
Memorandum

Date: March 19, 2024

From: FDA Food Traceability Rule Workgroup

Subject: Food Traceability List for “Requirements for Additional Traceability Records for Certain Foods” Final Rule

To: Memorandum for the Record

The FDA Food Safety Modernization Act (FSMA) section 204 (21 U.S.C. 2223) requires the Food and Drug Administration (FDA) to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. To assist the Agency in the process of designating these foods, FDA developed a Risk-Ranking Model for Food Tracing (Ref. 1), a data-driven science-based decision support tool. Using the results of the risk-ranking model (see “Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing” (Ref. 2)), we identified foods for which additional traceability records will be required in accordance with section 204(d) of FSMA under FDA’s regulations at 21 CFR part 1, subpart S (see list of foods below). The risk scores for these commodities and associated commodity-hazard pairs are available in Appendix I in Ref. 2.

As noted in the final rule, the additional recordkeeping requirements in the final rule apply to the foods specifically listed on the FTL, and to foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., “fresh”) in which it appears on the 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 or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.

Food Traceability List	Description
<ul style="list-style-type: none"> <li data-bbox="253 237 591 348">• 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 or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
<ul style="list-style-type: none"> <li data-bbox="253 459 639 571">• Cheese (made from unpasteurized milk), other than hard cheese¹ 	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen or previously 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. Includes all forms of nut butters, including shelf stable, refrigerated, frozen, and previously frozen products. 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 ²)	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 ³)	Includes all types of fresh-cut leafy greens, including single and mixed greens.

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 The designation “fresh” does not include previously frozen forms of the food.

³ The designation “fresh-cut” does not include previously frozen forms of the food.

Food Traceability List	Description
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 fruit 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, frozen, and previously 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.

Food Traceability List	Description
<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. ⁴ Siluriformes fish, such as catfish, are not included. ⁵
Smoked finfish (refrigerated, frozen, and previously frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish. ⁶
Crustaceans (fresh, frozen, and previously frozen)	Includes all crustacean species. Examples include, but are not limited to, shrimp, crab, lobster, and crayfish.
Molluscan shellfish, bivalves (fresh, frozen, and previously frozen) ⁷	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, including ready-to-eat deli salads that are frozen at some point in the supply chain prior to retail. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. Does not include meat salads.

⁴ 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>.

⁵ 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.

⁶ “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).

⁷ Per 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.

References

Ref. 1.

Food and Drug Administration. (2022). "Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223)." September 2022. Available at www.fda.gov.

Ref. 2.

Food and Drug Administration. (2022). "Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing." October 2022. Available at www.fda.gov.

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03/19/2024

Date