

The Food Traceability List

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Overview of Risk-Ranking Model for Food Tracing

- FSMA requirements
- Methodology
 - development process
 - model criteria
 - food classification and scoring of commodity-hazard pairs
- Result examples



FSMA Requirements



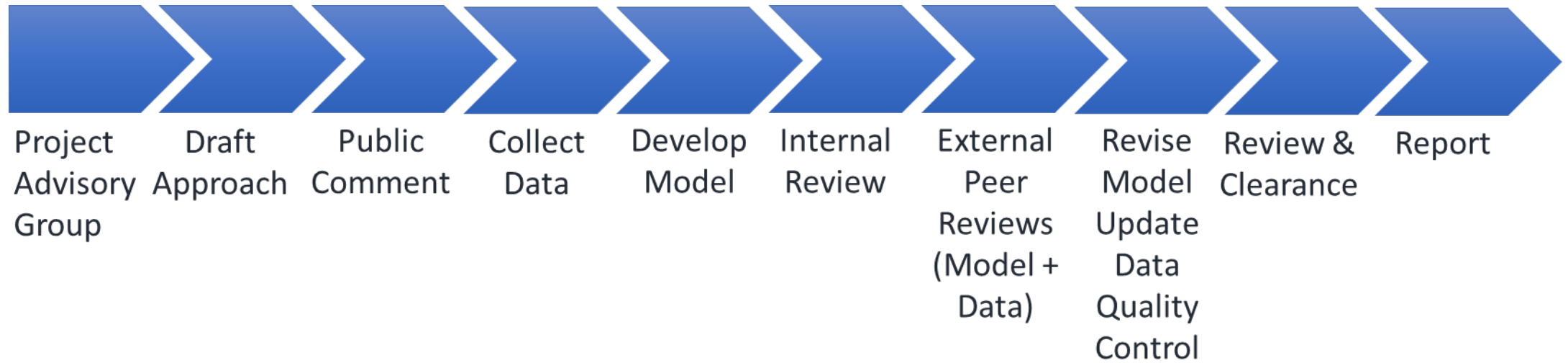
Section 204(d)(2)(A) (21 U.S. Code § 2223(d)(2)(A))

Designation of high-risk foods shall be based on

- (i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;
- (ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;
- (iii) the point in the manufacturing process of the food where contamination is most likely to occur;
- (iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- (v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- (vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.



A Systematic, Transparent, and Participatory Process



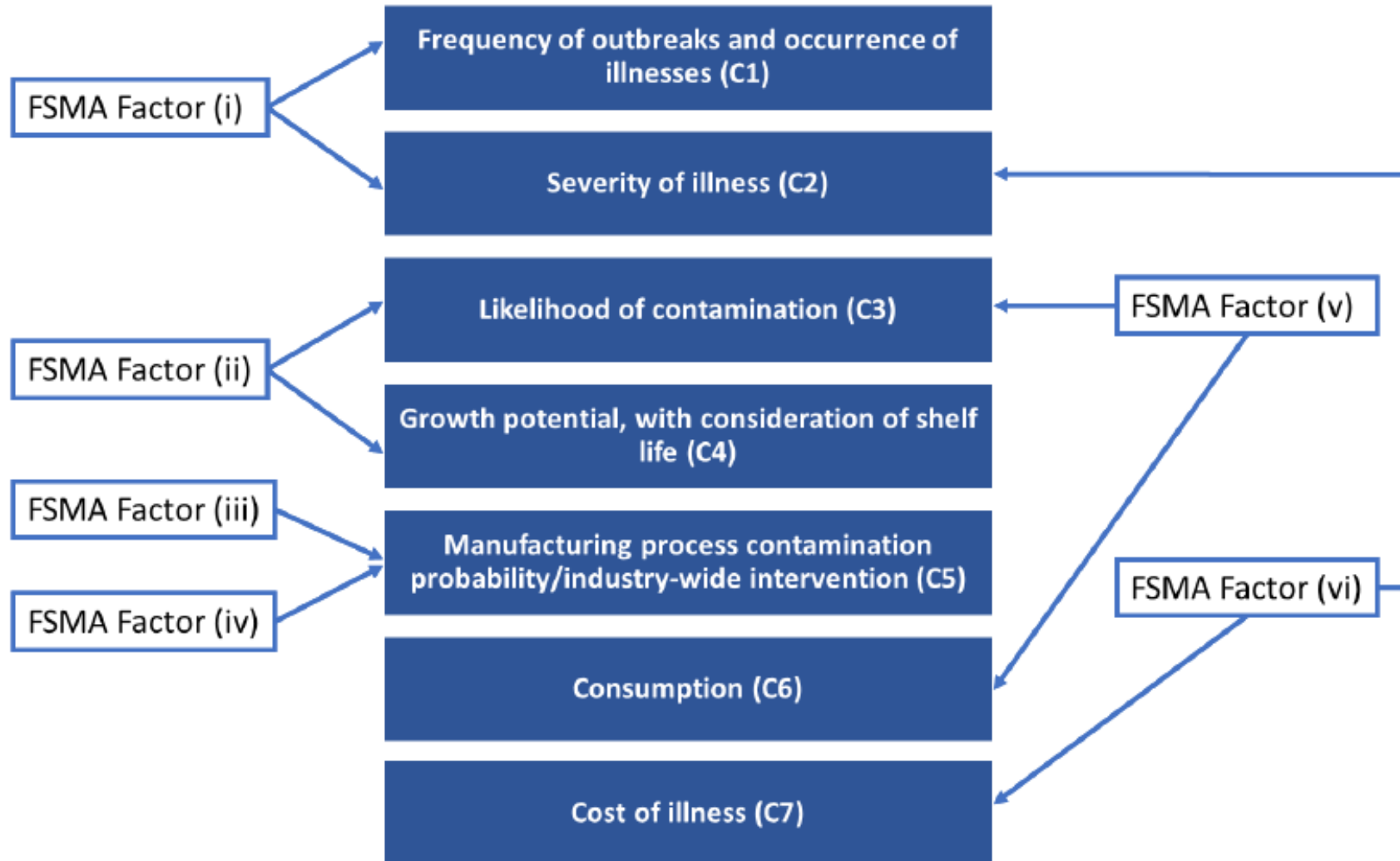


Overall Approach to Designation of the List

- Create a data driven risk-ranking model
 - Score food-hazard pairs based on risk factors specified in FSMA sec. 204(d)(2)(A)
 - Aggregate scores appropriately to create ranked list of foods (commodities and commodity categories)
-
- Designate Food Traceability List



Alignment of Model Criteria and Statutory Factors Required by FSMA





Classification of Commodities and Commodity Categories

- Commodity categories (n=47) based on Reportable Food Registry (RFR) and Industry Codes in FDA facility registration program
 - Consider both food characteristics and manufacturing processes (e.g., LACF, Produce-RAC)
- For each commodity category, identify commodities and a comprehensive list of food-hazard pairs for scoring based on data



Example Scoring Definitions

Criterion 1 - Frequency of outbreaks and occurrence of illnesses

Weighted Occurrence of Illnesses

High (thousands)

Medium (hundreds)

Low (tens)

3	9	9
1	3	9
1	1	3

Low

Medium

High

>0 to ≤1

>1 to <10

≥10

since 1999

since 1999

since 1999

Weighted Frequency of Outbreaks since 1999

Each outbreak weighted based on the year in which it occurred, using a value of 1, 0.7, and 0.4. For example, weight of 1 assigned for an outbreak in 2010 or later.



Example Scoring Definitions

Criterion 3 - Likelihood of Contamination of the Hazard in Food

Definition basis	Score = 0	Score = 1	Score = 3	Score = 9
Sampling data	No known occurrence ^a	Low (>0 to ≤0.1%) ^b	Medium (>0.1-1%)	High (>1%)
RFR and recall data, or other information	No recalls; or no RFR reports; other indicators ^c	>0 to ≤ 1 RFR reports/yr ^b ; or >0 to ≤ 5 recalls/yr; other indicators	>1-10 RFR reports/yr; or >5-10 recalls/yr; other indicators	>10 RFR reports/yr; or >10 recalls/yr; other indicators

^a No known detection of a microbial hazard, or of a chemical hazard above an action level or allowable level, based on data

^b Weighted contamination rate is used for scoring. Average RFR reports/yr or average recalls/yr.

^c Indicators such as eLEXNET or expert judgements.



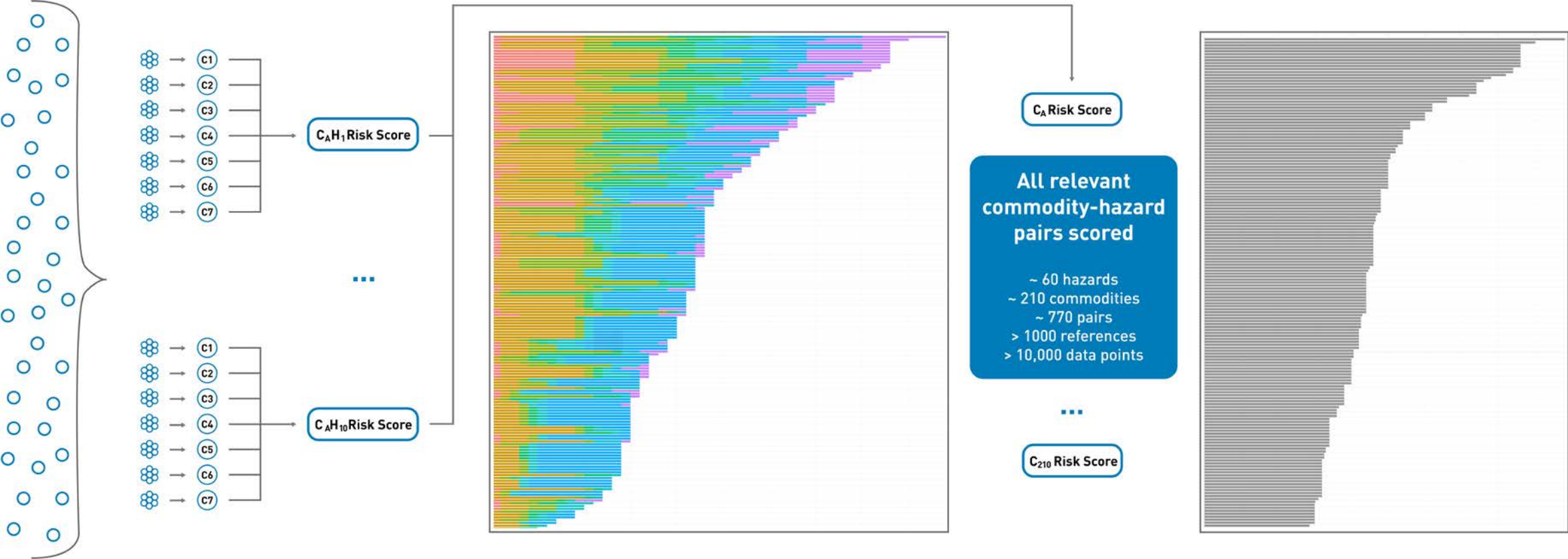
Data Sources

- Published literature
- Government surveys and investigations
- Expert elicitations
- Data calls via Federal Register Notice
 - data and information provided by stakeholders





RRM-FT Scoring and Ranking Process





Interactive RRM-FT Criteria and Results Webpage



Risk-Ranking Model for Food Tracing

This site is best viewed using current versions of Google Chrome, Mozilla Firefox or Microsoft Edge.

[Introduction](#) [Methods and Criteria](#) [RRM-FT Results Table](#) [RRM-FT Results Figure for Commodity-Hazard Pairs](#) [RRM-FT Results Figure for Commodities](#)

The [FDA Food Safety Modernization Act \(FSMA\) section 204](#) (21 U.S. Code § 2223), requires the Food and Drug Administration to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health.

The FDA developed a Risk-Ranking Model for Food Tracing (RRM-FT) as a data-driven science-based decision support tool to assist the Agency in the process of designating a Food Traceability List as required by FSMA Section 204.

This website is designed for users to view the RRM-FT results as well as the risk-ranking methodology. Users can navigate the RRM-FT website through the following tabs:

- **Methods and Criteria:** Click on the “Methods and Criteria” tab to view a description of the seven criteria in the RRM-FT, to download the “Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204” document, and to download the full list of references evaluated and used to obtain data for the scoring of the seven criteria for commodity-hazard pairs in the RRM-FT. This tab also provides an example of how a risk score is calculated for a commodity-hazard pair or for a commodity, as well as examples of how criteria scores are calculated;

The methods document “Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223))” is downloadable here.

[Download the current methods document](#)

The full list of references evaluated and used to obtain data for the scoring of the seven criteria for commodity-hazard pairs in the RRM-FT is downloadable here.

[Download the full list of references](#)

- **RRM-FT Results:** Click on the “RRM-FT Results Table” tab to view a list of the RRM-FT commodity categories, commodities and commodity scores, and commodity-hazard pairs and their scores. Interactive graphs are provided in the “RRM-FT Results Figure for Commodity-Hazard Pairs” and the “RRM-FT Results Figure for Commodities” tabs.

The results can be downloaded at the [Commodity level](#) or at the [Commodity-Hazard pair level](#).

<https://www.cfsanappsexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracing/>



Summary

- To inform designation of the Food Traceability List, FDA developed a risk ranking model that is
 - Aligned with FSMA criteria
 - Systematic
 - Science-based
 - Data driven
 - Peer-reviewed



Designating the Food Traceability List

In developing the Food Traceability List, FDA:

- Focused on biological or acute chemical toxins which pose an immediate public health risk
- Did not include results from the Model related to food allergens
- Did not include results from the Model for food-hazard pairs related to contamination and/or growth at retail or point-of-service



Designating the Food Traceability List

- FDA identified the appropriate level of granularity for the List as being at the level of “commodity”
 - “Tomatoes” rather than “Produce-RAC”
- Commodities and food-hazard pairs were ranked to identify foods for the Food Traceability List
- A commodity was included if there was sufficient evidence of a significant public health risk based on the data in the Model



Food Traceability List

Food Traceability List	Food Traceability List
Cheeses, other than hard cheeses	Sprouts
Shell eggs	Tomatoes
Nut butter	Tropical tree fruits
Cucumbers	Fruits and Vegetables (fresh-cut)
Herbs (fresh)	Finfish, including smoked finfish
Leafy greens, including fresh-cut leafy greens	Crustaceans
Melons	Mollusks, bivalves
Peppers	Ready-to-eat deli salads



Updating the Food Traceability List

- FDA does not anticipate updates to the list to happen very often.
- FDA will periodically review relevant data and information to determine if we need to update the FTL.
- If we tentatively determine we should update the FTL, we would use the process described in the proposed rule, which gives the public an opportunity to provide comment.
- Any additions to the list would generally become effective one year after the date we announce our final decision to make the addition.



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