

Food Traceability List

[Español \(Spanish\) \(/food/food-safety-modernization-act-fsma/lista-de-trazabilidad-de-los-alimentos\)](#) | [Bahasa Indonesia \(/media/164643/download\)](#) | [中文 \(Chinese, Simplified\) \(/media/164645/download\)](#) | [แบบไทย \(Thai\) \(/media/164646/download\)](#) | [Tiếng Việt \(Vietnamese\) \(/media/164644/download\)](#)

[FSMA Final Rule: Requirements for Additional Traceability Records for Certain Foods \(/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods\)](#)

Section 204 of the [FDA Food Safety Modernization Act \(FSMA\) \(/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma\)](#) requires the FDA to designate foods for which additional recordkeeping requirements are appropriate and necessary to protect public health. Additional recordkeeping requirements are outlined in the [Food Traceability Final Rule \(/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods\)](#) and are intended to allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

The Food Traceability List (FTL) identifies the foods for which the additional traceability records are required. The additional recordkeeping requirements 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.

The Food Traceability 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, shelf stable at ambient temperature, or aseptically processed and packaged.

Food Traceability List	Description
<ul style="list-style-type: none"> 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.
<ul style="list-style-type: none"> 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. Includes all forms of nut butters, including shelf stable, refrigerated, and 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)	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/bok 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.

Food Traceability List	Description
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:	
<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.
<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.[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).

Food Traceability List	Description
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 \(/media/80637/download\)](#).

[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.

Note: Foods for animals are not included in our current risk-ranking model and are not included on the FTL, and therefore not covered by the final rule.

Development of the Food Traceability List

In February 2014, the FDA issued a *Federal Register* (<https://www.federalregister.gov/documents/2014/02/04/2014-02255/designation-of-high-risk-foods-for-tracing-request-for-comments-and-for-scientific-data-and>) notice to solicit comments on our [draft approach for developing a list of high risk foods \(/media/124152/download\)](#). Taking into consideration the comments and other information submitted, the FDA developed a draft risk-ranking model (“the Model”) and collected data to populate the Model for chemical and microbiological hazards associated with specific foods, with technical assistance from external expert panels. Two [peer-review \(/science-research/peer-review-scientific-information-and-assessments/completed-peer-reviews\)](#) panels of independent external experts reviewed the draft Model and the types of data used to generate risk scores with the model, respectively. The FDA refined the Model and updated the data, taking into consideration comments from the peer reviews.

The Model was developed in conjunction with an FDA Project Advisory Group (PAG), consisting of members from the FDA and the [Centers for Disease Control and Prevention \(https://www.cdc.gov/\)](#) (CDC). The Model is designed to be flexible and to consider a wide range of known and reasonably foreseeable contaminants in FDA-regulated human foods. It

evaluates and ranks a comprehensive list of commodity-hazard pairs and the associated commodities to inform the Food Traceability List.

Based on data and results in the Model, we considered commodities and associated commodity-hazard pairs with criteria scores in the moderate to strong range, and identified foods for inclusion on the FTL. A tentative FTL was announced with the Food Traceability Proposed Rule on September 23, 2020.

For additional information, see the *Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing* memo (</media/142282/download>).

Risk-Ranking Model for Food Tracing

The risk-ranking model for food tracing is based on factors that Congress identified in Section 204(d)(2) of FSMA. The Model scores commodity-hazard pairs (e.g., Shiga toxin-producing *E.coli* O157 (STEC O157) in Leafy Greens) according to data and information relevant to seven criteria described in the report *Methodological Approach to developing a Risk-Ranking Model for Food Tracing* FSMA Section 204 (</media/142247/download>):

- Frequency of outbreaks and occurrences of illnesses
- Severity of illness
- Likelihood of contamination
- The potential for pathogen growth, with consideration of shelf life
- Manufacturing process contamination probability and industry-wide intervention
- Consumption rate and amount consumed
- Cost of illness

The FDA has developed a tool designed to allow users to explore the results of the Risk-Ranking Model for Food Tracing (<https://cfsanappsexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracingfinalrule/>) used in the development of the Food Traceability List. Users can access the tool (<https://cfsanappsexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracingfinalrule/>) or download the results to learn more about the methods and criteria used to determine which foods would be included on the FTL.

The results from the Risk-Ranking Model for Food Tracing (RRM-FT) are provided in the documents below for commodities that appear on the FTL (Table 1A) and the associated commodity-hazard pairs (Table 1B), and for all commodities evaluated in the Model (Tables 2A&2B). Table 2A provides risk scores for all commodities, including commodities that appear on the FTL and commodities that are not on the FTL (unless they include an ingredient on the FTL). Table 2B provides results for all commodity-hazard pairs, including

the criterion score for Criterion 1 through Criterion 7 (C1 through C7) and the risk score for each commodity-hazard pair. The commodity-hazard pairs (Table 2B) are associated with the commodities (Table 2A) evaluated in the Model.

- [Risk-Ranking Model for Food Tracing: Results \(Table 1A\) for FTL Commodities \(/media/166878/download\)](/media/166878/download) (PDF: 220KB)
- [Risk-Ranking Model for Food Tracing: Results \(Table 1B\) for FTL Commodity-Hazard Pairs \(/media/166879/download\)](/media/166879/download) (PDF: 649KB)
- [Risk-Ranking Model for Food Tracing: Results for All Commodities \(Table 2A\) and Commodity-Hazard Pairs \(Table 2B\) \(/media/166880/download\)](/media/166880/download) (PDF: 1.45MB)

Updates to the FTL

The final rule sets forth a process for the FDA to update the FTL if the agency concludes that updates are appropriate. When FDA tentatively concludes that an update is necessary, the FDA will publish a notice in the *Federal Register* stating the proposed changes to the list and the reasons for the changes and will solicit feedback and information on the proposal. After considering any feedback or information submitted, the FDA will 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 two years after the date of the second *Federal Register* notice, unless otherwise stated. Any deletions from the FTL would become effective immediately.

Additional Information

- [Memo: Food Traceability List for "Requirements for Additional Traceability Records for Certain Foods" Final Rule \(/media/142283/download\)](/media/142283/download)
- [Full List of References in the Risk-Ranking Model for Food Tracing \(/media/143495/download\)](/media/143495/download)