Needs, Gaps, and Opportunities Assessment (NGOA) for Microbial Risk Assessment in Food and Water

MICROBIAL RISK ASSESSMENT AS A FOUNDATION FOR INFORMED DECISION MAKING

APPENDIX

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1.1 Background
A part of the day-to-day functions of the Food Safety Risk Assessment Unit (FSRA), at the Laboratory for Foodborne Zoonoses, is the maintenance and expansion of a library of published materials on risk assessment, microbial pathogens and food safety issues. The intent of this library is to have on hand, a database of readily accessible information and data, should the need or requests arise. This activity has been ongoing since approximately 1990, resulting in a substantial database of microbial risk related articles held in hard-copy and individually catalogued in a series of Procite© databases. These databases are populated by more than 142,500 citations, a majority of which were obtained through regular electronic searches of Current Contents database collections: Life Sciences (LS) and Agriculture, Biology & Environmental Sciences (ABES), which together include approximately 2300 journals. Search results are normally scanned for especially relevant articles, and these articles are then retrieved in hard copy. Citations of articles found in publications not tracked by the aforementioned Current Contents collections, but retrieved by the unit through other means, are entered manually into the FSRA databases.

1.2 FSRA Current Contents Searches
The search profiles used to capture relevant citations have been modified and expanded over the years to reflect needs of the unit. The following searches are currently used to capture citations that populate the FSRA databases:

Search #1 (Abstract):
(Bioterror or biowarfare or bioweapon* or biological warfare or biological weapon*) or (risk assessment or risk analysis or predictive model) or (zoono* or encephalitozoon or enterotox* or mycotox*) or ((safety and evaluation) or microbiolog* assay*) or (hyg*ene or (biofilm* and food*) or (haccp or (hazard analysis or critical control) and (food* or water*)) or (sous vide or sous-vide or (irradiation and food) or (food* and (safe* or bacteria*)) or ready to eat or ready-to-eat or carcass or (consumer and food))

Search #2 (Abstract):
(Diarrh* or outbreak* or foodborne or food-borne or food borne) or (case control or case-control or (fuzzy and (sets or logic or math or model*)) and (food or health or biolog*)) or (bovine spongiform encephal* or bse or creutzfeld*) or (crohn* or mycobacterium paratuberculosis or mycobacterium avium*paratuberculosis or mycobacterium bovis or john*ne*) or (toxoplas* or neospor* or microsporid* or cryptosporid* or giardi*) or (Norwalk or enteric virus*) or (clostrid* not (acetobutylicum or thermocellum or thermoaceticum))
Search #3 (Abstract):
(Vtec or epec or ehec or o157* or o 157* or o-157* or verotoxi* or verocyto* or enteroh*em or enteroinvasive or shigell* or shiga-like or stec or (escherichi* and (adhe* or thrombocyt* or edema* or eae or enteropath* or attach*)) or (bacillus not (thuringiensis or stearothermophilus or megaterium or coagulans or licheniformis or subtilis)) or (staph* aureus or staph* epidermidis) or staphylococcal enterotoxin not methicillin*resistan*) or (aeromon* or plesiomona* or campylobacter* or arcobacter* or vibrio* or cholera* or enterobacter* or enterococc* or listeri* or salmonel* or streptococc*)

Excluding (in Journal Subject Categories):
Aquatic-sciences or biochemistry-and-biophysics or cardiovascular-and-haematology-research or cell-and-developmental-biology or chemistry-and-analysis or current-book-contents or entomology or pest-control or experimental-biology or medical-research-diagnosis-and-treatment or medical-research-organs-and-systems or neurosciences-and-behavior or oncogenesis-and-cancer-research or pharmacology-and-toxicology or plant-sciences

Excluding (in Journal Issues):
Endocrine-review* or chemosphere* or chemoecology* or rostlinna-vyroba* or american-journal-of-obstetrics-and-gynecology* or biochemistry* or journal-of-the-institute-of-brewing* or endoscopy* or entomologia-generalis* or european-journal-of-immunology* or hypertension* or laboratory-animal-science* or journal-of-experimental-zoology* or ophthalmology* or thorax* or transfusion* or transfusion-medicine* or radiology* or soil-biology-biochemistry* or molecular-plant-microbe-interactions* or physiologia-plantarum* or plant-cell* or plant-cell-reports* or plant-pathology* or plant physiology* or plant-physiology-and-biochemistry* or plant-science*

1.3 NGOA Project Search Strategies

Searches in Existing FSRA Databases
The already-existing FSRA Procite© databases served as a starting point in the collection of citations relevant to the current NGOA project. The databases were searched for the following keywords in the database fields “Keywords” and/or “Abstract”:

Food AND Risk Assessment
Food AND Risk Analysis
Food(-)borne AND Risk
Food(-)borne Pathogen(s) AND Model
Food(-)borne Pathogen(s) AND Modeling
Food(-)borne Pathogen(s) AND Modelling
Food(-)borne Pathogen(s) AND Predictive
Food(-)borne Pathogen(s) AND Probabilistic
After eliminating any irrelevant citations and combining the hits from each database search, there were 1966 records in the database, including articles from the early 1990s through July 2003.

**Further Searches in Current Contents**
The search strategy was expanded to incorporate the Current Contents collections *Physical, Chemical & Earth Sciences (PCET)* and *Engineering, Computing & Technology (ECT)*. The FSRA search profile was modified slightly for use in these searches to ensure inclusion of any relevant water- or food-related citations. Only citations dating from 01-01-99 were available to be searched using the current internet-based system. Combinations of the following search terms were used in this search:
- (assessment or analysis or model)
- (microb*)
- (risk and food)
- (risk and water)

The PCET and ECT searches yielded 189 new records.

In addition, an expanded search was conducted in *Current Contents* directly, of the LS and ABES collections but without the standard FSRA search profile parameters. The goal of this search was to eliminate the FSRA search limits and verify that the searches were as comprehensive and inclusive as possible of relevant citations. Again, only the most recent citations (01-01-99 to present) were available to be searched online. Combinations of the following search terms were used:
- (assessment or analysis or model)
- (microb*)
(risk and food)
(risk and water)

After pre-screening, 82 new hits were retrieved from this search.

Finally, a Current Contents search was conducted that specifically targeted articles related to antimicrobial resistance risk assessment and food or water. Without excluding any journal subject categories or establishing search limits, all four collections (LS, ABES, ECT, PCET) were searched, using combinations of the following terms:

- (AMR)
- (antimicrobial)
- (antimicrobial resistance)
- (food or water)
- (risk)

After pre-screening, there were 46 new records from this search.

After combining all of the smaller databases and discarding the duplicates, the General Database contained 2042 records.

Search strategies were designed to ensure that the collection of relevant records was as comprehensive as possible. An initial pre-screening eliminated any obviously irrelevant search hits. Each of the databases resulting from the searches was then scanned for citations that would be specifically relevant to the project. Relevant citations were assigned a preliminary code based on the area of focus for the article. Citations for articles that were not deemed to be immediately useful were not given any preliminary coding but were still retained in the database.

All of the smaller databases were eventually amalgamated, duplicates were discarded and the coding system was refined and expanded, such that every citation in the database has a category-based code. The articles were grouped into the following categories:

- Dose-Response
- Waterborne Risk Assessment
- Food Risk Assessment
- Antimicrobial Resistance
- Geographical Information Systems
- Cost Benefit
- Exposure Information
- Exposure modelling
- Methods from Other Fields
- Reviews
- Predictive Microbiology
- Methods for Risk Assessment
1.4 Literature Review

1.4.1 Dose-Response

Although the earliest work to quantify the relationships between infection/illness and numbers of microbes (or amount of toxin) ingested was published as early as the 1950s and 60’s (using human feeding trials) the work in this area is still relatively sparse. Of the thirty papers in the database on this topic since the work of (Haas, 1983) proposing a non-threshold model (versus earlier work establishing minimum infectious doses) only 16 deal specifically with developing and testing mathematical models, and the majority have been published only since 2000 (although a small number of dose-response models have been developed within the context of food and water safety risk assessment publications and not included here). However, it is evident that dose-response modelling is becoming a focus for many researchers, and largely in the context of recognizing this information is becoming a foundation for regulatory decisions, and strategies, in both water and food safety. This is seen in particularly USA and the EU publications. The majority of work currently focuses on Listeria monocytogenes, Escherichia coli O157:H7, Salmonella enterica and Cryptosporidium. Challenges include lack of accurate dose data (human volunteer feeding trials can be used only for less virulent pathogens, and use healthy subjects); epidemiological outbreak investigators generally do not, or cannot, collect quantitative data; the need for models to extrapolate from high doses (which typically cause the detectable outbreaks) to low doses (which may cause illness in certain susceptible populations, or over a widespread geographical region); differences in virulence among phenotypically similar strains; incomplete follow-up on outbreak victims to assess infected state, overt illness, and severity of illness in various subpopulations; exposures in a population from multiple sources. Closer cooperation with epidemiologists and others in public health agencies is seen to be critical to acquiring data, and to validate dose-response models. Research is needed to gain a better understanding of differences among species and strains, in order to target highly virulent pathogens specifically.


1.4.2 Waterborne Risk Assessment

Of 119 papers compiled, that fit into the “waterborne risk assessment” through our search parameters for water risk assessments, approximately one-quarter were ecological risk assessments, modeling the likelihood of contamination of water sources with effluents and fecal microorganisms, nutrients, carcinogens, and other chemical contaminants. In effect, these assessments provide the exposure input for human health risks.
Eighteen papers integrated models for the likelihood of microbial contamination with dose-response data for specific pathogens to estimate human health impacts in a population. Most studies have focused on Cryptosporidium parvum, followed by Giardia and enteroviruses; however risk assessment models have also included fecal bacteria (Campylobacter jejuni and Salmonella).

Concerns around agricultural produce have prompted risk model developments: 5 papers address the use of wastewater irrigation and modeling, the risk of human illness from consumption of contaminated crops. Several pathogens have been looked at: hepatitis A, rotavirus, Salmonella enterica, Campylobacter jejuni, Giardia lamblia, and Cryptosporidium parvum.

Much of the work in the area of water risk assessment is within the context of regulatory guidelines for water quality and treatment facilities; some specifically present findings in the context of risk management decision-making ((Wong & Yeh, 2002); (Hauger et al., 2002)). (Havelaar et al., 2000) developed an integrated case study comparing risk of infection from microbial versus chemical risk (i.e. eliminating a bacterial hazard using a chemical disinfectant), and measuring predicted outcomes of both in terms of DALY’s (disability-adjusted life-years). (Dewettinck et al., 2001) refer to quantitative risk assessments as a basis for establishing CCPs (critical control points) in a drinking water production facility’s HACCP program.

The balance of papers include epidemiological associations between drinking water quality indicators, such as turbidity, and human illness; general reviews of specific waterborne pathogens, data needs for risk assessments and risk management, uncertainty and variability in modeling exposures whether for chemical or microbial.


64. LopezPila JM, Szewzyk R. Estimating the infection risk in recreational waters from the faecal indicator concentration and from the ratio between pathogens and indicators. Water Research 2000;34(17):4195-200.


84. Payment P. Epidemiology of endemic gastrointestinal and respiratory diseases: Incidence, fraction attributable to tap water and costs to society. Water Science and Technology 1997;35(11-12):7-10.

85. Payment P, Berte A, PrTvost M, MTnard B , Barbeau B. Occurrence of pathogenic microorganisms in the Saint Lawrence River (Canada) and comparison of health risks for populations using it as their source of drinking water. Canadian Journal of Microbiology 2000;46(6):565-76.


87. Petterson SR, Ashbolt NJ. Viral risks associated with wastewater reuse: modeling virus persistence


Publications captured under the food risk assessment compilation demonstrate the increasing efforts in this field. Approximately one-third of 77 papers address both exposure models and dose-response relations to estimate human-health impacts associated with foods, dating from earlier semi-quantitative treatments of information ((Todd, 1996)) on risk of salmonellosis attributable to use of cracked eggs in Canada, ranking of microbial hazards associated with seafoods ((Huss et al., 2000)), quantitative assessment of risk of campylocteriosis from shellfish ((Teunis et al., 1997)) through one of the first farm-to-fork probabilistic models ((Cassin et al., 1998)) for E. coli 0157:H7 in ground beef, when the term “Process Risk Model” was introduced, and to addressing current regulatory concerns for Salmonella enteritidis in eggs ((Hope et al., 2002) and others) and Listeria monocytogenes in ready-to-eat foods ((Chen et al., 2003)). Health impacts due to accidental contamination of animal feeds with dioxins ((Stark et al., 2002)), and exposure to the BSE agent in foods or water sources ((Ferguson NM et al., 2002); (Gale, 1998a)) have also been quantified, under specific scenarios.

In this general category, investigators also have applied systematic quantitative approaches to analysing potential exposures to pathogens, particularly in the context of improving meat inspection practices. Although a number of general reviews of data gaps and limitations for risk assessment in different commodity groups, of note are the very few publications examining some of the critical data gaps and assumptions used in available quantitative risk assessments; for example, (Barber et al., 2003) examine assumptions and practical applications of risk models of antimicrobial resistance and foodborne illness. These types of critiques are needed to advance QRA as a discipline, help strengthen future assessment work, and ideally provide more robust foundations for risk management decision-making, particularly in a regulatory context. However, a lack of such critiques also reflects the paucity of fully developed quantitative risk assessments in food safety.


4. Alban L, Olsen AM, Nielsen B, Sorensen R, Jessen B. Qualitative and Quantitative Risk Assessment


49. Lindqvist R, Sylven S, Vagsholm I. Quantitative Microbial Risk Assessment Exemplified by Staphylococcus Aureus in Unripened Cheese Made From Raw Milk. International Journal...


70. Schlosser W, Ebel E. Use of a Markov-chain Monte Carlo model to evaluate the time value of historical testing information in animal populations. Preventive Veterinary Medicine 2001;48(3):167-75.


1.4.4 Antimicrobial Resistance

An increasing concern globally, countries are taking a risk analysis approach to the impacts of antimicrobial resistant pathogens in primarily food sources. Few quantitative risk assessment models have been developed, with only 2 publications quantifying potential exposure with human health risk ((Alban et al., 2002), on Salmonella DT104 in pork sausages; (Anderson et al., 2001), on fluoroquinolone-resistant Campylobacter jejuni in beef) (A note: 2 additional quantitative assessments have also been developed under the US regulatory system for fluoroquinolone use in poultry; these are available on the FDA website: www.fda.gov). A number (7 papers) address current issues, and identify data needs for quantitative risk assessment; an additional 5 describe specific data gathering programs in various countries, surveillance and laboratory methods. One publication describes a risk framework to integrate risk assessments for the interrelated hazards: induction of resistance by an antimicrobial agent; the specific pathogen; and horizontal gene transfer of resistance between microbial populations, indicating the complexity of conducting risk assessments in this area. Three risk assessments for exposure to antimicrobial agents/residues in foods and water are also noted.


10. Davison J. Genetic exchange between bacteria in the environment. PLASMID 1999 Sep;42(2):73-91.


15. FAO. Discussion Paper: Risk Profile on the Antimicrobial Resistant Bacteria in Food (Agenda Item 11).

16. FDA. The Human Health Impact of Fluoroquinolone Resistant Campylobacter Attributed to the Consumption of Chicken2000.
17. FDA. @Risk Model: Analysis of the human health effect of fluoroquinolone resistant Campylobacter in domestically reared and consumed broilers.


30. Lathers CM. Role of veterinary medicine in public health: Antibiotic use in food animals and humans and the effect on evolution of antibacterial resistance. JOURNAL-OF-CLINICAL-


### 1.4.5 Geographical Information Systems

This literature was examined within the context of predictive modelling tools that can be applied to exposure assessments for microbial hazards. Most of the work relates to chemical contaminants in water. However, (Kistemann et al., 2000), applied the GIS spatial and temporal associations to identify a likely food in an salmonellosis outbreak; (Michel et al., 1999) used GIS to identify an association between *E. coli* O157:H7-illnesses and rural areas of high cattle density; (Tian et al., 2002) for assessing microbial contaminants on grazing lands; and (Njemanze et al., 1999) to evaluate the health impact (diarrheal incidence) of water sources in Nigeria.


### 1.4.6 Cost Benefit
A large ratio of references, approximately half, (18 papers) focus on risks vs. benefits in water systems. Factors considered include: the balance of risk vs. abatement costs ((Andersson C & Destouni G, 2001)); competing risks (e.g. microbial vs. disinfection by-products ((Havelaar et al., 2000)) and risks to drinking water quality caused by alternate uses (e.g. recreational uses ((Stewart MH et al., 2002))). Of particular interest, two of the references consider specific regulations ((Odom R et al., 1999);(Regli S et al., 1999)). Measures used include: disability adjusted life years ((Havelaar et al., 2000); (Havelaar, 2003)); general risk measures ((Jonkman SN et al., 2003)); benefits in regulatory processes and uncertainty in measures ((Montgomery, 1998)).
Thirteen references focus on food systems. Two are at the interface between food and water systems: microbial quality of irrigation water (Shuval et al., 1997); chemical levels in sewage sludge applied to agricultural soil (Stenger, 2000). Five papers are general discussions; one focuses on a specific risk, Salmonella in poultry products (Brown, 2002). One paper considers consumer willingness to pay in cost-benefit analysis (Giamalva et al., 1998). Most papers focus on costs of immediate health problems but one paper considers long-term sequelae to foodborne disease (McDowell & McElvaine, 1997).


1.4.7 Exposure Information

The compilation of a list of research and data that could be used to describe exposure information one hazard at a time was not the primary focus of this project. Nevertheless, when relevant information of this nature was found it was included into the category titled “Exposure Information”. As a result, the information in this category should be looked upon as a general guide to the types of information that exist, as opposed to a comprehensive compilation of all information. There were an almost even number of waterborne (27) and foodborne (22) papers. A number of water papers considered watershed models and hydrological events ((Payment et al., 2000); (Conboy & Goss, 2000); (Walker & Stedinger, 1999); (Mallin et al., 2000)) and one paper considered swimming related risks ((Loge FN et al., 2002)). In addition, routes considered in food systems included: contamination through manufacturing systems ((Whiting & Golden, 2002); (Den Aantrekker et al., 2003)), home hygiene and consumer practices ((Scott et al., 1982); (Griffith et al., 1998); (Klontz et al., 1995)) and the derivation of individual consumption patterns ((Olendzki et al., 1999)).

Specific hazards considered included: Campylobacter jejuni (3 records), Cryptosporidium (13 records), Salmonella (7 records), E. coli 0157:H7 (8 records), gene transfer from bacterial to mammalian cells (1 record). A few papers considered exposure for specific subpopulations. These included: children ((Parkin et al., 2003), (Schwartz et al., 1997)), elderly ((Schwartz et al., 2000)) and ethnic populations ((Williams & Hammitt, 2001)).


10. Davison J. Genetic exchange between bacteria in the environment. PLASMID 1999 Sep;42(2):73-91.


Salmonella typhimurium 1041997.


32. Nnadi FN, Fulkerson M. Assessment of groundwater under direct influence of surface water. JOURNAL-OF-ENVIRONMENTAL-SCIENCE-AND-HEALTH-PART-A-


43. Thomson JA. Horizontal transfer of DNA from GM crops to bacteria and to mammalian cells. JOURNAL-OF-FOOD-SCIENCE 2001 Mar;66(2):188-93.


1.4.8 Exposure modelling

There appears to be, at least in the published literature, more papers dealing with food systems (30 records) than water systems (18 records). Typical examples for food systems: microbial risks in animal populations ((Jordan et al., 1999b); (Jordan et al., 1999a); (Turner et al., 2003)), growth/survivor variability for different processing operations ((Brul et al., 2002); (DelignetteMuller & Rosso, 2000); (Den Aantrekker et al., 2003), (Geeraerd et al., 2000); (Grijspeerdt & Herman, 2003); (Hoke et al., 2003); (Yang et al., 2002)), models of hygiene practises and food service handling ((Chen et al., 2001); (Montville et al., 2001); (Strachan et al., 2001); (Trick et al., 2003)), temporal variability of counts in food systems ((Corradini et al., 2002); (Gonzalez-Martinez et al., 2003); (Horowitz et al., 1999); (Nussinovitch & Peleg, 2000)) and consumption patterns ((Kynast-Wolf et al., 2002)). Exposure modelling in water systems included hazard transport by physical processes (e.g. detachment of biofilms, hydraulic, aerosols) ((Cane G & Clark ID, 1999); (Dowd et al., 2000); (Johnson et al., 1995); (Muslu, 1995); (Sanders BF et al., 2001); (Tian et al., 2002)), fate and transport models (combining growth and disinfection/degradation) ((Gale, 1998b); (Gyurek & Finch, 1998); (Jin G et al., 493-509); (McAvoy et al., 1998)) as well as sampling methods and bio-indicators ((Craig DL et al., 2003); (Young & Komisar, 1999)).


36. Nussinovitch A, Peleg M. Analysis of the fluctuating patterns of microbial counts in frozen


1.4.9 Methods from Other Fields
Almost one hundred of the references dealt with risks in water systems, particularly in groundwater. Many references were related to agricultural management practices (e.g. nitrogen, phosphorus, manure, pesticides). Non-agricultural hazards included a few
industrial (e.g. pulp mill effluents, heavy metals contamination soil and sediments, naval shipyard) and municipal (e.g. “down-the drain” chemicals, wastewater treatment plants, ocean outfalls) sources.

Twenty-five of the papers considered non-microbial foodborne risks: hormone residues, mycotoxins, food additives, allergens, BSE and genetic modifications. Several references dealt with biofilms (models of growth, competition and antibiotic resistance). Additional topics included antibiotic resistant bacteria in hospitals, air quality and transportation of hazardous substances.

Some mathematical methods were common to microbial risk assessment: use of GIS for spatially referenced data (14 papers); Monte Carlo methods to deal with stochastic elements (18 papers), Bayesian approaches (5). Methods that are less commonly used in microbial risk assessment included use of extreme value statistics in climate models, categorical regression to estimate minimum hazard levels for health impacts, smooth coloured noise to introduce stochastic elements in deterministic models, expectation functions to describe uncertain inputs, fault tree methods in risk assessment, relative risk ranking procedures, and multicriteria decision support tools.


1.4.10 Reviews

Twenty-three review papers dealt with water and about half of these papers focused specifically on drinking water quality. Risks included: Giardia (4 papers), Cryptosporidium (8 papers), bacteria (9 papers) and viruses (2 papers). Ten papers considered specific regulations, mainly US based. Three papers reviewed specific waterborne outbreaks and distribution system failures. One review paper compared food and water systems as microbial habitats.

Eighty review papers focused on food systems. Most focused on microbial risks including Listeria (11 papers), Salmonella (5 papers), E. coli (4 papers), Bacillus (4 papers), Clostridium (2 papers). Non-microbial risks in foods considered were: pesticides (2 papers), carcinogens (2 papers) and genetic modifications (10 papers). Eighteen reviews include discussion of HACCP in food risk assessment. A large number (17 papers) considered specific regulatory frameworks as well as international trade issues (10 papers). Eight references discussed consumer perceptions, ethics and risk communications.

1. Acar J, Rostel B. Antimicrobial resistance: an overview. REVUE-SCIENTIFIQUE-ET-


30. Davison J. Genetic exchange between bacteria in the environment. PLASMID 1999 Sep;42(2):73-91.


34. FAO/WHO Expert Consultation. Application of Risk Analysis to Food Standards Issues.


52. Goldstein BD. The precautionary principle also applies to public health actions. AMERICAN-JOURNAL-OF-PUBLIC-HEALTH 2001 Sep;91(9):1358-61.


70. Huss HH, Reilly A, BenEmbarek PK. Prevention and control of hazards in seafood. Food Control


89. Lloyd A, Drury D. Continuous Monitoring for Cryptosporidium - a Novel Approach to Public Health Protection. Water Science and Technology 2002;46(11-12):297-301.


137. Tomerlin JR. The US Food Quality Protection Act - policy implications of variability and consumer
1.4.11 Predictive Microbiology

The goal of predictive microbiology is to develop mathematical equations that describe risk. Food Additives and Contaminants 2000;17(7):641-8.


the behaviour of microorganisms under different environmental factors (physical, chemical, competitive). All of the references focused on predictive microbiology in food systems. Only one paper considered common elements between food and water systems. Growth, survival and thermal inactivation (death) models have been developed for the most important foodborne pathogens (Listeria spp. (58 papers), E.coli O157:H7 (34 papers), Salmonella spp. (21 papers), Yersinia spp. (16 papers), Staphylococcus spp. (16 papers), Clostridium botulinum (5 papers)). Many food systems have been studied: beef, poultry, fish, seafood, dairy, vegetables and processed foods. Although all of the papers included quantitative mathematical descriptions of microbial growth and inactivation, a relatively small number focused on the use of these models in quantitative risk assessment.

The effect of temperature on microbial growth or lethality was the most commonly studied environmental factor (100 papers). Other important factors were pH (90 papers), water activity (28 papers), salts (53 papers), fat (4 papers). Curve fitting techniques include statistical methods and neural networks. Some models described different growth phases (lag, exponential, stationary) while others classified boundaries between growth and no-growth, death and survival. User-friendly application software has been developed (e.g. Food MicroModel and Pathogen Modelling Program). Most studies were based on one species but a few considered mixed cultures and competition effects.

There are strong predictive microbiology research groups in the USA (USDA, National Food Processors Association), Europe (Food Research Institute, Katholieke Univ Leuven, RIVM Netherlands) and Australia (University of Tasmania). Agriculture and Agri-Food Canada researchers (McKellar and Piyasena) are conducting predictive microbiology studies in Canada.


38. Giannuzzi L, Pinotti A, Zaritzky N. Mathematical Modelling of Microbial Growth in Packaged


86. Panagou EZ, Skandamis PN, Nychas GJE. Modelling the Combined Effect of Temperature, pH and a(W) on the Growth Rate of Monascus Ruber, a Heat-Resistant Fungus Isolated From Green Table Olives. Journal of Applied Microbiology 2003;94(1):146-56.


99. Shimoni E, Anderson EM, Labuza TP. Reliability of Time Temperature Indicators Under
100. Skinner GE, Larkin JW. Conservative prediction of time to Clostridium botulinum toxin formation for use with time-temperature indicators to ensure the safety of foods. Journal of Food Protection 1998;61(9):1154-60.


114. Whiting RC, Golden MH. Variation among Escherichia coli O157:H7 strains relative to their


1.4.12 Methods for Risk Assessment

This subset of the literature, much of which is captured under other search topics, nevertheless provides a relatively comprehensive collection of current specific methodologies, plus broader issues relevant to the application of risk assessment, and risk management practices (for example, use of food safety objectives to satisfy the intent of food safety law, (Baker, 2002); mathematical models as tools for evaluating the effectiveness of interventions, (Kristinsson, 2001); microbiological double standards for enhanced treated sludge versus food requirements, (Mara & Horan, 2002).

Methodologies to improve inputs for microbial risk assessment are addressed, for example adding new factors to predictive models ((Masana & Baranyi, 2000)), evaluating time value of historical testing information in animal populations, (Schlosser & Ebel, 2001)) plus risk assessment tools designed to simplify the process ((Ross & Sumner, 2002)).


68. LopezPila JM, Szewczyk R. Estimating the infection risk in recreational waters from the faecal indicator concentration and from the ratio between pathogens and indicators. Water


85. Payment P. Epidemiology of endemic gastrointestinal and respiratory diseases: Incidence, fraction attributable to tap water and costs to society. Water Science and Technology 1997;35(11-12):7-10.


123. Vose DJ. The application of quantitative risk analysis to microbial food safety. Journal of Food Protection 1997;60(11):1416-.


2.0 Appendix 2: Expert Consultation

The expert consultation was held at the Westin Edmonton, 10135 - 100 Street, Edmonton, AB, T5J 0N7 on November 5th and 6th, 2003. The consultation drew upon the experience of a substantial roster of both Canadian and international expertise in risk assessment. The primary focus of the consultation was to tap into the experience and insight of the experts so as to ensure that the outputs from this product were in tune with a good cross-section of the risk assessment community, as well as to get feedback on the completeness of the environmental scan to that point and to critically evaluate the advancement directions proposed. This section of the appendix provides some of the background information related to the consultation including invitation and attendee lists.
2.1 Consultation Correspondence

2.1.1 Invitation

Laboratory for Foodborne Zoonoses
Microbial Risk Assessment Unit
110 Stone Road West
Guelph, Ontario
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Dear

The Canadian Institutes of Health Research (CIHR) Institute of Infection and Immunity, the Canadian Water Network, and the Natural Sciences and Engineering Research Council have funded a project entitled “Microbial Risk Assessment as a Foundation for Informed Decision Making” under the Strategic Initiative “Needs, Gaps and Opportunities Assessment in the area of microbial contamination of food and water.

The focus of the work is to identify needs and current barriers to the development of microbial risk assessment, what activities are being undertaken to meet needs and overcome barriers, and what opportunities exist to improve its application in decision-making.

One component of this project is to convene an expert consultation to gain insights into future directions, both short-term and long-term, and to identify opportunities to advance the development of microbial risk assessment with consideration for the tools available, synthesis methods, quality of information as well as its implementation as an information base for decision-making and policy development.

We invite you to participate in this consultation, November 5 and 6th, 2003, in Edmonton, Alberta. In appreciation of your expertise and your time, all travel and accommodation expenses will be provided. The format of the consultation will lead to a draft report, which once finalized, will be distributed to all participants.

We would appreciate it if you would advise us at your earliest convenience if you will be available to participate in the consultation. Once confirmed, you will receive further background information that will provide a basis for the agenda and discussions of the consultation.

With sincere regards

Aamir Fazil
Health Canada
2.1.2 **Attendee Travel Instructions**

Laboratory for Foodborne Zoonoses  
Microbial Risk Assessment Unit  
110 Stone Road West  
Guelph, Ontario  
N1G-3W4

Dear

We are pleased that you accepted our earlier invitation to attend the two-day expert consultation to look at the needs, gaps and opportunities for microbial risk assessment in food and water to be held November 5th and 6th, 2003 in Edmonton, Alberta. Since the date is quickly approaching and so that you can secure reasonably priced air tickets, we would appreciate it if you could proceed with flight bookings as soon as possible.

To assist you with the arrangements we are including some relevant information. The start and stop times for the meeting are:

- **Day 1 – Wednesday November 5th 2003 – 8:00 a.m. to 5:00 p.m.**
- **Day 2 – Thursday November 6th 2003 – 8:00 a.m. to 5:00 p.m.**

We would suggest that your arrival date be Tuesday November 4th, to accommodate the early start on the Wednesday. Departure can be anytime after we adjourn on Thursday November 6th at 5pm

As you are aware all travel and accommodation expenses will be provided within certain guidelines:

- Due to budgetary considerations we would ask that you make bookings on the basis of lowest economy flight fares.
- Accommodation and meetings will be at the Westin Edmonton Hotel located at 10135 - 100 Street, Edmonton, AB, T5J 0N7. To confirm your room, please contact Jennifer Robertson as soon as possible (contact information listed below) and at the latest before October 12th, specifying preferences (smoking etc.).
- Although accommodation expenses are covered, you will be responsible for incidental charges (phone, bar etc) billed to your room, which you will have to settle upon checkout
- Meals will be catered on both days including Breakfast, Lunch and Dinner (5th only).

If you would like assistance with booking your travel arrangements as well as to confirm your hotel booking, please contact:
Jennifer Robertson  
519-822-3300 ext. 252, or  
Jennifer_Robertson@hc-sc.gc.ca, as soon as possible.

Thank you for your interest in this project and we look forward to your contributions at the consultation.

With sincere regards

Aamir Fazil
Health Canada
2.2 Pre-consultation Update & Instruction

This memo/document is a follow up to the discussion document sent out last week (2003-10-23), that is intended to serve as the starting point for the consultation scheduled for Nov 5th and 6th, 2003. The purpose of this memo is to give you some additional information and direction on things you may want to think about and how the two-day Edmonton consultation will progress.

2.2.1 General Impressions
First of all, when reading the document over the next week or so, consider if you agree/disagree with the identified goals of risk based decision-making, or the objectives for microbial risk assessment for food and water (are they legitimate in your opinion, is anything missing, etc). The same sort of consideration should be given to the pathways, both major and the sub-pathways. Major pathways are things like "Methodology Development" and "Coordination", and sub-pathways are things like "Risk assessment tools for emerging pathogens are available" and “Prioritization and Co-ordination of Research and Information Gathering”

2.2.2 Roundtable Preparation
On the first day of the meeting, during the morning session, we would like to get all of you involved directly. So, there will be a roundtable introduction, but in addition to introducing yourselves we would like each of you to bring to the table a few key issues of importance to you in relation to the needs for microbial risk assessment in food or water. Keep in mind this is intended to be a quick roundtable, so 2-3 minutes a person is all that is allotted. The purpose of the roundtable is to try to ensure that everyone gets a chance to be heard initially and to present ideas of importance to them. Keep in mind there will be ample opportunity if warranted to revisit and expand on issues as the meeting progresses.

2.2.3 Breakout Session Questions
On the afternoon of the 5th we will be breaking up the larger group into a few breakout groups in which the intention is to tackle in more detail the "sub-pathways" identified in the document, as well as any other potential pathways that might have been introduced and consensus arrived at as to their applicability. In order to facilitate the groups and so as to maximize efficiency, there will be 4 questions that should be addressed as they relate to these sub-pathways. Each of you will be part of a breakout group that will be assigned a few of these "sub-pathways" to deal with, in reading the document prior to arrival, it may help to consider these questions and start formulating your thoughts and ideas. If you have thoughts about a sub-pathway that you are not subsequently assigned, you can of course still contribute those ideas either to the group dealing with them or
during plenary sessions when groups report back. The questions the groups will be asked to work on as they apply to the sub-pathways are as follows:

1) **Description of current pathway status**
   - Is the characterization of the current status fair?
   - Is there some critique from your position and as a group that you/we can level against the description of the current status of the pathway?

2) **Advancement along pathway**
   - What steps or action items need to be addressed in order to advance along this pathway?
   - Can these steps be categorized into short-term and more medium-term action items? (e.g., what needs to be done, and can be done now, and what needs to be done, but requires additional groundwork to be covered before they can be done)

3) **Limitations**
   - What are potential limitations to progress along this pathway? (even though an action item is achieved or steps are taken what are the potential limits to its contribution)

4) **Contribution**
   - If progress is made along this pathway, which objectives (listed in Figure 1, and in the text) will it contribute towards?

2.2.4 **Miscellaneous**

If any of you have reference material or other supporting information to help make a point or to raise an issue, or to highlight a development, please bring it along with you so that it can be incorporated in our records if necessary as quickly as possible.

In order to enhance the breadth of expertise to which these ideas are exposed, we hope to send the report to a group of reviewers. If you know of an individual that you think should be asked to review the report, please bring along the contact information for them.
### 2.3 Agenda

**Wednesday, November 5th, 2003**

<table>
<thead>
<tr>
<th>Start</th>
<th>End</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:00 AM</td>
<td>8:30 AM</td>
<td><strong>Continental Breakfast</strong></td>
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<td>8:30 AM</td>
<td>9:00 AM</td>
<td><strong>Introduction</strong></td>
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<td>Welcome and Housekeeping</td>
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<td>Project Background</td>
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<td>Objectives</td>
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<td>9:00 AM</td>
<td>10:15 AM</td>
<td><strong>Roundtable</strong></td>
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<td>Participant Introductions</td>
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<td></td>
<td>Statement on key issues of importance</td>
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<tr>
<td>10:15 AM</td>
<td>10:45 AM</td>
<td><strong>Coffee</strong></td>
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<tr>
<td>10:45 AM</td>
<td>12:00 PM</td>
<td><strong>Presentation of Framework</strong></td>
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<td>Presentation of &quot;Goals&quot;, &quot;Objectives&quot; &amp; &quot;Pathways&quot;</td>
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<td>Discussion on draft report content</td>
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<td>12:00 PM</td>
<td>12:30 PM</td>
<td><strong>Pathway prioritization</strong></td>
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<td>12:30 PM</td>
<td>1:30 PM</td>
<td><strong>Lunch</strong></td>
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<td>1:30 PM</td>
<td>1:45 PM</td>
<td><strong>Prioritization results and Group assignment</strong></td>
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<td>1:45 PM</td>
<td>3:00 PM</td>
<td><strong>Breakout Group Session</strong></td>
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<td>Address questions for each pathway</td>
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<td>3:00 PM</td>
<td>3:15 PM</td>
<td><strong>Coffee</strong></td>
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<tr>
<td>3:15 PM</td>
<td>4:15 PM</td>
<td><strong>Breakout Group Session</strong></td>
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<td>Address questions for each pathway</td>
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<tr>
<td>4:15 PM</td>
<td>5:00 PM</td>
<td><strong>Plenary Session</strong></td>
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<td>Presentation of breakout activities / results</td>
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<td>6:30 PM</td>
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<td><strong>Group Dinner</strong></td>
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### Thursday, November 6th, 2003

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<tr>
<th>Start</th>
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<th>Activity</th>
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<td>8:00 AM</td>
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<td><em>Continental Breakfast</em></td>
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<td>8:30 AM</td>
<td>9:00 AM</td>
<td><em>Plenary Session</em></td>
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<td>Regroup and review of charge</td>
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<td>9:00 AM</td>
<td>10:15 AM</td>
<td><em>Breakout Group Session</em></td>
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<td>Incorporate feedback</td>
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<td>Address questions for remaining pathways</td>
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<td>10:15 AM</td>
<td>10:45 AM</td>
<td><em>Coffee</em></td>
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<tr>
<td>10:45 AM</td>
<td>11:30 AM</td>
<td><em>Plenary Session</em></td>
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<tr>
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<td>Presentation of remaining breakout activities / results</td>
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<tr>
<td>11:30 AM</td>
<td>12:30 PM</td>
<td><em>Plenary Session</em></td>
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<td>Discussion and consideration of international issues</td>
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<td>12:30 PM</td>
<td>1:30 PM</td>
<td><em>Lunch</em></td>
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<td>1:30 PM</td>
<td>3:00 PM</td>
<td><em>Roundtable</em></td>
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<td>What has been learned</td>
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<td>Most important issue to advance the field</td>
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<td>3:00 PM</td>
<td>3:15 PM</td>
<td><em>Coffee</em></td>
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<td>3:15 PM</td>
<td>4:30 PM</td>
<td><em>Wrap Up</em></td>
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<td>Conclusions, Key Findings</td>
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<td>Strategy to progress</td>
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2.4 Introductory Presentation

Edmonton, Alberta
November 5th & 6th, 2003

NGOA for Microbial Risk Assessment in Food & Water

Introduction

Aamir Fazil
Health Canada

G. Paoli, M. Griffiths, A. Lammersing, S. Brudey, V. Daviau, J. Isaac Renton

Health Canada - University of Calgary - CIHR - DecisionAnalysis Risk Consultants -
University of Alberta - University of British Columbia - BCCDC

Project Background

• Funding Agencies
  – Canadian Institute for Health Research (CIHR)
  – Canadian Water Network (CWN)
  – Natural Science and Engineering Council (NSERC)

• 8 Month Project

• Overall initiative:
  – “Needs, Gaps & Opportunity Assessment in the area of Microbial Contamination of Food & Water and Antimicrobial resistance”

Project Background

• Funds for up to 8 NGOA awards were available in areas such as:
  – Anti-microbial resistance
  – Health impact of food & waterborne infections
  – Risk assessment
  – New technologies for real time diagnostics
  – Global climate change & emerging infectious disease
Project Background

- Early on recognized that unlike other areas in NGOA, risk assessment was distinct
  - a tool for the synthesis of information to address an issue as opposed to an issue (i.e. antimicrobial resistance, climate change etc)
  - basis for promoting the uptake of research into the policy making arena
- Evaluation of specific data needs for microbial risk assessment issue specific
- Focus on needs, gaps & opportunities to take microbial risk assessment, as a tool, to the next level

Environmental Scan

- Survey of published risk assessment work, and available unpublished work performed (microbial risk assessment, methodology, others …… difficult task given breadth of area)

Objectives

- The intention of this project:
  - to establish a recommended direction for microbial risk assessment to progress from
    - Current status
      - widely recognized tool for decision making that is still being developed and perhaps not being exploited to its full potential,
    - Future target
      - as a tool that is an integral part of the research and risk reduction strategies
      - employed by decision-makers and being used in practice to inform policy
      - going beyond theoretical frameworks
Plan

- The current project will propose “pathways” (needs, gaps & opportunities) to advance microbial risk assessment:
  - Set the stage with an environmental scan of the literature (published and unpublished), and activities underway
  - Incorporate the study team's experience
  - Enhance and add value through an expert consultation
  - Gain additional insight and comment through a circulation of the draft document to a wider circle of peer reviewers

Meeting Outline

- Roundtable
  - Participant introductions, key issues of importance for microbial risk assessment
    - 2-3 minutes

- Framework presentation
  - Participant participation
    - Agreement / disagreement / thoughts on:
    - Goals, Objectives & Pathways

Meeting Outline

- Prioritization of identified pathways

- Formation of Breakout Groups
  - Assignment of prioritized pathways to breakout groups
  - Tackle questions related to pathways in breakout groups
2.5 Framework Presentation

Edmonton, Alberta
November 5th & 6th, 2003

NGOA for Microbial Risk Assessment in Food & Water
Framework

Aamir Fazil
Health Canada

G. Fazil, M. Griffiths, A. Lammersing, S. Breden, V. Daviden, J. Isaac-Renton

Health Canada - University of Guelph CRIFs - Decisionfish Risk Consultants -
University of Alberta - University of British Columbia / BCCDC

Intent of this Session

• Refresh information in Background Document
• Opportunity to discuss broad scope
Goals

• Comprehensive Management of Microbial Risks
  – (full scope, risk attribution, multi-pathway)

• Efficient Management of Risks due to Microbial Hazards
  – (integration with cost, priority-setting)

• Responsive and Proactive Evidence-Based Management of Microbial Hazards
  – (timely, reasonable cost, incremental)

Goals (cont.)

• Risk-Based Analysis is a Credible and Acceptable Element of Public Health Decision-making
  – (approach acceptable to stakeholders, trading partners, no mistrust)

• Risk-Based Analysis becomes an essential day-to-day element of public health decision-making
  – (culture change within organizations).

Objectives

• Risk Assessment practice is of consistently high quality and clearly addresses risk management goals

• Risk Assessments are Designed to be Integrated with Cost Assessments and Other Decision-Relevant Evidence

• Comprehensive Systems Models of Microbial Risks in Food and Water are Developed and Maintained
Objectives (cont.)

- Priority-setting of Microbial Hazards is Performed, Updated and Includes Risk Reduction Potential

- Applied Research is Optimally Allocated to Support Risk-Based Decisions

- A variety of Risk Assessment Approaches are practically and actively used in decision-making for short, medium and long-term decision-making

Objectives (cont.)

- Risk Assessment tools contribute to effective interaction with risk managers, and result in improved credibility and transparency

- New evidence is rapidly integrated into decision-making and policy

- Risks are Communicated Effectively and risk assessment data, models, assumptions and outcomes are communicated / made available in language appropriate for broad audiences

Major Pathways

- Methodology Development

- Coordination

- Education & Infrastructure Development

- Communication
Major Pathway:
Methodology Development

- Methodological Problems in Risk Assessment are Foreseen and Solutions are Developed
- Diversity of Assessment Methodology is Promoted to Improve the Availability of Appropriate Methods for Diverse Problem Types
- Cross-disciplinary Interaction with Related Technical Fields

Major Pathway:
Methodology Development (cont.)

- Guidance for Risk Assessment is Available to Improve the Quality of Assessments and Increase the Capacity of New Practitioners
- Guidance is Developed for Qualitative and Semi-Quantitative Methods to Improve the Quality of Inference and Decision-Making
- Robust Tools for Rapid Risk-Based Decision-Making are Available

Major Pathway:
Methodology Development (cont.)

- Risk Assessment Tools for Addressing Emerging Hazards are Available
- Peer Review Processes for Risk Assessments are Developed and Applied.
- Quantitative Health Outcome Measures are developed for Microbial Illness and Sequelae (QALYs, etc.)
Major Pathway:
Coordination

- Decision-making Frameworks are designed to accommodate risk-based analysis
- Promotion of Improved Data-Sharing, Evidence and Analytical Tool Clearinghouse and collation of research outputs with negative results
- Prioritization and Co-ordination of Research and Information Gathering
- Co-ordination of the development and maintenance of comprehensive system models

Major Pathway:
Education & Infrastructure

- Education and Training Opportunities for Risk Assessment and Risk-Based Decision-Making
- Development of microbial risk assessment and decision analysis as a university training background and career path
- Establishment of University chairs in microbial risk assessment to foster a training, research and program direction
- Development of Professional Practitioner Network

Major Pathway:
Communication

- Good Risk Communication Practices are integrated into assessment and decision-making processes
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<tr>
<th>NAME</th>
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<tbody>
<tr>
<td>Aamir Fazil</td>
<td>Health Canada, Guelph, Ontario</td>
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<tr>
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<td>Decisionalysis Risk Consultants, Ottawa, Ontario</td>
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<td>University of Guelph, Guelph, Ontario</td>
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<td>Anna Lammerding</td>
<td>Health Canada, Guelph, Ontario</td>
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<tr>
<td>Steve Hrudey</td>
<td>University of Alberta, Edmonton, Alberta</td>
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<td>Judy Isaac-Renton</td>
<td>University of British Columbia / BCCDC, Vancouver, British Columbia</td>
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<td>Bruce McNab</td>
<td>Epidemiology and Risk Assessment, Ontario Ministry of Agriculture and Food, Guelph, Ontario</td>
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<td>Sandra Honour</td>
<td>Head, Agri-Food Systems Branch, Agriculture Food and Rural Development, Edmonton, Alberta</td>
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<td>Andrijana Rajic</td>
<td>Agriculture Food and Rural Development, Edmonton, Alberta</td>
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<td>Clinical Associate Professor, Dept. of Health Care and Epidemiology, University of British Columbia / BCCDC, Vancouver, British Columbia</td>
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<tr>
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<td>Program Director, Environmental Microbiology, Provincial Laboratory of Public Health, Calgary, Alberta</td>
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<tr>
<td>William Ross</td>
<td>Director&lt;br&gt;Health Products and Food Branch&lt;br&gt;Health Canada, Ottawa, Ontario</td>
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<tr>
<td>Tom Feltmate</td>
<td>Chief, Food Safety Risk Analysis Unit&lt;br&gt;Canadian Food Inspection Agency, Ottawa, Ontario</td>
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<tr>
<td>Pierre Payment</td>
<td>Professeur&lt;br&gt;INRS-Institut Armand-Frappier, University of Quebec, Laval, Quebec</td>
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<tr>
<td>Kevin Brand</td>
<td>Assistant Professor&lt;br&gt;McLaughlin Centre for Population Health RA&lt;br&gt;University of Ottawa, Ottawa, Ontario</td>
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<td>Further Poultry Processors Association, Ottawa, Ontario</td>
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<td>Head, Microbiology Section&lt;br&gt;Health Environments and Consumer Safety&lt;br&gt;Health Canada, Ottawa, Ontario</td>
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<tr>
<td>Diane Medeiros</td>
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<td>Civil Engineering, University of Waterloo / NSERC Chair in Water Treatment&lt;br&gt;Waterloo, Canada</td>
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<tr>
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<td>Homer Nowlin Chair in Water Research&lt;br&gt;Michigan State University&lt;br&gt;E. Lansing, Michigan</td>
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<td>Betz Professor of Environmental Engineering&lt;br&gt;Drexel University, Philadelphia, Pennsylvania</td>
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<td>US Department of Agriculture, ORACBA Washington, DC</td>
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<td>National Institute of Public Health and the Environment of the Netherlands (RIVM) Bilthoven, Netherlands</td>
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<td>Deputy Director, Centre for Water and Waste Technology University of New South Wales, Sydney, Australia</td>
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<td>Coordinator, Food Safety Science Unit Ontario Ministry of Agriculture and Food, Guelph, Ontario</td>
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<tr>
<td>Frances Natress</td>
<td>Lacombe Research Centre Agriculture Canada, Lacombe, Alberta</td>
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<tr>
<td>Shari Orders</td>
<td>Decisionalysis Risk Consultants, Ottawa, Ontario</td>
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