RUTGERS
New Jersey Agricultural Experiment Station

A General Introduction to Quantitative Microbial Risk Assessment and Some Examples From the US

Don Schaffner, PhD
Extension Specialist and Distinguished Professor
Food Safety Talk podcast

Risk Analysis Components

- (Quantitative) Risk Assessment
  - How big is the risk, what factors control the risk?
  - Scientific process
- Risk Communication
  - How can we talk about the risk with affected individuals?
  - Social and psychological process
- Risk Management
  - What can we do about the risk?
  - Societal, practical and political process

Presentation overview

- Peanut candy QMRA
  - Unpublished
  - Is a recall needed?

- Leafy Greens QMRA
  - Published
  - Can we simulate outbreak?

Peanut product risk assessment

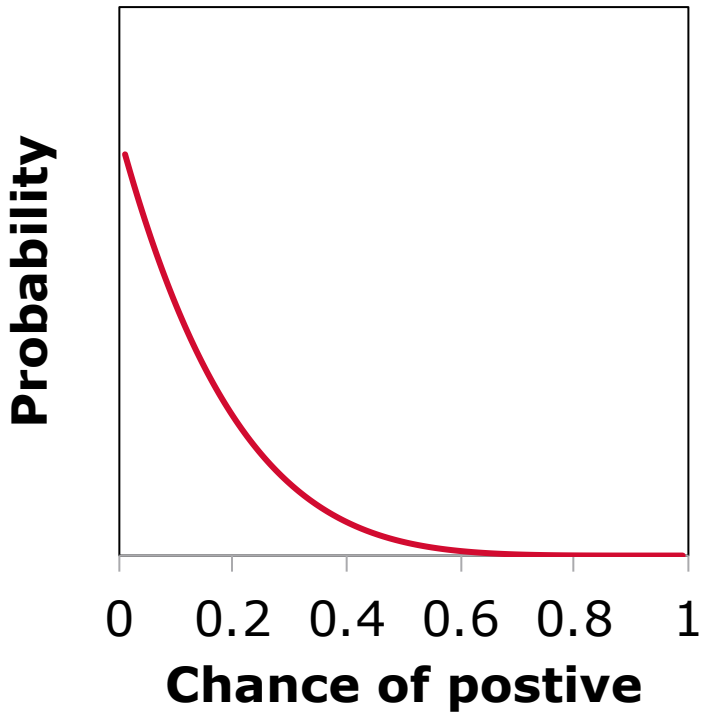
- Candy company had the misfortune to purchase peanut paste from the Peanut Corporation of America
- Facing a recall of most of their product line right before Valentines Day
- Many negative test results
- No tight control of thermal process
- Unknown effectiveness of thermal process
- Unknown survival post-process

Peanut product risk assessment

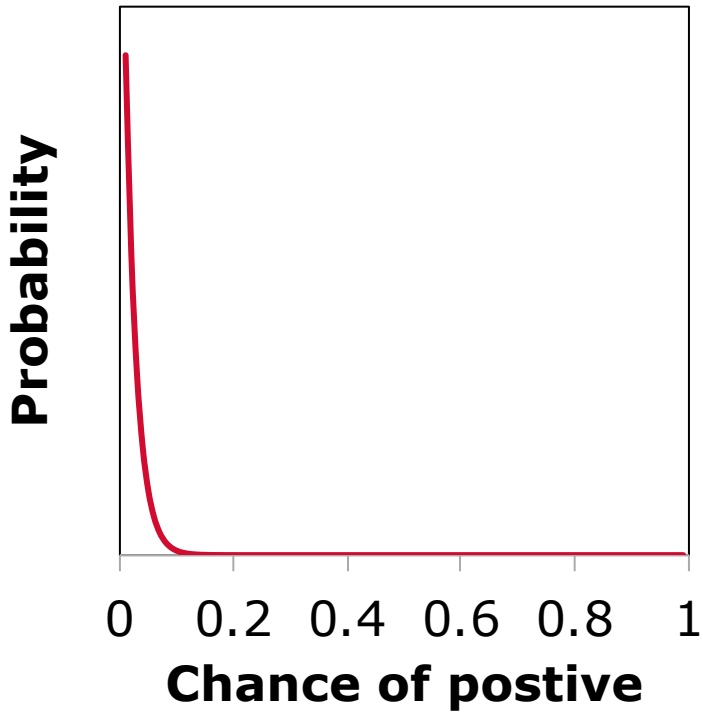
Formulation details	What is the serving size? How much of ingredient X per serving? How much peanut butter in ingredient X?
Effect of testing	Probability of a Salmonella positive, given tests
Salmonella concentrations	Assumed Salmonella cells per gram Grams per serving Cells per serving Log cell per serving initial Log reduction Log cell per serving, final Cell per serving, final
Human illness	Probability of illness – Dose response Is this person sick?

What use is sampling?

- Zero of 5 positive



- Zero of 50 positive



Non-linear thermal process

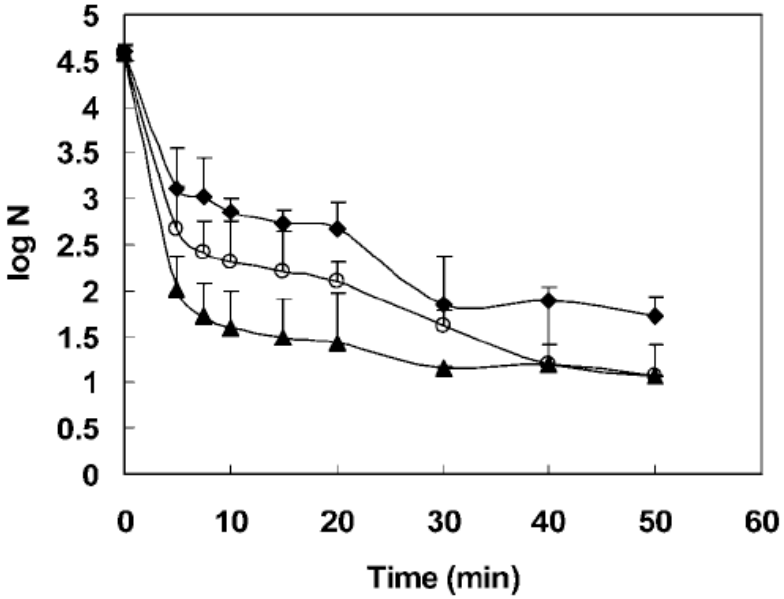
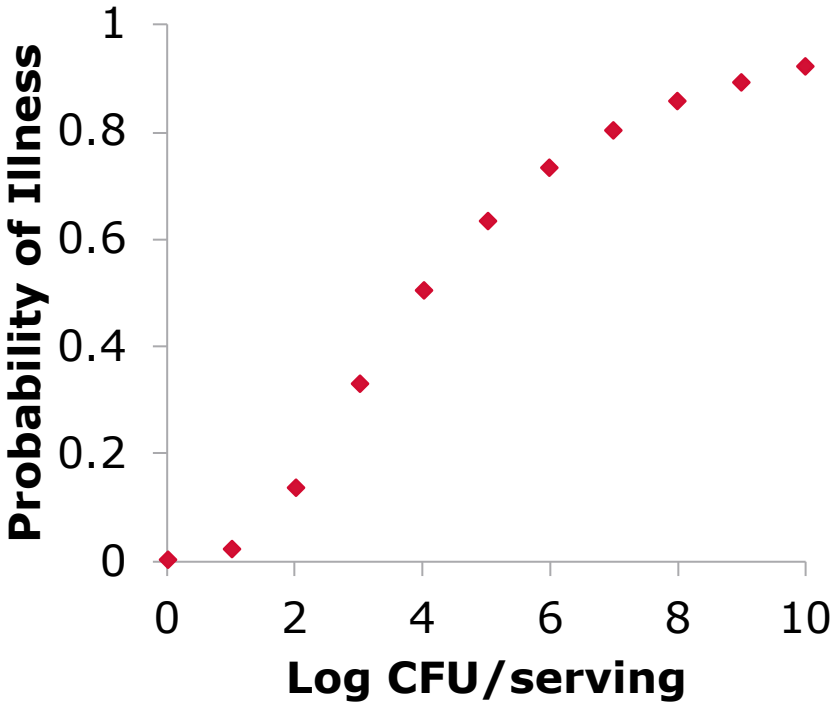


FIGURE 2. *Inactivation of low initial concentrations of* Salmonella *Agona,* Salmonella *Enteritidis, and* Salmonella *Typhimurium in peanut butter. Bacteria (approximately 5 × 10⁴ CFU/g) were introduced into preheated 25-g samples of peanut butter, and the number of surviving cells was determined from plate counts. Values are the log CFU per gram of sample. Bacteria were treated in peanut butter at 70°C (◆), 80°C (○), or 90°C (▲). The standard error of the mean for the results from the three serovars is shown.*

—

- ~~Log N = -D*t~~
- Log N = $-b*t^n$
- Sachar and Yaron (JFP, 2006)

Dose response

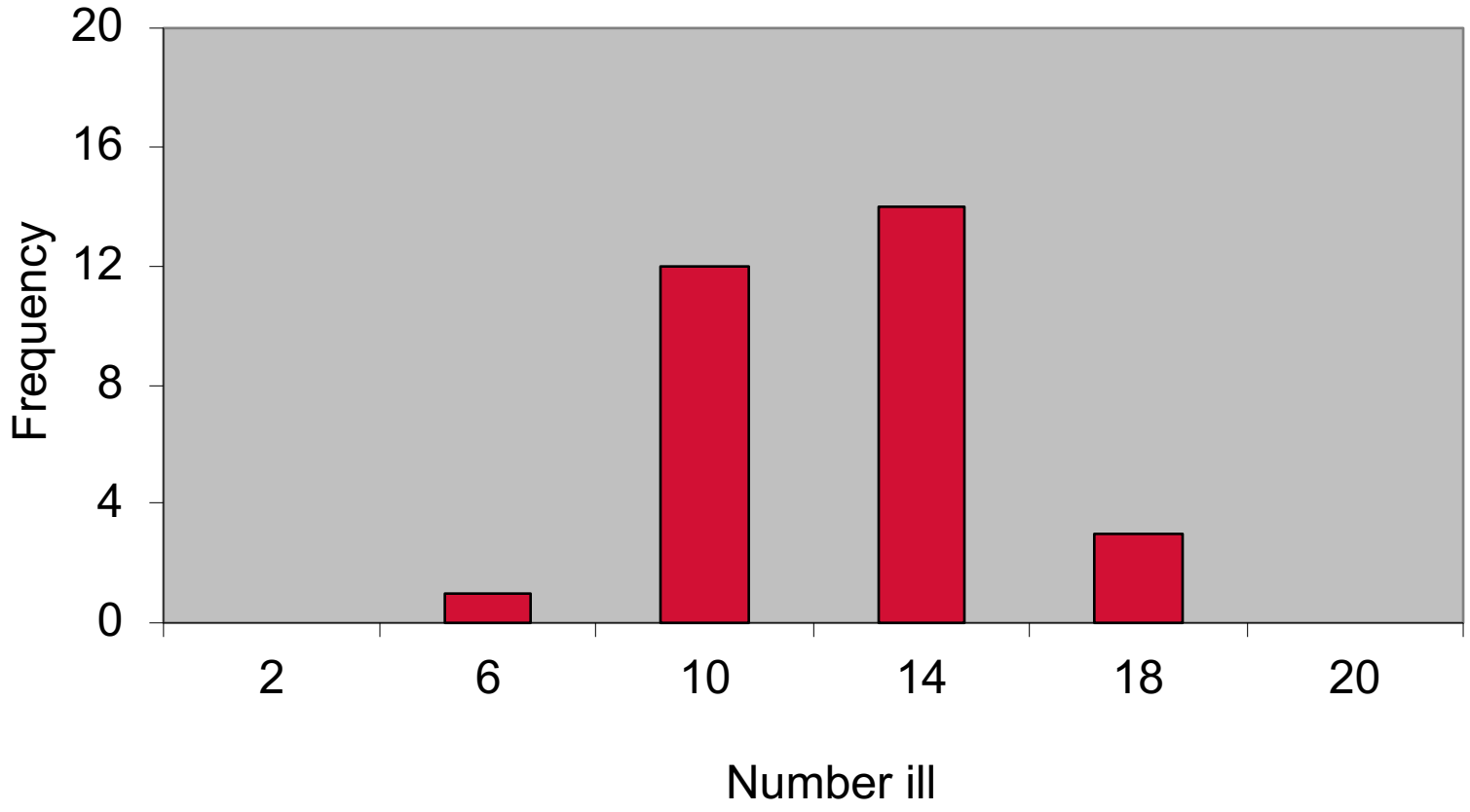


- There is no such concept as the "infectious dose"
- One cell can make you sick
- 1 cell = 0.02% prob of illness, 1/392 people
- DR model
  - FAO/WHO 2002. Risk assessments of Salmonella in eggs and broiler chickens.

Scenario assumptions

- The peanut butter is contaminated at 1.5 cells/g
- One serving contains 3.6 grams of peanut butter
- One hundred and fifty tests of peanut butter, all negative
- One and a half million servings
- Log reduction assumed to vary uniformly from 0.86 to 1.49 Log CFU
- Dose response model from FAO/WHO RA for *Salmonella* in eggs and broiler chickens
- Simulated 1.5 million servings, 30 times

Results: assuming ~0.9-1.5 log reduction



Updated with new data

- Company funded research to quantify their actual process, and to determine *Salmonella* post process survival over time
- QMRA updated with those data, to decrease risk

	Number of cases expected to result from fondant process as specified in report	
Storage time (days)	**Process A**	**Process B**
0	**0**	**3**
7	**0**	**1**
21	**0**	**0**
35	**0**	**0**

Peanut QMRA summary

- Risk assessment tells you the risk
  - Risk managers must decide what to do
  - No zero risk
- Quantitative microbial risk assessments can be a valuable tool for
  - Assisting food companies (as well as government policy makers)
  - Identifying data gaps
- Increased recognition of value of models and risk assessments

Leafy Greens QMRA, (JFP 2011:700–708)

- Microbial safety of fresh produce is increasingly important
- Major multistate outbreaks in the fall of 2006 were attributed *to E. coli* O157:H7 from spinach and shredded lettuce
- Summarize relevant published data on *E. coli* O157:H7, integrate into QMRA, "recreate" 2006 spinach outbreak

Methods outline

- Overview
  - Literature search, modeling
- Washing, Cross-contamination
- Time and temperature
  - Retail and home storage
- Growth modeling
- MPN in recalled spinach
- Dose-response modeling
- Simulation modeling
  - @risk, Monte Carlo modeling, 100,000 iterations

Model overview

TABLE 1. *Overview of simulation variables and parameters*

Cell	Variable	Value	Unit	Source
	In field			
D3	Starting level	—[a]	Log CFU/g	User input
D4	Days in the field after contamination	=RiskUniform(1,40)	Days	User input
D5	Log reduction in field	=RiskTriang(0.008,0.019,0.039)	Log CFU/g/day	*17*
D6	Level at harvest	=D3−(D4*D5)	Log CFU/g	Calculated
D7	Fraction contaminated on incoming servings	—	Percent	User input
D8	Fraction noncontaminated	=1−D7	Percent	Calculated
D9	**Washing data**			
D10	Mean log reduction on contaminated pieces	2.7	Log CFU	*42*
D11	SD log reduction on contaminated pieces	0.4	Log CFU	*42*
D12	Log reduction difference contaminated vs noncontaminated	0.9	Log CFU	*42*
D13	SD difference, contaminated vs noncontaminated	0.8	Log CFU	*42*
D14	Mean log reduction on cross-contaminated pieces	=D10+D12	Log CFU	Calculated
D15	SD log reduction on cross-contaminated pieces	=D11+D13	Log CFU	Calculated
D16	**Washing log reductions**			
D17	Log reduction on contaminated pieces	=RiskNormal(D10,D11)	Log CFU/g	Calculated
D18	Log reduction on noncontaminated pieces	=RiskNormal(D14,D15)	Log CFU/all pieces	Calculated
D19	**Washing final and cross-contamination**			
D20	Level on contaminated pieces after wash	=D6−D17	Log CFU/g	Calculated
D21	Log CFU reduction difference contaminated vs noncontaminated	=D17−D18	Log CFU	Calculated
D22	Log reduction by dilution, contaminated to noncontaminated	=LOG(D7)	Log CFU	Calculated
D23	Level on noncontaminated pieces after wash	=D20+D22+D21	Log CFU/g	Calculated
D24	Choose contaminated or noncontaminated	=RiskBinomial(1,D7)	No units	Calculated
D25	Chosen level	=IF(D24=0,D23,D20)	Log CFU/g	Calculated
D26	**Retail storage**			
D27	Temp, retail	=RiskExtvalue(4.9495,2.8227)	C	*13*
D28	Time, retail	=RiskUniform(4,7)	Days	User input
D29	Growth model b parameter	0.0616	√ Log CFU/day/C	This study
D30	Growth model T_0 parameter	2.628	C	This study
D31	Change during 1 day of storage	=(D29*(IF(D27−D30 <0,0,D27−D30)))^2	Log CFU/day	Calculated
D32	Change during retail storage	=D31*D28	Log CFU change	Calculated
D33	Level after retail storage	=D25+D32	Log CFU/g	Calculated
D34	**Home storage**			
D35	Temp, home, mean	4.06	C	*28*
D36	Temp, difference from mean	=RiskExpon(2.31)	C	*28*
D37	Temp, above or below mean	=RiskBinomial(1,0.5)	C	Calculated
D38	Home temp used	=IF(D37=1,D35 +D36,D35−D36)	C	Calculated
D39	Time to first	=RiskWeibull(1.13,2.84)	Days	*28*
D40	Time to last	=RiskWeibull(1.73,7.96)	Days	*28*
D41	Time used if first is after last	=IF(D39>D40,D39,0)	Days	Calculated
D42	Time from uniform distribution	=RiskUniform(D39,D40)	Days	Calculated
D43	Time selected	=IF(D41=0,D42,D41)	Days	Calculated
D44	Is product past 15-day shelf life?	=IF(D43+D28>15,1,0)	No units	Calculated
D45	Growth model b parameter	0.0616	√ Log CFU/day/C	This study
D46	Growth model T_0 parameter	2.628	C	This study
D47	Change during 1 day of storage	=(D45*(IF(D38−D46 <0,0,D38−D46)))^2	Log CFU/day	Calculated
D48	Change during home storage	=D47*D43	Log CFU change	Calculated
D49	Level after home storage	=D33+D48	Log CFU/g	Calculated
D50	Limit of level if $>10^7$	=IF(D49<7,D49,7)	Log CFU/g	Calculated
D51	**Serving and dose-response**			
D52	Serving size	85	G	*38*

TABLE 1. *Continued*

Cell	Variable	Value	Unit	Source
D53	Level (non-log)	=10^D33	CFU/g	Calculated
D54	Level per serving	=D53*D52	CFU	Calculated
D55	Dose-response alpha	0.267	No units	*8*
D56	Dose-response beta	229.2928	No units	*8*
D57	Probability of illness	=1−(1+D54/D56)^−D55	Percent	Calculated
D58	**Illnesses**			
D59	No. of servings to consider per iteration	—	Servings	User input
D60	Illnesses per no. of servings per iteration?	=RiskBinomial(D59,D57)	Illnesses	Calculated
D61	Was there illness?	=IF(D60>0,1,0)	No units	Calculated
D62	Was there cross-contamination?	=IF(D24=0,1,0)	No units	Calculated
D63	No. of illnesses due to cross-contamination	=IF(D62+D61=2,D60,0)	Illnesses	Calculated
D64	Illness on product older than 15 days?	=D61*D44	No units	Calculated
D65	Illness on product at maximum level?	=IF(D50=7,D61,0)	No units	Calculated
D66	**Outbreak-specific calculations**			
D68	No. of servings	—	Servings	User input
D69	Actual no. of illnesses	=D68*D57	Illnesses	Calculated
D70	CDC[b] underreporting factor	26.1	No units	*31*
D71	No. reported ill	=D79/D70	Illnesses	Calculated

[a] —, user inputs that are point values and have been omitted from this table.
[b] CDC, Centers for Disease Control and Prevention.

- Cell reference
- Variable
- Value
- Unit
- Source

Model sections

- In field
  - Starting prevalence and concentration
  - Reduction in the field
- Washing
  - Log reduction is easy (3 lines)
  - Cross-contamination is hard (10 lines)
- Retail storage
- Home storage
  - More data, more complicated
- Servings, dose response, Illnesses
- Outbreak specific calculations

Growth model

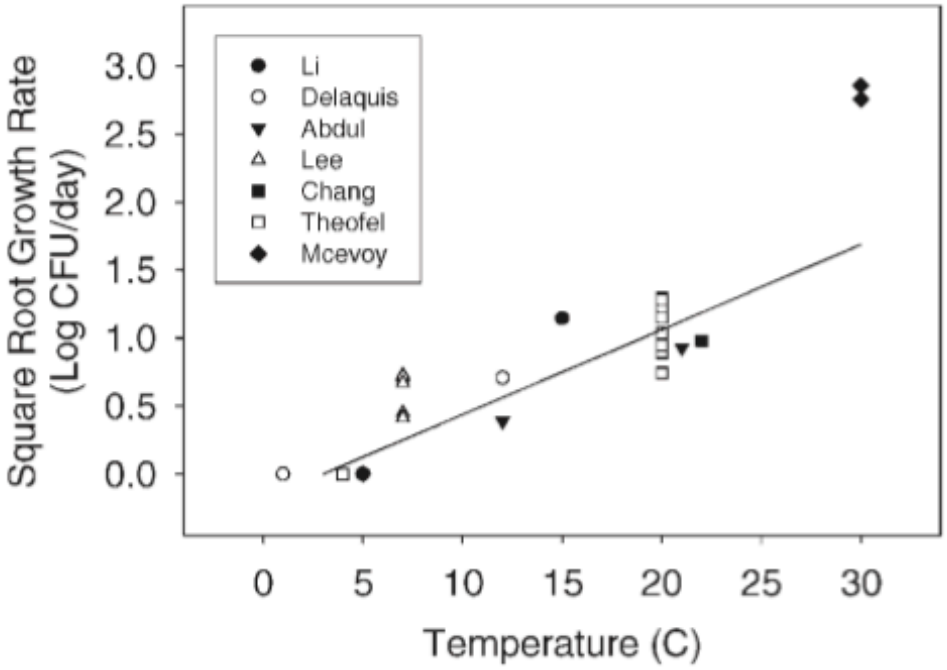


FIGURE 1. E. coli *O157:H7 literature data for growth on leafy greens as a function of temperature. Data adapted from Abdul-Raouf et al., 1993 (2) (▼); Chang and Fang, 2007 (10) (■); Delaquis et al., 2002 (12) (○); Lee and Baek, 2008 (21) (△); Li et al., 2001 (24) (●); McEvoy et al., 2009 (25) (◆); and Theofel and Harris, 2009 (36) (□). A linear regression of the literature data (solid line) is also shown.*

- Seven studies
- One excluded (cored iceberg lettuce)
- Some scatter but square root of GR linear with temperature acceptable

Simulation results

TABLE 3. *Simulated relationship between level and prevalence of* E. coli *O157:H7 of leafy greens in the field and number of illnesses, broken down into illnesses from directly contaminated pieces and those cross-contaminated during washing*

% of incoming serving of product positive:	1%			0.1%			0.01%		
Log CFU/g on product in the field:	0	−1	−2	0	−1	−2	0	−1	−2
Mean total no. of illnesses	10,903	6,597	4,363	6,726	4,112	2,950	4,195	3,019	2,010
SD of total no. of illnesses	1,857	1,619	1,202	1,559	1,525	1,007	1,538	1,045	797
Mean no. of illnesses due to cross-contamination	10,400	6,472	4,281	6,661	4,080	2,948	4,189	3,019	2,010
SD of illnesses due to cross-contamination	1,931	1,559	1,210	1,559	1,532	1,006	1,539	1,045	797
% of illnesses due to cross-contaminated pieces	95.4	98.1	98.1	99.0	99.2	~100	99.9	100	100
Mean total no. of illnesses reported	418	253	167	258	158	113	161	116	77

- Starting prevalence and concentration are low
- Simulated number illnesses are are high (CDC underreporting bias ~21 fold)
- Most simulated illnesses are from cross-contaminated pieces (water sanitizers real benefit may be in preventing cross-contamination)

What doses cause most illnesses?

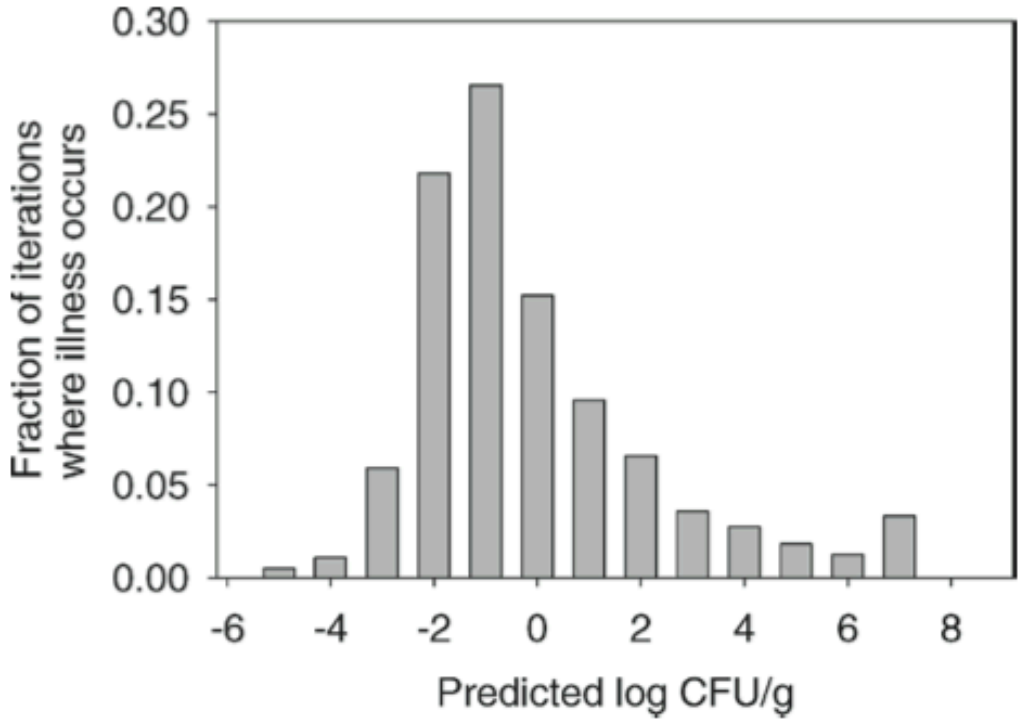


FIGURE 5. *Relative contribution of the range of simulated doses in CFU/g on illness, considering only those iterations where illness occurs, given a starting level of −1 log CFU/g and 0.1% of servings contaminated.*

- Most illnesses come from low doses
- Also supported by MPN test results
- Low doses * many, many servings = many illnesses

Leafy Greens Summary

- Critical data gaps remain
- Model predicts that a majority of simulated cases arise from leafy greens cross-contaminated during the washing process
  - Extrapolation from a single study, requires additional validation.
- Important findings
  - Literature-based growth model for E. coli O157:H7 in leafy greens
  - Estimate of the median number of cells per serving that lies within the range of best available estimates of actual pathogen levels during the outbreak

Overall summary

- QMRA is used by regulators and some large companies
- Even with data gaps, QMRA can be useful
- QMRA can help prioritize data collection
- Many, many servings * low dose = some illness
- No such thing as zero risk
- Quantitative data can help risk managers
- Food Safety Talk podcast