



FDA

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CENTER FOR FOOD SAFETY & APPLIED NUTRITION

**Methodological Approach to Developing a
Risk-Ranking Model for Food Tracing
FSMA Section 204 (21 U.S. Code § 2223)**

**Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services**

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same period. Most food safety risk-affecting factors are not expected to scale linearly; rather, they are usually multiplicative in nature operating on logarithmic scales. The C1 definitions (Figure 2-2) represent a difference in order-of-magnitude, signifying large differences in public health impact while accommodating data with differing precision. When summing criteria scores to determine a risk score for a food-hazard pair, this scoring strategy is reflective of a risk model that operates on a logarithmic scale.

Weighted Occurrence of Illnesses since 1999	High (Thousands)	3	9	9
	Medium (Hundreds)	1	3	9
	Low (Tens)	1	1	3
		Low	Medium	High
		>0 to ≤1 since 1999	>1 to <10 since 1999	≥10 since 1999

Weighted Frequency of Outbreaks since 1999

Figure 2-2. Scoring definition for frequency of outbreaks and occurrence of illnesses for a food-hazard pair

The scoring definitions in Figure 2-2 apply to microbial hazards that cause acute health effects and that have been involved in an outbreak (27, 43, 68). They apply to pathogenic bacteria (including toxigenic bacteria such as *C. botulinum*, *L. monocytogenes*, *B. cereus*, *Salmonella* spp., STEC O157, and *S. aureus*), viruses, and parasites. The scoring definitions in Figure 2-2 are also used for the C1 scoring for toxins of microbial origin, e.g., histamine, where growth of the associated microorganism(s) may impact toxin production, and for the scoring of C1 for marine and plant biotoxins, e.g., ciguatoxin and other algal toxins, where outbreak data are available. For a food-hazard pair involving a microbial hazard, toxin of microbial origin, or biotoxin for which no outbreaks and no occurrence of illnesses have been reported, expert judgement is used for C1 scoring (including C1=0). The occurrence of illnesses for C1 includes reported outbreak-associated cases only. To minimize the potential of “double counting” illnesses, unscaled outbreak data (i.e., the actual number of cases reported in the outbreak) are used for C1. Non-outbreak associated cases (i.e., sporadic illnesses) are considered in C7 scoring (see section 2.2.7 below), but are not included in C1 scoring.

For undeclared allergens and chemical hazards other than biotoxins, which usually have not been involved in outbreaks, scoring is based on expert elicitation and defined as follows:

For undeclared allergens, and the food-hazard pair under evaluation:

0 = no occurrence of illnesses in the U.S.

packaged product receiving an adequate kill step, with the no potential for post-lethality exposure (and thus low contamination potential), would score C5=1.

Contamination Probability During Manufacturing	High	3	9	9
	Moderate	1	3	9
	Low	1	1	3
		Strong	Moderate	Weak

Steps Taken to Reduce Contamination

Figure 2-3. Scoring for Manufacturing Process Contamination Probability and Industry-wide Intervention

Definitions for “Contamination probability” during manufacturing:

- High: Recurring or frequent detection of contamination
- Moderate: Known history of contamination and sporadic detection of contamination
- Low: Infrequent detection of contamination, contamination introduced post manufacturing, or that data indicate no detection of contamination during manufacturing. Note: Detection of contamination refers to known detection of a microbial hazard, or known detection of a chemical hazard above an action level or allowable level

Definitions for “Steps taken to reduce contamination” (considering industry-wide efforts):

- Strong: Control measures available and adequate, evidence for consistent implementation in industry
- Moderate: Control measures available but lack of an adequate kill step, lack of evidence for consistent implementation, or evidence for inconsistent implementation in industry
- Weak: Lack of adequate control measures, or evidence of poor implementation of control measures in industry

2.2.6 Criterion 6: Consumption

When contaminated, products that are consumed frequently or in large amount, or both frequently and in large amount, are more likely to cause widespread outbreaks or multiple illnesses compared with products consumed less often or eaten by only a limited segment of the population. For scoring of Criterion 6 (C6), consumption is defined as a composite matrix

Subject matter expert (SME) knowledge and judgement	<p>Where data were not available from other sources, SME judgement was elicited and used. This was mainly for the scoring of Criterion 5 (noted above) and data for multiple criteria for chemical hazards and the majority of undeclared allergens. To fill these data gaps, three external expert elicitations were conducted through contracts. After reviewing background material on RRM-FT and detailed information on the scoring process in each criterion, the SMEs individually provided criterion and confidence scores for the identified data gaps and participated in panel discussions, which included a structured process to determine consensus scores. The panel consisted of SMEs with expertise in the fields of microbiology, chemistry, food production and processing, food science, risk assessment, and allergens. FDA SMEs conducted QA/QC of Criterion 5 scores in 2015, and again in 2019, taking into consideration the current state of industry-wide interventions in light of implementation of FSMA and other regulations and guidance (<i>e.g.</i>, (53, 55-57, 76)); scores for selected food-hazard pairs were updated where appropriate.</p>
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5 Risk-Ranking Model

As described in previous sections, the purpose of the risk-ranking model is to calculate the risk scores associated with a comprehensive list of food-hazard pairs across seven criteria. Data and information related to the food-hazard pairs across 47 commodity categories and ~100 hazards were collected. The risk-ranking model database was then populated with these data and information.

The RRM-FT uses a risk scoring algorithm to generate risk scores for food-hazard pairs and aggregated risk scores for commodity or commodity categories based on the underpinning data. Across all data points, raw data values are binned into scoring bins such that scores of 0, 1, 3 and 9 are assigned to each criterion, representing respectively the absence, low, medium, and high degree of an attribute in the scoring definitions. In addition, the data sources used to determine each data point were evaluated to determine a confidence score based on the overall weight of evidence of the available data sources.

5.1 Calculating Risk Score for a Food-Hazard Pair

A risk score for a food-hazard pair is calculated by summing the weighted criteria scores across all seven criteria:

$$RS_{i,j} = \sum_{k=1}^7 w_k \times CS_{k,i,j} \quad \text{Equation [3]}$$

Where:

$RS_{i,j}$ = Risk score associated with i^{th} food and j^{th} hazard

w_k = Weight assigned to criterion k

$CS_{k,i,j}$ = Criterion score for the k^{th} criterion associated with i^{th} food and j^{th} hazard

By default, equal weighting (criteria weight=10) was used to determine the food risk score (referred to as the “baseline” scenario or baseline model). For example, the criterion score for the pair “Food A – Pathogen A” was [1, 9, 3, 9, 3, 1, 9] for Criteria 1 through 7; each given a criterion weight of 10 (for convenience), the risk score $RS = 10 \times (1+9+3+9+3+1+9) = 350$. Non-equal weights can be applied to calculate risk scores for the food-hazard pairs. Alternative scenarios with non-equal weighting schemes were developed in subsequent analysis.

After the risk scores are calculated for individual food-hazard pairs, these risk scores can be used to generate a ranked list for all the food-hazard pairs in the model, or a subset of the food-hazard pairs. For example, a subset can be generated for food-hazard pairs involving microbial hazards and chemical hazards that cause acute effects.

5.2 Calculating Confidence Scores

In addition to calculating risk scores for each food-hazard pair, confidence scores were also generated for each of the seven criteria for each pair. Confidence scores are based on the overall weight of evidence of the available data sources. The confidence score uses a scale of 1, 3 or 9 to correspond to a low, medium, and high level of confidence. More specifically, the confidence level is evaluated based on the availability and quality of data, using definitions shown in Table 5-1, based on the attributes of data and information contributing to confidence evaluation for the scoring of each criterion. These definitions were initially developed based on FDA PAG evaluation of methodologies where some measure of data quality was determined alongside the determination of food allergens of public health importance by Chung *et al.* (11). The external expert panel convened by IFT/RTI also evaluated these definitions and, after the evaluation, did not have additional suggestions or comments on these definitions.

Table 5-1. Scoring for the confidence level of data and information used in the model

Confidence Level	Definition	Confidence Score
High	Strong evidence, based on evaluation using one or more indicators applicable to the data and information required for the criterion. For example: <ul style="list-style-type: none"> a) data from government surveillance and survey, sampling data from a relatively large survey, <i>e.g.</i>, ≥ 100 samples for a food-hazard pair b) data obtained using well documented and accepted methods such as from peer-reviewed papers/reports or high consensus among expert judgements c) data available and of high quality/applicability to the food-hazard pair 	9
Medium	Moderate evidence, for example, using the same indicators as above with varying methods and/or limited documentation, different judgements and medium consensus among expert judgements; medium quality data and medium applicability to the food-hazard pair or use of proxy data	3
Low	Weak evidence, for example, inconclusive evidence or lack of data, poor documentation and/or method of questionable validity, disagreement or lack of judgements among experts	1

Subject matter experts, including those from three external expert panels convened by RTI/IFT, consultation with external experts by FDA in the peer review response process, technical members of the RTI team, the FDA project team and in some cases FDA SMEs, determined the

confidence score for the data and information used to score each criteria based on the definitions provided in Table 5-1. Once the subject matter experts determined the confidence level for the data and information, a score of 9, 3 or 1 is used to represent the confidence level. The information for confidence level for the data (*e.g.*, data for “Growth Potential, with Consideration of Shelf Life.” for a food-hazard pair) is documented together with the data themselves in the RRM-FT database system. For food-hazard pairs in which the food involved does not support pathogen growth or the hazard involved does not grow in food (*e.g.*, chemical hazards or undeclared allergens), “9” would be assigned as the confidence score for Criterion 4 “Growth Potential, with Consideration of Shelf Life.”

For each food-hazard pair, a confidence score is calculated by summing the confidence scores for the seven criteria. Confidence score for a food-hazard pair was calculated as:

$$\text{Confidence Score} = \sum_{k=1}^7 \text{CU}_{k,i,j} \quad \text{Equation [4]}$$

Where:

$\text{CU}_{k,i,j}$ = confidence score for the k^{th} criterion associated with i^{th} food and j^{th} hazard

In the case where a criterion is scored by two data indicators, multiple data sources were required and the score was based on evaluation of the combination of these data points, and thus a composite criteria confidence score was calculated as an average of the scores given for each indicator.

5.3 Aggregation of Risk Scores for Commodities and Commodity Categories

As described above, a risk score for each food-hazard pair was calculated by summing the equally weighted scores for each criterion. The results from the model show that the risk scores for food-hazard pairs encompass a range of values, including a range of risk scores for the same commodity in which multiple food-hazard pairs were identified. In order to facilitate the identification of a list of commodities for which additional recordkeeping requirements will be established, we used the risk scores for food-hazard pairs to determine an aggregated risk score for a commodity or a commodity category through an aggregating process. A total risk score for each commodity, and similarly for commodity category, was determined by aggregating the food-hazard pair risk scores using the method described below.

We evaluated different methodologies to aggregate scores for food-hazard pairs (one food associated with multiple hazards) to a commodity score. The methods included:

- summation of risk scores across all pairs associated with the food;
- calculating the average;
- limiting the number of hazards and then sum the risk scores from only the top pairs;
- assigning the highest food-hazard pair score to the food;

- using the maximum score by individual criterion among all pairs to calculate one commodity risk score;
- sum all food-hazard pairs in each commodity associated with multiple food-hazard pairs (note: this method has a limitation in that it does not differentiate commodities according to differences in risk scores between food-hazard pairs and, therefore, was not further considered in the model development); and
- review the distribution of food-hazard scores for all pairs, identify the pairs above a cut-off, then determine a method to “aggregate” food-hazard pair scores to commodity and commodity category scores.

We subjected the proposed aggregation methods to peer review in which the peer-reviewers were asked to evaluate whether any of the proposed methods was appropriate to aggregate food-hazard pairs in order to facilitate determination of commodities or commodity categories included versus not included on the Food Traceability List, and to identify other aggregation method(s) that might be considered. The peer reviewers indicated drawbacks for all of the proposed options, and suggested several new aggregation methods to address those drawbacks. Based on the peer review comments, we selected one of the suggested methods as the best scientific choice to calculate an aggregated risk score for a commodity or commodity category with multiple food-hazard pairs. The aggregation equation involves exponential transformation, summing and log transformation taking into account the risk scores for all food-hazard pairs under the food, as follows:

$$aggrRS_{i_C} = \log_{10}(\sum_{j=1}^{n_i} 10^{RS_{i,j}}) \quad \text{Equation [5a]}$$

Where,

aggrRS_{i_C} = Aggregated risk score associated with ith commodity
 RS_{i,j} = Risk score associated with ith food and jth hazard
 n_i = Number of hazards associated with ith commodity

As described above, the definitions for criteria scoring represent a difference in order-of-magnitude, where quantitative data were available, and thus help make the summing of criteria scores to determine a risk score for a food-hazard pair reflective of a risk model that operates on logarithmic scales.

When a food has risks attributable to multiple hazards (multiple food-hazard pairs for the same food), the overall risk is the *sum* of the risks, not the *product* of the individual risks. More specifically, adding risk scores that are based on logarithmic scales is logically equivalent to multiplying the risks from each hazard, rather than adding them together to achieve an overall risk estimate. Given this, Equation 5a above is a more appropriate approach to assessing the

combined risk from multiple hazards, by converting the risk estimates to an arithmetic scale, adding the risks together, and then converting the sum back to a logarithmic scale.

For computational reasons, in implementing Equation 5a, the risk scores for the individual food-hazard pairs were scaled downward by dividing by 10. To return to the original scale, the result was then multiplied by 10. As a result, Equation 5a was implemented as:

$$aggrRS_{i-C} = 10 * \log_{10}(\sum_{j=1}^{n_i} 10^{RS_{i,j}/10}) \quad \text{Equation [5b]}$$

The equation was applied similarly to calculate an aggregated risk score for a commodity category. The risk scores associated with all food-hazard pairs in the category (which includes not only multiple hazards but also multiple commodities) were used to determine the aggregated score for the commodity category. Aggregate risk score for a commodity category ($aggrRS_{CC}$), with risk score for each food-hazard pair given by $RS_1, RS_2 \dots RS_n$ for n food-hazard pairs is:

$$aggrRS_{CC} = 10 * (\log_{10} (10^{RS_{1-C}/10} + 10^{RS_{2-C}/10} + 10^{RS_{3-C}/10} + \dots + 10^{RS_{n-C}/10})) \quad \text{Equation [6]}$$

In this more logical approach, the aggregated risk score scales more naturally, and will be less affected by differences in the total number of hazards ascribed to the various food-hazard pairs, or by the total number of food-hazard pairs attributed to various commodities.

5.4 Criteria Weighting and Sensitivity Analysis

The risk score and ranking among the food-hazard pairs can change when non-equal weights are used for the seven criteria. In addition to using equal weights for the seven criteria (weight=10) in the risk-ranking model, the impact of non-equal weighting schemes on the outcome of the risk score and ranking of the food-hazard pairs can also be used.

As described above, an overall risk score for each food-hazard pair is calculated by multiplying the score for each criterion by the weight for that criterion and then sum across the seven criteria. Different weights can be assigned to each of the criteria that describe its importance relative to the others. The process used to identify alternative criteria weighting schemes involved a review of relevant methodologies in the literature, a review of stakeholder comments received on the draft approach of the risk-ranking model as well as expert elicitation. More specifically, the FDA PAG discussed different criteria weighting schemes, and considered an analysis of available methodologies prepared by external experts on different weighting methodologies typically used in multicriteria decision analysis. The PAG also reviewed and considered comments submitted

by stakeholders on criteria weighting, as well as comments by the external peer review-model review panel and peer review.

In the Federal Register Notice, we solicited comments on the specific question: “The draft approach would equally weight the criteria. Should individual weights be assigned to each criterion? If so, which criteria should receive more weight and how should those weights be assigned?” The majority of commenters stated that criteria should not be equally weighted but there were also commenters who indicated that the criteria should be equally weighted. Among those who recommended non-equal weighting, some suggested weighting Criterion 5 (C5, manufacturing process contamination probability and industry-wide intervention) higher as compared to the rest (*i.e.*, recommend Criterion 5 be given the highest multiplier to account for foods which undergo a manufacturing process that significantly reduces the possibility of contamination). Other commenters suggested that Criteria 1 (C1, frequency of outbreaks and occurrence of illnesses), Criterion 3 (C3, likelihood of contamination) and Criterion 5 should be weighted higher. Others further suggested that scoring associated with Criteria 1 and 2 should influence the food-hazard risk score to a greater extent than Criteria 3 through 6, which they believed the latter to be based on assumptions (rather than data). Some commenters additionally indicated that the scoring system of 0, 1, 3, and 9 already results in weighting more heavily the high ranges of the seven proposed criteria. Moreover, commenters suggested that any weighting FDA chooses should be vetted with scientific experts (*i.e.*, be subject to peer review).

Using an expert elicitation process, we considered available methodologies and evaluated different weighting schemes for sensitivity analysis. In the end, four options were identified for non-equal weighting schemes (Table 5-2). These options give emphasis to different aspects of the risk-ranking model: more weight on the epidemiology-related criteria, C1 and C2 (option 1), more weight on the criteria related to the characteristics of foods, C3 and C4 (option 2), more weight on industry-wide manufacturing controls, C5 (option 3), and option 4 that gives more weight for C6 (consumption) and C3 (likelihood of contamination). Option 4 gives less weight to Criterion 4 (growth potential, with consideration of shelf life) and is expected to result in some food-hazard pairs involving chemical hazards and undeclared allergens rising higher in the ranking. We decided to keep the sum of all weights assigned to the seven criteria constant (total 70 points) to aid in comparing results; thus in each of these options there is less weight for one or two other criteria, which are usually C7, C6, or C4. Taking into consideration comments from peer reviewers, the PAG recommended using equal criteria weighting (the baseline scenario) to generate risk-ranking results.

Table 5-2. Options for sensitivity analysis: non-equal weighting schemes compared to the baseline

Criteria	Baseline	Option 1	Option 2	Option 3	Option 4
C1. Frequency of outbreaks and occurrence of illnesses	10	15	10	10	10
C2. Severity of Illness	10	15	10	10	10
C3. Likelihood of contamination	10	10	15	10	15
C4. Growth potential, with consideration of shelf life	10	10	15	10	5
C5. Manufacturing process contamination probability and industry-wide intervention	10	10	10	15	10
C6. Consumption	10	5	5	10	15
C7. Cost of Illness	10	5	5	5	5

In addition, for reasons outlined in the Mutual Independence section below, we used an alternative definition for Criterion 4 outlined in Figure 5-1 to assign a score of 1, 3 or 9 for a food-hazard pair based on the shelf life of the food and the potential for pathogen growth in the product. Shelf life duration is defined as: long, 49 days or longer; moderate, 15-48 days; and short, 14 days or less.

Growth Potential	Strong	3	9	9
	Moderate	1	3	9
	Low	1	1	3
		Short	Moderate	Long
		Shelf Life		

Figure 5-1. Alternative Scoring Growth Potential, with Consideration of Shelf Life

Assign C4=0 for food-hazard pairs in which the hazard does not multiply in food (*e.g.*, chemical, allergen, virus and parasite) or the food does not support pathogen growth.

5.5 Further Considerations

As described in the Introduction section, we chose a multicriteria-based risk-ranking model to account for the factors required in FSMA 204(d)(2)(a). We did not choose a quantitative risk assessment approach in part because of the lack of data to predict risk of illness for all food-hazard pairs of interest. In developing the RRM-FT, there were several special considerations.

Among key issues are granularity of food definition, and mutual independence of criteria, and value functions used in scoring definitions.

Granularity of food definition

In the model, we evaluated the potential impact of two levels of granularity of food definition: commodity category and commodity. Given the same hazard, the model was used to score food-hazard pairs involving the food defined at a more or less granular level using the same seven criteria, *e.g.*, Dairy – Cheese and Cheese Products or different types of cheese (*e.g.*, fresh soft cheese, soft-ripened cheese, and hard cheese, Produce – RAC or different types of fresh produce (*e.g.*, leafy greens and melons).

Mutual Independence of Criteria, and Scoring Matrices and Definitions

Mutual independence of criteria is desirable in a multicriteria-based model (20, 85). In the RRM-FT, we developed a set of criteria that are “operationalizable” with minimum overlap, which is desirable when a multicriteria decision analysis approach is used (20). In cases where criteria are correlated it is important to define them to represent separate aspects of value to help ensure that the criteria represent independent preferences in ranking.

Among the seven criteria in the model, there are some unavoidable correlations or overlaps of data-informing criteria. One set is Criterion 2 “Severity of Illness” and Criterion 7 “Cost of Illness.” An illness with greater severity is likely to incur a higher cost for health-related cost of illness. To minimize potential overlap, we defined the scoring of Criteria 7 to account for both the total number of cases/year (taking into account under reporting and under diagnosis which differ among pathogens) and the public health cost per case, the latter being the aspect that correlates with the severity of illness. The other set is Criterion 3 “Likelihood of contamination” and Criterion 5 “Manufacturing process contamination probability and industry-wide intervention”. We defined C3 “Likelihood of contamination” as the overall contamination of the finished product (at consumer purchase or at consumption) while “Manufacturing process contamination” is defined as contamination introduced during manufacturing as part of the scoring matrix that also includes an indicator to account for steps taken to control contamination, *e.g.*, whether manufacturing process at an industry-wide level can and will control contamination. We formulated the criteria definitions so that the two sets of criteria, while correlated to some extent, represent as much as possible separate aspects of value.

Some of the limitations inherent in using risk matrices were described in stakeholder comments. For example, the comments included an analysis of desirable properties for risk matrices that had been reported in the literature, *e.g.*, by Cox 2008 (13). We took into consideration the comments and specifically revised the definitions for Criteria 1 (Figure 2-2), Criterion 4 alternative definitions (Figure 5-1, considered in our sensitivity analysis) and Criterion 5 (Figure 2-3) to

ensure the scores of 1 and 9 are not located adjacent to each other in the scoring matrix, a desirable property. Furthermore, the scoring matrices in the model pertain to how data are used to generate a risk score for ranking, which is different from the risk matrices described in the stakeholder comments and the study by Cox (2008) that pertain to the risk-ranking results themselves.

Multicriteria decision analysis models are also known to be sensitive to the value functions defined. The RRM-FT uses a scoring scale of 0, 1, 3, and 9 rather than a linear scale of 1, 2, 3, and 4, for example. The rationale behind this is that risk is not necessarily on a linear scale. Using essentially a logarithmic scale was also recommended by the external panel in the expert elicitation process and the peer reviewers in the model review panel. Furthermore, using the 0-1-3-9 scale facilitates a greater degree of differentiation between higher versus lower ranked food-hazard pairs, useful for informing the designation of the Food Traceability List. In addition, to address concerns about potential high volatility in the model around value functions, the model is designed to include the ability to use different criteria weighting schemes in sensitivity analysis. We identified several options for alternative weighting schemes, and results from the sensitivity analysis can be considered in determining which commodities or commodity categories are considered high vs. not high-ranked.

As is the case with all multi-criteria decision analysis models, results from the RRM-FT rank alternatives based on risk (as defined by the FSMA-mandated factors) but it does not directly quantify risk to the consumer (*e.g.*, the probability of illnesses). The approach we took is based on an evaluation of published risk-ranking studies, *e.g.*, reported by Anderson *et al.* 2011 (1), EFSA 2013 (15), and FAO/WHO 2014 (19). Others have reported the use of multicriteria-based approach to risk-ranking that include different value functions in the scoring definitions and different criteria weights, *e.g.*, for risk-ranking of emerging zoonoses by Havelaar *et al.* 2010 (23), foodborne parasites on a global scale by FAO/WHO 2014 (19), and exotic diseases in pigs by Brookes 2014 (6). In these other studies, scores and weights are mainly based on public health concerns and, in some cases, non-public health concerns (*e.g.*, economics and trade). The RRM-FT uses a similar approach but includes new types of data and information; in representing the FSMA required factors, the RRM-FT presented in this report is the first to include criteria specifically on food manufacturing processes.

5.6 Conclusion

The RRM-FT serves as a tool for continuously improving our understanding of the relative risks of foods and hazards. In the process of model development and refinement, we took into consideration comments from external peer reviewers for both the modeling approach and the underpinning data, including revision of the modeling approach, adding more food-hazard pairs, incorporating additional data, and refinements to finalize the model. The Risk-Ranking Model for Food Tracing provides FDA with a risk-based decision support tool to assist the Agency in the process of designating the Food Traceability List as required by FSMA Section 204 (21 U.S. Code § 2223).

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Appendix A. Commodity Categories and Commodities in the RRM-FT Model

The tables below show a list of the commodity categories (**Table A-1**) and commodities (**Table A-2**) for human foods in the RRM-FT. These commodity categories correspond to the appropriate commodity categories in the Reportable Food Registry, *i.e.*, RFR commodity definitions (82).

Table A-1. RRM-FT Commodity Categories with Associated RFR Commodity Categories

No.	RFR Commodity Category ^a	RRM-FT Commodity Categories (N=47)
1	Acidified / LACF ^a	Acidified/LACF - Baby (Infant and Junior) Food Products
2	Acidified / LACF	Acidified/LACF - N.E.C. ^a
3	Bakery	Bakery Products Dough, and Bakery Mixes
4	Bakery	Bakery - N.E.C.
5	Beverages	Beverages - Alcoholic Beverages
6	Beverages	Beverages - Beverage Bases
7	Beverages	Beverages - Coffee and Teas
8	Beverages	Beverages - Juices ^b
9	Beverages	Beverages - Soft Drinks and Waters
10	Beverages	Beverages - N.E.C.
11	Breakfast Cereals	Breakfast Cereals
12	Chocolate/Confections/Candy	Chocolate and Cocoa Products
13	Chocolate/Confections/Candy	Confections/Candy with Chocolate
14	Chocolate/Confections/Candy	Confections/Candy Without Chocolate, Candy Specialties, and Chewing Gum
15	Dairy	Dairy - Cheese and Cheese Products
16	Dairy	Dairy - Dried Milk Products
17	Dairy	Dairy - Fermented dairy products other than cheese ^c
18	Dairy	Dairy - Ice Cream and Related
19	Dairy	Dairy - Milk, Butter, Cream
20	Dairy	Dairy - N.E.C.
21	Dressings/Sauces/Gravies	Dressings/Sauces/Gravies
22	Egg	Eggs
23	Frozen Foods	Frozen Foods
24	Fruit and Vegetable Products	Fruit and Fruit Products ^d
25	Fruit and Vegetable Products	Vegetable and Vegetable Products ^e
26	Fruit and Vegetable Products	Vegetable Protein Products (<i>e.g.</i> , simulated Meats)
27	Game Meats	Game Meats

No.	RFR Commodity Category ^a	RRM-FT Commodity Categories (N=47)
28	Meal Replacement/Nutritional Food and Beverages	Meal Replacement/Nutritional Food and Beverages
	Multiple Food Products ^a	[not applicable]
29	Nuts, Nut Products, and Seed Products	Nuts and Nut Products
30	Nuts, Nut Products, and Seed Products	Seeds (Edible Seeds) and Seed Products
31	Oil/Margarine	Oil/Margarine
32	Pasta	Pasta - Dried Pasta
33	Pasta	Pasta - N.E.C.
34	Prepared Foods	Prepared Food - Refrigerated and Ready-to-Eat Salads
35	Prepared Foods	Prepared Foods - N.E.C.
36	Produce- Fresh Cut	Produce - Fresh Cut
37	Produce- RAC ^f	Produce - RAC
38	Seafood	Seafood - Finfish
39	Seafood	Seafood - Invertebrates
40	Seafood	Seafood - N.E.C.
41	Snack Foods	Snack Foods
42	Soup	Soup - not LACF
43	Spices/Seasonings	Spices/Seasonings
44	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
45	Sweeteners	Sweeteners
46	Whole & Milled Grains and Flours	Whole & Milled Grains and Flours
47	Other	Commodity Category N.E.C.

^a One of the 28 RFR Commodity Categories (“Multiple Food Products”) was removed from the list of RRM-FT Commodity Categories because: this category is less defined in the RFR definitions; a small number of foods identified in this category can be classified into other commodity categories, *e.g.*, RTE Dinners to "Frozen Food" category; salad kits and snack kits to "Prepared Foods" category; "chocolate candy with nuts and fruits" to "Confections/Candy with Chocolate" category. LACF: Low-Acid Canned Food. N.E.C: Not Elsewhere Classified.

^b See 21 CFR 120 Juice HACCP regulation for definition. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

^c examples: yogurt, Greek yogurt, drinkable yogurt, and other fermented milks and other dairy products

^d Not including fruit juices or juice concentrates (see Beverage-Juices Category).

^e Not including vegetable juices or juice concentrates (see Beverage-Juices Category).

^f RAC stands for Raw Agricultural Commodities.

Table A-2. RRM-FT Commodities Organized by Commodity Categories

Commodity	Commodity Category
Baby food	Acidified/LACF - Baby (Infant and Junior) Food Products
Canned broth, chicken or beef	Acidified/LACF - N.E.C.
Canned fruits and vegetables	Acidified/LACF - N.E.C.
Canned seafood	Acidified/LACF - N.E.C.
Cheese sauce (shelf-stable)	Acidified/LACF - N.E.C.
Diet and nutritional drinks (shelf-stable)	Acidified/LACF - N.E.C.
Milk (shelf-stable, not condensed)	Acidified/LACF - N.E.C.
Soups (canned)	Acidified/LACF - N.E.C.
Croutons	Bakery - N.E.C.
Tortilla	Bakery - N.E.C.
Waffles and toasts	Bakery - N.E.C.
Bakery mixes	Bakery Products, Dough, and Bakery Mixes
Batters and breading	Bakery Products, Dough, and Bakery Mixes
Biscuits	Bakery Products, Dough, and Bakery Mixes
Bread and rolls (fresh and frozen)	Bakery Products, Dough, and Bakery Mixes
Cakes	Bakery Products, Dough, and Bakery Mixes
Cookies	Bakery Products, Dough, and Bakery Mixes
Desserts fillings and toppings	Bakery Products, Dough, and Bakery Mixes
Dough	Bakery Products, Dough, and Bakery Mixes
Pancakes	Bakery Products, Dough, and Bakery Mixes
Pastries	Bakery Products, Dough, and Bakery Mixes
Pies	Bakery Products, Dough, and Bakery Mixes
Alcoholic beverages	Beverages - Alcoholic Beverages
Beverage mixes	Beverages - Beverage Bases
Flavored drink syrups	Beverages - Beverage Bases
Coffee	Beverages - Coffee and Teas
Tea	Beverages - Coffee and Teas
Fruit and vegetable juices (high-acid)	Beverages - Juices
Fruit and vegetable juices (low-acid)	Beverages - Juices
Smoothies	Beverages - Juices
Hot chocolate	Beverages - N.E.C.
Ice	Beverages - N.E.C.
Non-dairy beverages	Beverages - N.E.C.
Non-dairy milk	Beverages - N.E.C.

Commodity	Commodity Category
Bottled water	Beverages - Soft Drinks and Waters
Soft drinks	Beverages - Soft Drinks and Waters
Boxed cereals	Breakfast Cereals
Granola	Breakfast Cereals
Instant cereals	Breakfast Cereals
Chocolate products other than candy	Chocolate and Cocoa Products
Imitation bacon	Commodity Category N.E.C.
Imitation cheese, non-milk	Commodity Category N.E.C.
Chocolate candies and bars	Confections/Candy with Chocolate
Chocolate fudge	Confections/Candy with Chocolate
Confections or coatings	Confections/Candy Without Chocolate, Candy Specialties, and Chewing Gum
Frosting or icing	Confections/Candy Without Chocolate, Candy Specialties, and Chewing Gum
Cheese (made from pasteurized milk), fresh soft or soft unripened	Dairy - Cheese and Cheese Products
Cheese (made from pasteurized milk), hard	Dairy - Cheese and Cheese Products
Cheese (made from pasteurized milk), soft ripened or semi-soft	Dairy - Cheese and Cheese Products
Cheese (made from unpasteurized milk), hard	Dairy - Cheese and Cheese Products
Cheese (made from unpasteurized milk), other than hard cheese	Dairy - Cheese and Cheese Products
Whey powder	Dairy - Cheese and Cheese Products
Dried milk	Dairy - Dried Milk Products
Cultured products (excluding yogurt)	Dairy - Fermented dairy products other than cheese
Yogurt	Dairy - Fermented dairy products other than cheese
Ice cream	Dairy - Ice Cream and Related
Butter	Dairy - Milk, Butter, Cream
Buttermilk	Dairy - Milk, Butter, Cream
Condensed milk	Dairy - Milk, Butter, Cream
Cream (heavy or light or whipping)	Dairy - Milk, Butter, Cream
Milk (flavored)	Dairy - Milk, Butter, Cream
Milk (fluid and white and Grade-A pasteurized)	Dairy - Milk, Butter, Cream
Dips and spreads (dairy-based)	Dairy - N.E.C.
Eggnog	Dairy - N.E.C.

Commodity	Commodity Category
Condiments	Dressings/Sauces/Gravies
Dips (non dairy-based)	Dressings/Sauces/Gravies
Dry powder dips	Dressings/Sauces/Gravies
Gravies (liquid)	Dressings/Sauces/Gravies
Guacamole	Dressings/Sauces/Gravies
Marinades	Dressings/Sauces/Gravies
Salad dressings	Dressings/Sauces/Gravies
Salsa (fresh)	Dressings/Sauces/Gravies
Sauces	Dressings/Sauces/Gravies
Egg dishes	Eggs
Shell eggs	Eggs
Shell eggs (hard boiled)	Eggs
Coconut products (frozen)	Frozen Foods
Frozen meals	Frozen Foods
Fruits (frozen)	Frozen Foods
Pizza (frozen)	Frozen Foods
Vegetables (frozen)	Frozen Foods
Apple butter	Fruit and Fruit Products
Apple juice concentrate	Fruit and Fruit Products
Apple sauce	Fruit and Fruit Products
Fruits (dried)	Fruit and Fruit Products
Jams and jellies	Fruit and Fruit Products
Bear	Game Meats
Bison	Game Meats
Boar	Game Meats
Guinea pig	Game Meats
Opossum	Game Meats
Quail	Game Meats
Rabbit	Game Meats
Seal	Game Meats
Venison	Game Meats
Whale	Game Meats
Dietary supplements	Meal Replacement/Nutritional Food and Beverages
Dry instant breakfast	Meal Replacement/Nutritional Food and Beverages

Commodity	Commodity Category
Energy shakes and drinks	Meal Replacement/Nutritional Food and Beverages
Infant formula	Meal Replacement/Nutritional Food and Beverages
Meal shake and meal replacement products (raw)	Meal Replacement/Nutritional Food and Beverages
Medical foods	Meal Replacement/Nutritional Food and Beverages
Powdered drinks	Meal Replacement/Nutritional Food and Beverages
Nut butters	Nuts and Nut Products
Nut meal and powder	Nuts and Nut Products
Peanuts	Nuts and Nut Products
Whole shelled tree nuts	Nuts and Nut Products
Fats and oils	Oil/Margarine
Pasta (dried)	Pasta - Dried Pasta
Macaroni	Pasta - N.E.C.
Noodles	Pasta - N.E.C.
Pasta (filled)	Pasta - N.E.C.
Pasta (fresh or refrigerated)	Pasta - N.E.C.
Pasta (frozen)	Pasta - N.E.C.
RTE Deli salads	Prepared Food - Refrigerated and Ready-to-Eat Salads
Appetizers and prepared dishes	Prepared Foods - N.E.C.
Egg rolls	Prepared Foods - N.E.C.
Falafel	Prepared Foods - N.E.C.
Finfish (battered or breaded)	Prepared Foods - N.E.C.
Finfish (cooked)	Prepared Foods - N.E.C.
Macaroni and cheese	Prepared Foods - N.E.C.
Pasta dishes	Prepared Foods - N.E.C.
Potatoes (cooked)	Prepared Foods - N.E.C.
Rice dishes	Prepared Foods - N.E.C.
RTE dinners	Prepared Foods - N.E.C.
Salad kits	Prepared Foods - N.E.C.
Sandwiches	Prepared Foods - N.E.C.
Snacks and snack kits	Prepared Foods - N.E.C.
Stuffings	Prepared Foods - N.E.C.

Commodity	Commodity Category
Avocado, processed	Produce - Fresh Cut
Fruits (fresh-cut)	Produce - Fresh Cut
Leafy greens (fresh-cut)	Produce - Fresh Cut
Salads (fresh-cut)	Produce - Fresh Cut
Vegetables other than leafy greens (fresh-cut)	Produce - Fresh Cut
Berries (fresh)	Produce - RAC
Citrus	Produce - RAC
Corn	Produce - RAC
Crucifers	Produce - RAC
Cucumbers	Produce - RAC
Fresh pods and legumes	Produce - RAC
Fungi	Produce - RAC
Grapes	Produce - RAC
Herbs (fresh)	Produce - RAC
Leafy greens	Produce - RAC
Melons	Produce - RAC
Microgreens	Produce - RAC
Peppers	Produce - RAC
Pit fruits	Produce - RAC
Pome fruits	Produce - RAC
Root and tuber vegetables	Produce - RAC
Root vegetables (not eaten raw)	Produce - RAC
Sprouts	Produce - RAC
Squash, summer	Produce - RAC
Stem vegetables	Produce - RAC
Sugar crops	Produce - RAC
Tomatoes	Produce - RAC
Tropical tree fruits	Produce - RAC
Tropical fruits N.E.C.	Produce - RAC
Finfish (reduced oxygen-packaged)	Seafood - Finfish
Finfish, species not associated with histamine or ciguatoxin	Seafood - Finfish
Finfish, histamine-producing species	Seafood - Finfish
Finfish, species potentially contaminated with ciguatoxin	Seafood - Finfish
Semi-preserved fish	Seafood - Finfish

Commodity	Commodity Category
Smoked finfish	Seafood - Finfish
Crustaceans	Seafood - Invertebrates
Molluscan shellfish, bivalves	Seafood - Invertebrates
Squid	Seafood - Invertebrates
Alligator	Seafood - N.E.C.
Finfish (dried or salted)	Seafood - N.E.C.
Fish eggs	Seafood - N.E.C.
Frog legs	Seafood - N.E.C.
Octopus	Seafood - N.E.C.
Snails	Seafood - N.E.C.
Sushi	Seafood - N.E.C.
Hummus	Seeds (Edible Seeds) and Seed Products
Seed butters	Seeds (Edible Seeds) and Seed Products
Seeds (shelled)	Seeds (Edible Seeds) and Seed Products
Seeds meal or powder	Seeds (Edible Seeds) and Seed Products
Chips	Snack Foods
Crackers	Snack Foods
Gelatin desserts	Snack Foods
Novelty snacks	Snack Foods
Popcorn	Snack Foods
Pretzels	Snack Foods
Pudding	Snack Foods
Sorbet (frozen)	Snack Foods
Trail mix and granola bars	Snack Foods
Dry soup mixes	Soup - not LACF
Fresh or refrigerated soups	Soup - not LACF
Ramen	Soup - not LACF
Salt	Spices/Seasonings
Spices	Spices/Seasonings
Flavorings	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
Gelatin	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
Gums and thickeners	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
Hydrolyzed vegetable proteins	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers

Commodity	Commodity Category
Soy and egg lecithin	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
Starches	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
Yeast or yeast extracts	Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers
Honey	Sweeteners
Sugar	Sweeteners
Fried foods	Vegetable and Vegetable Products
Process fruits and vegetables	Vegetable and Vegetable Products
Tofu and tofu products	Vegetable and Vegetable Products
Vegetables (dried)	Vegetable and Vegetable Products
Imitation meat product	Vegetable Protein Products (simulated Meats)
Corn meal	Whole & Milled Grains and Flours
Flours (wheat or rice or soy)	Whole & Milled Grains and Flours
Grains	Whole & Milled Grains and Flours
Grits	Whole & Milled Grains and Flours
Oatmeal	Whole & Milled Grains and Flours

Appendix B. Hazards in the RRM-FT Model

Table B-1 shows a list of hazards in the RRM-FT model. The hazards are classified into three main categories: microbial agents, chemical agents, and undeclared allergens.

Table B-1. Hazards Included in the RRM-FT Model

No.	Hazard Sub-Type	Hazard (N=101)
<i>Microbial Hazards</i>		
1	Bacteria	<i>Aeromonas</i> spp.
2	Parasite	<i>Anisakis simplex</i>
3	Bacteria	<i>Bacillus cereus</i>
4	Bacteria	<i>Brucella</i> spp.
5	Bacteria	<i>Campylobacter</i> spp.
6	Parasite	Cestodes
7	Bacteria	<i>Clostridium botulinum</i>
8	Bacteria	<i>Clostridium perfringens</i>
9	Bacteria	<i>Cronobacter</i> spp.
10	Parasite	<i>Cryptosporidium parvum</i> or other spp.
11	Parasite	<i>Cyclospora cayetanensis</i>
12	Bacteria	<i>E. coli</i> , other pathogenic (EA) ^a
13	Bacteria	<i>E. coli</i> , other pathogenic (ETEC) ^b
14	Bacteria	<i>Enterococcus faecalis</i>
15	Parasite	<i>Giardia</i> spp.
16	Virus	Hepatitis A virus
17	Bacteria	<i>Listeria monocytogenes</i>
18	Virus	Norovirus
19	Parasite	<i>Paragonimus</i> spp.
20	Parasite	Parasites
21	Bacteria	<i>Plesiomonas shigelloides</i>
22	Virus	Rotavirus
23	Bacteria	<i>Salmonella</i> spp.
24	Bacteria	<i>Salmonella enterica</i> – serovar paratyphi

No.	Hazard Sub-Type	Hazard (N=101)
25	Bacteria	<i>Salmonella enterica</i> – serovar typhi
26	Marine biotoxin	Scombroid toxin (Histamine) ^c
27	Bacteria	<i>Shigella</i> spp.
28	Bacteria	<i>Staphylococcus aureus</i>
29	Bacteria	STEC non-O157 ^c
30	Bacteria	STEC O157 ^c
31	Parasite	<i>Toxoplasma gondii</i>
32	Parasite	Trematodes
33	Parasite	<i>Trichinella spiralis</i>
34	Parasite	<i>Trypanosoma cruzi</i>
35	Bacteria	<i>Vibrio cholerae</i>
36	Bacteria	<i>Vibrio parahaemolyticus</i>
37	Bacteria	<i>Vibrio vulnificus</i>
38	Bacteria	<i>Yersinia enterocolitica</i>
39	Bacteria	<i>Yersinia pseudotuberculosis</i>
Chemical Hazards		
40	Chemical	2- and 4-methylimidazoles
41	Chemical	Acrylamide
42	Chemical	Aluminum
43	Marine biotoxin	Amnesic shellfish poisoning (ASP) ^d
44	Antibiotic	Antibiotics
45	Chemical	Arsenic (inorganic)
46	Marine biotoxin	Azaspiracid shellfish poisoning (AZP)
47	Chemical	Benzene
48	Marine biotoxin	Brevitoxins (NSP) ^d
49	Chemical	Cadmium
50	Chemical	Chloropropanols
51	Chemical	Chromium, Selenium
52	Marine biotoxin	Ciguatoxin
53	Chemical	Colloidal silver

No.	Hazard Sub-Type	Hazard (N=101)
54	Biotoxin	Cucurbitacin toxin
55	Chemical	Dioxins
56	Marine biotoxin	Escolar toxin
57	Chemical	Ethyl carbamate
58	Antibiotics	Flumequine
59	Chemical	Fluoride
60	Chemical	Furan
61	Biotoxin	Grayanotoxins
62	Chemical	Heterocyclic amines
63	Biotoxin	Hypoglycin A toxin
64	Chemical	Lead
65	Chemical	Melamine
66	Chemical	Methanol
67	Pesticide	Methomyl
68	Chemical	Methyl mercury
69	Fungus/Mycotoxins	Mycotoxins ^e - Aflatoxins
70	Fungus/Mycotoxins	Mycotoxins - Aflatoxin M1
71	Fungus/Mycotoxins	Mycotoxins - Deoxynivalenol
72	Fungus/Mycotoxins	Mycotoxins - Fumonisin
73	Fungus/Mycotoxins	Mycotoxins - Ochratoxin A
74	Fungus/Mycotoxins	Mycotoxins - Patulin
75	Fungus/Mycotoxins	Mycotoxins - Afl DON Fum OTA ^e
76	Fungus/Mycotoxins	Mycotoxins - Afl OTA
77	Fungus/Mycotoxins	Mycotoxins - DON OTA
78	Chemical	Niacin (over exposure)
79	Pesticide	Nicotine
80	Chemical	Nitrates/Nitrites
81	Marine biotoxin	Okadaic acid (DSP) ^f
82	Chemical	PAHs ^g
83	Chemical	PAHs - PHAH ^g

No.	Hazard Sub-Type	Hazard (N=101)
84	Chemical	PBDEs ^g
85	Chemical	PCBs ^g
86	Chemical	PCDDs/PCDFs ^g
87	Chemical	Perchlorate
88	Pesticide	Pesticides
89	Chemical	Polydimethylsiloxane
90	Marine biotoxin	Rhabdomyolysis ^h
91	Marine biotoxin	Saxitoxin (PSP) ^h
92	Marine biotoxin	Tetrodotoxin
93	Chemical	Tin
94	Antibiotic	Veterinary drugs
<i>Undeclared Allergens and Related</i>		
95	Undeclared Allergens-like	Undeclared Sulfites
96	Undeclared Allergens	Undeclared allergens
97	Undeclared Allergens	Undeclared allergens (other than crustaceans) ⁱ
98	Undeclared Allergens	Undeclared allergens (other than fish) ⁱ
99	Undeclared allergens	Undeclared allergens (other than milk) ⁱ
100	Undeclared allergens	Undeclared allergens (other than nuts) ⁱ
101	Undeclared allergens	Undeclared allergens (other than shellfish) ⁱ

^a EA = Enterococci

^b ETEC = Enterotoxigenic *E. coli*

^c Scombroid toxin includes consideration of histamine-producing bacteria; STEC = Shiga-toxin producing *E. coli*

^d Amnesic shellfish poisoning (ASP) (*a.k.a.* domoic acid);

NSP = Neurologic shellfish poisoning, *a.k.a.* Brevetoxins

^e From growth of molds in food. Afl DON Fum OTA = Aflatoxins, Deoxynivalenol, Fumonisin and Ochratoxin A

^f DSP = Diarrhetic shellfish poisoning

^g Chemical Hazard Abbreviations:

PAHs = Polycyclic Aromatic Hydrocarbons;

PBDs = Polybrominated Diphenyl Ethers;

PCBs = Polychlorinated Biphenyls;

PCDDs = Polychlorinated Dibenzodioxins;

PCDFs = Polychlorinated Dibenzofurans;

PHAH = Polyhalogenated Aromatic Hydrocarbons

^h Rhabdomyolysis (*e.g.*, from Buffalo fish)

PSP = Paralytic shellfish poisoning

ⁱ Food indicated after “other than” is in a food-hazard pair involving this hazard (*i.e.*, the food is self-declared)

Appendix C. Considerations for Identifying a New Food-Hazard Pair for RRM-FT

Table C-1. Considerations for identifying a new food-hazard pair

Considerations for identification
Food is regulated by FDA
The food-hazard pair is not already in the RRM-FT
<p>The food-hazard pair meets any of the following observations using data since the last update:</p> <ul style="list-style-type: none"> ▪ Associated with at least one outbreak in the CDC outbreak database or the FDA CORE database ▪ Identified as risk factor in case-control study of sporadic illness in the U.S. ▪ Reported in RFR reports, or resulted in food recalls for FDA regulated product in the U.S. ▪ Reported in FDA sampling, eLEXNET, or a published study of detection of a microbial hazard in food (<i>e.g.</i>, for microbial hazards in the FDA Bag Bud Book, 2nd ed.), and of detection of a chemical hazard above an action level of a level of concern ▪ Appears in European Commission Rapid Alert System for Food and Feed (RASFF) notifications list ▪ Reported in a published risk assessment ▪ Improved granularity of commodity definition, hazard or food-hazard pairs in RRM-FT suggested by FDA subject matter experts ▪ Suggested by subject matter experts, with supporting references or information ▪ Suggested by peer-reviewers, with supporting references or information

Most often new food-hazard pairs involve known food-safety hazards, such as those that were previously reported in the FDA or CDC outbreak database, the FDA Bad Bug Book (2nd edition) (68), or that have been addressed by FDA in guidance documents. For an emerging hazard that has not been previously recognized, the Bradford-Hill considerations (25, 44) below can be taken into consideration. A food-hazard pair involving an emerging hazard can be considered for inclusion as a candidate for scoring using the RRM-FT model, if the food is of relevance to the U.S. diet, and the food-hazard pair meets the plausibility and coherence considerations and at least one other consideration in Table C-2.

Table C-2. Considerations for identifying a food-hazard pair involving an emerging hazard

Bradford-Hill Considerations	Description
Strength	There is a strong relationship between exposure to the food-hazard pair and illness (<i>e.g.</i> , outbreaks, case-control studies, FoodNet population studies, PulseNet data).
Consistency	There are multiple observations of a hazard being likely to occur in a food (<i>e.g.</i> , recalls, positive test results).
Specificity	Illness has been predicted from exposure to hazard (<i>e.g.</i> , risk assessment).
Temporality	There is evidence that exposure to food-hazard pair precedes illness (<i>e.g.</i> , outbreaks, sporadic cases).
Dose-Response	There is evidence of a direct relationship between the level of hazard exposure and the risk of illness.
Plausibility	It is biologically plausible that the hazard can occur in the food or cause illness in humans (<i>e.g.</i> , by expression of known virulence factors).
Coherence	The food-hazard pair “makes sense” given current knowledge about the food supply and food safety.
Experimental Evidence	There is experimental evidence suggesting that hazard exposure causes illness (<i>e.g.</i> , in vitro work, animal models, human volunteer experiments, including control groups in vaccine trials) or that the hazard can occur in the food (prevalence studies, RFR reports).
Analogy	The food supports the growth/maintenance of a similar hazard (<i>e.g.</i> , if STEC O157 is known hazard for food then STEC non-O157 should also be considered) or hazard is associated with a similar food (<i>e.g.</i> , <i>Cyclospora</i> in raspberries and strawberries).