commodity is covered by the final rule. If the form of the food changes so that it is no longer fresh, such as frozen spinach, frozen cut mango, dried peppers, or dried herbs, then the food would no longer be covered by the final rule.
- When a FTL food is used as an ingredient in a multi-ingredient food, the multi-ingredient food is covered by the rule if the FTL ingredient remains in the form listed on the FTL:

    - When a “fresh” commodity on the FTL is used as an ingredient in a multi-ingredient food, the multi-ingredient food is covered under the final rule (i.e. fresh lettuce in a bagged salad mix or fresh tomato slices in a sandwich). If the ingredient in the multi-ingredient food is not in the form designated on the FTL, the food is not covered by the final rule (i.e. spinach on a frozen pizza or trail mix with dried papaya).
    - Multi-ingredient foods including foods on the FTL which are not designated “fresh” are also covered by the final rule if the FTL food does not receive a kill step and is not transformed so that it is no longer on the FTL (i.e. peanut butter in a sandwich cracker that did not receive a kill step).

- The final rule specifies that the FTL does not include cheeses that are frozen, shelf stable or aseptically processed and packaged.[5]
- FDA specifies that “nut meals and powders,” “flours (wheat, rice or soy),” and “flavorings” are separate commodity designations from “nut butters” and therefore are not on the FTL. “Peanut butter chips” are also a separate commodity, but if they are produced using peanut butter as an ingredient without the application of a kill step, the peanut butter chips would be covered by the rule as they contain an ingredient on the FTL.

FDA intends to update the FTL every five years, subject to available resources. When initiating an update to the FTL, FDA will publish a notice to the *Federal Register* stating the proposed changes and requesting information and views on the proposed changes. Any additions to the FTL as a result of this process would take effect after two years, while any deletions from the FTL would be effective immediately. The full Food Traceability List is included in Appendix A below.

Traceability Plan

Similar to the proposed rule, covered entities are required to maintain information on how they conduct their required traceability operations. Rather than describe the reference records used to document traceability information and how they are linked, the final rule requires firms to describe their procedures for maintaining records (including the format and where stored); and rather than maintaining a list of foods on the FTL shipped and received, the final rule requires firms to describe their procedures for identifying the FTL foods they handle. In addition, if the entity grows or raises foods on the FTL, the traceability plan must include a farm map showing the location and name of each field where food on the FTL was grown, including geographic coordinates. The final rule also requires the traceability plan to identify a point of contact for questions about the plan and associated records. Consistent with the proposed rule, the traceability plan must also include information on how the entity assigns lot codes.

Expanded List of Exemptions

The final rule provides new full and partial exemptions for different entities and types of food. In addition to those already exempted in the proposed rule, the following are subject to additional exemptions in the final rule.

FDA allows complete exemptions for the following types of food:

- Raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program or covered by a final equivalence determination by FDA.
- Food designated for research or evaluation use provided that the food is not intended for retail sale and is not sold or distributed to the public. The food must be accompanied by the statement “food for research or evaluation use.”

FDA allows complete exemptions for the following types of entities:

- Persons who manufacture, process, pack, or hold foods on the FTL during or after the time the food is within the exclusive jurisdiction of the USDA under the Federal Meat Inspection Act, The Poultry Products Inspection Act, or the Egg Products Inspection Act.
- Small retail food establishments or restaurants with a rolling three year average of sales no more than $250,000 are exempt.

FDA allows partial exemptions for the following types of entities:

- Recordkeeping requirements do not apply to either entity when a purchase is made by one retail food establishment or restaurant from another retail food establishment or restaurant on an ad hoc basis. The purchasing entity must maintain a record documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase.
- With respect to the requirement that the entity must produce an electronic, sortable spreadsheet the following entities are exempt: (1) farms with a three year rolling sales average of no more than $250,000, (2) retail food establishments and restaurants with a three year rolling sales average of no more than $1 million, and (3) persons other than a farm, retail food establishment, or restaurant whose three year rolling sales average of related to the sale or processing of food is no more $ 1 million.

Foods Subject to Further Processing

In the final rule, FDA expands the modified exemption for FTL foods that undergo a kill step and provides a new modified exemption for foods that will be changed such that the food is no longer on the FTL. Under the proposed rule, for foods subject to a kill step, the entity performing the kill step would have been required to maintain a record of the application of the kill step, transformation records, and records for the receipt of the food. In the final rule, FDA has eliminated the requirement to maintain transformation records, and provided an additional option such that in lieu of receiving records, the entity performing the kill step can enter into a written agreement with the shipper of the food stating that the receiver will apply a kill step.

Similarly, foods that are changed such that they are no longer on the FTL (e.g., freezing fresh spinach) are exempt if the entity performing the change maintains receiving records. For foods where it is known early in the supply chain that the food will be subject to a kill step or be changed by another entity (other than by a restaurant, retail food establishment, or consumer) such that the food is no longer on the FTL, the food is exempt from traceability requirements provided there is a written agreement between the shipper and receiver stating that that the receiver will apply a kill step or change the food such that it is no longer on the FTL. Foods to which a kill step already has been applied or that have been changed such that they are no longer on the FTL are exempt from the rule.

Adjusted Critical Tracking Events

The Proposed Rule introduced six distinct CTEs: growing, first receiver, receiving, transforming, creating, and shipping. Within these CTEs, traceability lot codes were to be issued by those who originated, transformed, or created a food on the FTL. To address concerns that these terms and stages did not provide clear direction to industry on what entities and activities were considered part of each CTE and were inconsistent with industry practices, FDA removed the CTE's of growing and first receiver and merged the CTE of creating with transforming. The final rule includes seven CTEs:

- Harvesting

- Cooling
- Initial Packing – Packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time. [6]
- First Land-Based Receiving – The person taking possession of a food for the first time on land directly from a fishing vessel.
- Shipping – Shipping includes intracompany shipments between different physical addresses.
- Receiving – Receiving includes receipt of intracompany shipments of food from a different physical address.
- Transforming – An event in a food's supply chain that involves manufacturing/processing a food or changing a food or its packaging when the output is on the FTL. Transformation does not include the initial packing of a food or preceding cooling and harvesting events.

Changes to Key Data Elements

In general, the final rule simplifies and streamlines KDE's across the various CTEs, recognizing that the proposed rule included KDEs that were novel in the supply chain and did not provide extensive value to FDA's tracking efforts. For example, the final rule eliminates the need for location identifiers and traceability product identifiers, instead recognizing that sufficient information is captured in the required location description and product description KDEs to identify the foods and locations at issue without the need to generate a unique identifier.

The proposed rule required the maintenance and passing forward in the supply chain information about the "traceability lot code generator," defined as the person who assigned the traceability lot code to a product. Commenters expressed concern that this KDE resulted in both personal and competitive privacy issues. In response to these concerns, FDA replaced the "traceability lot code generator" with the "traceability lot code source" and "traceability lot code source reference." The traceability lot code source refers to the place rather than the person assigning the traceability lot code, eliminating the need to share employee information through the supply chain. The traceability lot code source reference is an alternative method for providing FDA with access to the location description for the traceability lot code source, without fully disclosing this information to others in the supply chain. Rather than provide a full location description for the traceability lot code source in the linked KDEs, the final rule allows another record such as the FDA Food Facility Registration Number or a web address which would contain location description information to be assigned via the traceability lot code source reference. This would allow FDA to quickly identify the traceability lot code source without that information being directly shared with the broader supply chain.

Additionally, a number of other changes to KDEs were made in the final rule including:

- Deleting "physical location name" as this is captured in the "location description."
- Simplifying the "product description" to eliminate the elements of "category code/term" and "category name" and to require the "brand name, commodity, and variety" "if applicable."
- Providing a "point of contact" to others in the supply chain is no longer required, but contact information for someone familiar with an entity's traceability program must be identified in the program documents. This can be by title or position, rather than a specific individual.
- Requiring additional KDEs for sprouts at the initial packing stage.
- For shippers and receivers, deleting the entry number for imported foods, the time of shipping or receiving, and the name of the transporter.
- Eliminating the definition for a "lot" for the purposes of the traceability rule, allowing covered entities to determine the lot for an FTL food.

Records Availability

Similar to the proposed rule, the final rule requires covered entities to provide required records to FDA within 24 hours of a request, unless FDA agrees to an alternative time frame. It also retains the proposed requirement to provide FDA requested information via an electronic, sortable spreadsheet within 24 hours of request when necessary to help prevent or mitigate a foodborne illness outbreak or address a threat to the public health. However, the final rule also provides for FDA to agree to an extended timeframe for production of the spreadsheet. As noted above, the requirement to provide FDA with an electronic sortable spreadsheet does not apply to certain smaller retail food establishments, farms, and restaurants. Additionally, FDA will accommodate religious beliefs that prohibit the use of an electronic, sortable spreadsheet.

The final rule adds a requirement to make available any information needed to understand the traceability records, such as internal or external coding systems, glossaries, abbreviations, and a description of the how the records provided correspond to the information required by the rule. This information originally was to be included in a firm's traceability plan, but the agency concluded it was more appropriate that it be provided in response to a records request.

The preamble to the final rule also clarifies that FDA may request review of a firm's traceability records at any time, regardless of whether the agency has reason to believe that the firm may have handled an FTL food suspected of being the source of an outbreak. FDA expects to conduct routine records inspections to ensure compliance with the rule. The final rule also notes that FDA may request traceability records by phone or in-person. When a request is made by phone, the agency will also provide the request for records in writing if asked to do so by the firm. For requests made in-person, the agency will work with the firm to ensure the request is understood, including by providing the request in writing as needed.

Compliance Date

In addition to the changes listed above, the final rule also designates a three year implementation period after the effective date on January 20, 2023 before compliance with the final rule is required, in contrast to the two years originally proposed. This places the compliance date of the traceability program rule on January 20, 2026.

Next Steps

The food industry should begin to determine how the rule will impact industry operations. If you have any questions on this or any matter, or if we can assist in your development of a traceability program, please do not hesitate to contact us.

We will continue to monitor FDA's implementation and enforcement of FSMA and the traceability rule and will keep you apprised of any developments.

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References

1 Requirements for Additional Traceability Records for Certain Foods, 21 C.F.R. §§ 1.1300 - 1.1465, available at https://www.govinfo.gov/content/pkg/FR-2022-11-21/pdf/2022-24417.pdf.

2 *See* Hogan Lovells memorandum dated September 23, 2020, *FSMA Update – FDA Issues Proposed Rule for Traceability and Tentative Food Traceability List*.

3 The final rule recognizes, however, that there may be circumstances where an entity receives food on the FTL from a supplier who is exempt from the rule. In those cases, the receiver must assign a traceability lot code to the food and maintain other related information on the food received.

4 *Designation of the Food Traceability List Using the Risk Ranking Model for Food Tracing (2022 Version)*, available at https://www.fda.gov/media/142282/download.

5 In the preamble to the final rule, FDA recognizes that cottage cheese produced in the US is regulated under the Pasteurized Milk Ordinance (PMO). Therefore, FDA is considering initiating an exemption process under § 1.1360 to determine whether to exempt cottage cheese regulated under the PMO from the traceability rule requirements.

6 Initial packing of an RAC and the first land-based receiving CTEs are designed to help eliminate the confusion and burden associated with the proposed rule's "first receiver" CTE.

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Appendix A: Food Traceability List as of November 21, 2022

Food Traceability List	Description
Cheeses, other than hard cheeses, specifically:	
• 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. Food Traceability List Description
• 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.
• 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.
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).
Finfish (fresh and frozen), specifically:	
• 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.
• 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.
• 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.

[1] "Hard cheese" includes hard cheeses as defined in 21 CFR 133.150, colby cheese as defined in 21 CFR 133.118 and caciocavallo siciliano as defined in 21 CFR 133.111. Examples of hard cheese include, but are not limited to, cheddar, romano, and parmesan.

[2] For a more comprehensive list, see Chapter 3 of the Fish and Fishery Products Hazards and Controls Guidance at https://www.fda.gov/media/80637/download.

[3] Data 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.

[4] "Smoked finfish" refers to a finfish product that meets the definition of a smoked or smoke-flavored fishery product in 21 CFR 123.3(s).

[5] Under 21 CFR 123.3(h), *molluscan shellfish* means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.