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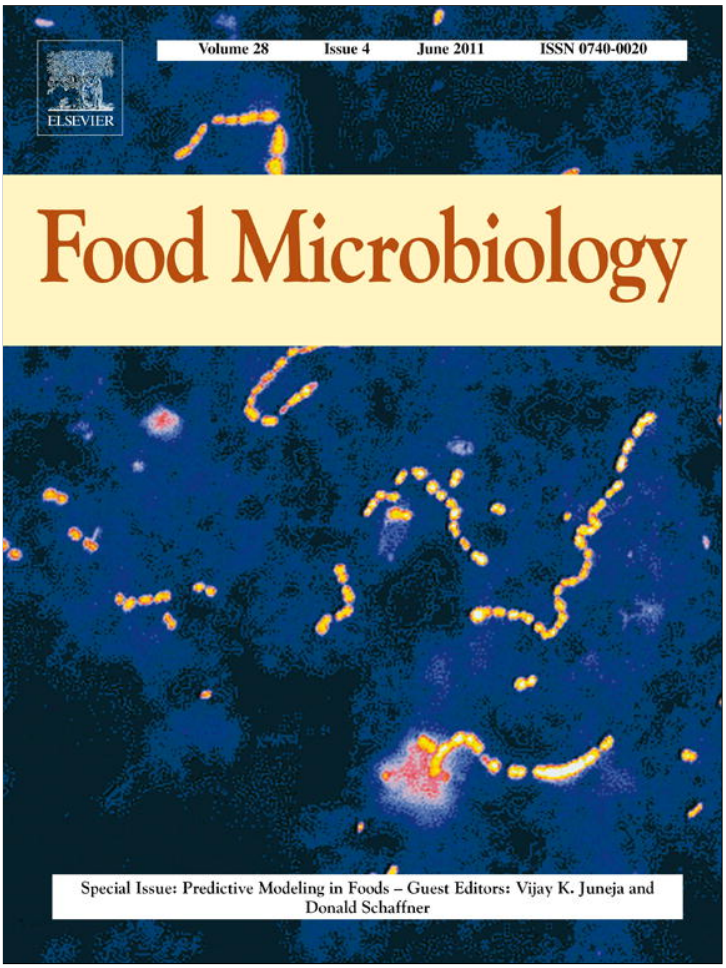

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Plenary lecture: Innovative modeling approaches applicable to risk assessments

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ABSTRACT

Proper identification of safe and unsafe food at the processing plant is important for maximizing the public health benefit of food by ensuring both its consumption and safety. Risk assessment is a holistic approach to food safety that consists of four steps: 1) hazard identification; 2) exposure assessment; 3) hazard characterization; and 4) risk characterization. Risk assessments are modeled by mapping the risk pathway as a series of unit operations and associated pathogen events and then using probability distributions and a random sampling method to simulate the rare, random, variable and uncertain nature of pathogen events in the risk pathway. To model pathogen events, a rare event modeling approach is used that links a discrete distribution for incidence of the pathogen event with a continuous distribution for extent of the pathogen event. When applied to risk assessment, rare event modeling leads to the conclusion that the most highly contaminated food at the processing plant does not necessarily pose the highest risk to public health because of differences in post-processing risk factors among distribution channels and consumer populations. Predictive microbiology models for individual pathogen events can be integrated with risk assessment models using the rare event modeling method.

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1. Introduction[1]

Risk assessment is a holistic approach to food safety that is the umbrella under which all food safety information can be organized to protect public health. It consists of four steps: 1) hazard identification; 2) exposure assessment; 3) hazard characterization; and 4) risk characterization. Predictive microbiology has an important role in risk assessment but innovative modeling methods are needed to integrate predictive models with risk assessment models. One way to approach this integration is to develop the risk assessment model first and then use it as a guide to develop predictive models. By developing predictive models that are specific for risk assessments, a better assessment and management of food safety risks can be obtained (Oscar, 2004a).

Although food is contaminated with physical, chemical and microbial hazards, the focus here will be on innovative modeling methods that have been applied to assessing the risk of microbial hazards. In contrast to chemical and physical hazards, microbial hazards in food are dynamic because of pathogen events (i.e. growth, survival, death, physical removal and cross-contamination) that increase and decrease their number as the food moves through the risk pathway. Pathogen events in food are often rare events, which mean that they occur much less than 100% of the time. They are also random, variable and uncertain.

To model pathogen events properly, a rare event modeling method is used in which a probability distribution for incidence of the pathogen event is linked to a probability distribution for extent of the pathogen event and then the distributions are randomly sampled to obtain inputs for formulas that are used to calculate changes in pathogen numbers on individual servings of food as they move through the risk pathway (Fig. 1). For microbial hazards, it is important to round the pathogen number results to whole numbers because it is not possible to have a fraction of a microbe. An important feature of rare event modeling is that it allows risk assessors to simulate changes in pathogen incidence and number as food moves through the risk pathway.

2. Rare event modeling for risk assessment

An example of a risk assessment model that uses the rare event modeling method is that of Oscar (1998) for *Salmonella* and whole chickens. This risk assessment model was constructed in an Excel spreadsheet and is simulated using @Risk (Palisade Corp. Newfield, NY), a spreadsheet add-in program that performs random sampling

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[1] The plenary lecture upon which this paper is based was presented at the 6th International Conference on Predictive Modeling Foods held in Washington, D.C. from September 8 to 12, 2009. The slides used in the presentation are available at: http://www.icpmf.org/pp/Plenary%20lecture_Oscar.pdf Access date: February 2, 2010.

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Iteration	Discrete	Pert (0,1,4)	Power	Round
1	1	1.8	63.1	63
2	0	1.2	0	0
3	0	0.2	0	0
:	:	:	:	:
100	0	2.2	0	0

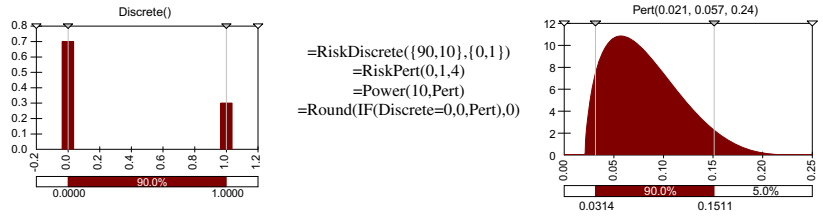

Fig. 1. Diagram of the rare event modeling method that involves linking a discrete distribution for incidence of the pathogen event to a continuous (i.e. pert) distribution for extent of the pathogen event. Only when the output of the discrete distribution is a '1' indicating that the pathogen event occurred is the output from the pert distribution used to calculate pathogen number. Outputs from the pert distribution are log numbers. The 'Power' function converts the log numbers from the pert distribution to their anti-log numbers and the 'Round' function converts the numbers to whole numbers because it is not possible to have a fraction of a pathogen. The example shown here is for initial contamination of a food at packaging. Food unit or iteration one was contaminated with 63 cells of the pathogen, whereas food units 2, 3 and 100 were not contaminated with the pathogen.

of probability distributions. The model calculates the change in the number of *Salmonella* on individual chickens as they move from the processing plant to the table. A series of graphs are presented that show the number of *Salmonella* on individual chickens after each unit operation and pathogen event versus the number of *Salmonella* on those same chickens at packaging in the processing plant. The results demonstrate that which chickens are temperature-abused during distribution, under-cooked during meal preparation and cross-contaminated with *Salmonella* during serving occurs randomly. Likewise, which chickens are associated with a normal or high risk dose of *Salmonella* at consumption occurs randomly. A high risk dose would be associated for example with a highly virulent strain of *Salmonella*, consumption of an anti-acid pill with the meal and(or) a consumer with an underlying health problem. Consequently, at consumption, Oscar (1998) found that there is a low correlation between the probability of a *Salmonella* infection and the initial level of *Salmonella* contamination on the chicken at the processing plant. Rather, a chicken with a lower level of *Salmonella* contamination at packaging could pose a higher risk of foodborne illness if it had by random chance been temperature-abused during distribution, under-cooked and then consumed by someone with an underlying health problem.

2.1. Rare event modeling for hazard identification

The cornerstone of any risk assessment is knowledge of the initial distribution of hazard in the food at some point in the risk pathway. Determining the level of a microbial hazard in samples of food is time consuming and expensive and thus, realistically can only be done at one point in the risk pathway. A good place for a food company to apply hazard identification is at packaging in the processing plant.

Another important consideration for hazard identification is the microbial ecology of the food. Most microbial hazards are minority members of the microbial community of food and as a result they are not uniformly distributed in the food. In fact, most samples of a food will not contain the hazard. It is also important to consider that the hazard can be in various states of attachment (i.e. unattached, attached and entrapped) within the food matrix and thus, the method used must be capable of quantifying the hazard regardless of how it is associated with the food.

One approach to quantify all forms of a microbial hazard in a food for risk assessment is to develop a rare event model that predicts the initial contamination or distribution of the microbial hazard in the food as a function of detection time during whole food sample enrichment and as a function of food sample size (Oscar, 2004c, 2008a). At the beginning of the enrichment period, the target pathogen will be below the detection limit of the assay. However, during incubation under standard growth conditions, the target pathogen will multiply and eventually reach the detection limit of the assay. For example, in an experiment conducted by Oscar (2004c), chicken meat (25 g) was inoculated with a known number of *Salmonella* from one to 10^6 cells and then a sample of the enrichment broth was collected at different times of incubation and subjected to detection by a polymerase chain reaction (PCR) method for *Salmonella*. As the *Salmonella* grew from non-detectable ($<$2 log/ml) to detectable ($>$2 log/ml) levels, the PCR band in the agarose gel went from none to faint to less than full to full. The bands were then scored and a PCR detection time score was obtained for the sample. Next, a standard curve with a 95% prediction interval was constructed by plotting the PCR detection time score as a function of the initial number of *Salmonella* that were inoculated into the samples. This standard curve was then used to construct a rare event model. First, a pert distribution for each PCR detection time score was determined from the standard

Table 1
Input settings for the hazard identification and exposure assessment module A for plants A and B: first risk assessment.

Unit Operation	Pathogen Event	Incidence		Extent			
		Plant A	Plant B	Minimum	Median	Maximum	Units
Packaging	Contamination	25%	10%	0	1	4	log Δ
Distribution	Growth	20%	20%	0.1	1	3	log Δ
Washing	Removal	15%	15%	−0.1	−1	−3	log Δ
Cooking	Survival	10%	10%	−0.1	−5	−7	log Δ
Serving	Contamination	15%	15%	−3	−2	−1	log rate

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curve and its 95% prediction interval and then these distributions were assembled in an Excel spreadsheet. Next, a discrete distribution for incidence of PCR detection time scores was added. The model was then simulated with @Risk to determine the initial contamination for any size sample that was a multiple of the original sample size, which was 25 g. The outputs from this model were the incidence of contaminated servings and a pert distribution for the extent of contamination among contaminated servings. These distributions can be directly used as inputs in a risk assessment model that uses the rare event modeling method.

2.2. Rare event modeling for exposure assessment

As mentioned before, hazard identification is too expensive to apply at more than one point in the risk pathway. Consequently, after the initial distribution of hazard in the food is determined by microbiological testing and rare event modeling, as described in the previous section, predictive models for unit operations and associated pathogen events that define the risk pathway from hazard identification to consumption can be developed and used to predict how the initial distribution of the pathogen changes from hazard identification to consumption.

Important considerations for the development of predictive models for exposure assessment are that they should be developed in real food with native microflora and from a low and ecological initial dose of the pathogen so that the predictions provided reduce uncertainty in the risk assessment model. This has been accomplished for chicken products using *Salmonella* strains with natural resistance to multiple antibiotics and a combination MPN and CFU method to enumerate low and high numbers of the pathogen (Oscar, 2006, 2007, 2008b, 2009a,b). For example, Oscar (2009a) developed a predictive model that uses rare event and neural network modeling methods to predict growth and survival of *Salmonella* from a low initial dose (<10 cells) on raw chicken skin with native microflora and as a function of serotype prevalence. The output from this model is a distribution that can be used directly in a risk assessment model. This is a good example of a predictive microbiology model that uses innovative modeling methods to reduce uncertainty in a risk assessment model.

2.3. Rare event modeling for hazard characterization and risk characterization

When a food serving that is contaminated with a microbial hazard is consumed, the response of the host falls on a continuum from no response to death. To model the host response, criteria are used to classify the response into a specific category, such as infection or illness. The percentage of hosts that exhibit the specific response of interest is then graphed as a function of the log dose of the test pathogen and the data are fitted to a sigmoid-shaped dose-response curve to determine the log dose of pathogen that causes 50% of the host population to exhibit the response of interest. Data for such dose-response curves are usually obtained in outbreak investigations or controlled feeding trials with a uniform pathogen, uniform food and uniform host population.

Although human feeding trials are no longer ethical, a human feeding trial was conducted in which healthy male prisoners were fed different doses of 13 strains of *Salmonella* in eggnog after their noon meal (McCullough et al., 1951a–c). Illness data from this feeding trial have been modeled using the rare event method (Oscar, 2004b). When the latter dose-response model was used to simulate feeding trials in which the eggnog was contaminated with multiple strains of *Salmonella* with different virulence potentials, the population dose-response curves obtained were non-sigmoid in shape indicating that when a food is contaminated with multiple hazards of different virulence a sigmoid dose-response curve is not obtained and thus, a different approach to modeling hazard characterization is needed.

Table 2
Input settings for the hazard characterization and risk characterization module B for plants A and B: first risk assessment.[a]

Class			Incidence (%)		Extent (log dose)		
Hazard	Food	Host	Plant A	Plant B	RD_{min}	RD_{50}	RD_{max}
Normal	Normal	Normal	70	70	4.0	6.0	8.0
High	Normal	Normal	6	6	3.0	5.0	7.0
Normal	High	Normal	2	2	3.5	5.5	7.5
High	High	Normal	2	2	2.5	4.5	6.5
Normal	Normal	High	5	5	2.0	4.0	6.0
High	Normal	High	9	9	1.0	3.0	5.0
Normal	High	High	3	3	1.5	3.5	5.5
High	High	High	3	3	0.5	2.5	4.5
		% High risk					
		Hazard	20	20			
		Food	10	10			
		Host	20	20			

[a] Abbreviations: RD_{min} = minimum response dose; RD_{50} = median response dose; and RD_{max} = maximum response dose.

In a new approach (i.e. disease triangle modeling) to dose-response modeling developed by Oscar (1998, in press), a rare event modeling approach is used to simulate the disease triangle (i.e. interaction among the food, pathogen and host that determines the host response). In this approach, hazard, food and host factors are classified as normal or high risk. When the hazard, food or host factor is classified as high risk (e.g. top clinical isolate of the pathogen, consumption of an anti-acid pill with the meal or a host with an underlying health problem), the probability distribution for illness dose is shifted to the left by 0.5, 1 or 2 log, respectively. In this method of modeling hazard characterization, a discrete distribution is used to model incidence of the eight classes or combinations of normal and high risk hazard, food and host factors, whereas pert distributions are used to model extent of response doses within each class of risk factors. During simulation of the model, @Risk randomly assigns a response dose to the consumption event and when the response dose is greater than the dose consumed in the simulated serving of food, no response occurs; otherwise, a response occurs (Oscar, 1998, 2004a,b).

3. Scenario analysis for assessing relative risk

Because human feeding trials are not ethical, it will never be possible to make absolute predictions of food safety risks with low

Table 3
Predicted cases of foodborne illness per 100,000 food units for plants A and B: first risk assessment.[a]

	Plant A	Plant B
Replicate simulations	200	200
Minimum	0	0
25% Percentile	2	0
Median	3	1
75% Percentile	4	2
Maximum	11	5
Mean	3.25	1.26
Std. Deviation	1.98	1.14
Std. Error	0.140	0.081
Lower 95% CI of mean	2.97	1.10
Upper 95% CI of mean	3.53	1.42

[a] Foodborne illness differed ($P < 0.05$) between plants A and B as determined by a one-tailed Mann Whitney nonparametric *t* test using version 5.0 of the GraphPad Prism software program (GraphPad Inc., San Diego, CA).

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Table 4
Input settings for the hazard identification and exposure assessment module A for plants A and B: second risk assessment.

Unit Operation	Pathogen Event	Incidence		Extent			
		Plant A	Plant B	Minimum	Median	Maximum	Units
Packaging	Contamination	25%	10%	0	1	4	log Δ
Distribution	Growth	20%	40%	0.1	1	3	log Δ
Washing	Removal	15%	30%	−0.1	−1	−3	log Δ
Cooking	Survival	10%	10%	−0.1	−5	−7	log Δ
Serving	Contamination	15%	30%	−3	−2	−1	log rate

uncertainty because information about the dose of pathogens that cause illness in humans will not be available. Thus, the best that can be accomplished is to make relative predictions of risk and then to use these risk assessments to better inform food safety decisions. One of the best tools available for making relative assessments of risk is scenario analysis where a scenario in the context of a risk assessment model is defined as a unique set of input distributions. By comparing the relative risk of different 'what if' scenarios, risk assessors can determine the relative safety of different batches of food destined for specific distribution channels and consumer populations and in the process better identify unsafe food before it is consumed.

To illustrate this concept, Oscar (in press) described a fictional example of a food company that has two processing plants that are located in different regions of a country but that produce the same food product that is contaminated with the same microbial hazard. Food from Plant A is more highly contaminated than food from Plant B but only food from Plant B has caused foodborne illness. To determine why this is so, the company hired a risk assessor who created a rare event risk assessment model to assess the situation. The model consisted of a series of unit operations and associated hazard events (Table 1). The risk assessor made the assumption that the risk pathway after packaging was the same for food from Plant A and Plant B.

The rare event model for risk assessment was created in an Excel spreadsheet and was simulated using @Risk (Oscar, in press). The input settings for the hazard identification and exposure assessment module were the same for Plants A and B except that when the scenario for Plant B was simulated the setting for hazard incidence at packaging was changed from 25% to 10% to reflect the lower level of contamination for food from Plant B (Table 1).

Module B was used for hazard characterization and risk characterization and used the disease triangle modeling method for dose-response that was described above. The settings for Plants A and B were the same in Module B (Table 2). To determine the illness rate the model was simulated for 100,000 servings of food (i.e. 100,000 iterations). To characterize the uncertainty of the illness rate, 200 replicate simulations for each scenario were conducted using a different random number generator seed (RNGS) to initiate each replicate simulation. The RNGS is a number that initiates the random selection process in @Risk; each RNGS produces a unique outcome of the model.

Results of the simulations indicated that the food from Plant A was more likely to cause illness than the food from Plant B (Table 3). However, this did not explain why only consumers of food from Plant B were getting ill. So the food company hired a second risk assessor with a different vision. This risk assessor, using the risk assessment model developed by the first risk assessor as a guide, had the company collect data (i.e. hazard strain, product time and temperature during distribution, and food handling practices and demographics of consumers in the two distribution channels) and develop predictive models to better assess the risk of illness from Plants A and B.

Results of this research indicated that there were important differences between Plants A and B after the food left the plant. It was discovered that food from Plant B was more often subjected to temperature abuse and cross-contamination after cooking than food from Plant A (Table 4). In addition, food from Plant B was more often contaminated with a high risk strain of the hazard and was more often consumed by someone from the high risk population (Table 5).

After simulating the model using the new data, the risk assessor filtered the results to remove the non-contaminated servings. He then used the filtered results to prepare summary tables for the risk managers. The first table (Table 6) presented to the risk managers showed the change in hazard incidence and number as a function of unit operations. Although the total hazard load was lower for Plant B at packaging, at serving the hazard load was slightly higher for food from Plant B than Plant A because of the higher incidence of temperature abuse and cross-contamination for food from Plant B. The second table (Table 7) presented to the risk managers showed the population dose–response curves for Plants A and B and indicated that the RD_{50} was lower for food from Plant B than food from plant A. This occurred because food from plant B was more often contaminated with a high risk strain of the hazard and was more

Table 5
Input settings for the hazard characterization and risk characterization module B for plants A and B: second risk assessment.[a]

Class			Incidence (%)		Extent (log dose)		
Hazard	Food	Host	Plant A	Plant B	RD_{min}	RD_{50}	RD_{max}
Normal	Normal	Normal	70	30	4.0	6.0	8.0
High	Normal	Normal	6	38	3.0	5.0	7.0
Normal	High	Normal	2	1	3.5	5.5	7.5
High	High	Normal	2	1	2.5	4.5	6.5
Normal	Normal	High	5	5	2.0	4.0	6.0
High	Normal	High	9	17	1.0	3.0	5.0
Normal	High	High	3	4	1.5	3.5	5.5
High	High	High	3	4	0.5	2.5	4.5
		% High risk					
		Hazard	20	60			
		Food	10	10			
		Host	20	30			

[a] Abbreviations: RD_{min} = minimum response dose; RD_{50} = median response dose; and RD_{max} = maximum response dose.

Table 6
Hazard identification and exposure assessment results for plants A and B: second risk assessment.

Unit Operation	Pathogen Event	Incidence (%)		Extent (pathogens/100,000 food units)	
		Plant A	Plant B	Plant A	Plant B
Packaging	Contamination	25.0	10.0	2,331,774	943,943
Distribution	Growth	25.0	10.0	18,498,300	14,373,100
Washing	Removal	24.0	9.4	15,479,740	10,548,820
Cooking	Survival	0.11	0.05	5265	317
Serving	Contamination	1.55	1.47	44,076	52,142

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Table 7
Hazard characterization results for plants A and B: second risk assessment.

Percentile	Log dose	
	Plant A	Plant B
0	0.60	0.60
5	2.59	2.27
10	3.22	2.75
15	3.78	3.15
20	4.32	3.51
25	4.68	3.80
30	4.93	4.07
35	5.13	4.31
40	5.30	4.52
45	5.46	4.72
50	**5.61**	**4.90**
55	5.75	5.08
60	5.89	5.25
65	6.04	5.42
70	6.18	5.60
75	6.33	5.78
80	6.49	5.97
85	6.66	6.18
90	6.87	6.44
95	7.14	6.80
100	7.97	7.95

Table 8
Predicted cases of foodborne illness per 100,000 food units for plants A and B: second risk assessment.[a]

	Plant A	Plant B
Replicate simulations	200	200
Minimum	0	1
25% Percentile	2	6
Median	3	7.5
75% Percentile	4	10
Maximum	11	14
Mean	3.25	7.75
Std. Deviation	1.98	2.59
Std. Error	0.140	0.183
Lower 95% CI of mean	2.97	7.39
Upper 95% CI of mean	3.53	8.11

[a] Foodborne illness differed ($P < 0.05$) between plants A and B as determined by a one-tailed Mann Whitney nonparametric *t* test using version 5.0 of the GraphPad Prism software program (GraphPad Inc., San Diego, CA).

often consumed by someone from the high-risk population (Table 5). Finally, the table (Table 8) showing the relative risk of illness was presented to the risk managers and showed that the risk of illness was higher for food from Plant B than for food from Plant A. These results, which considered differences in pathogen virulence and post-process risk factors among plants, differed from those of the previous risk assessment that did not consider differences in pathogen virulence and post-process risk factors among plants. The food company was happy with the results of this risk assessment because it provided an explanation for why food from Plant B was causing more illness than food from Plant A.

4. Conclusions

In our current approach to food safety, food safety objectives and microbial performance standards applied at the processing plant are used to identify safe and unsafe food. This approach to food safety is supported by risk assessments that assume a single risk pathway after food leaves the processing plant and that do not employ the rare event modeling approach. However, this approach to food safety only on rare occasions is successful at identifying unsafe food because it fails to consider differences in pathogen virulence and post-process risk factors among processing plants. In contrast, by implementing the rare event modeling approach described in this paper, a risk assessment based approach that considers differences in pathogen virulence and post-process risk factors among processing plants in its evaluation of food safety can be implemented and will result in a better assessment and management of food safety risks.

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