

**FDA's Draft Approach for Designating High-Risk Foods
as Required by Section 204 of FSMA
February 2014**

Section 204(d)(2) of the FDA Food Safety Modernization Act (FSMA) requires the Food and Drug Administration (“FDA” or “we”) to designate high-risk foods¹ (HRFs) 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. Designation of HRFs 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 food- and processing-related factors.

Factors to Be Considered

Under section 204(d)(2)(A) of FSMA, FDA’s designation of HRFs must be based on the following factors:

- 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 (CDC);
- 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.

The choice of the specific approach to be used to designate the HRFs will depend on the specific questions to be addressed, the availability of data, methods, and the timeframe. Available risk tools developed by FDA and others from the published literature span the range of 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 (Bernard et al., 2006); 2) semi-quantitative risk scoring, such as the produce risk ranking model (Anderson et al., 2011); and 3) quantitative risk assessment models,

¹ The term “food” is defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321(f)] as: “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”

including comparative risk assessment / risk ranking such as the 2003 FDA/FSIS *Listeria monocytogenes* in ready-to-eat (RTE) foods risk assessment (FDA/FSIS, 2003), and predictive models such as the *Vibrio parahaemolyticus* in raw oysters risk assessment (FDA, 2005). We are considering using a semi-quantitative risk ranking model similar to the produce risk ranking model published by Anderson et al. (available on FoodRisk.org at <http://foodrisk.org/exclusives/rrt/>), with adaptations to account for the specific factors identified in FSMA. Semi-quantitative risk ranking approaches, for example the additive linear aggregation model, have also been used in other fields (Belton and Steward, 2002; Stewart, 1992). We are considering this approach following an evaluation of a variety of methods and tools developed for identifying, ranking, comparing, and prioritizing food safety risks.

A semi-quantitative risk ranking model is the methodology being considered by FDA as the most appropriate for the HRF list because it would be data-driven and comprehensive, using explicit criteria related to public health risk; it would be adaptive to a variety of hazards (microbial and chemical contamination in foods); and it would be flexible to consider different foods or categories of food. Additionally, this approach would provide a means for considering all of the FSMA criteria and linking those criteria to develop a risk score. In addition to the draft semi-quantitative risk ranking model, FDA-iRISK – FDA’s quantitative risk ranking tool (FDA, 2011a) - may be useful to validate a selected subset of the risk ranking results from the draft semi-quantitative risk model to help inform the HRF list.

Procedure for Designating HRFs

The draft approach to designate HRFs would include the following steps:

- 1) Using the statutory factors to be considered, define criteria and scoring
- 2) To the extent applicable, develop a comprehensive list of food-hazard pairs representative of FDA regulated foods or food categories
- 3) Collect data relevant to the scoring criteria for the food-hazard pairs identified
- 4) Execute the draft risk model to determine risk scores for the food-hazard pairs
- 5) Determine the total risk score for a food or food category in which multiple hazards occur
- 6) Validate risk ranking results from the draft semi-quantitative risk model by using FDA-iRISK[®] (available at <http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/>), where necessary
- 7) Using the total risk score for foods or food categories, create a preliminary list of high-risk foods. This is not anticipated to be a food hazard list but rather a food list.

This draft approach may be revised based on comments and scientific data and information received from stakeholders, in particular (though not exclusively) with regard to evaluating risk associated with animal food.² We intend to obtain additional external input for the HRF model and a preliminary HRF list.

Designation of High-Risk Foods

We are considering designating high-risk foods based on a comprehensive evaluation of a set of criteria that encompasses the factors required by section 204(d)(2)(A) of FSMA, including the consideration of: outbreak frequency, illness occurrence, severity of illness, the likelihood of microbial or chemical contamination, potential for the food to support pathogen growth, food

² The term “animal food” applies to food for both livestock and companion animals.

consumption patterns, the probability of contamination and steps taken during manufacturing to reduce contamination (see Figure 1 below for relationship between the draft risk model criteria and the FSMA factors). Health and economic impacts, e.g. DALY (disability adjusted life year), QALYs (quality adjusted life year), and COI (cost of illness) would also be taken into consideration, as required by section 204(d)(2)(A)(vi) of FSMA. This section of FSMA provides specific factors upon which the designation of high-risk foods must be based.

Food and Food Commodity Classification

We are considering that the classification of foods or categories of food for risk ranking be based on the Reportable Food Registry (RFR) commodity definitions

(<http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM211534.pdf>).

The RFR commodity definitions would be appropriate for the risk ranking because food characteristics as well as manufacturing processes are considered in the definitions (e.g., fresh-cut produce, acidified/low-acid canned foods). Representative foods within each of the RFR categories would be selected and used in the model.

Risk Model Criteria and Scoring

Although section 204 of FSMA requires FDA to designate “high-risk foods,” in order to apply the FSMA factors it is necessary to first take into account both the characteristics of foods and known or reasonably foreseeable hazards, i.e., food-hazard pairs. The draft risk model includes the following criteria that account for factors (i) through (vi) identified in section 204(d)(2)(A) of FSMA, which would be 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/shelf life

Criterion 5. Manufacturing process contamination probability/intervention

Criterion 6. Consumption

Criterion 7. Economic impact

FSMA requires that both microbial and chemical hazards be considered in HRF designation.

The relationship between the criteria in the draft risk model and the factors required by FSMA is shown in Figure 1. Each factor required by FSMA would be represented in the model by one or more criteria.

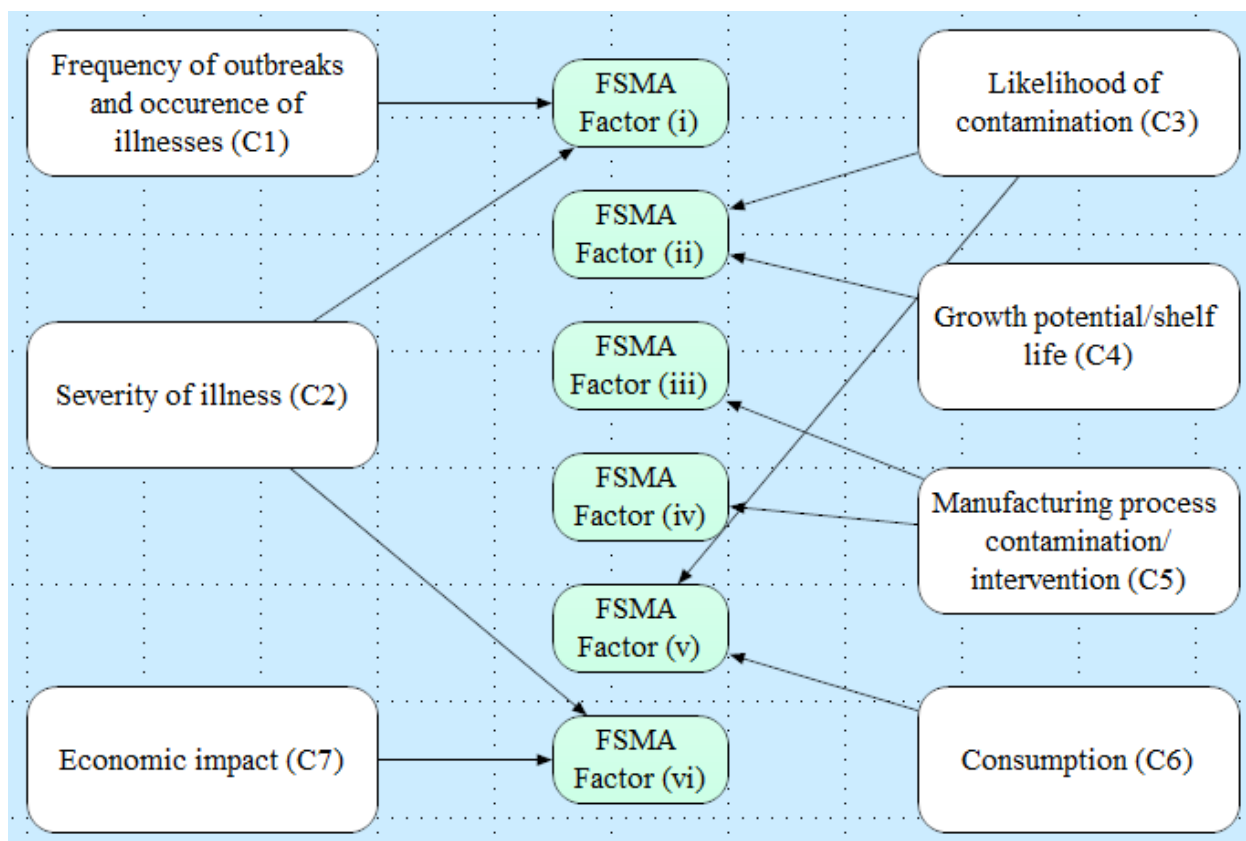


Figure 1. Relationship between Criteria in the Draft High Risk Food Model and Factors Required by FSMA

For food-hazard pairs where quantitative data are available, e.g., frequency of outbreaks, number of cases, hospitalization rate, prevalence of pathogen in a food, the data would be used for scoring. Where data are not available, alternatives such as qualitative descriptions and scoring methods based on elicitation of subject matter expert opinions would be employed. For each criterion, data and information would be grouped into scoring bins, which would be defined and assigned a numerical value from 0 to 9. A risk score for each food-hazard pair would be calculated by summing the scores for each criterion. A total risk score for each food would be determined by using the food-hazard pair risk scores, in cases for which multiple hazards occur in the food.

Description of Tentative Model Criteria and Scoring

C1: Frequency of Outbreaks and Occurrence of Illnesses

This criterion would be applicable to both microbial and chemical food safety hazards. For hazards that have been involved in outbreaks, both the frequency of reported outbreaks and the occurrence of illnesses (i.e., the number of reported outbreaks and sporadic cases per year) of related acute or chronic health problems would be used in scoring (Figure 2). This analysis would first focus on acute effects (from both microbial and chemical hazards) because the public health impact of foodborne exposure can be more clearly defined and directly assessed. However, to the extent possible, efforts would be made to assess the public health impact of

chronic exposure to chemical hazards. Chemical hazards to be considered would include allergens, mycotoxins, pesticides metals and other toxic elements, and other chemicals such as industrial chemicals and chemicals formed during processing.

Occurrence of Illnesses since 1998	H Thousands	3	9	9
	M Hundreds	1	3	9
	L Teens	1	1	1
		L ≤1 since 1998	M >1-12 since 1998	H ≥13 since 1998
Frequency of Outbreaks since 1998				

Figure 2. Scoring for Frequency of Outbreaks and the Occurrence of Illnesses for a Food-Hazard Pair. Assign 0=no outbreaks and no occurrence of illnesses. The occurrence of illnesses includes both sporadic and outbreak-associated cases since 1998.

For hazards that have been involved in an outbreak (e.g., microbial hazards and marine biotoxins), data since 1998 from existing databases (see examples in Table 5 below) would be used in scoring according to Figure 2. For hazards that have not been involved in an outbreak (e.g., undeclared allergens and chemical hazards), scoring would be as follows:

For undeclared allergens:

0=no occurrence of illnesses

1=fewer than 10 illnesses per year

3=ten to 100 illnesses per year

9=more than 100 illnesses per year

For chemical hazards:

0 = No evidence that the chemical occurs in the food commodity

1 = Despite the association of the chemical with a food, there is little evidence of illnesses in the United States

3 = Some evidence that this chemical may cause illnesses in the United States

9 = Compelling evidence that this chemical causes illnesses in the specific food in the United States

C2: Severity of Illness

For microbial pathogens and some toxins of microbial origin, where data on hospitalization and mortality rate are available, e.g., from Scallan et al. (2011), the data would be used for severity scoring. For food safety hazards such as certain toxins of microbial origin and chemical hazards where quantitative indicators for illness severity are not available, qualitative information on

illness duration, sequelae and severity (e.g., information from ICMSF, 2001) would be used for scoring in the draft risk model.

Table 1. Scoring for Severity of Illness from the Hazard

Score = 0	Score = 1	Score = 3	Score = 9	References
Hospitalization rate 0%	Hospitalization rate $\leq 10\%$ or mortality rate 0%	Hospitalization rate $>10\text{-}20\%$ or mortality rate $\leq 0.5\%$	Hospitalization rate $>20\%$ or mortality rate $>0.5\%$	Anderson et al. 2011 with modifications
No known hospitalization	Moderate hazard: not usually life threatening; no sequelae; normally short duration; symptoms self-limiting; can be severe discomfort; transient effects, resolved with little medical intervention.	Serious hazard, for general or susceptible ^a population: incapacitating, but not 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.	ICMSF 2001 with modifications

^a 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).

Either the Anderson et al. (2011) approach or the ICMSF (2001) approach with modifications would be used to define the scoring, depending on available data and information. Examples for illness severity associated with microbial pathogens and chemical hazards, as well as food vehicles, are shown in Appendix 8-A (Chapter 8) of the International Commission on Microbiological Specifications for Foods Book 7 (ICMSF, 2001).

C3. 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 – that consuming a food will result in illness – is a function of the likelihood that the food is contaminated with a given hazard. (It is also a function of the frequency of consumption, as described in Criterion 6, below.) The likelihood of contamination for microbial hazards would be determined by percent contamination rate, e.g., by using weighted average prevalence based on the method reported by Anderson et al. (2011), or by using prevalence data from survey studies, e.g., *L. monocytogenes* in RTE foods (Gombas et al. 2003), pathogens in fresh produce from the USDA Microbiological Data Program (MDP) program (<http://www.ams.usda.gov>), and FDA surveillance data. The likelihood of contamination for chemical hazards would be determined by the percent positive above action levels (e.g., aflatoxins) or above allowable levels. Where data are not available for contamination rate, other indicators for contamination

would be used for scoring, e.g., RFR reports, FDA recall database, and FDA compliance programs.

Table 2. Scoring for Likelihood of Contamination of the Hazard in Food

Score = 0	Score = 1	Score = 3	Score = 9	References
No known occurrence ^a	Low ($\leq 1\%$)	Medium (1-5%)	High ($>5\%$)	Anderson et al. 2011 with modifications
No recalls; or no RFR reports; other indicators	≤ 5 recalls/yr; and ≤ 5 RFR reports/yr; other indicators	$>5-10$ recalls/yr; and $>5-10$ RFR reports/yr; other indicators	>10 recalls/yr; or >10 RFR reports/yr; other indicators	FDA

^a No known detection of a microbial hazard, or no known detection of a chemical hazard above an action level or allowable level.

C4: Growth Potential/Shelf Life

Foods differ in shelf life and their ability to support pathogen growth. Some microbial pathogens may multiply in foods while chemical hazards do not. A food may have intrinsic characteristics such as pH, water activity, the presence of inhibitory compounds, or a combination of these factors that prevent the growth of pathogens (NACMCF, 2010). A score of 0 would be 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. (Growth of microorganism(s) involved in producing biotoxin would be considered in a similar fashion as appropriate.) The scoring system outlined in Figure 3 would be used to assign a score of 1, 3 or 9 for a food-hazard pair based on the shelf life of the food as well as the potential for pathogen growth in the product according to the following definitions (adapted with modifications from Anderson et al., 2011).

Growth potential:

Strong: Likely growth at temperature at which the food is intended to be held and stored, including refrigeration or room temperature

Moderate: 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

Low: No evidence that pathogens may grow and includes conflicting studies where inconsistent results are reported in different studies

Example of shelf life duration using produce:

Long: 49 days or longer

Moderate: 15-48 days

Short: 14 days or less

Growth potential	Strong	3	9	9
	Moderate	1	3	9
	Low	1	1	1
		Short	Moderate	Long
		Shelf life		

Figure 3. Scoring for Growth Potential and Shelf Life. Assign 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.

C5: Manufacturing Process Contamination Probability/Intervention

Food safety hazards may be introduced during primary production on the farm, during processing, manufacturing, retail distribution, and during food preparation at retail establishments or in homes. Criterion 3 above would address the overall likelihood of contamination in the finished product from various points in the food supply system. Criterion 5 specifically would address the ability to control contamination that could be introduced during the manufacturing process. This criterion also would address hazards that may be introduced during manufacturing, in particular for products that do not receive an adequate kill step, e.g., certain fresh-cut vegetables (FDA, 2008a), or products that are exposed to the processing environment post-lethality, e.g., contamination of *L. monocytogenes* in ready-to-eat foods (FDA, 2008b) and *Salmonella* in low-moisture foods (GMA, 2009) that have been implicated in illnesses and outbreaks. The scoring would take into account available control measures and interventions that have been validated (e.g., FDA, 2009b and 2011b; NACMCF, 2010) and can be applied during manufacturing to eliminate, reduce (to acceptable levels), or otherwise control a hazard. The probability of contamination during manufacturing and the effectiveness of steps taken to reduce contamination would be defined qualitatively as follows and this information would be used in the scoring system outlined in Figure 4.

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, or contamination introduced post manufacturing

Steps taken to reduce contamination:

Strong: Control measures available and 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

Contamination probability	High	3	9	9
	Moderate	1	3	9
	Low	1	1	1
		Strong	Moderate	Weak
		Steps taken to reduce contamination		

Figure 4. Scoring for Manufacturing Process Contamination Probability and Intervention. Assign 0 = data that indicates no detection of contamination during manufacturing.

C6: Consumption

When contaminated, products that are consumed frequently 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, consumption would be defined as the percent population consuming the food. Consumption would be determined by using survey and consumption databases, e.g., the National Health and Nutrition Examination Survey (NHANES). Thus, it would be the consideration of the scores for both C3 and C6 that qualitatively would define the likelihood that consuming a particular (contaminated) food will result in illness.

Table 3. Scoring for Consumption*

Score = 0	Score = 1	Score = 3	Score = 9	References
≤1%	1-5%	>5-10%	>10%	Anderson et al. 2011 with modifications

* Based on total U.S. population.

C7: Economic Impact

The estimated annual incidence and illness cost, e.g., costs of diagnosis, medical treatment, lost QALYs (quality adjusted life years), and premature mortality, would be used to calculate the annual costs of illness attributed to food-hazard pairs. Where this information is available, it would be used as described in the scoring system outlined in Table 4. Non-public health economic impacts such as potential industry costs and loss of market costs would not be included in this criterion. While the economic impact (monetary value) for 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 may consider additional economic factors such as lost productivity and lost utility due to foodborne illness.

Table 4. Scoring for Economic Impact

Score = 0	Score = 1	Score = 3	Score = 9	Reference
Unknown or ≤\$100K /year	Lower or >\$100K to 500K /year	Medium >\$500K to 10M	Higher >\$10M	Not applicable

Data Needs

Data needs for the draft semi-quantitative risk ranking model are summarized in Table 5. A number of references and sources have been identified to obtain data and information for scoring according to the seven criteria. Examples of preliminary scoring results for several food-hazard pairs are provided in Appendix I.

Table 5. Data Needs and Example Data Sources for Risk Ranking Criteria

Criteria	Data Needs	Example Data Sources
C1	Frequency of outbreaks, the number of cases per year (outbreak and sporadic cases), disease multiplier	Outbreak and illness data from FDA and CDC; CSPI database (http://www.cspinet.org/foodsafety/outbreak/pathogen.php); Scallan et al., 2011
C2	Severity of illness (including hospitalization rate, mortality rate and other indicators)	Scallan et al. 2011; CDC data; ICMSF Book 7 (ICMSF, 2001)
C3	Likelihood of contamination	Recalls (http://www.fda.gov/Safety/Recalls/default.htm), Reportable Food Registry (RFR) reports (http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm); Anderson et al. 2011; ICMSF Book 6 (ICMSF, 2005); regulatory surveillance and monitoring data (e.g., FDA Total Diet Study); USDA MDP program ^a ; FDA compliance programs; industry data
C4	Growth potential/shelf life	Food Code definition for TCS Foods ^b (FDA, 2009a); NACMCF, 2010; Anderson et al., 2011; FDA guidance documents; typical shelf life from USDA agriculture handbook 66 (USDA, 2004); industry data
C5	Manufacturing process contamination/intervention	FDA guidance documents; regulatory surveillance and inspection data; industry data
C6	Consumption	NHANES/WWEIA ^c ; FoodNet Population Survey
C7	Economic impact	FDA & CDC data; Batz et al., 2011; Scallan et al., 2011; Scharff, 2012; Hoffmann et al., 2012

^a Data from the MDP program is available at <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateO&topNav=&leftNav=ScienceandLaboratories&page=MDPProgramReports&description=MDP+Program+Reports&acct=microbiodataprg>.

^b More information on TCS (Temperature Control for Safety) food at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm189170.htm>.

^c The National Health and Nutrition Examination Survey “What We Eat in America” (NHANES/WWEIA) at <http://www.cdc.gov/nchs/nhanes.htm>.

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Appendix I

Examples: Risk ranking for food-hazard pairs based on tentative semi-quantitative criteria ^a

Food-Hazard	C1	C2	C3	C4	C5	C6	C7	Total Score
Food A-Pathogen A	3	9	1	3	3	9	1	29
Food B-Pathogen A	9	9	1	3	3	9	3	37
Food B-Pathogen B	0	1	9	1	1	9	0	21
Food C-Chemical C	1	9	1	0	1	9	1	22
Food D-Chemical D	1	1	3	0	3	1	1	10

^a Criteria (see more information on criteria descriptions and scoring above):

C1. Frequency of outbreaks and occurrence of illnesses

C2. Severity of illness, including hospitalization rate, mortality rate and other indicators

C3. Likelihood of contamination

C4. Growth potential/shelf life

C5. Manufacturing process contamination probability/intervention

C6. Consumption

C7. Economic impact

In these hypothetical examples, risk scores were determined using the tentative criteria outlined in the draft semi-quantitative risk ranking model for five food-hazard pairs including four foods and four hazards. Food A and Food B were both known to be associated with outbreaks caused by Pathogen A, but fewer outbreaks/illnesses were associated with Food A than in Food B. When illnesses occurred, hospitalization rate was above 20% for both food-hazard pairs. Both Foods A and B were contaminated with Pathogen A at low prevalence (<1%). Both products had similar shelf life and similar ability to support the growth of the pathogen, with comparable manufacturing process contamination probability and intervention. Both products were consumed by >10% of the population. Food A-Pathogen A had a lower risk score than Food B-Pathogen A because of fewer outbreaks/illnesses and less economic impact.

Food B was known to be contaminated by Pathogen B in addition to pathogen A. The risk score for Food B-Pathogen B was lower than Food B-Pathogen A because, even though the prevalence of contamination with pathogen B was high (>5%), there was no reported outbreaks or illnesses associated with pathogen B in Food B. In addition, the growth potential for Pathogen B in Food B was low and there were control measures in place during manufacturing to control the pathogen (i.e., strong steps taken to reduce/control contamination).

The risk scores for Food C-Chemical C and Food D-Chemical D differ primarily because Chemical C caused severe illness (while chemical D caused mild illness), and Food C was consumed by >10% of the population (while Food D was consumed by 1-5% of the population).

For Food B in which multiple hazards occur, the total score (58) from Food B-Pathogen A and Food B-Pathogen B would be used in risk ranking.