
Memorandum

Date: January 12, 2021

From: FDA Food Traceability Rule Workgroup

Subject: Food Traceability List for “Requirements for Additional Traceability Records for Certain Foods” Proposed Rule – Clarified Language

To: Memorandum for the Record

The FDA Food Safety Modernization Act (FSMA) section 204 (21 U.S. Code § 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 tentatively identified foods for which additional traceability records will be required in accordance with section 204 of FSMA (see list below). The risk score for these commodities and associated commodity-hazard pairs are available in Appendix I in Ref. 2.

The following chart encompasses the same foods that were identified in our August 12, 2020, [memorandum](#) to the record entitled, “Food Traceability List for ‘Requirements for Additional Traceability Records for Certain Foods’ Proposed Rule,” and that appeared as “Table 2 – Tentative Food Traceability List” in the preamble to the proposed rule, “Requirements for Additional Traceability Records for Certain Foods,” 85 FR 59984, 59991 (Sept. 23, 2020). The following chart includes clarifying language that was not part of those earlier charts. These changes are identified in footnotes 2, 3, 4, and 6.

Food Traceability List	Description
Cheeses, other than hard cheeses ¹ ,	Includes all cheeses made with either pasteurized or unpasteurized milk, other than hard cheeses. ² Includes soft ripened/semi-soft cheeses (e.g., brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster) and soft unripened/fresh soft cheeses (e.g., cottage, chevre/goat, cream, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna). ³
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 (fresh) ⁴	Includes all varieties of cucumbers
Herbs (fresh)	Includes all types of herbs, such as parsley, cilantro, basil, etc.
Leafy greens (fresh), including fresh-cut leafy greens ⁵	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, endive, etc. ⁶

¹ In Appendix I in Ref. 2, this is designated as: (1) Cheese (made from pasteurized milk), fresh soft; (2) Cheese (made from pasteurized milk), soft or soft ripened or semi-soft; and (3) Cheese (made from unpasteurized milk), other than hard cheese.

² “Hard cheese” is defined in the Risk-Ranking Model for Food Tracing as cheese with less than 39% moisture, such as cheddar, Romano, and parmesan. This footnote, which did not appear in the August 12, 2020, memorandum, has been added here to clarify the meaning of “hard cheese” within the context of this chart. It does not reflect a change in which foods are on the Food Traceability List.

³ The description of “Cheeses, other than hard cheeses” in the earlier versions of this chart read as follows: “Includes all soft ripened or semi-soft cheeses, and fresh soft cheeses that are made with pasteurized or unpasteurized milk.” That description has been revised here to clarify which cheeses are part of this designation, and to include several examples of such cheeses. These edits are only for clarity and do not reflect a change in which foods are on the Food Traceability List.

⁴ The word “(fresh)” was not included in the earlier versions of this chart. We have added it here to clarify that the commodity “cucumbers” only includes fresh cucumbers. Similarly, we have added the description “(fresh)” in several other places where it did not previously appear to clarify the commodities “leafy greens,” “melons,” “peppers,” “sprouts,” “tomatoes,” and “tropical tree fruits.” These edits are only for clarity and do not reflect a change in which foods are on the Food Traceability List.

⁵ In Appendix I in Ref. 2, this is designated as: (1) Leafy Greens; and (2) Leafy Greens (Fresh-Cut).

⁶ The earlier versions of this chart included “collards” as an example of leafy greens. However, because collards are listed as “rarely consumed raw” in the produce safety regulation (see 21 CFR 112.2(a)(1)), they would be exempt from the requirements of this proposed rule under proposed 21 CFR 1.1305(e). Therefore, to avoid confusion, we have removed collards from the description of leafy greens.

Food Traceability List	Description
Melons (fresh)	Includes all types of melons, such as cantaloupe, honeydew, watermelon, etc.
Peppers (fresh)	Includes all varieties of peppers
Sprouts (fresh)	Includes all varieties of sprouts
Tomatoes (fresh)	Includes all varieties of tomatoes
Tropical tree fruits (fresh)	Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, starfruit, etc.
Fruits and Vegetables (fresh-cut) ⁷	Includes all types of fresh-cut fruits and vegetables
Finfish, including smoked finfish ⁸	Includes all finfish species, such as cod, haddock, Alaska pollock, tuna, mahi mahi, mackerel, grouper, barracuda, salmon, etc.; except does not include siluriformes fish, such as catfish ⁹
Crustaceans	Includes all crustacean species, such as shrimp, crab, lobster, crayfish, etc.
Mollusks, bivalves	Includes all species of bivalve mollusks, such as oysters, clams, mussels, etc.; 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, seafood salad, etc.; does not include meat salads

References

Ref. 1.

Food and Drug Administration. (2020). "Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223)." August 2020. Available at www.fda.gov.

Ref. 2.

⁷ In Appendix I in Ref. 2, this is designated as: (1) Fruits (Fresh-Cut); and (2) Vegetables other than leafy greens (Fresh-Cut).

⁸ In Appendix I in Ref. 2, this is designated as: (1) Open ocean finfish (histamine-producing species); (2) Reef finfish (potentially contaminated with ciguatoxin); and (3) Finfish, species not associated with histamine or ciguatoxin.

⁹ 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.

Food and Drug Administration. (2020). "Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing." September 2020. Available at www.fda.gov.

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01/11/2021

Date