Supplemental Materials

FDA-iRISK — A Comparative Risk Assessment System for Evaluating and Ranking Food-Hazard Pairs: Case Studies on Microbial Hazards

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Supplemental Table IA. Inputs in FDA-iRISK for elements of the *Salmonella* in Peanut Butter in Total Population risk scenario

Element of a Risk Scenario	Input	Description [a]
Food	Peanut Butter	Paste made of roasted, ground peanuts plus up to 10% stabilizing and seasoning ingredients, and not exceeding 55% fat content (*42*).
Hazard	*Salmonella*	*Salmonella* spp. has been detected in a number of low-moisture foods, including peanut butter (*34*). *Salmonella* outbreaks associated with low-moisture products have been reported worldwide (*34*). Illness is usually self-limiting but can lead to hospitalization and death. While salmonellosis may occur in healthy individuals, those most at risk are young children, pregnant women, older adults, and immunocompromised individuals (*40*).
Process Model	See Suppl. Table IB	The process model begins at post-roasting and it was assumed that contamination occurs in some instances in the peanut butter processing environment (*9, 34*). The prevalence of this contamination was based on the occurrence of past outbreaks in the U.S.
Consumption Model	See Suppl. Table IC	Based on consumption of peanut butter among women in the U. S. Nurses' Health Study as cited in Jiang et al. (*20*) and data extrapolated to represent consumption in the total population.
Dose Response Model	See Suppl. Table IC	*Salmonella* dose-response model developed by an expert panel (*13*).
Health Effects	See Suppl. Table IC	Based on data from the U.S. (*33*) and Australia (*2*).

[a] Templates in FDA-iRISK allow the description of each of the elements, including as much information as needed to describe the element, assumptions and references.

Supplemental Table IB. Inputs for the process model of the *Salmonella* in Peanut Butter in Total Population risk scenario

iRISK template, Input parameter	Input data	Reference/Rationale
Initial prevalence	5.5E-6	Prevalence based on estimated finished product contamination in previous outbreaks. There were outbreaks of salmonellosis associated with peanut butter in 2006-2007 and in 2008-2009 (*7*, *8*). In both cases the contamination was traced to a single processor. The processor involved in the 2009 outbreak handled <2% of the U.S. peanut supply (*36*). It was assumed that contamination affects half a day's production and the processor produces 1% of consumed peanut butter. The potential retail product affected is (0.5/365) x 1% of national consumption (5E+8 kg: see Consumption Model), or (0.5/365) x 0.01 x 5E+8 = 6849 kg. Prevalence at retail: Two outbreaks over 5 years; this indicated (2 x 6849)/(5 x 5E+8)=5.5E-6
Initial concentration	Uniform (-1.52, 2.55) log CFU/g	A range of <0.03 to 2 cells/g for peanuts in the shell was reported by Kirk et al. (*22*) in an outbreak of *Salmonella* attributed to that food in Australia, Canada and the U.K. Burnett et al. (*5*) reported a *Salmonella* level of as low as 3 cells per gram in peanut butter associated with an outbreak in Australia. In the 2006–2007 outbreak associated with peanut butter in the U.S., *Salmonella* was found at 1.5 MPN/g in an unopened jar and a lower level was found in another product sample (*34, 44*). A range up to 2.55 log CFU/g (0.48+2.07) was defined to take into account decrease during 2-week storage at 21°C since the outbreak data presumably were obtained sometime after production or retail (survival data below).
Unit mass	6.85E+6 g	Unit mass: represented half a day's production, 6849 kg (6.85E+6 g).
Process stage1: Packaging	Process type: Partitioning. Unit mass 250g	Change in unit mass used in FDA-iRISK calculation.
Process stage 2: Storage	Process type: Decrease. Uniform (0.49, 3.47) log CFU	Burnett et al. (*5*) reported log populations surviving in inoculated peanut butter up to 24 weeks at 21°C. We assumed a uniform distribution consisting of the log decreases at 1 week and at 24 weeks, at 5° and 21°C, in which survival data 1-hr post inoculation was used in calculating log reduction to represent *Salmonella* adapted to the processing environment.

Supplemental Table IC. Inputs for consumption model, dose-response model and health effects of the *Salmonella* in Peanut Butter in Total Population risk scenario

Element of a Risk Scenario	iRISK template, Input parameter	Input data	Reference/Rationale
Consumption Model	Grams per eating occasion (eo)	30 g	Based on consumption of peanut butter as cited in Jiang et al. (*20*). Assigned eo/wk as follows: 0 for "never/almost never"; 0.5 for "once/wk"; 2.5 for "1-4 times/wk"; 5 for ">=5 times/wk". Multiplied these eo by the proportion for each group x population of U.S. (3.07E+8) x 52 and summed across the 4 groups, for total annual eo of 1.7E+10.
	Eating occasions per year	1.7E+10	Assuming an amount per eo of 30g as per Jiang et al. (*20*), this predicted total US consumption of 5E+8 kg/yr, which is consistent with reported availability adjusted for loss of peanuts of 7.5E+8 kg/yr based on 5.4 lbs per capita annually (*37*).
Dose Response Model	Beta-Poisson model	α=0.1324 β=51.45	Maximum Likelihood techniques were used by an FAO/WHO expert panel (*13*; Table 3-16) to generate the best-fitting dose response relationship using real world data including outbreak data. The best fit results were used to generate the expected values of parameters α and β.
	Probability of adverse effect given response	100% for all three scenarios	The dose-response models were developed using illness as an endpoint (*13*).
Health Effects	DALY template, salmonellosis in general population	0.019 DALYs per case	The health endpoints were complicated (i.e. hospitalized) and uncomplicated gastroenteritis, and mortality, with fractions derived from the ratios of estimated hospitalized cases, and fatal cases, of estimated total cases in the U.S. (*33*). Illness duration and severity weight were based on AIWH (*2*).

Supplemental Table IIA. Inputs in FDA-iRISK for *L. monocytogenes* in Soft Ripened Cheese in Three Population Groups risk scenarios [a]

Element of a Risk Scenario	Input	Description
Food	Soft ripened cheese	Soft ripened cheese, such as brie and camembert, made from pasteurized milk. Soft ripened cheese with >50% moisture (*41*).
Hazard	*L. monocytogenes*	This pathogen occurs widely in both agricultural (soil, plants and water) and food processing environments. Although destroyed by pasteurization and cooking, it may re-contaminate cooked ready-to-eat foods prior to packaging. Ingestion of *L. monocytogenes* can cause listeriosis. Illness symptoms include fever and gastroenteritis (flu-like) in healthy people, and may include serious outcomes such meningitis, septicemia and death in neonates, immunocompromised individuals, and the elderly (*41*).
Process Model	See Suppl. Table IIB	Initial conditions were based on a retail survey of ready-to-eat foods in the U.S. (*15*). Growth during consumer storage was predicted by using the ComBase Predictor (http://www.combase.cc) given consumer practices.
Consumption Model	See Suppl. Table IIC	Annual eating occasions were taken from Table III-2 and grams per eating occasion estimated from Table III-3 in the FDA/FSIS risk assessment (*41*).
Dose Response Model	See Suppl. Table IIC	The r-value of the exponential model was calculated according to the relative susceptibility of the population group compared to the reference population ("intermediate age") in the U.S., and is "the probability that a single cell of *L. monocytogenes* would cause an illness" (*14*; Table 5.6).
Health Effects	See Suppl. Table IIC	Health endpoints and severity weights, duration, fraction of cases, and mortality rate were based on data from Kemmeren et al. (*21*) and McLauchlin et al. (*25*). Assumed these data (mostly from the Netherlands and the U.K.) is applicable to the U.S. population.

[a] Different scenarios were developed for three population groups: perinatal population, adults 60 years of age or older, and general population (intermediate-aged).

Supplemental Table IIB. Inputs for the process model element of the *L. monocytogenes* in Soft Ripened Cheese in Three Population Groups risk scenarios

iRISK template, Process type	Input data	Reference/Rationale
Initial prevalence	0.0104	Data from a retail survey by the National Food Processors Association (*15*).
Initial concentration	Triangular [a] (-1.39, -1.15, 0.699) log CFU/g	Prevalence: 1.04% in mold-ripened cheeses, same as soft ripened cheese defined in FDA/FSIS (*41*) across Maryland and California. Level: Of 14 positive samples, 12 contained between 0.04 and 0.1 CFU/g, and 2 contained between 1 and 10 CFU/g. The minimum was taken as 0.04 CFU/g, the mode as the midpoint of 0.04 and 0.1, and the maximum as the midpoint of 1 and 10 CFU/g. Use minimum, mode and maximum (all in log CFU/g) for the Triangular distribution.
Unit mass	227 g	Unit mass: Sampling method used 25g food; it was assumed to be representative of individual units of food 227g.
Process stage 1 [b]: Consumer storage	Process type: Increase by growth Triangular [a] (0,0.03,5.79) log CFU	The initial contamination data was collected at retail, and therefore, growth of *L. monocytogenes* may occur during consumer storage prior to consumption. The most likely storage time was 6 to 10 days, with a minimum of 0.5 days and a maximum of 15 to 45 days (*41*). Consumer refrigerator temperatures averaged 3.4°C with a standard deviation of 2.4°C (*12*). The log increase was modeled as a Triangular distribution, where the minimum increase was 0, the mode increase predicted for 8 days at 3.4°C, and the maximum increase predicted for 15 days at 13.0°C (i.e. mean temperature + 4SD). The ComBase Predictor (http://www.combase.cc/) was used to estimate the log increase in population for these conditions, specifying a pH of 4.65, and salt content of 1.7%.

[a] Other templates available as an option in FDA-iRISK include Normal distribution, Beta PERT, Empirical distribution, Uniform distribution and fixed value, that can be used to define a concentration distribution or growth.

[b] For the case studies only one process stage was included. However, multiple stages can be defined in a process model using the built-in process type templates for increase, decrease, redistribution, etc.

Supplemental Table IIC. Inputs for the consumption model, dose-response model and health effects of the *L. monocytogenes* in Soft Ripened Cheese in Three Population Groups risk scenarios

Element of a Risk Scenario	iRISK template-Input parameter	Input data [a]	Reference/Rationale
Consumption Model	Grams per eating occasion	(i) Triangular (10,28,85) [b] g (ii) Triangular (10,28,85) g (iii) Triangular (10,28,168) g	Grams per eating occasions taken from Table III-3 of the FDA/FSIS risk assessment (*41*), weighted percentiles consumption for total U.S. population. The minimum for the Triangular distribution was assumed to be 10 g for all three population groups. The 50th (28g) from Table III-2 was used as the mode, the 95th percentile was used as the maximum for the perinatal and the elderly (adults 60+) populations, and the 99th percentile was used for the maximum for the intermediate-aged population.
	Eating occasions per year	(i) 1.2E+07 (ii) 1.8E+08 (iii) 1.7E+09	Annul eating occasions was taken from Table III-2 of the FDA/FSIS risk assessment (*41*).
Dose Response Model	Exponential [c]	(i) 4.51E-11 (ii) 8.39E-12 (iii) 5.34E-14	The r-value was calculated according to the relative susceptibility of the perinatal population or the adults 60+ population compared to the reference population ("intermediate age") in the U.S. The r-value is "the probability that a single cell of *L. monocytogenes* would cause an illness" (*14*; Table 5.6).
	Probability of adverse effect given response	100% for all three scenarios	The dose-response models were developed using illness as an endpoint (*14*).
Health Effects	DALY templates for listeriosis	(i) 14 DALYs per case (ii) 2.6 DALYs per case (iii) 5.0 DALYs per case	Templates: (i) listeriosis in the perinatal population, (ii) listeriosis in adults 60 years of age or older, and (iii) listeriosis in the intermediate age population developed using data from Kemmeren et al. (*21*) and McLauchlin et al. (*25*).

[a] Input data are defined separately for consumption, dose-response and health effects for the three separate risk scenarios: (i) the perinatal population, (ii) adults 60 years of age or older, and (iii) the intermediate-aged population (general population aged 5-59).

[b] Other templates available as an option in FDA-iRISK include Normal distribution, Beta PERT, Empirical distribution, Uniform distribution and fixed value that can be used to describe serving size distribution.

[c] Other templates are available in FDA-iRISK, e.g., Beta-Poisson distribution and Non-Threshold Linear distribution, and can be used to describe dose-response relationships for microbial hazards.

Supplemental Table IIIA. Inputs in FDA-iRISK for *L. monocytogenes* in Cantaloupe Adults 60+ Population risk scenario

Element of a Risk Scenario	Input	Description
Hazard	*L. monocytogenes*	See Supplemental Table IIA.
Food	Cantaloupe	Ready-to-eat cut cantaloupe obtained from retail stores.
Process Model	See Suppl. Table IIIB	Initial conditions were based on a retail survey of ready-to-eat low-acid cut fruits (Abstract available at https://iafp.confex.com/iafp/2012/webprogram/Paper3006.html, in poster presented at the International Association for Food Protection 2012 meeting). Growth during consumer storage was predicted by using the ComBase Predictor (http://www.combase.cc) given consumer practices.
Consumption Model	See Suppl. Table IIIC	National Health and Nutrition Examination Survey (NHANES) data 2003-2008 (available at http://www.cdc.gov/nchs/nhanes.htm).
Dose Response Model	Exponential model	See Supplemental Table II C, exponential model for adults 60 years of age or older, r-value is 8.39E-12.
Health Effects	DALY template for listeriosis	See Supplemental Table II C, DALY template for listeriosis for adults 60 years of age or older, 2.6 DALYs per case.

Supplemental Table IIIB. Inputs for the process model of *L. monocytogenes* in Cantaloupe Adults 60+ Population risk scenario

iRISK template, Process type	Input data	Reference/Rationale
Initial prevalence	0.013	Initial contamination of *L. monocytogenes* was based on preliminary data obtained for ready-to-eat cut cantaloupe at retail from an ongoing market basket survey for year one of a 2-year survey. Raw data: 425 samples collected across four states (Maryland, California, Connecticut and Georgia) over one year. There were 5 positive samples. A dilution assay was used to determine concentration in the positive samples, using a 4-dilution 3-tube MPN protocol, with dilutions corresponding to 10g, 1g, 0.1g, 0.01g. The MPN patterns observed were (3,0,0,0), (2,1,0,0), (2,1,0,0), (2,0,0,0) and (0,1,0,0). The prevalence and the distribution that best describes the concentrations in positive sample were determined from the raw data, using the method described in Pouillot et al. (*31*). Prevalence: 1.3% in cut cantaloupe; level in contaminated products: Normal (-0.97, 0.003) log10 CFU/g. (The prevalence estimate and concentration distribution may change and may be updated in the risk scenario, when additional data from year 2 of the survey is available and with further consideration of potential influence of clustering of positive samples on the prevalence estimate). Unit mass: Testing method used 25g food, but prevalence is assumed to be representative of individual units of food 227 g (8 oz.).
Initial concentration	Normal (-0.97, 0.003) log CFU/g	
Unit mass	227 g	
Process stage 1: Consumer storage	Process type: Increase by growth Empirical distribution: [0.0,0.0], [0.506,0.384], [0.767,0.768], [0.868,1.15], [0.928,1.54], [0.961,1.92],	Ready-to-eat cut cantaloupe may be stored in the home refrigerator after purchase and prior to consumption. Home storage time is represented by a triangular distribution with minimum 0.5 day, mode 3.5 days, and maximum 10 days, according to the FDA/FSIS 2003 *L. monocytogenes* risk assessment (*41*), where the mode for storage time is 3 to 4 days, with a minimum of 0.5 days and a maximum of 8 to 12 days for the Fruit Food Category. Consumer refrigerator temperatures average 3.4°C with a standard deviation of Consumer refrigerator temperatures average 3.4°C with a standard deviation of 2.4°C based on EcoSure data (*12*). Growth was predicted using EGR5 (growth rate at 5 °C) distribution and the time and temperature distributions for consumer storage. EGR5 was derived by using data reported in the literature. Specifically, data reported in studies by Leverentz et al. (*23, 24*) for *L. monocytogenes* growth at 10 °C in melon cubes (pH 5.8), and data

[0.978,2.30], [0.987,2.69], [0.992,3.07], [0.996,3.46], [0.997,3.84], [0.998,4.61], [0.9994,4.99], [0.9998,6.15], [1,7.7] log CFU	reported by Penteado and Leitao (*30*) for growth at 10 and 20 °C in Muskmelon pulps (pH 5.87) was extracted from the studies. The ComBase modeling tool DMFit (http://modelling.combase.cc) was used to fit the data to determine growth rate at 10 or 20 °C; then equivalent EGR5 was determined according to the method described in the Exposure Assessment chapter in the 2003 FDA/FSIS *L. monocytogenes* risk assessment (*41*). The EGR5 was represented by Triangular (0.11, 0.16, 0.25) log CFU/day. The log increase was modeled as an empirical distribution. Growth distribution data was obtained by a simulation in Analytica (version 4.4; Lumina Decision Systems, Los Gatos, CA) based on the times, temperatures and growth rates. The growth predicted (i.e., output from the Analytica simulation) was used as the input for the *L. monocytogenes*-cantaloupe risk scenario, as an empirical distribution.

Supplemental Table IIIC. Inputs for consumption model of the *L. monocytogenes* in Cantaloupe Adults 60+ Population risk scenario

iRISK template, Input parameter	Input data	Reference/Rationale
Grams per eating occasion	Empirical distribution: [0,0], [0.10,47.95], [0.20,57.99], [0.25,62.74], [0.30,67.96], [0.40,82.23], [0.50,115.7], [0.60,134.8], [0.70,159.6], [0.75,202.0], [0.80,206.2], [0.90,273.9], [0.95,314.1], [0.975,357.7], [0.99,415.2], [0.995,495.2], [1,500] g	Serving size based on NHANES 2003-2008, cantaloupe consumption by seniors (adults 55+). The analysis was conducted using the Foods Analysis and Residue Evaluation Program (FARE; Exponent & Durango Software, Washington, DC), version 9.28). The distribution percentiles for users of cantaloupe obtained from the FARE program were the input, as an empirical distribution. Estimate of the number of servings: Analysis based on the NHANES 2003-2008 data shows that the number of eating occasions is 2,947,140 per day for the adults 55+ subpopulation. The total number of servings per year is 365 x 2,947,140 = 1.08E+09.
Eating occasions per year	1.08E+09	