
Memorandum

Date: August 12, 2020

From: FDA Food Traceability Rule Workgroup

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

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.

| Food Traceability List | Description |
|---|---|
| Cheeses, other than hard cheeses ¹ | 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 |

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

| Food Traceability List | Description |
|---|--|
| Herbs (fresh) | Includes all types of herbs, such as parsley, cilantro, basil, etc. |
| Leafy greens, including fresh-cut leafy greens ² | 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, endive, etc. |
| Melons | Includes all types of melons, such as cantaloupe, honeydew, watermelon, etc. |
| 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, starfruit, etc. |
| Fruits and Vegetables (fresh-cut) ³ | Includes all types of fresh-cut fruits and vegetables |
| Finfish, including smoked finfish ⁴ | Includes all finfish species, such as cod, haddock, Alaska pollack, tuna, mahi mahi, mackerel, grouper, barracuda, salmon, etc.; except does not include siluriformes fish, such as catfish ⁵ |
| 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 |

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

³ In Appendix I in Ref. 2, this is designated as: (1) Fruits (Fresh-Cut); and (2) Vegetables other than leafy greens (Fresh-Cut).

⁴ 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.

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.

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.

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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09/17/2020

Date