



























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 >0 to ≤1 since 1999	Medium >1 to <10 since 1999	High ≥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. 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 would have a C1=0 assigned. 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.
- 1 = fewer than 10 illnesses per year in the U.S.
- 3 = 10 to 100 illnesses per year in the U.S.
- 9 = more than 100 illnesses per year 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.

<b>Contamination Probability During Manufacturing</b>	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





























- 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<sub>i\_C</sub> = Aggregated risk score associated with i<sup>th</sup> commodity  
 RS<sub>i,j</sub> = Risk score associated with i<sup>th</sup> food and j<sup>th</sup> hazard  
 n<sub>i</sub> = Number of hazards associated with i<sup>th</sup> 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.

<b>Growth Potential</b>	Strong	3	9	9
	Moderate	1	3	9
	Low	1	1	3
		Short	Moderate	Long
		<b>Shelf Life</b>		

**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 a more 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).



## 6 References

1. Anderson, M., L. Jaykus, S. Beaulieu, and S. Dennis. 2011. Pathogen-produce pair attribution risk ranking tool to prioritize fresh produce commodity and pathogen combinations for further evaluation (P<sup>3</sup>ARRT). *Food Control*. 22:1865-1872.
2. Batz, M. B., S. Hoffmann, and J. G. Morris Jr. 2011. Ranking the risks: the 10 pathogen-food combinations with the greatest burden on public health. Emerging Pathogens Institute, University of Florida. Available at: <http://www.epi.ufl.edu/sites/www.epi.ufl.edu/files/>. Accessed April 5, 2012.
3. Belton, V., and T. J. Stewart. 2002. Multiple Criteria Decision Analysis: An Integrated Approach. Kluwer Academic Publishers, Norwell, Massachusetts.
4. Bernard, D. T., K. E. Stevenson, and V. N. Scott. 2006. Hazard analysis, appendix 8-B. p. 57-68. *In*, HACCP: a Systematic Approach to Food Safety Food Products Association, Washington, D.C.
5. Beuchat, L. R., D. W. Schaffner, and Versar. 2016. Expert consultation on risk ranking model for product tracing data review and response. Report to FDA, November 22, 2016.
6. Brookes, V. 2014. Stakeholder-driven prioritization of exotic diseases for the Australian pig industry using multi-criteria decision analysis. International Association for Food Protection (IAFP) Symposium S5 – Ranking More Than Risk: Multicriteria Approaches to the Prioritization of Foodborne and Zoonotic Pathogens. IAFP Annual Meeting, August 3-6, Indianapolis, Indiana.
7. Center for Science in the Public Interest (CSPI). 2012. Outbreak Alert! Database Available at: <http://www.cspinet.org/foodsafety/outbreak/pathogen.php>. Accessed June 15, 2013.
8. Centers for Disease Control and Prevention. 2017. Foodborne Outbreak Online Database (FOOD), United States, 1998-2015. Available at: <http://wwwn.cdc.gov/foodborneoutbreaks/>. Accessed August 4, 2017.
9. Centers for Disease Control and Prevention. 2019. National Health and Nutrition Examination Survey (NHANES) database, 2011-2012, 2013-2014, and 2015-2016 cycles. Available at: <https://www.cdc.gov/nchs/nhanes/wweia.htm>. Accessed October 16, 2019.
10. Centers for Disease Control and Prevention. 2019. National Outbreak Reporting System (NORS), United States, 1999-2017. Available at: <https://www.cdc.gov/nors/index.html>. Accessed November 20, 2019.
11. Chung, Y., S. Ronsmans, R. Crevel, G. Houben, R. Rona, R. Ward, and A. Baka. 2012. Application of scientific criteria to food allergens of public health importance. *Regulatory Toxicology and Pharmacology*. 64:315-323.
12. ComBase Consortium. 2019. ComBase and predictive models. Available at: <https://www.combase.cc/index.php/en/>. Accessed December 10, 2019.

13. Cox, L. A. 2008. What's wrong with risk matrices? *Risk Analysis*. 28:497-512.
14. Danyluk, M. D., L. M. Friedrich, and D. W. Schaffner. 2014. Modeling the growth of *Listeria monocytogenes* on cut cantaloupe, honeydew and watermelon. *Food Microbiology*. 38:52-55.
15. European Food Safety Authority. 2013. Scientific Opinion on the risk posed by pathogens in food of non-animal origin. Part 1 (outbreak data analysis and risk ranking of food/pathogen combinations). *EFSA Journal*. 11:3025.
16. European Food Safety Authority (EFSA). 2013. Publications. Available at: <http://www.efsa.europa.eu/en/publications.htm>. Accessed June 7, 2013.
17. European Union. 2019. Rapid Alert System for Food and Feed (RASFF). Available at: [https://ec.europa.eu/food/safety/rasff\\_en](https://ec.europa.eu/food/safety/rasff_en). Accessed December 16, 2019.
18. Feng, P. C., and S. P. Reddy. 2014. Prevalence and diversity of enterotoxigenic *Escherichia coli* strains in fresh produce. *Journal of Food Protection*. 77:820-823.
19. Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO). 2014. Multicriteria-based ranking for risk management of food-borne parasites. Microbiological Risk Assessment Series 23. FAO/WHO, Rome. Available at: <http://www.fao.org/docrep/010/y5394e/y5394e00.htm>. Accessed August 28, 2015.
20. Goetghebeur, M. M. 2011. Lessons learned from a multicriteria decision analysis (MCDA) framework. Workshop on Country-Level Decision Making for Control of Chronic Diseases. July 19-21, Institute of Medicine, Washington, DC. Available at: <http://iom.nationalacademies.org/activities/global/controlchronicdiseases/2011-jul-19.aspx>. Accessed August 28, 2015.
21. Gombas, D. E., Y. Chen, R. S. Clavero, and V. N. Scott. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *Journal of Food Protection*. 66:559-69.
22. Grocery Manufacturers Association (GMA). 2009. Control of *Salmonella* in low-moisture foods. Available at: <http://www.gmaonline.org/downloads/technical-guidance-and-tools/SalmonellaControlGuidance.pdf>. Accessed April 5, 2012.
23. Havelaar, A. H., F. Van Rosse, C. Bucura, M. A. Toetenel, J. A. Haagsma, D. Kurowicka, J. H. A. Heesterbeek, N. Speybroeck, M. F. Langelaar, and J. W. van der Giessen. 2010. Prioritizing emerging zoonoses in the Netherlands. *PloS One*. 5:e13965.
24. Hoelzer, K., R. Pouillot, and S. Dennis. 2012. *Listeria monocytogenes* growth dynamics on produce: A review of the available data for predictive modeling. *Foodborne Pathogens and Disease*. 9:661-673.
25. Höfler, M. 2005. The Bradford Hill considerations on causality: a counterfactual perspective. *Emerging Themes in Epidemiology*. 2:11. doi:10.1186/1742-7622-2-11.

26. Interagency Food Safety Analytics Collaboration. 2019. Foodborne illness source attribution estimates for 2017 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. GA and D.C.: U.S. Department of Health and Human Services, CDC, FDA, USDA-FSIS. Available at: <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2017-report-TriAgency-508.pdf>. Accessed January 9, 2019.
27. International Commission on Microbiological Specifications for Foods. 2005. Microorganisms in Foods 6: Microbial Ecology of Food Commodities, 2nd ed. Kluwer Academic/Plenum Publishers, New York.
28. International Commission on Microbiological Specifications for Foods (ICMSF). 2001. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. pp. 145-166, Chapter 8. Selection of cases and attributes plans, Appendix 8-A. New York: Kluwer Academic/Plenum Publishers.
29. Li, D., L. M. Friedrich, M. D. Danyluk, L. J. Harris, and D. W. Schaffner. 2013. Development and validation of a mathematical model for growth of pathogens in cut melons. *Journal of Food Protection*. 76:953-958.
30. Luchansky, J. B., Y. Chen, A. C. Porto-Fett, R. Pouillot, B. A. Shoyer, R. Johnson-DeRycke, D. R. Eblen, K. Hoelzer, W. K. Shaw Jr, J. M. Van Doren, M. Catlin, J. Lee, R. Tikekar, D. Gallagher, J. A. Lindsay, Lm MBS Team, and S. Dennis. 2017. Survey for *Listeria monocytogenes* in and on ready-to-eat foods from retail establishments in the United States (2010 through 2013): assessing potential changes of pathogen prevalence and levels in a decade. *Journal of Food Protection*. 80:903-921.
31. Mejlholm, O., A. Gunvig, C. Borggaard, J. Blom-Hanssen, L. Mellefont, T. Ross, F. Leroi, T. Else, D. Visser, and P. Dalgaard. 2010. Predicting growth rates and growth boundary of *Listeria monocytogenes*—An international validation study with focus on processed and ready-to-eat meat and seafood. *International Journal of Food Microbiology*. 141:137-150.
32. Minor, T., A. Lasher, K. Klontz, B. Brown, C. Nardinelli, and D. Zorn. 2015. The per case and total annual costs of foodborne illness in the United States. *Risk Analysis*. 35:1125-1139.
33. Mishra, A., M. Guo, R. L. Buchanan, D. W. Schaffner, and A. K. Pradhan. 2017. Development of growth and survival models for *Salmonella* and *Listeria monocytogenes* during non-isothermal time-temperature profiles in leafy greens. *Food Control*. 71:32-41.
34. Montville, T. J., and K. R. Matthews. 2013. Physiology, growth, and inhibition of microbes in foods. p. 3-18. In M.P. Doyle, and R.L. Buchanan (ed.), *Food Microbiology: Fundamentals and Frontiers* American Society of Microbiology, Washington DC.
35. National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 2010. Parameters for determining inoculated pack/challenge study protocols. *Journal of Food Protection*. 73:140.

36. National Institute for Public Health and the Environment (Netherlands RIVM). 2013. Technical reports by the National Institute for Public Health and the Environment: Ministry of Health, Welfare, and Sport. Available at: <https://www.rivm.nl/en/Search/Library>. Accessed June 17, 2013.
37. Nguyen, K. T. N., and D. Ryu. 2014. Concentration of ochratoxin A in breakfast cereals and snacks consumed in the United States. *Food Control*. 40:140-144.
38. Painter, J., R. M. Hoekstra, T. Ayers, R. V. Tauxe, C. R. Braden, F. J. Angulo, and P. M. Griffin. 2013. Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998-2008. *Emerging Infectious Diseases*. 19:407-415.
39. Painter, J. A., T. Ayers, R. Woodruff, E. Blanton, N. Perez, R. M. Hoekstra, P. M. Griffin, and C. Braden. 2009. Recipes for foodborne outbreaks: a scheme for categorizing and grouping implicated foods. *Foodborne Pathogens and Disease*. 6:1259-1264.
40. Pennotti, R., E. Scallan, L. Backer, J. Thomas, and F. J. Angulo. 2013. Ciguatera and scombroid fish poisoning in the United States. *Foodborne Pathogens and Disease*. 10:1059-1066.
41. Reddy, S. P., H. Wang, J. K. Adams, and P. C. Feng. 2016. Prevalence and characteristics of *Salmonella* serotypes isolated from fresh produce marketed in the United States. *Journal of Food Protection*. 79:6-16.
42. Richardson, L. C., M. C. Bazaco, C. C. Parker, D. Dewey-Mattia, N. Golden, K. Jones, K. Klontz, C. Travis, J. Z. Kufel, and D. Cole. 2017. An updated scheme for categorizing foods implicated in foodborne disease outbreaks: a tri-agency collaboration. *Foodborne Pathogens and Disease*. 14:701-710.
43. Ross, T. 2008. Microbial ecology in food safety risk assessment. p. 51-97. In D.W. Schaffner (ed.), *Microbial Risk Analysis of Foods* American Society of Microbiology, Washington DC.
44. Rothman, K. J., and S. Greenland. 2005. Causation and causal inference in epidemiology. *American Journal of Public Health*. 95:S144-S150.
45. Salazar, J. K., S. N. Sahu, I. M. Hildebrandt, L. Zhang, Y. Qi, G. Liggins, A. R. Datta, and M. L. Tortorello. 2017. Growth kinetics of *Listeria monocytogenes* in cut produce. *Journal of Food Protection*. 80:1328-1336.
46. Scallan, E., R. Hoekstra, F. Angulo, R. Tauxe, M. Widdowson, S. Roy, J. Jones, and P. Griffin. 2011. Foodborne illness acquired in the United States - major pathogens. *Emerging Infectious Diseases*. 17:7-15.
47. Scharff, R. L. 2012. Economic burden from health losses due to foodborne illness in the United States. *Journal of Food Protection*. 75:123-131.

48. Scharff, R. L. 2018. The economic burden of foodborne illness in the United States. p. 123-142. *In* T. Roberts (ed.), Food Safety Economics Springer, New York.
49. Scott, V. N., Y. Chen, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. A. Smoot, S. Hood, J. Shebuski, and J. Banks. 2009. Control of *Salmonella* in low-moisture foods I: minimizing entry of *Salmonella* into a processing facility. *Food Protection Trends*. 29:342-353.
50. Scott, V. N., and K. E. Stevenson. 2006. HACCP: a Systematic Approach to Food Safety. Food Products Association, Washington, D.C.
51. Stewart, T. J. 1992. A critical survey on the status of multiple criteria decision making theory and practice. *Omega International Journal of Management Science*. 20:569-586.
52. U. S. Department of Agriculture Agricultural Marketing Service. 2019. Microbiological Data Program (MDP) 2001-2012. Available at: <https://www.ams.usda.gov/datasets/mdp>. Accessed December 16, 2019.
53. U. S. Food and Drug Administration. 2015. Guidance for industry: questions and answers regarding the final rule, Prevention of *Salmonella* Enteritidis in shell eggs during production, storage, and transportation. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-final-rule-prevention-salmonella-enteritidis-shell>. Accessed December 16, 2019.
54. U. S. Food and Drug Administration. 2015. Multicriteria-based ranking model for risk management of animal drug residues in milk and milk products. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm>. Accessed July 2, 2015.
55. U. S. Food and Drug Administration. 2018. Draft guidance for industry: foreign supplier verification programs for importers of food for humans and animals. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-foreign-supplier-verification-programs-importers-food-humans-and-animals>. Accessed December 16, 2019.
56. U. S. Food and Drug Administration. 2018. Draft guidance for industry: hazard analysis and risk-based preventive controls for human food. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>. Accessed December 16, 2019.
57. U. S. Food and Drug Administration. 2018. Draft guidance for industry: standards for the growing, harvesting, packing, and holding of produce for human consumption. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-standards-growing-harvesting-packing-and-holding-produce-human-consumption>. Accessed December 16, 2019.

58. U.S. Department of Agriculture Agricultural Research Service. 2019. Pathogen Modeling Program (PMP) Online. Available at: <https://pmp.errc.ars.usda.gov/PMPOnline.aspx>. Accessed December 4, 2019.
59. U.S. Department of Health and Human Services Food and Drug Administration and U.S. Department of Agriculture Food Safety and Inspection Service. 2003. Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm183966.htm>. Accessed October 22, 2015.
60. U.S. Food and Drug Administration. 2005. Quantitative risk assessment on the public health impact of pathogenic *Vibrio parahaemolyticus* in raw oysters. Available at: <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm050421.htm>. Accessed April 5, 2012.
61. U.S. Food and Drug Administration. 2008. Guidance for industry: control of *Listeria monocytogenes* in refrigerated or frozen ready-to-eat foods; Draft guidance. Available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodProcessingHACCP/ucm073110.htm>. Accessed October 22, 2015.
62. U.S. Food and Drug Administration. 2008. Guidance for industry: guide to minimize microbial food safety hazards of fresh-cut fruits and vegetables. Available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm>. Accessed December 20, 2017.
63. U.S. Food and Drug Administration. 2009. Guidance for industry: measures to address the risk for contamination by *Salmonella* species in food containing a peanut-derived product as an ingredient. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm169160.htm>. Accessed December 20, 2017.
64. U.S. Food and Drug Administration. 2010. Leafy greens survey report (analysis of samples for *Salmonella*, *Shigella*, enterohemorrhagic *E. coli*, shiga toxin-producing *E. coli* and other organisms). FDA unpublished data.
65. U.S. Food and Drug Administration. 2010. Tomatoes survey report (analysis of samples for *Salmonella*). FDA unpublished data.
66. U.S. Food and Drug Administration. 2011. Guidance for industry: measures to address the risk for contamination by *Salmonella* species in food containing a pistachio-derived product as an ingredient. Available at: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm169160.htm>. Accessed December 20, 2017.
67. U.S. Food and Drug Administration. 2011. Leafy greens survey report (analysis of samples for *Salmonella*, *L. monocytogenes*, and enterohemorrhagic *E. coli*). FDA unpublished data.

68. U.S. Food and Drug Administration. 2012. Bad Bug Book: Handbook of Foodborne Pathogenic Microorganisms and Natural Toxins, 2nd ed. Available at: <https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition>. Accessed December 16, 2019.
69. U.S. Food and Drug Administration. 2013. Food Code 2013. Annex 3. Public health reasons/administrative guidelines. Available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf>. Accessed December 20, 2017.
70. U.S. Food and Drug Administration. 2015. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule. *Federal Register*. 80:55908-56168.
71. U.S. Food and Drug Administration. 2015. Food allergies: What you need to know. Available at: <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079311.htm>. Accessed May 11, 2015.
72. U.S. Food and Drug Administration. 2015. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule. *Federal Register*. 80:74353-74568.
73. U.S. Food and Drug Administration. 2015. Summary of data submitted to Docket FDA-2013-N-0747 on contamination of *Salmonella* in different treenuts by the Almond Board of California, California Walnut Board, Administrative Committee for Pistachios, and National Pecan Shellers Association.
74. U.S. Food and Drug Administration. 2015. Summary of preventive control regulations and guidance for FDA-regulated food commodities.
75. U.S. Food and Drug Administration. 2015. Survey of *L. monocytogenes* in refrigerated ready-to-eat food: smoked seafood, seafood salads, fresh crab meat and sushi (Seafood); low acid cut fruits, cut vegetables, sprouts (Produce); soft ripened and semi-soft cheese, artisanal cheese, raw milk, cultured milk product (Dairy); deli-type salad, sandwiches (Combination Foods); and eggs. Analysis of pH and  $a_w$  in selected samples. (FDA/ARS/FSIS Market Basket Survey, compiled data 2015). FDA unpublished data.
76. U.S. Food and Drug Administration. 2017. Draft guidance for industry: control of *Listeria monocytogenes* in ready-to-eat foods. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods>. Accessed December 16, 2019.
77. U.S. Food and Drug Administration. 2017. FY 2014 – 2016 microbiological sampling assignment summary report: sprouts. Available at: <https://www.fda.gov/Food/ComplianceEnforcement/Sampling/ucm566966.htm>. Accessed October 26, 2017.

78. U.S. Food and Drug Administration. 2019. Coordinated Outbreak Response and Evaluation (CORE) Network: outbreaks of foodborne illness - outbreak investigations by year. Available at: <https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness>. Accessed December 16, 2019.
79. U.S. Food and Drug Administration. 2019. The Electronic Laboratory Exchange Network (eLEXNET). Available at: <https://elexnet.fda.gov/elex/>. Accessed December 16, 2019.
80. U.S. Food and Drug Administration. 2019. Microbiological surveillance sampling. Available at: <https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling>. Accessed December 16, 2019.
81. U.S. Food and Drug Administration. 2019. Recalls, market withdrawals, and safety alerts. Available at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>. Accessed December 16, 2019.
82. U.S. Food and Drug Administration. 2019. Reportable Food Registry for industry: Commodity Definitions and Annual Report. Available at: <https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry> and <https://www.fda.gov/media/78732/download> (RFR commodity definitions). Accessed December 16, 2019.
83. U.S. Food and Drug Administration. 2019. Total Diet Study data. Available at: <https://www.fda.gov/food/science-research-food/total-diet-study>. Accessed December 16, 2019.
84. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition and the Joint Institute for Food Safety and Applied Nutrition and Risk Sciences International. 2017. FDA-iRISK<sup>®</sup> 4.0: Food Safety Modeling Tool Technical Document. Available at: <https://irisk.foodrisk.org/Documents/FDAiRISKTechnicalDocumentation.pdf>. Accessed January 23, 2018.
85. U.S. Food and Drug Administration. 2015. Multicriteria-based ranking model for risk management of animal drug residues in milk and milk products. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm>. Accessed July 2, 2015.
86. Veys, O., S. d. O. Elias, I. Sampers, and E. C. Tondo. 2016. Modelling the growth of *Salmonella* spp. and *Escherichia coli* O157 on lettuce. *Procedia Food Science*. 7:168-172.
87. World Health Organization (WHO). 2013. Data and statistics. Available at: <http://www.who.int/research/en>. Accessed June 7, 2013.
88. World Health Organization (WHO). 2013. Publications. Available at: <http://www.who.int/publications/en>. Accessed June 7, 2013.



## 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 <sup>a</sup>	RRM-FT Commodity Categories (N=47)
1	Acidified / LACF <sup>a</sup>	Acidified/LACF - Baby (Infant and Junior) Food Products
2	Acidified / LACF	Acidified/LACF - N.E.C. <sup>a</sup>
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 <sup>b</sup>
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 <sup>c</sup>
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	Egg
23	Frozen Foods	Frozen Foods
24	Fruit and Vegetable Products	Fruit and Fruit Products <sup>d</sup>
25	Fruit and Vegetable Products	Vegetable and Vegetable Products <sup>e</sup>
26	Fruit and Vegetable Products	Vegetable Protein Products ( <i>e.g.</i> , simulated Meats)
27	Game Meats	Game Meats

No.	RFR Commodity Category <sup>a</sup>	RRM-FT Commodity Categories (N=47)
28	Meal Replacement/Nutritional Food and Beverages	Meal Replacement/Nutritional Food and Beverages
	Multiple Food Products <sup>a</sup>	[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 <sup>f</sup>	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.

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> examples: yogurt, Greek yogurt, drinkable yogurt, and other fermented milks and other dairy products

<sup>d</sup> Not including fruit juices or juice concentrates (see Beverage-Juices Category).

<sup>e</sup> Not including vegetable juices or juice concentrates (see Beverage-Juices Category).

<sup>f</sup> RAC stands for Raw Agricultural Commodities.

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

<b>Commodity</b>	<b>Commodity Category</b>
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)	Acidified/LACF - N.E.C.
Soups (canned)	Acidified/LACF - N.E.C.
Croutons	Bakery - N.E.C.
Tortilla	Bakery - N.E.C.
Waffles and toast	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
Smoothie	Beverages - Juices
Hot chocolate	Beverages - N.E.C.
Ice	Beverages - N.E.C.
Non-dairy beverage	Beverages - N.E.C.
Non-dairy milk	Beverages - N.E.C.

<b>Commodity</b>	<b>Commodity Category</b>
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 candy 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	Dairy - Cheese and Cheese Products
Cheese (made from pasteurized milk), hard	Dairy - Cheese and Cheese Products
Cheese (made from pasteurized milk), soft or 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.

<b>Commodity</b>	<b>Commodity Category</b>
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	Egg
Shell eggs	Egg
Shell eggs (hard boiled)	Egg
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

<b>Commodity</b>	<b>Commodity Category</b>
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 butter	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.
Stuffing	Prepared Foods - N.E.C.

<b>Commodity</b>	<b>Commodity Category</b>
Avocado, processed	Produce - Fresh Cut
Fruits (Fresh-cut)	Produce - Fresh Cut
Leafy Greens (Fresh-cut)	Produce - Fresh Cut
Salad (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 Fruit	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 crop	Produce - RAC
Tomatoes	Produce - RAC
Tropical Tree Fruit	Produce - RAC
Tropical Fruit N.E.C.	Produce - RAC
Finfish, reduced oxygen-packaged	Seafood - Finfish
Finfish, species not associated with histamine or ciguatoxin	Seafood - Finfish
Open ocean finfish (histamine-producing species)	Seafood - Finfish
Reef finfish (potentially contaminated with ciguatoxin)	Seafood - Finfish
Semi-preserved fish	Seafood - Finfish

<b>Commodity</b>	<b>Commodity Category</b>
Smoked Finfish	Seafood - Finfish
Crustaceans	Seafood - Invertebrates
Mollusks, bivalve	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 butter	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 Soup	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



<b>Commodity</b>	<b>Commodity Category</b>
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)
<b><i>Microbial Hazards</i></b>		
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) <sup>a</sup>
13	Bacteria	<i>E. coli</i> , other pathogenic (ETEC) <sup>b</sup>
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) <sup>c</sup>
27	Bacteria	<i>Shigella</i> spp.
28	Bacteria	<i>Staphylococcus aureus</i>
29	Bacteria	STEC non-O157 <sup>c</sup>
30	Bacteria	STEC O157 <sup>c</sup>
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>
<b>Chemical Hazards</b>		
40	Chemical	2- and 4-methylimidazoles
41	Chemical	Acrylamide
42	Chemical	Aluminum
43	Marine biotoxin	Amnesic shellfish poisoning (ASP) <sup>d</sup>
44	Antibiotic	Antibiotics
45	Chemical	Arsenic (inorganic)
46	Marine biotoxin	Azaspiracid Shellfish Poisoning (AZP)
47	Chemical	Benzene
48	Marine biotoxin	Brevitoxins (NSP) <sup>d</sup>
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 <sup>e</sup> - 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 <sup>e</sup>
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) <sup>f</sup>
82	Chemical	PAHs <sup>g</sup>
83	Chemical	PAHs - PHAH <sup>g</sup>

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

<sup>a</sup> EA = Enteroaggregative

<sup>b</sup> ETEC = Enterotoxigenic *E. coli*

<sup>c</sup> Scombroid toxin includes consideration of histamine-producing bacteria; STEC = Shiga-toxin producing *E. coli*

<sup>d</sup> Amnesic shellfish poisoning (ASP) (*a.k.a.* domoic acid);

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

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

<sup>f</sup> DSP = Diarrhetic shellfish poisoning

<sup>g</sup> Chemical Hazard Abbreviations:

PAHs = Polycyclic Aromatic Hydrocarbons;

PBDs = Polybrominated Diphenyl Ethers;

PCBs = Polychlorinated Biphenyls;

PCDDs = Polychlorinated Dibenzodioxins;

PCDFs = Polychlorinated Dibenzofurans;

PHAH = Polyhalogenated Aromatic Hydrocarbons

<sup>h</sup> Rhabdomyolysis (*e.g.*, from Buffalo fish)

PSP = Paralytic shellfish poisoning

<sup>i</sup> 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"> <li>▪ Associated with at least one outbreak in the CDC outbreak database or the FDA CORE database</li> <li>▪ Identified as risk factor in case-control study of sporadic illness in the U.S.</li> <li>▪ Reported in RFR reports, or resulted in food recalls for FDA regulated product in the U.S.</li> <li>▪ 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, 2<sup>nd</sup> ed.), and of detection of a chemical hazard above an action level of a level of concern</li> <li>▪ Appears in European Commission Rapid Alert System for Food and Feed (RASFF) notifications list</li> <li>▪ Reported in a published risk assessment</li> <li>▪ Improved granularity of commodity definition, hazard or food-hazard pairs in RRM-FT suggested by FDA subject matter experts</li> <li>▪ Suggested by subject matter experts, with supporting references or information</li> <li>▪ Suggested by peer-reviewers, with supporting references or information</li> </ul>

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 (2<sup>nd</sup> 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**

<b>Bradford-Hill Considerations</b>	<b>Description</b>
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).