DATA GAPS FOR SELECTED MICROBIAL RISK ASSESSMENTS[1]

Data Gaps Working Group - Risk Assessment Consortium (RAC)

This document contains lists of data gaps identified in published microbial risk assessments by the US Food and Drug Administration, US Department of Agriculture's Food Safety and Inspection Service, and the World Health Organization/Food and Agriculture Organization of the United Nations[2]. Each data gap is identified by exposure assessment category, the type of information needed, and a brief explanation of the specific data gap. Food safety researchers and risk assessors are invited to rank the data gaps to identify research priority and forward their ranking[3] or comments to Dr. Mark Tamplin at mtamplin@errc.ars.usda.gov (Tel: 215-836-3794) or Dr. Andy Hwang at ahwang@errc.ars.usda.gov (Tel: 215-233-6416).

Contents

[1] Also available at http://www.foodriskclearinghouse.umd.edu/RAC_data_gaps.htm
[2] These lists do not necessarily represent the views of the individual agencies.
[3] Use numbers to indicate priority, e.g., 1 as the highest priority, 2 as the next high priority, etc.

Listeria in Ready-to-Eat Foods

References

Food and Agricultural Organization of the United Nations/World Health Organization. 2001. Risk characterization of Salmonella spp. in eggs and broiler chickens and Listeria monocytogenes in ready-to-eat foods. http://www.who.int/fsf/Micro/report30April01.pdf

Gallagher, D.L., Ebel, E.D., and Kause, J.R. 2003. FSIS risk assessment for *Listeria monocytogenes* in deli meats. http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F/ListeriaReport.pdf

Center for Food Safety and Applied Nutrition, Food and Drug Administration/Food Safety and Inspection Service, US Department of Agriculture/Centers for Disease Control and Prevention. 2001

Draft assessment of the relative risk to public health from *Listeria monocytogenes* among selected categories of ready-to-eat foods. http://www.foodsafety.gov/~dms/lmrisk.html

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Immunity	Immunological defense mechanisms of individuals to understand variation in individual vulnerability to listeriosis and the immune system's role in preventing listeriosis. [Comment]:
		Strain virulence	Development of methodologies to identify high vs. low virulence strains of *Listeria*. [Comment]:
		Strain virulence	Systematically survey strain virulence in US food supply. [Comment]:
		Strain virulence	Identification of virulence markers for L. monocytogenes so that exposure to those strains can be assessed specifically. [Comment]:
		Epidemiology	Routine analysis of strains in outbreaks to link human cases to food isolates. [Comment]:
		Epidemiology	Enhanced investigative techniques. [Comment]:
		Epidemiology	Expanded surveillance and outbreak investigations. [Comment]:
		Epidemiology	Epidemiological data that distinguish serious or life threatening (usually systemic) vs. mild disease. [Comment]:
		Susceptibility	Effect of food matrix, stomach acidity, achlorhydria, and use of antacids on rate of listeriosis. [Comment]:
		Susceptibility	Develop animal and biochemical tests to correlate epidemiological data to new *L. monocytogenes* isolates and establish relevant biomarkers of human susceptibility. [Comment]:
		Susceptibility	Determine genes/genetic markers of human susceptibility and identify affected population groups. [Comment]:
		Animal models	Determine relationship between animal model dose-response and human dose-response. [Comment]:
	Exposure	Consumption	Surveys of food consumption as it relates to food safety questions (i.e., was cheese made from

	unpasteurized milk, was smoked seafood hot or cold smoked). [Comment]:
Consumption	Dietary information for specific susceptible subpopulations (i.e., women of childbearing age, elderly living in nursing homes, pregnant women). [Comment]:
Consumption	Specific RTE product consumption data for meal servings and frequency by specific populations of individuals, including in developing countries, and particularly for those who are immunocompromised or otherwise susceptible. [Comment]:
Handling/preparation	Consumer food preparation and eating practices; cross-contamination; reheating of hot dogs. [Comment]:
Handling/preparation	Storage time and temperature in home refrigerators; time stored after opening package. [Comment]:
Handling/preparation	Retail and consumer handling practices, in particular, storage time and temperature and including more accurate measurements of home storage conditions including refrigeration temperatures by country or region. [Comment]:
Handling/preparation	Data on the degree of compliance to regulations established for control of L. monocytogenes cell numbers in food and the influence these regulations have on prevalence and cell numbers. This information will influence estimates of the efficacy of the control program. [Comment]:
Prevalence/enumeration	A systematic quantitative survey of US food supply for *L. monocytogenes.* [Comment]:
Prevalence/enumeration	Frequency of in-plant product contamination. [Comment]:
Prevalence/enumeration	L. monocytogenes prevalence in potential environmental sources, including i) agricultural environments, e.g. ground and well water; cultivated soil used for different crops or uncultivated soil for grazing pasture at different times of the year, silage, fresh and composted manure, farm equipment and farm workers; ii) aquatic environments, marine and freshwater where fish or shellfish are harvested including the effects of sewage or agricultural runoffs into water, fishing equipment, and commercial and recreational fishers. [Comment]:
Prevalence/enumeration	L. monocytogenes prevalence and cell numbers in production including i) primary production: animals, fish, and crops; ii) secondary production, e.g. initial preparation, cleaned carcasses, gutted and stored fish, shucked shellfish, washed produce. [Comment]:
Prevalence/enumeration	Prevalence and cell numbers of L. monocytogenes in finished packages of RTE foods from around the world on which risk assessment is being or will be undertaken. [Comment]:
Prevalence/enumeration	Information on the frequency of naturally occurring very high levels of contamination. [Comment]:
Contamination	Duration of in-plant contamination event. [Comment]:
Contamination	Distribution of food contact surface area during in-plant processing. [Comment]:
Contamination	Transfer coefficients for home and in-plant food contact surfaces. [Comment]:
Contamination	Ratio of the levels of Listeria spp. to listeria monocytogenes on food and non-food surfaces. [Comment]:
Contamination	Identification of sources and levels of contamination and recontamination, at the point of

	processing, retail and the consumer, with information on frequency, and microbial load transferred. [Comment]:
Growth/survival	Inoculated pack studies to determine growth rates and maximum growth in the presence of normal spoilage. [Comment]:
Growth/survival	Examine distribution of LM in food (i.e. is growth restricted to surface of food product or is there substantial penetration). [Comment]:
Growth/survival	Models for the growth of L. monocytogenes on specific food commodities
Growth/survival	Product formulation information, e.g. pH, water activity, humectants and preservatives (e.g. nitrite and organic acids, lactic acid bacteria) and their distributions to enable best estimates of microbial growth, survival or death. [Comment]:
Growth/survival	Better knowledge on the growth of L. monocytogenes in naturally contaminated food. [Comment]:
Growth/survival	Impact of microbiota, including spoilage organisms on the growth and survival of L. monocytogenes in RTE foods or their ingredients, and on the shelf-life of products. [Comment]:
Models	Data for evaluating the validity of predictive models for L. monocytogenes in specific products, recognizing the effect of prior history of the culture and potential differences between naturally contaminated products and those deliberately inoculated in challenge tests. [Comment]:
Industry practices	Data on the capacity to which industry can control the prevalence and numbers of L. monocytogenes in foods and meet different tolerance levels. [Comment]:
Growth/survival	Data is needed on the concentrations of antimicrobial (listeriocidal or listeriostatic) agents in formulations of deli meats and their effectiveness, in terms of bacterial log reduction, of such formulations during storage at retail and by the consumer. [Comment]:

Listeria monocytogenes in Smoked Finfish

Ranking	Category	Information Type	Specific Need
	Exposure	**Processing** (mitigation, growth/survival)	Measure the impact of different brining conditions (e.g., elimination of brine injection or recirculation) on LM numbers and inhibition of growth of LM on raw finfish (salmon, trout). [Comment]:
		(contamination)	Measure the impact of cross-contamination (e.g., slicer, during brining). [Comment]:
		(mitigation, growth/survival)	Measure the impact of treatments (e.g., type of smoke extract) on LM numbers and inhibition of growth of LM in cold-smoked finfish. [Comment]:
		Post-Processing (mitigation, growth/survival)	Measure the impact of post-process mitigation treatments (e.g., high hydrostatic pressure, irradiation, pasteurization) on LM inactivation on packaged product. [Comment]:
		(mitigation, growth/survival)	Measure the impact of treatments (e.g., high hydrostatic pressure) on LM numbers and inhibition of growth of LM in cold-smoked finfish. [Comment]:
		(re-contamination)	Measure the impact of re-contamination of finished product (e.g., packaging). [Comment]:

Listeria monocytogenes in Fresh-Cut Vegetables

Ranking	Category	Information Type	Specific Need
	Exposure	**Processing** (mitigation, growth/survival)	More information is needed on the impact of bacteriocidal treatments (e.g., nisin, organic acids, chlorinated water, sodium hypochlorite) and methods (e.g., overhead spray, tanks, friction, etc) during the processing of fresh-cut vegetables. [Comment]:
		(contamination)	Measure the impact of using LM contaminated water to wash vegetables on LM levels on processed produce. [Comment]:
		(prevalence/contamination)	Measure the influence of processing environments (temperate vs. tropical) on product contamination levels and frequency. [Comment]:
		(mitigation, growth/survival)	More information is needed on the impact of mitigation treatments during packaging (e.g., inhibitory substances such as citric acid, lactate, phosphates, sulphates, bacteriocins; or bacteriostatic or controlled atmospheric conditions within the package) on the levels and frequency of LM in packaged produce at time of consumption. [Comment]:
		(industry practices, contamination)	Ascertain the frequency of GMP's or GAP's breakdown (failures) or absence of these practices throughout the field and processing operations on product contamination levels and frequency. [Comment]:
		Post-Processing (mitigation, growth/survival)	Measure the impact of post-processing treatments (e.g., high pressure, irradiation, ozonation) on LM levels and frequency on processed fresh-cut vegetables. [Comment]:
		(mitigation, growth/survival)	Measure the impact of modified atmosphere packaging and lower temperatures during storage on growth of LM in packaged produce. [Comment]:

Listeria monocytogenes in Soft Unripened Cheese

Ranking	Category	Information Type	Specific Need
		On-Farm (mitigation, growth/survival)	Measure the impact of: 1) reducing/minimizing LM in dairy cattle feed and contamination in raw milk; 2) reducing milk storage time before and after pasteurization; and 3) lowering storage temperature from 45 to 41ºF during transport and at the manufacturer. [Comment]:
		Processing (mitigation, growth/survival)	Measure the impact of using cultures that produce anti-listerial bacteriocins during cheese production (i.e., extend lag time or inhibit). [Comment]:
		(growth/survival)	Develop Thermal Death Time curves for LM during cooking steps in cheese manufacturing. [Comment]:
		(growth/survival)	Measure the impact of cold pack vs. hot pack on levels of LM in cheeses. [Comment]:
		Post-Processing (growth/survival)	Measure the impact of LM levels in cheese during storage (i.e., cheese properties such as pH and salt). [Comment]:

Escherichia coli in Ground Beef

Reference

Escherichia coli O157:H7 risk assessment team, Food Safety and Inspection Service, US Department of Agriculture. 2001. Draft risk assessment of the public health impact of Escherichia coli O157:H7 in ground beef http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-023NReport.pdf

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Susceptibility	Definition of susceptible sub-populations, such as children under a certain age, the immunocompromised or institutionalized, or the elderly over a given age, that might be more susceptible than healthy adults to *E. coli* O157:H7 illness. [Comment]:
		Dose-response	Research to resolve difficulties in relating the conditions used in human clinical trials to naturally occurring foodborne disease, such as the effects of food matrices, stomach acid neutralization, and lack of expression of virulence gene products. [Comment]:
		Dose-response	Data relating dose of surviving *E. coli* O157:H7 in cooked ground beef servings to adverse effects in humans or animals. [Comment]:
		Dose-response	Data to support the estimation of the *E. coli* O157:H7 dose-response curve based on dose-response curves for Shigella and Salmonella spp. [Comment]:
		Dose-response	Number and severity of illness among children ages 0 to 5 from *E. coli* O157:H7 in ground beef from surveillance and/or outbreak data. [Comment]:
		Dose-response	Data from foodborne outbreaks of *E. coli* O157:H7 in ground beef servings (e.g., the number of *E. coli* O157:H7 organisms in a serving and resulting severity of illness). [Comment]:
		Dose-response	Descriptive epidemiologic information about sporadic cases of *E. coli* O157:H7 illness, including the month of disease onset, age, sex, hospitalizations, summary of clinical manifestations including severe disease manifestations, and food vehicles involved (if known). [Comment]:
		Dose-response	Case-control studies of sporadic *E. coli* O157:H7 cases to calculate etiologic fraction attributable to ground beef. [Comment]:
	Exposure	Contamination	Frequency and distribution of *E. coli* O157:H7 on animal hides. [Comment]:
		Contamination	On-farm risk factors. [Comment]:
		Growth/survival	Maximum density of *E. coli* O157:H7 organisms in ground beef servings as a result of matrix effects, competitive microflora in ground beef, and environmental conditions (e.g., pH, water activity). [Comment]:
		Growth/survival	Predictive microbiological data on the increase and decrease in the number of *E. coli* O157:H7 organisms in ground beef under various storage and preparation conditions. [Comment]:
		Contamination	Cross-contamination of *E. coli* O157:H7 between carcasses during carcass splitting. [Comment]:
		Environment	Time-temperature data (quantitative) for chillers in slaughter establishments. [Comment]:

Marketing	Marketing data on the proportion of beef ground at slaughter versus at retail.
Handling/preparation	Retail (HRI) and consumer storage, cooking, and consumption (frequency and serving size) patterns by type of ground beef meal (e.g., grilled hamburger in July and baked meat loaf in October). [Comment]:

Campylobacter in Broiler Chickens

Reference

Food and Agricultural Organization of the United Nations/World Health Organization. 2002. Risk assessment of *Campylobacter* in broiler chickens and *Vibrio* spp. in seafood. http://www.who.int/fsf/Micro/ReportCV02english.pdf

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Dose-response	Additional data on dose-response. [Comment]:
		Strain variability	Data on strain variability in relation to virulence and pathogenicity. [Comment]:
		Strain variability	Data on strain variability in relation to survival during processing. [Comment]:
		Virulence/pathogenicity	Studies on the mechanisms of infectivity, virulence/pathogenicity of campylobacter in the human host. [Comment]:
		Virulence/pathogenicity	Studies/data on the development of antimicrobial resistance; transference to human host. [Comment]:
		Pathogenicity	Data/studies on links to cancer in human host (cancer initiating factors?) [Comment]:
		Dose-response	Quantitative information about infection and illness rates at low doses of C. jejuni, and also at a range of doses of different strains of C. jejuni and strains of C. coli. [Comment]:
		Epidemiology	Complete epidemiological data from outbreak studies including enumeration of thermophilic campylobacter in suspected food items or in drinking water, numbers of people exposed, attack rates, and demographics of those exposed, particularly immunocompromised population groups and children under the age of five. [Comment]:
		Epidemiology	Enhanced surveillance and outbreak investigations. [Comment]:
		Immunity	Data describing the impact of and longevity of acquired immunity resulting from recent exposure to thermophilic campylobacter. [Comment]:
	Exposure assessment	Survival	Information about the influence of strain-specific variation on campylobacter survival on poultry meat. [Comment]:
		Prevalence	Survey data on the prevalence of campylobacter-positive flocks for slaughter, that includes information on sample size, test methods etc. [Comment]:
		Contamination	Data on the routes of campylobacter colonization of broilers at the farm level so that farm interventions can be appropriately targeted. [Comment]:
		Contamination	Data on the probability of contamination of birds during transport. [Comment]:

Contamination	Studies on the dynamics of within-flock transmission of campylobacter. [Comment]:
Prevalence/enumeration	Prevalence and enumeration data for campylobacter on carcasses before and after various processing steps such as scalding, defeathering, evisceration, washing and chilling. [Comment]:
Prevalence/enumeration	Prevalence and enumeration data for campylobacter on carcasses comparing various methods of chilling (e.g. air chilling, water chilling, water chilling with chlorine). [Comment]:
Prevalence/enumeration	Prevalence and enumeration data for campylobacter on carcasses comparing different scalding temperatures or alternate scalding configurations (e.g. multi-tank scalding systems). [Comment]:
Contamination	Data describing the actual cross-contamination between positive and negative flocks and within flocks during the different slaughter processes. [Comment]:
Handling/preparation	Additional data on the cooking of chicken that addresses areas of the chicken where campylobacter may be protected from heat. [Comment]:
Handling/preparation	Survey data and direct observational data on consumer practices in preparation and handling of chicken that especially detail the frequency and degree that transfer of campylobacter and subsequent ingestion of campylobacter could occur. [Comment]:

Salmonella spp. in Eggs

Reference

Food and Agricultural Organization of the United Nations/World Health Organization. 2001. Risk characterization of *Salmonella* spp. in eggs and broiler chickens and Listeria monocytogenes in ready-to-eat foods. http://www.who.int/fsf/Micro/report30April01.pdf

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Epidemiology	Outbreak and epidemiological data, specifically indicating: cell number in the implicated food, amount of food consumed, accurate estimates of the size of ill and exposed populations, accurate characterization of the population including age profiles, medical status, sex and other potential susceptibility factors. [Comment]:
		Response	Characterization and quantification of the impact of the food matrix effects, host-pathogen interactions and virulence factors and their effect on the probability of infection and/or illness. [Comment]:
		Models	New dose-response models that improve the ability to estimate the probability of illness. [Comment]:
		Sequelae	Quantitative information to facilitate estimating the probability of developing sequelae following illness. [Comment]:
	Exposure	Growth/survival	Data relating to the biology of *Salmonella* Enteritidis in eggs. This need is seemingly universal in its application to previous and future exposure assessments. [Comment]:
		Growth/survival	Additional studies on the numbers, and factors that influence the survival and growth of *Salmonella* Enteritidis in naturally (yolk) contaminated intact shell eggs (information is currently available for intact shell eggs) and enumeration data of *Salmonella* Enteritidis in raw liquid egg. [Comment]:
		Growth/survival	More studies on the survival and growth of *Salmonella* Enteritidis in eggs, particularly as a function of egg composition, and the attributes of infecting strains of organism (e.g. heat sensitivity). [Comment]:
		Prevalence/enumeration	More data on the prevalence of *Salmonella* Enteritidis in breeder and pullet flocks and the environment, as well as in feedstuffs is needed to adequately assess the benefit of pre-harvest interventions. In particular, associations between the occurrence of *Salmonella* Enteritidis in these pre-harvest steps and its occurrence in commercial layers should be quantified. [Comment]:
		Prevalence/enumeration	Additional data concerning the numbers of *Salmonella* Enteritidis in raw liquid egg before pasteurization in order to reliably predict the effectiveness of a regulatory standard

	concerning egg products. [Comment]:
Handling/preparation	Better data on time and temperature, specifically in relation to egg storage would serve to build confidence in the modeling results. The importance of time and temperature distributions in predicting growth of *Salmonella* Enteritidis in eggs – combined with the lack of reliable data to describe these distributions – highlights the need for these data. [Comment]:
Inactivation	New studies on the relationship between cooking time, cooking method and cooking temperature on the death of *Salmonella* Enteritidis. [Comment]:

Salmonella Enteritidis in Shell Eggs and *Salmonella* Spp. in Egg Products

Reference

Food Safety and Inspection Service, US Department of Agriculture. 2004. Draft Risk Assessments of *Salmonella* Enteritidis Shell Eggs and *Salmonella* spp. in Egg Products. http://www.fsis.usda.gov/Science/Risk_Assessment_SE_Eggs/index.asp

Ranking	**Category**	**Information Type**	**Specific Need**
	Hazard characterization	Epidemiology	Studies to determine the fraction of U.S. salmonellosis cases attributable to shell egg and liquid egg product consumption. [Comment]:
	Exposure	Growth/survival	Characterization of growth parameters of SE in shell eggs. [Comment]:
		Growth/survival	Investigation into the behavior and survival of SE in eggs. [Comment]:
		Growth/survival	Quantitative study of cross-contamination during processing of shell eggs and liquid egg products. [Comment]:
		Growth/survival	Studies on how SE differs from other salmonellae in their ability to persist in chicken reproductive tissue and egg contents.
		Growth/survival	Characterization of egg storage times and temperatures on farm and in homes; for eggs produced off-line; and at retail.
		Growth/survival	Studies to determine the initial levels of *Salmonella* spp. in liquid egg products prior to pasteurization. [Comment]:
		Growth/survival	The effect of pasteurization on reducing SE in shells eggs and *Salmonella* spp. in liquid egg products. [Comment]:
		Prevalence/enumeration	A nationally representative survey over all seasons on the prevalence of SE in domestically produced flocks, hens, and shell eggs. [Comment]:

Salmonella spp. in Broiler Chickens

Reference

Food and Agricultural Organization of the United Nations/World Health Organization. 2001. Risk characterization of *Salmonella* spp. in eggs and broiler chickens and Listeria monocytogenes in ready-to-eat foods. http://www.who.int/fsf/Micro/report30April01.pdf

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Epidemiology	Outbreak and epidemiological data, specifically indicating: cell number in the implicated food, amount of food consumed, accurate estimates of the size of ill and exposed populations, accurate characterization of the population including age profiles, medical status, sex and other potential susceptibility factors. [Comment]:
		Response	Characterization and quantification of the impact of the food matrix effects, host-pathogen interactions and virulence factors and their effect on the probability of infection and/or illness. [Comment]:
		Models	New dose-response models that improve the ability to estimate the probability of illness. [Comment]:
		Sequelae	Quantitative information to facilitate estimating the probability of developing sequelae following illness. [Comment]:
	Exposure	Prevalence/enumeration	Prevalence data of *Salmonella* in broiler chickens during production and at slaughter, and on carcasses post processing and information on study design for many regions of the world. [Comment]:
		Prevalence/enumeration	Microbial ecology studies to determine sources and numbers of the pathogen. [Comment]:
		Prevalence/enumeration	Studies on the correlation between within-flock prevalence levels and the number of *Salmonella* cells shed in feces and/or on birds. [Comment]:
		Prevalence/enumeration	Precise estimates of the numbers of organisms per bird for all stages of the exposure pathway and improvements in the sensitivity and availability of cost effective methods to enumerate small populations of *Salmonella*. [Comment]:
		Contamination	Between-bird (bird-to-bird) cross-contamination data suitable for modeling this phenomenon at the pre-harvest, transport, and processing stages. [Comment]:
		Survival	Data on the survival of *Salmonella* spp. under chilling and freezing conditions. This information will improve the predictive microbiology component of exposure assessments relevant to the international trade of poultry products. [Comment]:
		Handling/preparation	Specific consumption data and information about food preparation practices for most geographical locations preferably presented as portion size and frequency of consumption rather than average consumption per day. [Comment]:

Handling/preparation	Information on the distribution of time and temperature for storage and cooking in domestic kitchens in a variety of national environments. [Comment]:
Contamination	Data on the magnitude of cross-contamination in the domestic kitchen and the pathways for cross contamination. [Comment]:
Interventions	Data on the effect of scalding, de-feathering, evisceration, washing and chilling processes as well as other decontamination treatments are needed to effectively model the benefits of control interventions at the level of processing. [Comment]:

Salmonella spp. in raw Beef and Poultry

Ranking	Category	Information Type	Specific Need
	Exposure	Enumeration	Level of *Salmonella* spp**.** on raw beef and poultry products. A nationally representative survey conducted over all seasons to estimate the levels of *Salmonella* spp. on raw beef and poultry carcasses (e.g. steer/heifer, cow/bull, chicken, turkey, market hogs, ground beef, chicken and turkey). There is a particular interest for data on the level of multidrug-resistant (MDR) *Salmonella* (such as DT104) in these products. Ideally, the level could also be correlated with prevalence, antimicrobial resistance, serotype, and the presence of other pathogens (e.g. *E. coli* O157:H7 and *Campylobacter* spp.). [Comment]:
		Growth/survival	Additional predictive microbiology data of multi-drug resistant Salmonella spp., such as *Salmonella* Typhimurium DT104. There are a limited number of studies using a limited number of MDR strains that directly compare MDR strains with their pansusceptible *Salmonella* counterparts. More data on growth in representative foods (considering pH, a_w, presence of competitive flora, time, temperature, etc.), ability to survive the processing environment, and ability to be cross-contaminated during food preparation are needed. [Comment]:
		Handling/preparation	Data on consumer behaviors including handling, storage, cooking, and consumption pattern (frequency and serving size) for raw beef and poultry. [Comment]:
	Hazard Characterization	Dose-response	Human dose-response data of multi-drug resistant Salmonella spp., such as *Salmonella* Typhimurium DT104. ***E***pidemiological data suggests that MDR *Salmonella* may have a lower infections dose and/or apparent infectious dose in those taking antibiotics. Data is needed to determine the dose-response relationship for MDR *Salmonella* compared to pansusceptible *Salmonella* strains for the general and susceptible populations. Outbreak studies could be used. [Comment]:

Vibrio parahaemolyticus in Shellfish

References

Food and Agricultural Organization of the United Nations/World Health Organization. 2002. Risk assessment of *Campylobacter* in broiler chickens and *Vibrio* spp. in seafood. http://www.who.int/fsf/Micro/ReportCV02english.pdf.

Vibrio parahaemolyticus risk assessment task force, Center for Food Safety and Applied Nutrition, US Food And Drug Administration. 2001. Draft risk assessment on the public health impact of *Vibrio parahaemolyticus* in raw molluscan shellfish. http://www.cfsan.fda.gov/~dms/vprisk.html

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Dose reconstruction	Incorporating outbreak investigation data into the dose-response characterization by reconstructing doses consumed by ill and well individuals through measurement of pathogen levels in oysters that were not consumed and reconstructing consumed dose. [Comment]:
		Dose	Dose-response data from volunteer and/or animal model studies. [Comment]:
		Strain variability	Development of assays to compare virulence potential among different strains, including identifying virulence factors other than TDH. [Comment]:
		Host variability	Determination of indices that relate to the likelihood of an individual consumer to become ill at a given dose. [Comment]:
		Epidemiology	Methodology for estimating the ratio of reported to total cases of illness for different countries and geographical areas. [Comment]:
	Exposure	Prevalence	Environmental factors that influence presence and levels of *V. parahaemolyticus*. [Comment]:
		Prevalence	Environmental data to determine the relationship of *V. parahaemolyticus* numbers to seawater temperature and salinity in harvesting areas. [Comment]:
		Prevalence	Data for tdh+ and trh+ prevalence among total *V. parahaemolyticus* populations in national harvesting waters. [Comment]:
		Prevalence	Role of the oyster physiology and defense status in controlling levels of *V. parahaemolyticus*, including variations among oyster species. [Comment]:
		Prevalence	Multi-year temperature data for seawater and air at harvesting areas. [Comment]:
		Growth/survival	Growth/survival of *V. parahaemolyticus* in oysters at different temperatures. [Comment]:
		Consumption	Consumption patterns (frequency of raw oyster consumption from different harvest regions or seasons, and consumption patterns by at-risk groups). [Comment]:
		Consumption	Consumer handling practices of oysters prior to consumption. [Comment]:
		Harvesting practices	Characterization of harvesting activities in harvest areas. [Comment]:
	Models	Validation	Validation of the risk assessment model at intermediate stages. [Comment]:

Adjustments	Mechanisms for adjusting models based on variations in methodologies. [Comment]:

Vibrio parahaemolyticus in Fin Fish

Reference

Food and Agricultural Organization of the United Nations/World Health Organization. 2002. Risk assessment of Campylobacter in broiler chickens and Vibrio spp. in seafood. http://www.who.int/fsf/Micro/ReportCV02english.pdf

Ranking	Category	Information Type	Specific Need
	Exposure	Prevalence/enumeration	Number and proportion of pathogenic V. parahaemolyticus cells in various species of finfish. [Comment]:
		Consumption	Frequency of consumption and quantity of raw fish consumed. [Comment]:
		Handling/preparation	Transportation practices (time and temperature). [Comment]:

Vibrio parahaemolyticus in Bloody Clams

Reference

Food and Agricultural Organization of the United Nations/World Health Organization. 2002. Risk assessment of Campylobacter in broiler chickens and Vibrio spp. in seafood. http://www.who.int/fsf/Micro/ReportCV02english.pdf

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Epidemiology	Data from a case control study or an outbreak investigation to strengthen the linkage between consumption of bloody clams and V. parahaemolyticus illness in humans. [Comment]:
	Exposure	Consumption	Consumption data for bloody clams. [Comment]:
		Inactivation	Effect of cooking practices on thermal inactivation. [Comment]:
		Inactivation	Differences in sensitivity between virulent strain and non-virulent strain to heating and other mitigations steps. [Comment]:
		Handling/preparation	Storage practices. [Comment]:
		Contamination	Cross-contamination models. [Comment]:
		Prevalence/enumeration	Quantitative data on V. parahaemolyticus in bloody clams and other shellfish in seasonal and various combinations of water temperature and salinity. [Comment]:
		Strain variation	Proportion of virulent strains in various shellfish, areas and seasons. [Comment]:

Vibrio vulnificus in Raw Oysters

Reference

Food and Agricultural Organization of the United Nations/World Health Organization. 2002. Risk assessment of Campylobacter in broiler chickens and Vibrio spp. in seafood. http://www.who.int/fsf/Micro/ReportCV02english.pdf

Ranking	Category	Information Type	Specific Need
	Hazard characterization	Dose-response	Dose response data for various countries and subpopulations. [Comment]:
		Risk factors	Identification of risk factors and variation by country. [Comment]:
		Epidemiology	Exposure and illness data for different countries. [Comment]:
	Exposure	Growth/survival	Growth and inactivation models for virulent and non-virulent V. vulnificus in various oyster species. [Comment]:
		Models	Models for the occurrence of V. vulnificus in high salinity waters (30-35ppt). [Comment]:
		Handling/preparation	Description of industry practices for harvesting, handling, processing, transporting and storing oysters. [Comment]:
		Consumption	Consumption practices at retail and home. [Comment]:
		Strain virulence	Proportion of virulent strains in oysters at harvest and retail. [Comment]:

Vibrio cholerae in Export Shrimp

References

Food and Agricultural Organization of the United Nations/World Health Organization. 2002
Risk assessment of Campylobacter in broiler chickens and Vibrio spp. in seafood. http://www.who.int/fsf/Micro/ReportCV02english.pdf

Ranking	Category	Information Type	Specific Need
	Hazard Characterization	Dose-response	Data to clarify the dose-response when the El Tor biotype form is ingested in food. [Comment]:
	Exposure	Growth/survival	Multiplication of choleragenic V. cholerae in cooked and raw shrimp. [Comment]:
		Contamination	Levels of fecal cross contamination during handling of shrimp. [Comment]:
		Prevalence/enumeration	Levels of choleragenic V. cholerae O1 and O139 in natural waters and aquaculture environments. [Comment]:
		Contamination	Data on the level of choleragenic V. cholerae O1 and O139 in shrimp at harvest. [Comment]:

Clostridium perfringens and *Clostridium botulinum* in Ready-to-Eat and Partially Cooked Meat and Poultry Products

Reference

A Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and Partially Cooked Meat & Poultry Products

http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp.

Ranking	Category	Information Type	Specific Need
	Exposure	Prevalence/enumeration	A large nationally and seasonally representative survey to estimate the prevalence and levels of *C. perfringens* type A, enterotoxin positive (CP) spores in raw whole and comminuted meat and poultry products is needed. [Comment]:
		Contamination	Distribution of possible maximum CP vegetative cell densities as a function of initial inoculum level, food matrix and temperature in RTE and partially cooked foods (PCF). [Comment]:
		Contamination	Data on prevalence and level of CP spores in spices and herbs used in RTE and PCF. [Comment]:
		Growth/survival	Growth of CP in RTE and PCF at low temperatures (12-21 C) as a function of competitive bacterial flora, strain variation, and food matrix. [Comment]:
		Growth/survival	Quantitative estimate of the variation of CP growth rate using a variety of strains in different food matrices representative of RTE and PCF with different formulations (e.g. nitrite and salt). [Comment]:
		Growth/survival	Data on the temperature, time, and strain variation or of processing conditions, to allow prediction of the fraction of CP spores that will germinate during processing of either RTE or partially cooked foods. [Comment]:
		Handling/preparation	Additional data on storage times in consumer refrigerator/freezers (estimated storage time in consumer refrigerators/freezers is based on a small survey asking a non-representative sample of consumers for the mean time of storage of deli meats and hot dogs). [Comment]:
		Handling/preparation	Data on consumer cooking times is needed for RTE and PCF that are re-heated by consumers. [Comment]:
		Handling/preparation	Percentage of RTE and PCF that are hot-held and their hot-holding times. [Comment]:
	Exposure	Growth/survival	Data are needed to better quantify the variability of lag time, growth rates and time to toxin production in cooked beef and poultry products of proteolytic *C. botulinum* A and B. This study should include variables such as: strain variation, food matrix and physiology (including *pH*, salt concentration, and water activity), temperature, additives (*e.g.* nitrites, phosphates) and the effect of competing microflora. [Comment]:

Hepatitis A Virus: Relationship of Virus Infection Associated with Handling and Consumption of Produce

Ranking	Category	Information Type	Specific Need
	Hazard Characterization	Dose Response	Dose-response data from volunteer studies (retrospective studies). [Comment]: Currently being conducted.
		Epidemiology	Attack rates from outbreaks. [Comment]:
	Exposure	Detection methods	Evaluate/validate detection methods. [Comment]:
		Prevalence	Levels in foods (under different conditions, e.g., temperature, pH). [Comment]:
			Levels in food (from outbreaks). [Comment]:
			Persistence in environment. [Comment]:
			Route and level of exposure. [Comment]:
		Control	Efficacy of existing control measures. [Comment]:

Norovirus: Elucidation of the Mode of Transmission

Ranking	Category	Information Type	Specific Need
Hazard Characterization	Hazard Characterization	Dose-response	Dose-response data from volunteer studies (retrospective studies). [Comment]: Currently being conducted.
		Epidemiology	Attack rates from outbreaks. [Comment]:
	Exposure Assessment	Detection methods	Identify/ select appropriate surrogates in order to Evaluate/validate detection methods. [Comment]:
		Prevalence	Levels in foods (under different conditions, e.g., temperature, pH). [Comment]:
			Levels in food (from outbreaks). [Comment]:
			Persistence in environment. [Comment]:
		Control	Efficacy of existing control measures. [Comment]: