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

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Abbreviations

CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CVM	Center for Veterinary Medicine (FDA)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FOOD	Foodborne Outbreak Online Database (CDC)
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
ICMSF	International Commission on Microbiological Specifications for Foods
IFT	Institute of Food Technologists
LACF	Low-Acid Canned Food
MDP	Microbiological Data Program (USDA)
N.E.C.	Not Elsewhere Classified
NHANES	National Health and Nutrition Examination Survey
NORS	National Outbreak Reporting System (CDC)
NRTE	Not-Ready-To-Eat
OFPR	Office of Food Policy and Response (FDA)
OPLIA	Office of Policy, Legislation and International Affairs (FDA)
OFVM	Office of Foods and Veterinary Medicine (FDA, previous)
PAG	Project Advisory Group (FDA)
QALD	Quality-Adjusted Life Day
RAC	Raw Agricultural Commodity
RASFF	Rapid Alert System for Food and Feed (EU)
RFR	Reportable Food Registry (FDA)
RRM-FT	Risk-Ranking Model for Food Tracing
RS	Risk Score (for food-hazard pair)
RS_C	Risk Score for Commodity
RS_CC	Risk Score for Commodity Category
RTE	Ready-To-Eat
SME	Subject Matter Expert
STEC	Shiga Toxin-Producing *Escherichia coli*
TDS	Total Diet Study (FDA)
USDA	United States Department of Agriculture
WHO	World Health Organization

1 Introduction

The FDA Food Safety Modernization Act (FSMA) section 204 (21 U.S. Code § 2223), requires the Food and Drug Administration ("FDA" or "we") to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. These additional recordkeeping requirements will make it easier to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak, and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded. The FDA developed a risk-ranking model as a data-driven science-based decision support tool to assist the Agency in the process of designating a Food Traceability List as required by FSMA Section 204. The semi-quantitative risk-ranking model scores food-hazard pairs according to data and seven criteria: (1) Frequency of Outbreaks and Occurrence of Illnesses, (2) Severity of Illness, (3) Likelihood of Contamination, (4) Growth Potential, with Consideration of Shelf Life, (5) Manufacturing Process Contamination Probability and Industry-wide Intervention, (6) Consumption, and (7) Cost of Illness. These criteria are consistent with the requirements in FSMA section 204(d)(2)(A) (21 U.S. Code § 2223(d)(2)(A)).

1.1 FSMA Requirements for Food Traceability List Designation

FSMA section 204(d)(2)(A) requires that the designation of a Food Traceability List must be based on the historical public health significance of the food with respect to outbreaks and cases of foodborne disease, as well as a number of factors related to food characteristics and manufacturing processes.

The specific statutory factors to be considered are:

i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;

ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;

iii) the point in the manufacturing process of the food where contamination is most likely to occur;

iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

1.2 Process for Developing a Risk-Ranking Model to Inform the Designation of the Food Traceability List

A risk-ranking model was developed for human foods regulated by FDA to inform the designation of foods on a Food Traceability List. Considering the broad range of FDA-regulated foods, we developed an overall approach and process that includes, among other things, the following steps:

Develop a draft model approach. This involved using the statutory factors and decision analysis methodology to define criteria and scoring of the criteria for a risk-ranking model.

Collect data and implement the model. This involved collecting data relevant to the scoring criteria for identified food-hazard pairs, developing the model code, and implementing the model to determine a risk score for each food-hazard pair.

Determine ranking for food-hazard pairs and foods. This involved ranking food-hazard pairs based on risk scores, developing methodologies for further analysis to aggregate scores for foods in which multiple hazards occur and, separately, to generate a ranked list of commodities and commodity categories.

The FDA developed the Risk-Ranking Model for Food Tracing (RRM-FT) in consultation with an FDA Project Advisory Group (PAG) consisting of members from CFSAN, the FDA's Office of Foods and Veterinary Medicine, Office of Food Policy and Response, Office of Policy, Legislation and International Affairs, Center for Veterinary Medicine, and Office of Regulatory Affairs, and the Centers for Disease Control and Prevention. Contracts with RTI International and the Institute of Food Technologists (IFT) provided technical assistance that included conducting several expert elicitations from external expert panels and a contract with Versar, Inc. provided external and internal peer reviews. The overarching process involved in the model development is summarized in Figure 1-1.

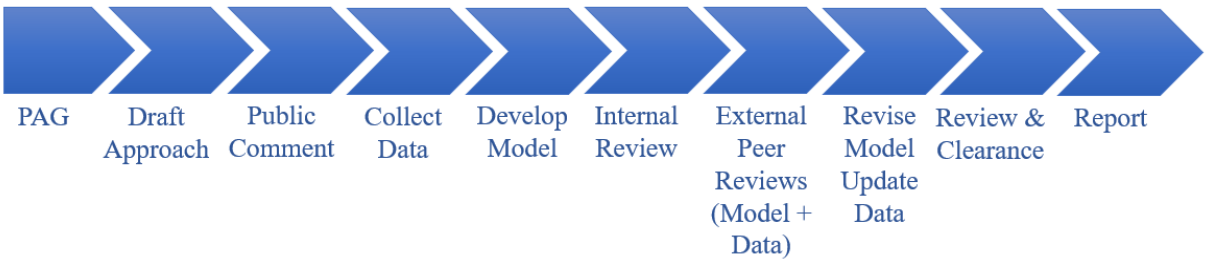

Figure 1-1. Overall Process for RRM-FT Development and Refinement

Our first step was formulating a draft approach for developing a RRM-FT and publishing it in the Federal Register for public comment (79 FR 6596 (Feb. 4, 2014)). We then refined the approach, taking into consideration the public comments received. We developed a draft model and collected data to populate the model, with technical assistance from external expert panels. We conducted an extensive internal review of the model and data with Agency subject-matter experts. Two separate peer-review panels of independent external experts reviewed a draft model and the data used to generate risk scores with the model, respectively. Subsequently, we finalized the model and updated the data, taking into consideration comments from the peer reviews. Figure 1-1 shows the overarching process where some of the steps are iterative, *e.g.*, data collection also took place following internal review, as well as subsequent to peer reviews to update and refine the scoring of food-hazard pairs.

To assist in the process of developing the RRM-FT, FDA contracted with RTI and IFT to provide technical and logistical support. Together these contracts included activities to collect data from the literature, compile data provided by FDA, conduct three expert elicitations to fill data gaps, design a system to store and manage data, and develop a draft risk-ranking model. FDA updated the data and model to respond to comments and suggestions from external peer reviewers to generate risk-ranking results.

As noted above, we sought public comments early in the development of the model. In the published Federal Register Notice (79 RF 6596) and the associated docket (Docket FDA-2014-N-0053), we sought public comments on the initial draft modeling approach and solicited scientific data and information to help refine the approach. Some of the specific issues on which we invited comments included: alternative approaches, whether or not the criteria should be weighted equally, changes in the scoring system, and how foods should be categorized. We received 52 submissions from stakeholders including industry and consumer groups, academic and governmental institutions, and individual citizens.

With regard to the contribution of the FDA PAG to the overall process, the FDA PAG discussed and made decisions on how to address key issues in the modeling approach, and revised the approach, where appropriate, taking into consideration public comments and peer review comments. The PAG also provided subject matter expertise to evaluate data, refine scoring, where appropriate, and to explore additional scenarios (see section 5.4 Criteria Weighting and Sensitivity Analysis) relevant to developing the RRM-FT and using it to generate a ranked list of commodities or commodity categories.

2 Risk-Ranking Model Approach

In developing an approach for a risk-ranking model to inform the designation of foods on a Food Traceability List, we took into consideration the FSMA mandated factors, the policy objective and specific questions to be addressed as well as the availability of data, methods, and resources. We reviewed available risk tools developed by FDA and others from the published literature, ranging from qualitative, semi-quantitative, and quantitative methods. Examples of different methods and their application include: 1) qualitative decision trees or risk rules, such as a likelihood-severity grid for qualitative risk-ranking by Bernard *et al. (4)*; 2) semi-quantitative risk scoring, such as the FDA produce risk-ranking model reported by Anderson *et al. (1)* and the multicriteria-based ranking model for animal drug residues in milk and milk products by FDA *(54)*; 3) foodborne illness attribution model by Batz *et al. (2)*; and 4) quantitative risk assessment models, including comparative risk assessment / risk-ranking such as the 2003 FDA/FSIS *Listeria monocytogenes* in ready-to-eat (RTE) foods risk assessment *(59)*, and predictive models such as the *Vibrio parahaemolyticus* in raw oysters risk assessment *(60)*, and the FDA-iRISK® quantitative risk assessment and risk-ranking tool *(84)*.

We selected a semi-quantitative risk-ranking model and adapted the approach to account for the specific factors required in FSMA section 204 (d)(2)(A). We selected this approach for in-depth evaluation following the review of a variety of methods and tools developed for identifying, ranking, comparing, and prioritizing food safety risks, including multicriteria decision analysis methodology *(1, 3, 51)* and qualitative and quantitative risk assessment methods and tools described above. This approach, including proposed criteria and scoring, was shared with stakeholders through a Federal Register Notice (79 RF 6596) and evaluated by peer reviewers through the external peer review process.

After consideration of public comments and the external peer review, we determined that a semi-quantitative risk-ranking modeling approach is the most appropriate approach for informing the designation of the Food Traceability List, because (a) it is data-driven and comprehensive, using explicit criteria related to public health risk; (b) it can be adapted to a variety of foodborne hazards (microbial and chemical contamination, including undeclared allergens); (c) it can be designed to include the full spectrum of FDA-regulated commodities or commodity categories; (d) it can integrate a diversity of data and information; and (e) it provides a means for considering all of the specific factors to be considered in designation of the Food Traceability List required in FSMA section 204 (d)(2)(A) and linking those factors to develop a risk score. Using this approach, FDA is able to rank, on the basis of the specified public health risk criteria, food-hazard pairs, and subsequently, foods regulated by the FDA.

2.1 Food Classification

In order to apply the factors specified in FSMA section 204(d)(2)(A), it is necessary to take into account both the characteristics of foods and known or reasonably foreseeable hazards, *i.e.*, to consider food-hazard pairs.

The objective of the food category classification scheme was to develop a comprehensive list of food-hazard pairs to be used as candidates for scoring in the model. We initially classified commodity categories based on the Reportable Food Registry (RFR) commodity definitions *(82)*. There are 28 RFR commodity categories and the definitions take into account food characteristics as well as manufacturing processes (*e.g.*, fresh-cut produce, acidified/low-acid canned foods).

We sought additional input on food classification schemes from an external expert panel (the first of two panels convened by IFT/RTI). The experts evaluated two different classification schemes – the RFR commodity categories and the CDC commodity groups *(38, 39)* – which could be applied for classification of foods in the risk-ranking model. The external panel indicated that the RFR commodity categories are designed to facilitate industry reporting, while the CDC groups are mainly based on food type or origin (*e.g.*, aquatic, land, plant) to facilitate outbreak analysis. When determining food classification for the risk-ranking model, the experts recommended following the RFR commodity categories for two main reasons: i) the RFR categorization scheme is much more in line with FDA's regulatory framework that emphasizes preventive controls; for example, LACF/Acidified Foods is classified as a category based on the hazard of concern associated with LACF (*Clostridium botulinum*); and ii) the available CDC approach did not explicitly consider the form of processing (*e.g.*, raw vs. cooked), which is a key consideration in estimating risk.

Through the Federal Register notice, we sought public comments on what other practical alternatives to the RFR food categorization scheme should be considered, in light of the practical constraints of evaluating individual commodities. We considered the public comments received and refined the food classification scheme based on the 28 RFR commodity categories using relevant Industry Codes in the FDA facility registration program. We developed a revised set of Commodity Categories that included 47 categories (Appendix A). These categories provide a more granular classification of foods than the RFR classification, with further consideration of product-specific categories, process-specific categories, and the role of processing and preventive controls.

Within each of the commodity categories, we identified commodities and associated known or reasonably foreseeable hazards (see below the section Identification of Food-Hazard Pairs) based

on available data, information, and expert opinion. Using this approach, we created a comprehensive list of food-hazard pairs.

2.2 Model Criteria and Description of Scoring Definitions

For the RRM-FT, we developed seven criteria that encompass the factors required by section 204(d)(2)(A) of FSMA, including consideration of: outbreak frequency, illness occurrence, severity of illness, the likelihood of microbial or chemical contamination, potential for the food to support pathogen growth during customary shelf life, food consumption patterns, the probability of contamination and steps taken during manufacturing to reduce contamination, and economic impact of foodborne illnesses.

The RRM-FT includes the following criteria that account for factors (i) through (vi) in section 204(d)(2)(A) of FSMA (see description of the statutory factors in section 1.1 above). The RRM-FT is operationalized based on data and other relevant information:

Criterion 1. Frequency of outbreaks and occurrence of illnesses
Criterion 2. Severity of illness, taking into account illness duration, hospitalization and mortality
Criterion 3. Likelihood of contamination
Criterion 4. Growth potential, with consideration of shelf life
Criterion 5. Manufacturing process contamination probability and industry-wide intervention
Criterion 6. Consumption
Criterion 7. Cost of illness

To implement the statutory factors within the model framework, we captured each factor in one of seven criteria using standard multicriteria decision analysis principles. For example, the FSMA factor (i) includes two types of information – outbreak history and severity of illnesses. Therefore this factor was implemented in the model as two separate criteria – C1 outbreak frequency and occurrences and C2 illness severity. We did not add or delete any of the types of information required in the statutory factors as part of this implementation. The relationships between the criteria in the RRM-FT and the factors required by FSMA are shown in Figure 2-1.

Overall, in implementing the RRM-FT to generate risk scores for food-hazard pairs, both quantitative data and qualitative information were used for scoring criteria. For food-hazard pairs where adequate quantitative data were available (*e.g.*, frequency of outbreaks, number of cases, hospitalization rate, prevalence of pathogen in a food), the data were used for scoring. Where adequate data were not available, scoring based on qualitative descriptions and expert judgement (subject matter experts and expert elicitation panels) were employed. For each criterion, data and information were grouped into scoring bins, which were generally defined to represent an order-of-magnitude difference in value among the data characterizing the criterion and were assigned a

numerical value of 0, 1, 3, or 9, consistent with other multi-criteria decision analysis tools used by FDA. A risk score for each food-hazard pair was calculated by summing the equally weighted scores for each criterion.

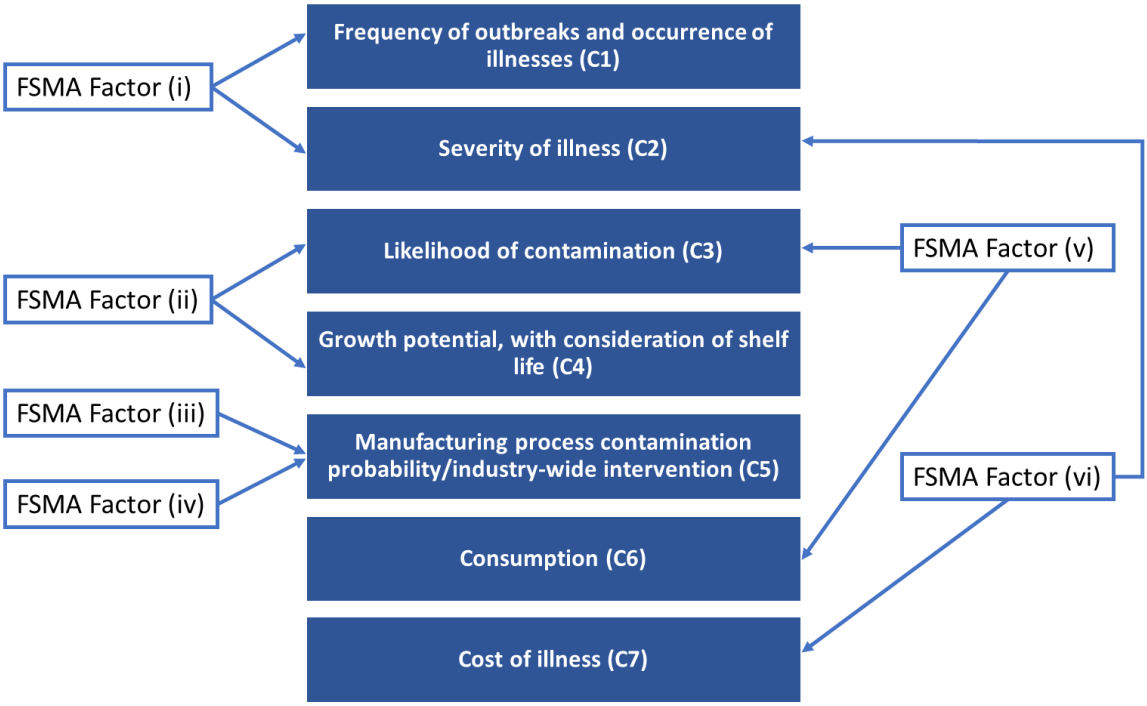

Figure 2-1. Relationship between Criteria in RRM-FT and Factors Required by FSMA

2.2.1 Criterion 1: Frequency of Outbreaks and Occurrence of Illnesses

Criterion 1 (C1) characterizes the public health impact of exposure to hazards in foods based on frequency of outbreaks (where applicable) and occurrence of illnesses in the U.S. The definition and scoring were developed to address illnesses from acute exposure to foodborne hazards (*i.e.*, from microbial pathogens, biotoxins, or undeclared allergens) or chronic exposure to foodborne chemical hazards.

For microbial hazards and marine biotoxins that have been involved in an outbreak in the U.S., both the frequency of reported outbreaks and the occurrence of illnesses (*i.e.*, the number of reported outbreaks and the number of outbreak-related cases) are used in scoring (Figure 2-2). The frequency of outbreak is the total weighted number of outbreaks for a food-hazard pair in a 20-year period, where the most recent outbreaks are weighted most heavily. Similarly, the Interagency Food Safety Analytics Collaboration uses data from 1998 to the present for foodborne illness source attribution *(26, 42)*. The occurrence of illnesses is the total weighted number of outbreak-related cases from all the outbreaks associated with a food-hazard pair in the

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.

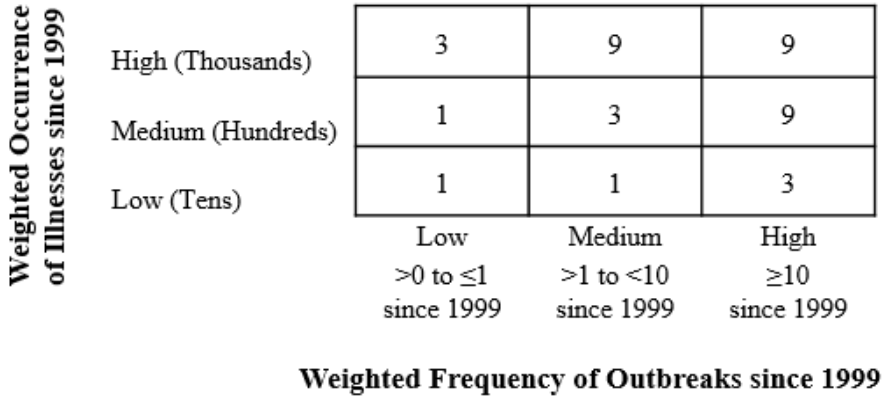

Figure 2-2. Scoring definition for frequency of outbreaks and occurrence of illnesses for a food-hazard pair

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.

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.

For chemical hazards other than biotoxins (including chronic exposure to a chemical hazard), and the food-hazard pair under evaluation:

0 = No association of the chemical with the food for consumption in the U.S., and no evidence that the chemical has been associated with foodborne illnesses or adverse health consequences in the U.S.
1 = Association of the chemical with the food for consumption in the U.S., but little evidence that the chemical has been associated with foodborne illnesses or adverse health consequences in the U.S.
3 = Association of the chemical with the food for consumption in the U.S., and some evidence that the chemical has been associated with foodborne illnesses or adverse health consequences in the U.S.
9 = Association of the chemical with the food for consumption in the U.S., and compelling evidence that this chemical has been associated with foodborne illnesses or adverse health consequences in the U.S.

The definition of C1 for chemical hazards associated with chronic exposure emphasizes food for consumption in the U.S. so that the evaluation is specific to the U.S. population, which is also the emphasis for other hazards in the RRM-FT.

Data weighting

The data used in C1 scoring spans a 20-year period of time. To address data relevance, we adopted a data weighting scheme used in the 2003 FDA/FSIS *L. monocytogenes* risk assessment *(59)*, where each outbreak is weighted based on the year it took place. Data from each outbreak are weighted based on the year in which the outbreak occurred, using a value of 1, 0.7, and 0.4 as follows:

01/1999-12/2004 = weight of 0.4
01/2005-12/2009 = weight of 0.7
01/2010-2019 = weight of 1

The weight is applied to each outbreak, including the outbreak itself (*e.g.*, an outbreak in 2001 is equivalent to 0.4x1=0.4 weighted outbreak) and the number of cases in the outbreak. The point in time when outbreaks used for scoring Criterion 1 occurred, reflects to some degree the state of food production, processing and handling practices at the time when an outbreak occurred or when contamination was detected. By using data weighting, more recent outbreaks have a greater effect on the scoring and thus provide a means to more accurately represent current state of industry practices.

2.2.2 Criterion 2: Severity of Illness

For microbial pathogens, some toxins of microbial origin, and marine biotoxins, where data on hospitalization and mortality rate are available, *e.g.*, from the studies by Scallan *et al. (46)* and Pennotti *et al. (40)*, these data are used for Criterion 2 (C2) scoring using the definitions in the first row of Table 2-1. Examples for illness severity associated with microbial pathogens and toxins of micromial origin, as well as food vehicles, are also available in Appendix 8-A (Chapter 8) of the International Commission on Microbiological Specifications for Foods (ICMSF) Book 7 *(28)*. We developed these definitions based on the Anderson *et al. (1)* approach and the ICMSF *(28)* approach with modifications, taking into consideration available data and information.

For food safety hazards, such as certain toxins of microbial origin and chemical hazards that cause acute adverse health effects, where quantitative indicators for illness severity are not available, qualitative information on illness duration, sequelae and severity, *e.g.*, information on histamine from ICMSF *(28)*, is used for scoring according to the definitions in the second row of Table 2-1. These definitions are also used for scoring the severity of the adverse health consequences from undeclared allergens, which are usually acute in nature.

Table 2-1. Scoring definitions for severity of illness in humans from the hazard (acute effects) [a]

Definition basis	Score = 0	Score = 1	Score = 3	Score = 9
Quantitative data	No known adverse health consequences (not a hazard)	Hospitalization rate ≤10% [b] and mortality rate 0% [b]	Hospitalization rate >10-20% and mortality rate 0%; or rate ≤20% and mortality rate >0% to ≤0.5%	Hospitalization rate >20% or mortality rate >0.5%
Qualitative information	No known adverse health consequences (not a hazard)	Moderate hazard: not usually life threatening; no sequelae; normally short duration; symptoms self-limiting; can be severe discomfort; transient effects, resolved with little or no medical intervention.	Serious hazard, for general or susceptible[b] population: incapacitating, but not usually life threatening; sequelae infrequent; moderate duration.	Severe hazard, for general or susceptible population: life threatening or substantial chronic sequelae; long duration; death or death likely to occur.

[a] Based on approaches in Anderson *et al. (1)* and ICMSF *(28)* with modifications, taking into consideration available data and information, as well as peer review comments.

[b] The rate is hospitalization or mortality % of laboratory-confirmed cases. Susceptible population includes a restricted subpopulation that is sensitive to a hazard (*e.g.*, a food allergen) or otherwise has increased susceptibility to a hazard compared with the general population (*e.g., L. monocytogenes* infections in the elderly population).

For chronic exposure to chemical hazards, for which there are adverse health effects but there are no reported data on foodborne hospitalization or mortality rate, evaluation of severity takes into consideration the range of adverse health consequences associated with the hazard (Table 2-2), assuming an exposure over a prolonged period to that hazard from food consumption in the U.S.

Table 2-2. Scoring definitions for severity of illness in humans from chemical hazards (chronic exposure)

Score = 0	Score = 1	Score = 3	Score = 9
No known association with adverse health consequences (not a hazard)	Moderate hazard: not usually life threatening; no sequelae; normally short duration; symptoms self-limiting; can be severe discomfort; transient effects, resolved with little or no medical intervention.	Serious hazard, for general or susceptible [a] population: incapacitating, but not usually life threatening; sequelae infrequent; moderate duration. For example, IQ reduction (incapacitating)	Severe hazard, for general or susceptible population: life threatening or substantial chronic sequelae; long duration; severe adverse health consequences; death. For example, cancer.

[a] Susceptible population includes a restricted subpopulation that is sensitive to a hazard, or otherwise has increased susceptibility to a hazard compared with the general population (*e.g.*, developmental effects on the brains of infants).

2.2.3 Criterion 3. Likelihood of Contamination

Section 204(d)(2)(A)(v) of FSMA requires consideration of the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food. That likelihood is a function of the likelihood that the food is contaminated with a given hazard (C3). (It is also a function of the frequency of consumption, which is captured by Criterion 6, below.) The likelihood of contamination for microbial hazards is determined by the fraction of the food available to consumers that is contaminated (the contamination rate or percent positive). Relevant data from the most recent 20 years were used. This fraction can be determined from surveillance studies *e.g.*, by using weighted average prevalence or contamination rate based on the method reported by Anderson *et al. (1)* with modifications. For example, prevalence data from survey studies on *L. monocytogenes* in RTE foods reported by Gombas *et al. (21)* and Luchansky *et al. (30)*, pathogens in fresh produce from the USDA Microbiological Data

Program (MDP) program *(52)* such as *Salmonella* in fresh produce reported by Reddy *et al. (41)*, and FDA surveillance data were used in scoring Criterion 3 (C3). The likelihood of contamination for a chemical hazard is determined by the contamination rate above an action level (*e.g.*, aflatoxins) or above an allowable level, *e.g.*, Ochratoxin A in boxed cereal containing wheat and corn reported by Nguyen and Ryu *(37)*. Where data are not available to determine contamination rate, other indicators for contamination (*e.g.*, RFR reports, FDA recall database, or data from other FDA compliance programs) and expert knowledge are used for scoring.

The likelihood of contamination captured by C3 is the overall likelihood of contamination in the finished product that may arise from various points in the food supply chain, from the process of making food from one or more ingredients or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. The finished product may be RTE or NRTE.

The determination of the likelihood of contamination takes into consideration relevant studies that are individually weighted by sample size, geographic region, and study date using the method reported in the 2003 FDA/FSIS *L. monocytogenes* risk assessment *(59)*, as follows:

Study Weight = *n* * *gw* * *dw* **Equation [1]**

Where:

n is the total number of samples in the study. A larger study would provide a better estimate of the percent positive samples than a smaller study.

gw is the geographic weight for the location in which contamination data were collected. A value of 1 is used unless the study was conducted in a region and food for which there is a minor contribution (importation) to the U. S. food supply, in which case a value of 0.3 is used. Studies were evaluated for their relevance to the U.S. food supply.

dw is weight for the date of the study, defined as follows:

dw = 1 for studies published since 01/2010 - present;

dw =0.7 is used for studies published between 01/2005 - 12/2009;

dw =0.4 is used for studies published between01/1999 - 12/2004.

For a food-hazard pair for which multiple studies reported contamination data, for each of the studies, the weighting scheme is applied to the number of positive samples and the total number of samples separately. The weighted number of samples, either positive or total, is summed across studies, which is used to determine a weighted percent prevalence value (or weighted percent contaminated rate). The weighted contamination rate (percent positive) is used in the scoring of the likelihood of contamination for C3 according to the definitions in Table 2-3.

Table 2-3. Scoring definitions for likelihood of contamination of the hazard in food

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

[a] No known detection of a microbial hazard, or of a chemical hazard above an action level or allowable level, based on data from the scientific literature, FDA sampling programs (*e.g.*, domestic sampling, import sampling and "for-cause" sampling data), and other sources (*e.g.*, the Electronic Laboratory Exchange Network (eLEXNET) database).
[b] Weighted contamination rate is used for scoring. Average RFR reports/yr or average recalls/yr.
[c] Indicators such as eLEXNET or expert judgements.

Data for RFR reports (09/2009-08/2019) are used to calculate the average RFR report/year and data for recalls (1999-2019) are used to calculate the average recalls/year, when needed, for scoring. A score is assigned to Criterion 3 for the food-hazard pair based on available data according to an order of preference, whereby prevalence (sampling) data are used first, if available, followed by RFR data, recalls data, expert elicitation, or lastly, eLEXNET data.

2.2.4 Criterion 4: Growth Potential, with Consideration of Shelf Life

Foods differ in their ability to support pathogen growth during their customary shelf life. Some microbial pathogens may multiply in foods while chemical hazards do not. In the case of scombroid toxin, histamine itself is a chemical hazard but it is treated in the same way as a microbial hazard in the risk-ranking model, *e.g.*, for the scoring of Criterion 4, since it is produced from growth of certain bacteria. A food may have intrinsic characteristics such as pH, water activity (a_w), the presence of preservatives or inhibitory compounds, or a combination of these factors that prevent the growth of pathogens, *e.g.*, as described in the FDA Food Code *(69)* and a report by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) *(35)*.

The scoring definitions for Criterion 4 (C4) outlined in Table 2-4 are used to assign a score of 1, 3 or 9 for a food-hazard pair based on the potential for pathogen growth in the product, adapted with modifications from Anderson *et al. (1)*. A score of 0 is assigned for a food-hazard pair in which the hazard is a chemical or an allergen, a microbial hazard of such nature that it does not replicate in food (*e.g.*, viruses and parasites), or the food does not support pathogen growth, such as a frozen food according to a report by the National Advisory Committee on Microbiological Criteria for Foods *(35)* and a low-moisture food according to a review by Scott *et al. (49)*.

Table 2-4. Scoring definitions for growth potential, with consideration of shelf life

Growth potential [a]	Definitions	Examples
Strong (score=9)	Likely growth at temperature at which the food is intended to be held and stored, including refrigeration or room temperature, given customary shelf life	Growth ≥3 $\log_{10}$CFU based on published study, or predictive microbiology models
Moderate (score=3)	Some evidence that pathogens may grow (*e.g.*, higher pH or bruising/damage) and includes conflicting studies where inconsistent results are reported in different studies, given customary shelf life	Growth 1-3 $\log_{10}$CFU based on published study, or predictive microbiology models
Low (score=1)	No evidence that pathogens may grow and includes conflicting studies where inconsistent results are reported in different studies, given customary shelf life	Growth >0 to ≤1 $\log_{10}$CFU based on published study, or predictive microbiology models

[a] Growth potential given customary shelf life.

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 (*e.g.*, frozen food), C4=0.

The determination of growth potential takes into consideration, where appropriate, the point(s) in the food supply chain where contamination is most likely to occur, for example, whether it was contaminated in raw ingredient/product or in the processed product, before or after microbial reduction steps. The determination uses available data on amount of growth (log increase) based on published data on observed growth in a food-hazard pair and, where appropriate, by expected growth estimated using predictive microbiology database modeling tools such as ComBase *(12)* and the USDA Pathogen Modeling Program *(58)*, given knowledge on the customary shelf life of the product and how the product is stored. It also considers microbial ecology in food and intrinsic and extrinsic factors that influence bacterial growth in food *(34, 35, 43)*. Published growth studies, *e.g.*, *L. monocytogenes* growth in cut produce by Salazar *et al. (45)*, as well as published predictive microbiology models, *e.g.*, modeling growth of *L. monocytogenes* and *Salmonella* by Mishra *et al. (33)* and of STEC O157 and *Salmonella* by Veys *et al. (86)* in leafy greens, modeling *L. monocytogenes* growth in seafood by Mejlholm *et al. (31)* and in produce commodities by Hoelzer *et al. (24)*, modeling *Salmonella* growth by Li *et al. (29)* and *L. monocytogenes* growth on cut melons by Danyluk *et al. (14)*, were used in scoring Criterion 4. As appropriate, the determination takes into consideration the characteristics of the food (*e.g.*, pH and a_w) to estimate potential pathogen growth within the typical packaging (*e.g.*, aerobic, anaerobic, etc.), and storage environment (*e.g.*, temperature) including the potential for growth

under moderate abuse conditions. Growth of microorganism(s) involved in producing biotoxin is considered in a similar fashion as described above for a bacterial pathogen, where appropriate.

2.2.5 Criterion 5: Manufacturing Process Contamination Probability and Industry-wide Intervention

Food safety hazards may be introduced during primary production, during processing, manufacturing, retail distribution, and/or during food preparation at retail establishments or in homes. Criterion 5 (C5) specifically addresses the ability to control contamination of microbial hazards, chemical hazards and undeclared allergens that could be introduced anywhere during the entire food supply chain, including manufacturing/processing and retail, but not including activities in the home. Criterion 5 also addresses the potential for hazards to be introduced during manufacturing, differing from Criterion 3 that addresses the overall likelihood of contamination in the finished product from various points in the food supply chain. Criterion 5 considers contamination potential during manufacturing, particularly for products that do not receive an adequate kill step, such as certain fresh-cut vegetables as described in FDA guidance *(62)*; or products that have the potential to be exposed to the processing environment post-lethality treatment, *e.g.*, contamination of *L. monocytogenes* in RTE foods as described in FDA guidance *(61, 76)* and *Salmonella* in low-moisture foods as described in industry guidance *(22)* that have been implicated in illnesses and outbreaks.

In the scoring of Criterion 5, "manufacturing process" is interpreted consistent with FDA's definition for manufacturing. Under 21 CFR 1.328, manufacturing is defined as: making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Therefore, "manufacturing process" is the process of manufacturing, or the process of making food from one or more ingredients or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. The scoring of C5 takes into consideration activities, physical locations and processes involved in manufacturing food across the supply chain, not necessarily the physical location (*i.e.*, in a manufacturing facility).

The probability of contamination during manufacturing and the effectiveness of steps taken to reduce contamination are defined qualitatively, and this information is used in the scoring definitions for Criterion 5 outlined in Figure 2-3. The scoring takes into account available control measures and interventions that have been validated (*e.g.*, FDA *(63, 66)*; NACMCF *(35)*; Scott and Stevenson *(50)*) and can be applied during manufacturing to eliminate, or otherwise control a hazard. For each food-hazard pair, industry-wide data or programs are considered in the scoring. For example, a product that has an adequate kill step with processing that significantly minimizes pathogens in a food ("Strong" step), but is subsequently exposed to a post-lethality processing environment with high contamination potential would score C5=3. In comparison, a

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

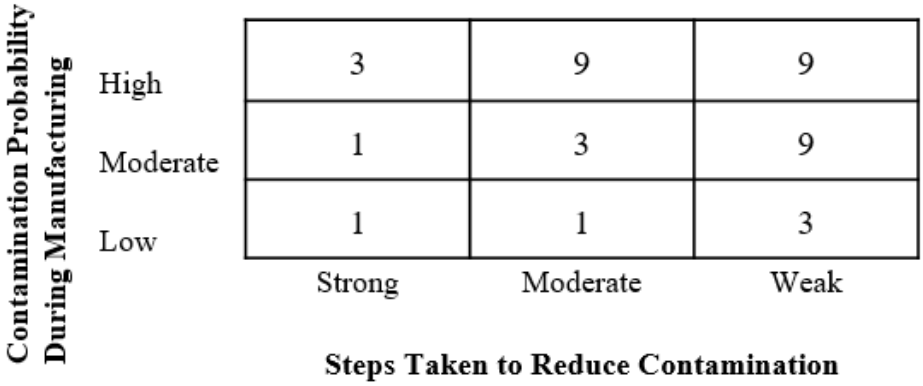

Figure 2-3. Scoring for Manufacturing Process Contamination Probability and Industry-wide Intervention

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

representing the percent population consuming the food and the amount consumed per serving (Table 2-5), according to the method used in Anderson *et al. (1)* with modifications.

The consumption of a food (*i.e.*, at the commodity level) in the U.S. population is determined by using survey and consumption databases, *e.g.*, the National Health and Nutrition Examination Survey (NHANES) What We Eat in America (WWEIA) database (hereafter referred to as the NHANES database). As described above in the section on Criterion 3 definitions, it is the consideration of the scores for both C3 and C6 that qualitatively contributes to the likelihood that consuming a particular (contaminated) food will result in illness.

Table 2-5. Scoring definitions for consumption

Consumption rate [a] (% consumers)	Amount consumed (gram per serving) [a]		
	>0-10	>10-100	>100
>10%	3	9	9
>5-10%	1	3	9
1-5%	1	1	3
≤1%	0	0	0

[a] Based on consumption rate and amount consumed in the total U.S. population.

NHANES consumption data from the 2015-2016, 2013-2014, and 2011-2012 cycles *(9)* were used to estimate consumption rates and amounts consumed for the commodities in RRM-FT. The NHANES database contains data from a two-day dietary recall survey. Consumption rate was determined by calculating the sum of the dietary two-day sample weights of participants eating a given food and the sum of the dietary sample weights for all participants on each day of dietary recall. The amount consumed was determined by calculating the average weighted grams per serving per person and the average grams per serving of food. Consumption data from three cycles (2011 to 2016) were used to calculate consumption rate in the U.S. population and the average amount consumed per serving. If no data from the three cycles were available from NHANES, the model then relied on expert judgement to score consumption following the scoring definitions in Table 2-5.

2.2.7 Criterion 7: Cost of Illness

The definitions for scoring Criterion 7 (C7) are shown in Table 2-6. The estimated annual incidence and illness cost, *e.g.*, costs of diagnosis, medical treatment, lost quality-adjusted life days (QALDs), and premature mortality, is used to calculate the annual cost of illnesses attributed to a food-hazard pair. We evaluated data on cost per case from published studies, for example by Minor *et al. (32)* and Scharff *(47, 48)*. Non-public health economic impacts such as potential industry costs and loss of market costs are not included in this criterion. While the

economic impact (monetary value) associated with a food-hazard pair considers the number of foodborne illnesses and severity of the illnesses, Criterion 7 represents a separate aspect of value that is distinct from those represented in Criteria 1 and 2. Criterion 7 includes consideration of additional economic factors such as lost productivity and lost utility due to foodborne illness (not considered in Criterion 2), and under-reporting and under-diagnosis of cases (not considered in Criterion 1).

A scaled number of cases per year for the food-hazard pair is multiplied by the cost per case for the hazard from Minor *et al. (32)* (with 2018 update by FDA for cost adjustment to reflect inflation) to determine the C7 Cost of Illness score. The number of cases per year for the food-hazard pair is scaled using a multiplier for under reporting and a multiplier for under diagnosis, using multipliers reported by CDC in the literature, *e.g.*, by Scallan *et al. (46)*, Painter *et al. (38)*, and Pennotti *et al. (40)*. The Criterion 7 quantitative definitions (Table 2-6) represent a difference in order-of-magnitude, 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.

Table 2-6. Scoring definitions for cost of illness

Score = 0	Score = 1	Score = 3	Score = 9
Unknown or ≤$100K /year	Low [a] or >$100K to 1M /year	Medium or >$1M to 10M	High or >$10M

[a] Qualitative description is used for expert elicitation where data on the number of cases was not available to determine cost.

Although in principle, the total number of cases used for C7 scoring includes both outbreak and sporadic cases, few data were available on sporadic cases. Thus, outbreak data were used, where the number of cases from Criterion 1 was used to calculate the number of cases per year for the food-hazard pair, to which the multipliers were applied.

3 Identification of Food-Hazard Pairs

To generate a ranked list of commodities, the model relies on data and information related to specific food-hazard pairs. In general, data and information on the food-hazard pairs were collected for the seven criteria and assigned a numerical score of 0, 1, 3, or 9 based on the scoring definitions and the data. For each of the 47 commodity categories (FDA-regulated human foods), we identified commodities and food-hazard pairs based on representative foods and associated known or reasonably foreseeable hazards, using outbreak and contamination data and other information from multiple sources. A reasonably foreseeable hazard (*e.g.*, microbial, chemical, or undeclared allergens) is one that has the potential to be associated with production environment, facility or the food *(56)*, for example, based on knowledge of microbial ecology, behavior, and sources. The model considers both microbial and chemical hazards. Allergenic components of major food allergens are chemicals (proteins). However, for the purposes for the RRM-FT, "undeclared allergen" is considered a separate hazard category. Chemical hazards considered in the model include marine and plant biotoxins, mycotoxins (which are of microbial origin), pesticides, heavy metals and other toxic elements, industrial chemicals, and chemicals formed during processing.

Food-hazard pairs were identified based on the history of food and hazard associations, including outbreaks, recalls, FDA sampling data, published risk assessments, RFR commodity descriptions and example food commodities *(82)*, and subject matter expert judgements (see section 4 below).

We identified food-hazard pairs based on available data, particularly data relevant to Criterion 1 (Frequency of outbreaks and occurrence of illnesses) and Criterion 3 (Likelihood of Contamination), *e.g.*, foods and hazards associated with outbreaks and illnesses, or detection of hazards in foods. For foods that have been implicated in outbreaks and illnesses, food-hazard pairs were identified by using the CDC's Foodborne Outbreak Online Database (CDC FOOD) *(8)* and National Outbreak Reporting System (NORS) *(10)*, FDA's outbreak database that includes a subset of the CDC outbreak data for which the outbreak investigation demonstrated an association with FDA-regulated products *(78)* and, in some instances, information from the Center for Science in the Public Interest's "Outbreak Alert!" database *(7)*. Food-hazard pairs were also identified based on reported detection of foodborne hazards in foods (not necessarily implicated in illnesses) using information from FDA RFR reports *(82)*, FDA recalls *(81)*, the FDA Total Diet Study *(83)*, FDA surveillance and testing data *(80)*, a review of world-wide published risk assessments, and scientific studies and technical reports from governmental and other organizations. For example, food-hazard pairs included in the FDA produce ranking model *(1)* and those included in the European Food Safety Authority (EFSA) scientific opinions on risk posed by pathogens in food of non-animal origin Part I *(15)* were reviewed and included in this study, as appropriate. Information on the detection of microbial and chemical hazards was also obtained from other sources such as the European Union Rapid Alert System for Food and Feed (EU RASFF) *(17)*, and ICMSF Book 6 Microbial Ecology of Food Commodities *(27)*.

We reviewed investigation reports from FDA's Coordinated Outbreak Response and Evaluation network (CORE) on potential foodborne illness incidents and outbreaks suspected (or eventually confirmed) of being linked to FDA-regulated products *(78)*. Furthermore, to identify additional food-hazard pairs, we utilized information regarding known and foreseeable hazards described in the FDA proposed preventive controls rule (available at https://www.regulations.gov/document?D=FDA-2011-N-0920-0001), in particular Background Section D entitled *Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding of Food for Human Consumption (70)*. FDA subject matter experts also suggested a number of food-hazard pairs based on their experience evaluating contaminants in food.

Food-hazard pairs were identified in an incremental and iterative process. During the model development, an initial list of food-hazard pairs were identified. After the peer reviews, the list of food-hazard pairs was revised and expanded. Subject matter experts (both external experts and internal FDA experts) reviewed all the example food commodities in the RFR definitions *(82)*. For any of the example food commodities that had not already been identified from the data sources described above, we identified at least one food-hazard pair based on expert judgement. In addition to the FDA subject matter experts, the expert panels convened by IFT/RTI also reviewed the food-hazard pairs, provided suggestions for additional food-hazard pairs to consider, and provided input in finalizing the selection of the food-hazard pairs. Similarly, the peer reviewers for the data review provided suggestions on a number of food-hazard pairs to be considered, many of which were included in the model. We finalized the list to the current food-hazard pairs, taking into consideration peer review comments and most up to date data and information available, including CORE reports and FDA outbreak data (up to 2019), CDC NORS outbreak data (up to 2017), RFR reports (up to 2019), and other information.

In total, a comprehensive list of food-hazard pairs were identified for scoring in the model, representing ~200 commodities in 47 commodity categories (Appendix A) and ~100 hazards (Appendix B). As new data and information on food-hazard associations becomes available, food-hazard pairs can be added to the model for scoring. A summary of considerations, including those described above, used to identify future food-hazard pairs is shown in Appendix C.

The Commodities included in the model were grouped under 47 commodity categories, which are linked to the 28 RFR commodity categories (as shown in Appendix A). The commodity categories provide food descriptions on a broader degree that connect to classification schemes used in existing FDA programs (*e.g.*, RFR Reporting and Facility Registration). For example, we used the definition in the FSMA produce safety rule *(72)* as a reference to classify food-hazard pairs included in the "Produce –RAC" Commodity Category. Pasteurized milk is categorized as "Dairy" (RFR Category) and "Dairy – Milk, Butter, Cream" (RRM-FT Commodity Category), and "Milk (fluid and white and Grade-A pasteurized" (RRM-FT Commodity). Other

commodities included in the Category "Dairy - Milk, Butter, Cream" are butter, butter milk, cream (heavy or light or whipping), etc.

The ~100 hazards in the model (Appendix B) are classified within three hazard categories: microbial hazards, chemical hazards, and undeclared allergens.

Microbial hazards include bacteria, *e.g.*, *Salmonella, C. botulinum*; parasites, *e.g.*, *Cryptosporidium parvum*, *Cyclospora cayetanensis*; viruses, *e.g.*, Hepatitis A, Norovirus; and several toxins of microbial origin, *i.e.*, scombroid toxin (histamine) and mycotoxins. In the case of scombroid toxin, histamine itself is a chemical hazard but it is treated in the same way as a microbial hazard in the risk-ranking model, e.g., for the scoring of Criterion 4, since it is produced from growth of certain bacteria. The histamine level in a food may be affected by time/temperature control (or lack of control) in a way similar to bacterial pathogens. Similarly, levels of mycotoxins depend on growth of molds in food (*e.g.*, raw commodities such as grains and nuts), which in turn may be controlled by time, temperature, moisture and other control measures. Mycotoxins (*e.g.*, aflatoxin M1, fumonisins, Ochratoxin A, and patulin) are included in the RRM-FT under microbial hazards because microbial growth and control of microbial growth are relevant in addressing mycotoxins; however, contamination data available are for mycotoxins (not the molds) and thus the Criterion 4 score is 0 in the model.

Chemical hazards include toxic elements (*e.g.*, arsenic, cadmium, and lead), industrial chemicals (*e.g.*, melamine, and Polycyclic Aromatic Hydrocarbons (PAHs)), pesticides, marine biotoxins (*i.e.*, Azaspiracid Shellfish Poisoning (AZP), Brevitoxins (NSP), Rhabdomyolysis (*e.g.*, associated with Buffalo fish), Ciguatoxin, Amnesic shellfish poisoning (ASP), Escolar toxin, Okadaic acid (DSP), Saxitoxin (PSP), and Tetrodotoxin), and other chemicals (*e.g.*, Acrylamide that is formed during heating processes).

The undeclared allergens category focuses on the presence of the eight major food allergens *(71),* which are milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. A food-hazard pair for undeclared allergens contains all undeclared allergens in that food. The undeclared allergens in these food-hazard pairs are defined to include all undeclared allergens other than the specific food allergen, *e.g.*, the hazard is defined to include undeclared allergens other than nuts, in the pair "Whole shelled tree nuts – Undeclared allergens (other than nuts)-.", since the hazard is the presence of allergens in foods where it is not apparent that the food contains an allergen.

The model scores food-hazard pairs. For example, commodities in the Category "Produce – RAC" (raw agricultural commodity) include "Melons." Within this classification structure, all data for six of the seven criteria (all except for Criterion 2, which is hazard-based only) associated with different types of melons (such as cantaloupe, honeydew, and watermelon), were

entered into the database used in scoring, *e.g.*, prevalence studies for different types of melons were combined, as described above in Section 2.2.3, to determine a contamination rate for the "Melons" commodity in scoring Criterion 3.

The RRM-FT by design independently scores each of the food-hazard pairs. This characteristic of the model allows determination of high scoring food-hazard pairs (through the scoring of the seven criteria using the model) independent of identifying candidate food-hazard pairs, *i.e.*, the score for one food-hazard pair has no influence on the score for another food-hazard pair. Furthermore, this approach can accommodate different granularity of the food definition, provided that the commodity is clearly identified and that data consistent with the commodity definition are used in scoring. Furthermore, the number of food-hazard pairs identified for each commodity category or commodity does not affect whether the food-hazard pairs will have a high score. This approach facilitates the identification of a comprehensive list of food-hazard pairs without requiring an *a priori* assumption about the score the food-hazard pair might receive.

4 Data and Data Sources

Data and information used for scoring food-hazard pairs in the RRM-FT were compiled from a number of sources. We obtained data from scientific studies, technical reports, and expert elicitations to score the seven criteria for each of the food-hazard pairs. When data for scoring some of the criteria were not available in the literature, we obtained science-based expert judgements from three external expert panels convened by RTI/IFT, and another external expert consultation specific to data and information for Criteria 3 and 4 *(5)*, as well as FDA subject matter experts. Table 4-1 shows examples of the type and data sources used to score the seven criteria in the model. Data and information used to identify food-hazard pairs for inclusion in the model are described in Section 3.

Table 4-1. Overview of major data sources used for scoring in RRM-FT

Type of Data	Example Data Sources and Descriptions
Foodborne outbreak data	• Foodborne outbreaks of confirmed etiology associated with FDA-regulated commodities from 1999 to 2019 (present; total 20 years) were compiled from 1999 to mid-2011 using the FDA Outbreak Database and from mid-2011 to 2019 (present) using the FDA CORE Incident Database. FDA's outbreak data includes a subset of the CDC outbreak data for which the outbreak investigation demonstrated an association with FDA-regulated products. • For additional outbreaks involving *Vibrio* spp. and marine and plant biotoxins, data from CDC's National Outbreak Reporting System (NORS), previously known as the Foodborne Outbreak Online Database (FOOD), from 1999 to 2017 were also considered *(8, 10)*.
FDA recall data (including undeclared allergens)	Data on the number of Class I and Class II recalls of foods associated with microbial and chemical hazards were compiled from the FDA recall database (FDA, Jan 1999-to Sept 2019).
Reportable Food Registry (RFR) annual reports	Data on incidences of reportable food were compiled from the FDA RFR reports[1] (FDA, Sept 2009 – Aug 2019).
USDA Microbiological Data Program (MDP)	Data on the prevalence of contamination in certain foods were obtained from USDA MPD program (2001-2012) *(52)* and peer-reviewed papers published based on the MDP data *(18, 41)*.

[1] Note that there is overlap in RFR data and recall data, since a RFR report can lead to a recall. However, either RFR data or recall data (not both) were used in C3 scoring.

Total Diet Study (TDS)	The TDS is one of the sources that provided data on chemical associations with foods, contamination rates, and contamination levels (1999 to 2017).
FDA surveillance data and other data and information	Examples include data from a comprehensive survey of *L. monocytogenes* contamination in refrigerated RTE foods, as well as pH and a_w of RTE foods *(30, 75)*; data on retail time/temperature distribution and growth potential for selected product items; FDA Tomatoes Survey Report *(65)* and Leafy Greens Survey Report *(64, 67)*, FDA Sprouts Survey Report *(77)*; data from eLEXNET *(79)* on detection of microbial hazards in human foods (data from 2008-2019); FDA-compiled data submitted to the Federal Register Docket (FDA-2014-N-0053, 2014) on prevalence and concentration of *Salmonella* in almonds, walnuts, pistachios, and pecans *(73)*.
Manufacturing process and control data and information	Expert elicitations, including three expert panels (with expertise in the fields of microbiology, chemistry, food production and processing, food science, risk assessment, and allergens), were convened by IFT/RTI and by RTI. Expert elicitations were also conducted with FDA subject matter experts. Data on potential hazards associated with food production and the possibility of their control were compiled from the ICMSF Books, *e.g.*, Book 6 *(27)*. A list of preventive controls guidance (from both FDA and industry) and FDA regulations *(74)*; compiled relevant comments (data and information) submitted by stakeholders *(73)* in response to FDA request in Federal Register Notice 79 RF 6596 (Docket FDA-2014-N-0053, 2014).
National Health and Nutrition Examination Survey (NHANES) What We Eat in America database	Consumption data for foods were compiled from the NHANES survey (a two-day dietary recall database) using data from the 2015-2016, 2013-2014, and 2011-2012 cycles *(9)*. The consumption rate among all participants, and the amount consumed among participants who consumed the food was calculated taking into consideration dietary two-day sample weights.
Peer-reviewed literature and technical reports	Up to 2019, as available. For example, data on hospitalization and mortality rates and information on under-reporting were obtained from Scallan *et al. (46)*, Pennotti *et al. (40)* and other sources. Data on prevalence of contamination in FDA-regulated commodities, and data on the growth potential of bacterial hazards in food were obtained from the literature via databases such as Web of Science, PubMed, Google Scholar, and from technical reports by the World Health Organization *(87, 88)*, the European Food Safety Authority *(15, 16)*, the Dutch National Institute for Public Health and the Environment *(36)*, FDA, and others. Data update for microbial hazard pairs in response to peer-review comments also included a consultation with external subject matter experts in microbial food safety.

Subject matter expert (SME) knowledge and judgement	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 (*e.g.*, *(53, 55-57, 76)*); scores for selected food-hazard pairs were updated where appropriate.

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 commoditiy 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:

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

Where:

$RS_{i,j}$ = Risk score associated with ith food and jth hazard
w_k = Weight assigned to criterion k
$CS_{k,i,j}$ = Criterion score for the kth criterion associated with ith food and jth 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 Criterions 1 through 7; each given a criterion weight of 10 (for convenience), the risk score RS = 10 x (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: a) data from government surveillance and survey, sampling data from a relatively large survey, *e.g.*, ≥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:

$$\boldsymbol{Confidence\ Score} = \sum_{\mathbf{k=1}}^{\mathbf{7}} \mathbf{CU_{k,i,j}} \qquad \textbf{Equation [4]}$$

Where:

$CU_{k,i,j}$ = 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:

$$\boldsymbol{aggrRS_{i}\_C = log_{10}(\sum_{j=1}^{n_i} 10^{RS_{i,j}})} \qquad \textbf{Equation [5a]}$$

Where,

aggrRSi_C = Aggregated risk score associated with i^{th} commodity
$RS_{i,j}$ = Risk score associated with i^{th} food and j^{th} hazard
n_i = Number of hazards associated with i^{th} 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:

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

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 … RS_n for *n* food-hazard pairs is:

$$aggrRS\_CC = 10 * (log_{10}(10^{RS_1\_C/10} + 10^{RS_2\_C/10} + 10^{RS_3\_C/10} + \ldots + 10^{RS_n\_C/10}))$$

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.

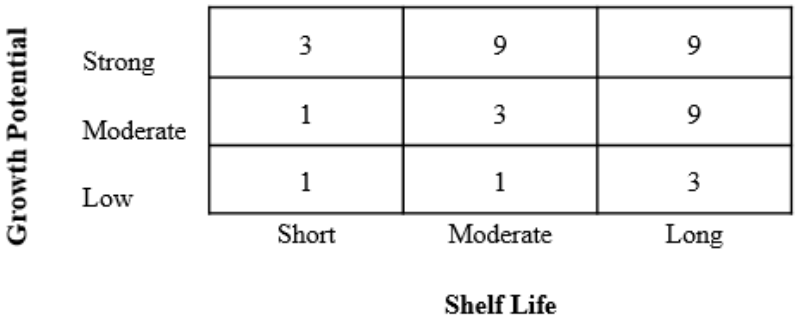

Figure 5-1. Alternative Scoring Growth Potential, with Consideration of Shelf Life

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).

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^3ARRT). *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. 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. Liggans, 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® 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 Adminstration. 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. de Oliveira 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 [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 (*e.g.*, 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)
Microbial Hazards		
1	Bacteria	*Aeromonas* spp.
2	Parasite	*Anisakis simplex*
3	Bacteria	*Bacillus cereus*
4	Bacteria	*Brucella* spp.
5	Bacteria	*Campylobacter* spp.
6	Parasite	Cestodes
7	Bacteria	*Clostridium botulinum*
8	Bacteria	*Clostridium perfringens*
9	Bacteria	*Cronobacter* spp.
10	Parasite	*Cryptosporidium parvum* or other spp.
11	Parasite	*Cyclospora cayetanensis*
12	Bacteria	*E. coli*, other pathogenic (EA)[a]
13	Bacteria	*E. coli*, other pathogenic (ETEC)[b]
14	Bacteria	*Enterococcus faecalis*
15	Parasite	*Giardia* spp.
16	Virus	Hepatitis A virus
17	Bacteria	*Listeria monocytogenes*
18	Virus	Norovirus
19	Parasite	*Paragonimus* spp.
20	Parasite	Parasites
21	Bacteria	*Plesiomonas shigelloides*
22	Virus	Rotavirus
23	Bacteria	*Salmonella* spp.
24	Bacteria	*Salmonella enterica* – serovar paratyphi

No.	Hazard Sub-Type	Hazard (N=101)
25	Bacteria	*Salmonella enterica* – serovar typhi
26	Marine biotoxin	Scombroid toxin (Histamine)[c]
27	Bacteria	*Shigella* spp.
28	Bacteria	*Staphylococcus aureus*
29	Bacteria	STEC non-O157[c]
30	Bacteria	STEC O157[c]
31	Parasite	*Toxoplasma gondii*
32	Parasite	Trematodes
33	Parasite	*Trichinella spiralis*
34	Parasite	*Trypanosoma cruzi*
35	Bacteria	*Vibrio cholerae*
36	Bacteria	*Vibrio parahaemolyticus*
37	Bacteria	*Vibrio vulnificus*
38	Bacteria	*Yersinia enterocolitica*
39	Bacteria	*Yersinia pseudotuberculosis*
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 - Fumonisins
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
Undeclared Allergens and Related		
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 = Enteroaggregative

[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, Fumonisins 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
The food-hazard pair meets any of the following observations using data since the last update: ▪ 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 (*e.g.*, 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 (*e.g.*, outbreaks, case-control studies, FoodNet population studies, PulseNet data).
Consistency	There are multiple observations of a hazard being likely to occur in a food (*e.g.*, recalls, positive test results).
Specificity	Illness has been predicted from exposure to hazard (*e.g.*, risk assessment).
Temporality	There is evidence that exposure to food-hazard pair precedes illness (*e.g.*, 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 (*e.g.*, 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 (*e.g.*, 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 (*e.g.*, if STEC O157 is known hazard for food then STEC non-O157 should also be considered) or hazard is associated with a similar food (*e.g.*, *Cyclospora* in raspberries and strawberries).