A Generic Model for Risk-Based Food Inspection in Canada: Assessment of Initial Biological Hazards and Risk Ranking for Inspection

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A Thesis Submitted to the Faculty of Graduate Studies of

The University of Manitoba

in partial fulfillment of the requirements of the degree of

MASTER OF SCIENCE

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ABSTRACT

Risk-based inspection provides a framework whereby inspection resources can be prioritized and targeted towards foods that pose the highest risk to human health. To provide a risk assessment of the initial biological hazards associated with foods consumed, criteria related to hazard identification, hazard characterization and exposure assessment were developed for all foods (dairy, eggs, meat [beef, poultry, pork and game], fats and oils, honey and maple, grains and bakery products, fruits and vegetables, and aquatic animals [fish, crustaceans and mollusks]) inspected by the Canadian Food Inspection Agency (CFIA). Using Canadian scientific data, food-pathogen pairs most responsible for foodborne illness were developed and ranked. *Campylobacter* spp. and poultry, *Campylobacter* spp. and dairy, *Salmonella* spp. and poultry, *Salmonella* spp. and eggs, *Escherichia coli* and beef were the top five food-pathogen pairs (in descending order) implicated in Canada. To characterize the overall population burden of these food-pathogen pairs, a model adapted from the European Food Safety Authority (EFSA) was developed which incorporated criteria related to pathogen characteristics and probability of exposure of humans by food. The 6 criteria included in the model were: strength of associations between food and pathogen based on food-pathogen attribution data, incidence of illness, burden of disease, dose-response relationships, prevalence of contamination and food consumption. The top risk-ranked food-pathogen pairs were *Campylobacter* spp. and poultry, pathogenic *Escherichia coli* and beef, *Salmonella* spp. and poultry, *Salmonella* spp. and produce, and *Campylobacter* spp. and dairy. Limitations of the model and gaps identified in the scientific literature were also discussed.

ACKNOWLEDGEMENTS

I would like to thank my advisor Dr. Rick Holley for his guidance, support, patience and more importantly for kindling my interest in food safety and setting me on this course. My sincerest gratitude to my committee members, Dr. Susan Arntfield and Dr. Loreen Onischuk for their time and efforts on my behalf.

My appreciation to Robert Mancini of Manitoba Health for his input and advice throughout this work especially in providing technical expertise and knowledge during the identification and assessment of initial biological hazards.

I would also like to thank the Public Health Agency of Canada and the National Microbiology Laboratory for providing information and assistance whenever needed.

The financial support provided by the Canadian Food Inspection Agency and the James. W. Barlow Graduate Fellowship is gratefully acknowledged.

My deepest gratitude to all the technical and administrative staff in the department of Food Science for their support and kindness.

A special thanks to my champion Mohammed Suleiman, for always being there and cheering me on throughout this work, I love you. To my family, especially my sister Estella Marmah, words cannot express my gratitude for your support. Thank you for being my corner stone and anchoring me. Thank you Miss Moss for all your support. I would also like to thank my partners in crime; Mingjue Wu, Wieja Xie, Kuuku Biney, Victoria Ndolo, Yuan Fang, Yuming Chen, May-fong Yee, Lilei Yu, Kun Wang, Yao Wu and Lan Shi for creating memories that would last a life time.

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CHAPTER 1: INTRODUCTION

In November 2012, the Canadian government in a bid to improve the safety of food passed the Safe Food for Canadians Act (SFCA) with the aim of centralizing the inspection authorities of the Meat Inspection Act, the Fish Inspection Act, the Canada Agricultural Products Act, and the food provisions of the Consumer Packaging and Labeling Act (CFIA, 2013). The purpose of this legislation was to consolidate the inspection legislation and to make inspection a scientific process based on risk analysis. The main goals of the SFCA were to improve food safety, enable the centralization and integration of Canadian food legislation, and to improve export opportunities for Canadian foods (CFIA, 2013).

The Canadian Food Inspection Agency (CFIA), to achieve the goals and aims of SFCA, established a Scientific Advisory Committee (SAC) to provide expert opinion and targeted research, including literature reviews. Included in this advisory committee were the Universities of Manitoba, Montreal, Guelph and Dalhousie University. The University of Manitoba was assigned the task of providing a generic biological hazard model for Risk Based Inspection (RBI) initially for animal products, fruit and vegetable production, and processing plants, but it had to be applicable to other food processing facilities. The University of Manitoba voluntarily accepted the responsibility to develop a risk ranking of food based on as much Canadian data as possible and identify where gaps in these data exist.

CHAPTER 2: LITERATURE REVIEW

2.1. Background

The CFIA was set up to enhance the efficiency and effectiveness of the Federal food inspection program (McEachern & Mountjoy, 1999). Prior to that, Federal inspection was conducted by Agriculture and Agri-food Canada, Health Canada, Industry Canada, and Fisheries and Oceans Canada. Despite the amalgamation of these inspection activities, the CFIA still operated under the Fish Inspection, Meat Inspection and the Canadian Agricultural Products Acts (CFIA, 2013). Under the SFCA, the CFIA aims to modernize its inspection system using a RBI framework.

RBI assures a higher level of inspection of foods with more likelihood of contamination compared to foods with lower risks (inspection optimization). It also determines the likelihood of failure and the consequence of that failure (Lammerding & Fazil, 2000). RBI also has the added benefit of eliminating unnecessary inspections and prioritizing essential ones. Risk analysis of hazards includes risk assessment, risk management and risk communication (Coleman & Marks, 2003).

The nature of the hazard determines the framework and criterion that is assigned to it. Detailed and extensive assessments of hazards are important when new regulations are being implemented in order to prevent and resolve disputes between and within organizations (Lammerding & Todd, 2006). Risk analysis in this case can be used to set priorities, especially since different health concerns are competing for limited resources. More importantly, a risk-based approach to food safety such as Hazard Analysis Critical

Control Points (HACCP) enables inspections to move from an end-product food safety inspection system towards a scientific risk-based preventative management system where responsibility for food safety is placed on the producer (Loader & Hobbs, 1999). The consequences of alternative approaches lead to failures of controls at one or more points of the farm to fork process yielding foodborne illness.

According to the Codex Alimentarius Commission (CAC), Microbial Risk Assessment (MRA) should be conducted using a structured approach (Fig. 2.1) (CAC GL-30, 1999). The most important ingredients for this structured approach are hazard identification, exposure assessment, hazard characterization and risk characterization (Lammerding & Fazil, 2000).

Hazard identification describes the nature of the hazard and the vehicles that cause these adverse effects (Coleman & Marks, 2003). This step formulates the problem to be assessed, and must be comprehensive and detailed in order to provide guidelines for risk assessors and risk managers. Hazard identification is mainly a qualitative evaluation of risk and involves a preliminary examination of the information that will be analysed further in the assessment. For MRA, pathogens are often isolated from the individuals that exhibit adverse effects, therefore providing a positive cause-effect relationship (Lammerding & Fazil, 2000). Hazards can be identified through national surveillance reporting, epidemiological, clinical and laboratory studies of pathogens, and their interactions in the food chain (Lammerding & Todd, 2006). In hazard identification, issues associated with acute versus chronic disease, and the effect of the hazard on specific sub-populations must be noted.

The World Health Organization (WHO) defines hazard characterization as an evaluation of the adverse effects associated with chemical, physical and biological agents that may be present in food using quantitative and/or qualitative analysis (WHO, 2013a). For biological hazards this may be done through a dose response assessment if the data are available (Lammerding & Todd, 2006).

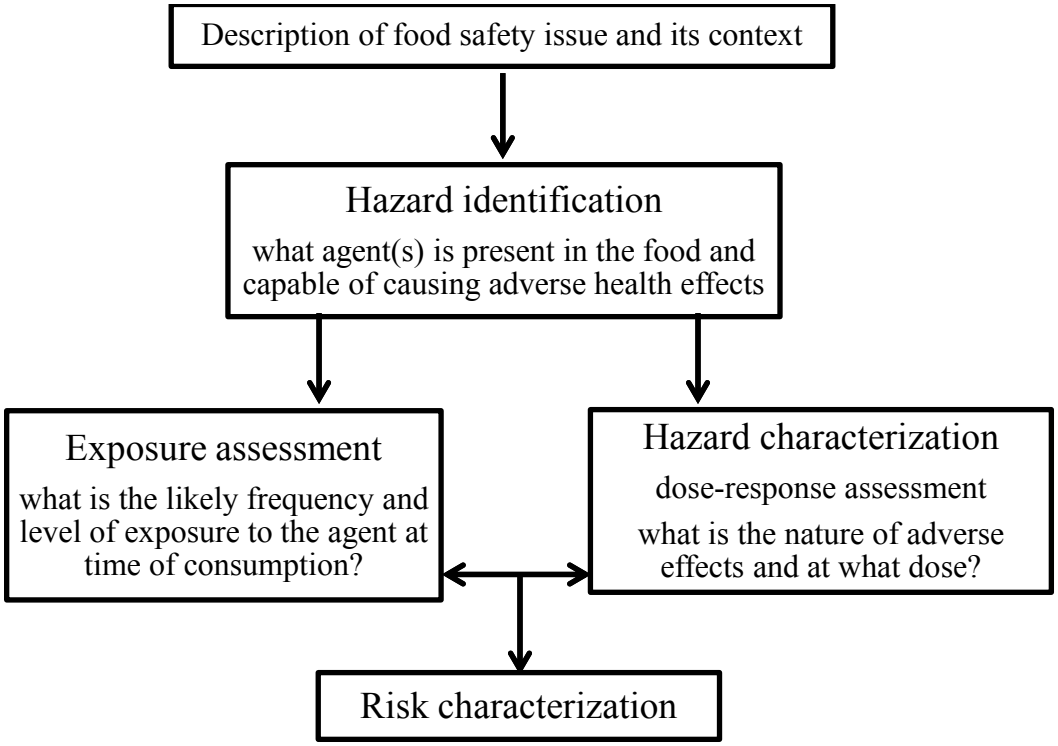
Exposure assessment predicts the probable rate of an individual exposure to the hazard and the magnitude of that exposure (in this context, the number of pathogens likely to be ingested) (EC, 2013). Since it is unlikely that the numbers of microorganisms present in the contaminated food are measured at the time of consumption, models and assumptions are important aspects of the exposure assessment (Lammerding & Fazil, 2000). Therefore, initial contamination of raw material, growth rate of pathogen, effects of processing steps and patterns of consumptions are all important tools in exposure assessment (Lammerding & Fazil, 2000). A unit of exposure can be defined as a serving or portion size of food. In exposure assessment, information from specific sub-groups such as infants, children, pregnant women and the elderly should also be included. Special attention must be focused on vulnerable sub-populations such as children since reduced stomach acid and pepsin secretion are factors that might predispose them to higher infection rates at lower doses compared to adults (Nwachuku & Gerba, 2004). Also, where the possibility for international trade exists, differences in exposure data between countries and regions and for different localized populations must also be considered (Lindqvist et al., 2002). In obtaining data for exposure assessment, poor methodology might require rejection of information, and this must be noted by the

assessor and the rationale for rejection included in the assessment document (Lammerding & Fazil, 2000).

Risk characterization combines hazard identification, hazard characterization and exposure assessment into a quantitative and/or qualitative estimate of the probability of the occurrence and severity of health effects in a given population (WHO, 2013b). The degree of uncertainty in risk assessment must be recognized by the assessor and included in the risk analysis (Manning & Soon, 2013). This should be estimated and, where possible, quantified to reduce errors with risk ranking (Walls, 2006).

In analyzing the biological hazards associated with food, attention is normally focused on microbial hazards such as bacteria, viruses and parasites. The difference between microbial and chemical hazards is that microbial hazards are not considered cumulative; therefore they can be classified as single exposure hazards (Lammerding & Todd, 2006). Mycotoxins act like chemical hazards by having an additive effect in the human body; therefore they will not be included in this risk assessment.

Figure 2. 1. Steps in microbial food safety risk assessment.



(adapted from Lammerding & Todd, 2006)

Microbial risk analysis cannot be performed in a vacuum since the interactions between microbes and their environment is critical. Therefore, specific characteristics of the food such as pH, water activity, nutrient content and composition are important parameters in risk assessment (Lammerding & Fazil, 2000). For instance, pathogens such as viruses and parasites do not grow in food therefore an inactivation step during processing will be critical in eliminating their presence. Also, significant attention must also be paid to toxin-producing bacteria such as *Staphylococcus aureus* and *Clostridium botulinum*, and the heat resistance of the former toxin (Lammerding & Todd, 2006).

2.2. Public Health Estimates for Microbial Risk Assessments (MRA)

In risk analysis, several standards have been set up to help quantify risks associated with pathogens in foods and the effects of those hazards. On a population basis, a calculation of risk can predict the expected number of specific illnesses or deaths per 100,000 population per year attributable to the food/pathogen in question (Lammerding & Fazil, 2000). It can also be defined as the probability of a specific adverse outcome per exposure to the food (Lammerding & Fazil, 2000). Since risk assessments provide estimates of incidence of illnesses from exposure to food sources, this serves as a common basis for which debate surrounding alternative health policy making can be implemented.

However, using incidence of illness alone for decision making and ignoring the health impacts of specific pathogens as they relate to duration of illness, quality of life, end-point of illness, related sequelae and social costs does not allow for comparative study of the overall burden of illness (Ponce et al., 2001). To bridge this gap Health-adjusted life years (HALYs), which are summary measures that combine the effect of death and morbidity concurrently, have been developed to provide estimates of the overall population burden of illness (Gold, Stevenson & Fryback, 2002). To be able to compare and integrate the biological endpoints posed by microbial hazards in foods into a common metric, different measures have been developed (Lindqvist et al., 2002; Chen et al., 2013).

Disability-adjusted life years (DALYs) are HALYs which measure the sum of years of life lost by premature mortality and years lived with disability (Lindqvist et al., 2002). A

DALY per-case value is used to measure the average burden of disease per illness including the relative frequency of each potential health impact (Chen et al., 2013). This relative burden is weighted between a factor of 0 and 1 for the severity of illness (Lindqvist et al., 2002). In the case of death, duration is phrased as years of life lost based on the age of the person affected, and the severity is set to a maximum of 1.0 (Chen et al., 2013). DALY can be defined mathematically as:

$$DALYs = YLL + YLD$$

Where YLL is the years of life lost to due to mortality and YLD is the number of years lived with a disability (Lake et al., 2010). Disability weights are a measure of health state preferences and were originally derived using a personal trade-off (PTO) approach (Lake et al., 2010).

From one analysis of the Dutch population, *Campylobacter* had a DALY of 1440, Guillan-Barré had a DALY of 340, and frequent acute gastroenteritis was 440 (Lindqvist et al., 2002). Chen et al. (2013) provided a DALY for the risk of *Listeria monocytogenes* in soft ripened cheese. DALY losses of 11.7, 6.12 and 1.20 were predicted for perinatal, adults 60+ and intermediate-age populations, respectively, and this formed the basis of the risk assessment that was subsequently carried out (Chen et al., 2013). Therefore, DALY losses per year is used to measure the overall annual burden a microbial hazard places on a population using a combination of assumptions and a structured approach is used in risk assessment for a given scenario (Chen et al., 2013; Lake et al., 2010).

Cost of Illness (COI) estimates can also be used to characterize the burden of a microbial hazard (Lake et al., 2010). COI uses a societal perspective and includes in its calculations

direct health care costs, direct and indirect non-health-care costs derived from the foodborne illness. For fatalities and long-term disabilities, lost production is also included (Lake et al., 2010). The similarity between DALY and COI is that they both use the incidence approach to calculate population burdens of microbial hazards.

Quality-adjusted life years (QALYs) is another measurement for which HALYs can be used to estimate the public health costs associated with foodborne diseases. The concept of QALYs has been regularly used to guide health care policy making since its inception about 30 years ago (Garcia-Hernandez, 2014). QALYs provide a means for comparing health outcomes that differ in survivability and quality of life (Ponce et al. 2001). QALYs are calculated based on several standardized instruments which enable the input of parameters consisting of five health domains obtained from a EuroQoL (EQ-5D) standardized survey (Hoffmann et al., 2012). It has been recommended for federal policy analysis because QALY preference weights are population and country specific, and therefore reflect public health preferences better than DALYs which rely on expert assessment (Hoffmann et al., 2012).

Batz et al. (2011) estimated that for the top 10 foodborne pathogens in the United States, *Salmonella* was first because it has the highest QALYs and COI. This was then followed by *Toxoplasma gondii*, *Campylobacter* spp., *Listeria monocytogenes*, Norovirus, *Escherichia coli* O157:H7, *Clostridium perfringens*, *Yersinia enterocolitica*, *Vibrio vulnificus*, *Shigella* spp., other *Vibrio* spp, *Cryptosporidium parvum*, and non-O157 Shiga toxin-producing *Escherichia coli* (STEC). Even though QALY is an important instrument is assessing HALYs, due to its limited use in the published literature, DALYs were the preferred choice in the present work.

2.3. Modelling in Microbial Risk Assessment

For qualitative risk assessment, simple models that describe exposure pathways can be developed (Lammerding & Fazil, 2000). For more complex analyses such as quantitative risk assessments, relationships between components can be described mathematically. Lindqvist et al. (2002) described several modelling structures that could be used in a microbial risk assessment. The first was an "event tree" which described a scenario from the initiating event to a defined end point of the assessment. This describes the high risk pathway that might be associated with the process. The "event tree" begins with the occurrence of the hazard and from there describes the events that must have occurred for the hazard to be present. A "dynamic flow tree" emphasizes the dynamic nature of bacterial growth and incorporates predictive microbiology using statistical analysis, and finally, a "process risk model" focuses on the integration of predictive microbiology and scenario analysis to provide assessments of the hygienic characteristics of the process.

Due to the complexity of food processing sequences, it is of interest to simplify the process by separating the overall sequence into distinct modules, each representing a particular stage from production to consumption (Lammerding & Fazil, 2000). An example is a Modular Process Risk Modelling (MPRM) paradigm where the food process is divided into different modules which describe the dynamics of pathogens in the processing environment (Smid et al., 2010). These bacterial processes are growth, inactivation, partitioning, mixing, removal and cross-contamination (Lindqvist et al., 2002). A model should be broken down and disaggregated as much as necessary, but must still maintain efficiency and be accurate for modelling in relation to the assessment. It might, however, not be necessary to model the whole farm to fork pathway or every

conceivable event in a system that may result in exposure (Lindqvist et al., 2002). Predictive microbial models are useful as sub-plots within a larger model since they provide a mathematical model for the way bacteria evolve under different processing and environmental conditions (Lammerding & Fazil, 2000).

The degree of precision required in the exposure assessment increases the complexity of the model developed. For risk ranking, the primary goal is to estimate as closely as possible the risk to a population that a food-pathogen pair poses (Lindqvist et al., 2002). Therefore, the exposure assessment should be structured such that data and information as close to the final exposure point are incorporated. This assessment will then focus on one issue, an estimate of the expected number of illness in a population (Lindqvist et al. 2002).

A risk assessment model that is able to incorporate the influence of various factors before the food reaches the consumer provides the most information relevant to risk management and an "event tree" approach is the more attractive method available to achieve this goal. It will enable following food items from farm to process, to retail, and to homes whilst incorporating predictive microbiology to model the probability of exposure and infection (Lammerding & Fazil, 2000).

Accurate statistical analysis is needed in MRA to provide a clear framework for risk management. Several important issues associated with statistical analysis must be addressed. Data from surveys of food consumption from different geographical locations must be weighted to correct for bias in sampling. This can be done based on the annual production in different regions (Lindqvist et al., 2002). Data from different sources that

are collected from different temporal and spatial scales must also be integrated. It is important to note that estimates may be biased due to different methodologies used to gather data, for instance sensitivity and specificity (Lindqvist et al., 2002). The estimate must then be adjusted to make up for these differences. Information as close to the point of consumption as possible is useful in risk ranking (Lindqvist et al., 2002), but is not as useful when trying to gain insight into the factors that magnify the risk or for consideration of options to reduce that risk. Differences in populations used for exposure assessment must also be acknowledged and accounted for in the final risk assessment documents.

Uncertainty and variability are two criteria that must be defined in order to carry out modeling, (Nauta, 2000). Uncertainty represents the lack of absolute knowledge about a parameter and can be reduced by further study (Whiting, 2011). Uncertainty can arise from the model, the scenario and other parameters used to create the distribution (Lindqvist et al., 2002). Variability represents the normal distribution of the data and its true heterogeneity, and it cannot be reduced by further measurements (Nauta, 2000). Since point-estimates ignore variability and uncertainty (and use a single value to represent a given data set, i.e. a mean), probabilistic assessments have been proposed to incorporate these variables (Lammerding & Fazil, 2000). Whilst a point estimate specifies the value a parameter could take, a probability distribution specifies the range of values and how frequently they could occur (Lammerding & Fazil, 2000). It is important for the risk assessor to state explicitly where there is uncertainty in the data or where assumptions have been made such that the risk management team would be able to take all factors into consideration when structuring and providing health policy guidelines.

2.4. Estimates of Foodborne Gastroenteritis and Food Attribution

2.4.1. Foodborne Gastroenteritis

In estimating foodborne gastroenteritis, Scallan et al. (2011b) described two modelling approaches that could be used for different types of data. The first is by using a bottom–up approach where laboratory-confirmed cases of illnesses are used to estimate overall population burdens of foodborne illnesses (by scaling up using multipliers for under-reporting and under-diagnosis). The second approach utilizes the entire population and incidence data are scaled down to the estimated number of illnesses.

A definition of "diarrheal illness" is important so that only data that is relevant and provide a criterion for eliminating non-relevant data are included in the estimate. Scallan et al. (2011b) defined acute diarrhea as the experience of ≥ 3 loose stools in the past 24 h lasting ≥ 1 day or resulting in restriction of daily activities. Since the work by Scallan et al. (2011b) was based on laboratory confirmed cases of gastroenteritis, in order to estimate the proportion of overall illness and number of people who would seek medical aid for illness, under–reporting and under–diagnosis multipliers were developed.

For *Listeria monocytogenes* a multiplier of 90% was used for under-diagnosis since the authors assumed that due to the severity of disease the likelihood of seeking medical intervention would be high. For less severe disease resulting in non-bloody diarrhea, under–diagnosis multipliers of 18% and 19% for seeking medical care and stool sample submission, respectively, were used to estimate disease rates (Scallan et al., 2011b). For data from passive surveillance of gastroenteritis, under–reporting multipliers of 1.1 and

1.3 were developed for bacteria and parasites, respectively. Thomas et al. (2013) adapted this method for their estimate of foodborne illnesses in Canada.

Thomas et al. (2013) estimated that in Canada that there are 4 million cases of gastroenteritis directly attributable to consumption of food. Of this, 1.6 million (90% credible interval, Crl, 1.2-2.0 million) can be directly attributed to 30 pathogens and 2.4 million (90% Crl 1.8-3.0 million) can be attributed to unspecified agents. Scallan et al. (2011b) estimated that in the United States annually there are 9.4 million (90% Crl 6.6-12.7 million) cases of foodborne illness associated with 31 major pathogens, while 38.4 million (90% Crl 19.8-61.2 million) could not be traced back to specific agents (Scallan et al., 2011a). Earlier, Mead et al. (1999) estimated that in the United States the overall burden of foodborne diseases was 76 million cases annually. Scallan et al. (2011b) pointed out that their results differed from the latter because different methodologies were utilized; therefore, these estimates should be considered complimentary, but are not directly comparable to each other. According to Scallan et al. (2011b) 88% of foodborne diseases with known agents can be attributed to five pathogens: (Norovirus (58%), non-typhoidal *Salmonella* spp. (11%), *Clostridium perfringens* (10%) and *Campylobacter* spp. (9%)). It is not surprising Thomas et al. (2013) reported that in Canada, Norovirus accounted for 65.12% of foodborne illnesses followed by *Clostridium perfringens* (11%), *Campylobacter* spp. (8.42%) and non-typhoidal *Salmonella* spp. (5.07%) since US FoodNet data were heavily used along with some other foreign (UK) as well as Canadian data. These assignments accounted for 89.61% of foodborne illness where an attributable source was known. Unspecified agents were believed responsible for 60% of foodborne illnesses.

Hoffmann et al. (2012), using estimates provided by Scallan et al. (2011b), developed public health estimates (COI and QALY) for 14 of the 31 pathogens reported in the latter work. These 14 pathogens were estimated to cause $14.0 billion in COI and 61,000 in QALYs annually in the United States. Ninety percent of loss was attributed to five pathogens which were, in order of cost: non-typhoidal *Salmonella enterica*, *Campylobacter*, *Listeria monocytogenes*, *Toxoplasma gondii* and Norovirus. This ranking illustrates the importance of health-adjusted estimates since it provides not just the numbers of illnesses, but their total societal cost. For instance, *Toxoplasma gondii* and *Listeria monocytogenes* were ranked higher since COI and QALYs are heavily mortality driven. Notably absent was *Clostridium perfringens* in the top five pathogens because of a lower COI and QALY compared to other pathogens.

2.4.2. Food-pathogen Attribution

Due to changes in food systems and in human behaviour toward food, attribution should be considered a dynamic process; therefore its estimates may only be valid for a short period (Ravel et al., 2009). The approaches that can be used for food attribution include analysis of outbreak data, case-control and epidemiological studies, use of microbial serotyping to compare pathogen strains in foods and in clinical cases, as well as expert elicitation (Batz et al., 2012; Ravel et al., 2009).

An important aspect of food attribution is categorisation of food commodities as this significantly impacts the distribution of attribution (Batz et al., 2012; Painter et al., 2013; Ravel et al., 2009). Different studies have utilized different classifications which are

broadly similar except for the "multi-ingredient" foods category. Batz et al. (2012) classified multi-ingredient foods and its attribution in three stages. For foods that have ingredients mainly from one commodity, the food was classified in that category, for instance, salads were classified under produce. For zoonotic pathogens, outbreaks that had beef, poultry, pork or seafood as the primary ingredient were classified by animal species. All others were grouped as multi-ingredient foods when it was possible there was more than one source of contamination. For instance, salads with dressing and cheese would fall under this category (Batz et al., 2012). Painter et al. (2013) classified multi-ingredient foods as complex foods. However, for attribution of illnesses, outbreaks were partitioned to the implicated commodities in proportion to the relative number of illnesses in all simple food outbreaks that implicated that specific food. However, Batz et al. (2012) cautioned that this approach was subjective and required making assumptions about which recipes were used for each dish and how risk could be accurately assigned to constituent ingredients. Ravel et al. (2009) classified multi-ingredient foods as either cooked dishes or other (excluding cooked dishes). For attribution of illness, the latter authors did not state how illnesses or outbreaks were distributed across categories.

Based on the work by Mead et al. (1999), Hoffmann et al. (2007) performed a food-pathogen pair attribution for foods consumed in the United States using expert elicitation. Based on a foodborne illness survey conducted for food attribution, the combination produce-Norwalk-like viruses was ranked as causing the most illnesses. More importantly, produce, seafood and poultry were reported to cause 70% of foodborne illnesses (Hoffman et al., 2007). However, *Campylobacter*-poultry, *E. coli*-beef, and luncheon and other meats-*Listeria monocytogenes* were shown to be important pairs for

food attribution. Batz et al. (2012) and Painter et al. (2013) also performed food attribution in the United States based on outbreak data ranging from 1998-2008. Both studies were quantitatively based on available data from the FoodNet active surveillance program in the United States, whereas Hoffmann et al. (2007) exclusively used expert opinion to develop pathogen-food pair ranks. In their attribution study, Painter et al. (2013) divided food into 17 commodities and assigned rank order by only including illnesses with known etiology and vehicle of transmission (laboratory confirmed or statistically-based epidemiology evidence) for their estimates of food attribution. They found that more illnesses were attributed to leafy vegetables than to any other food commodity. However, more deaths were attributed to poultry than to any other food. These results were similar to those of Hoffmann et al. (2007) in terms of ranking of foods that pose the most risk to public health. Batz et al. (2012) ranked food-pathogen pairs using data from foodborne outbreaks in the United States occurring from 1999 - 2008 and expert elicitation. Based on COI and QALYs, *Campylobacter* spp.-poultry was ranked first, followed by *Toxoplasma gondii*-pork and *Listeria monocytogenes*-deli meats. It must be noted that for estimates of *Campylobacter* spp. and *Toxoplasma gondii*, since outbreak information was insufficient, expert elicitation was utilized (Batz et al., 2012). The Center for Science in the Public interest (CSPI) recently published a report based on outbreak data in the United States during 2001 - 2010. Data were obtained from the Centers for Disease Control and Prevention (CDC) and other sources including scientific articles, Federal government publications, state health postings and newspaper reports (DeWaal & Glassman, 2013). The final results were based on 4229 outbreaks and were similar to the number (4589) of outbreaks analyzed by Painter et al. (2013). In contrast,

Batz et al. (2012) included only 2588 outbreaks (1999-2008), all of which were supported by laboratory confirmed data. DeWaal & Glassman (2013) indicated that whilst outbreaks associated with beef, seafood, pork and poultry declined over the reporting period, those associated with produce remained steady. For United States Department of Agriculture (USDA) regulated foods, non-typhoidal *Salmonella* spp. in poultry; *C. perfringens* and *E. coli* O157:H7 in beef; *Staphylococcus aureus*, *C. perfringens* and non-typhoidal *Salmonella* spp. in pork; and *C. perfringens,* non-typhoidal *Salmonella* spp. and Norovirus in luncheon and other meats were considered important food-pathogen pairs. For Food and Drug Administration (FDA) regulated foods, Norovirus in produce; scombrotoxin and ciguatoxin in seafood; *Campylobacter* spp. in dairy; and non-typhoidal *Salmonella* in eggs were classified as significant food-pathogen pairs (DeWaal & Glassman, 2013). These results differ from those of Batz et al. (2012) where *Vibrio* spp.-seafood and *Cyclospora cayetanensis*-produce were identified as important pairs. It is important to note that scombrotoxin, ciguatoxin, *Bacillus cereus* and *Staphylococcus aureus* were not included in the report by Batz et al. (2012) and this might have significantly influenced the results of their work. CSPI also published a report ranking meat products according to risk associated with foodborne illness over 12 years (1998-2010). In this work ranking was developed by multiplying the number of illnesses by the hospitalization rates characteristic of specific pathogens, thereby providing an index of severity for each meat product (CSPI, 2013). Using this process, the highest risk was associated with chicken and ground beef, followed by beef (other), steak and turkey. Medium risk meats included barbeque (beef or pork), deli meat, and roast beef. The lowest risk meats were chicken nuggets, ham and sausages.

Ravel et al. (2009) provided human attribution data for foods consumed in Canada over 30 years (1976-2005). Of 6908 outbreaks that were reported during this period, data from only 2107 were used in the study because both pathogen and food vehicle information were complete for these. Results indicated that non-typhoidal *Salmonella* spp., *S. aureus* and *B. cereus* were the most frequent causes of foodborne illness during this period. Within food categories, multi-ingredient foods (both categories) were most associated with outbreaks followed by poultry. The three food-pathogen pairs most involved in outbreaks were poultry-*Salmonella*, multi ingredient foods (cooked dishes)-*B. cereus* and multi-ingredient foods (cooked dishes)-*C. perfringens*. The results of this study differed significantly from the work previously reviewed. Whilst the previous studies focused on the recent past, this study used significantly older data. Therefore recent changes in food industry systems and methods of food preparation plus consumption changes are not reflected in this study.

The European Food Safety Authority (EFSA) and the European Center for Disease Control and Prevention (ECDC) have published information on the occurrence of zoonoses and foodborne outbreaks in the EU annually since 2005. Outbreaks in their approach were classified as having either “strong evidence” or “weak evidence” based on the strength implicating a suspected food vehicle. In 2011, 5,648 outbreaks were reported in the EU resulting in 69,553 reports of human cases of illness, 7,125 hospitalizations and 93 deaths. However, only 701 outbreaks with strong evidence were reported and used in the subsequent analysis. *Salmonella* spp. resulted in the highest number of outbreaks followed by bacterial toxins, *Campylobacter jejuni* and *viruses*. However, outbreaks linked to STEC/VTEC on sprouted seeds were associated with most human cases of

illness. The report further indicated that a majority of outbreaks could be traced back to foods of animal origin which included eggs and egg products (21.4%), mixed foods (13.7%), other foods (13.1%), and fish and fish products (10.1%). From food-pathogen pair attribution they noted that 95.3% of outbreaks caused by eggs and egg products were due to non-typhoidal *Salmonella* spp. With regards to mixed foods, non-typhoidal *Salmonella* spp. (21.9%) and calicivirus (18.8%) were most frequently detected followed by the bacterial toxins of *C. perfringens* (14.6%), *Staphylococcus* (14.6%) and *Bacillus* (12.5%). The majority of outbreaks related to fish and fish products were attributed to histamine (78.9%). Eighty outbreaks with strong evidence were linked to foods of non-animal origin. Vegetables were implicated in 37 outbreaks with *Salmonella* (21.6%), while pathogenic *E. coli* (18.9%), viruses (16.2%), mycotoxins (10.8%), *Clostridium* (10.8%) and *Bacillus* (8.1%) were the main pathogens responsible for illnesses. Overall, campylobacteriosis tended to continue to be the most commonly reported zoonosis. The number of salmonellosis cases had decreased by 37.9% compared to 2007 data. However, numbers of confirmed VTEC cases increased 2.6 fold and this was mainly due to the large outbreak that occurred in Germany from the consumption of tainted fenugreek sprouts (EFSA, 2013b). In 2012, a total of 5,363 foodborne outbreaks were reported resulting in 55,453 human reported cases, 5,118 hospitalizations and 41 deaths. Most illnesses were attributable to non-typhoidal *Salmonella* spp. (28.6%) bacterial toxins (14.5%), viruses (14.1%) and *Campylobacter* spp.(9.3%). There was an increasing trend in the number of foodborne outbreaks caused by non-typhoidal *Salmonella* spp. (1,533 outbreaks) but an overall decrease in the numbers of foodborne illnesses attributable to this pathogen. More importantly, confirmed cases of verocytotoxigenic *E. coli* decreased

by 40% compared to 2011. However, over a five year period, the number of *E. coli* cases has continued to rise significantly. The numbers of illnesses attributable to *Listeria monocytogenes* also increased slightly from 2011 to 2012 with 1,642 cases and 198 deaths (17.8% mortality rate) reported (EFSA, 2014).

It is clear that results from food attribution studies have value that lasts for only a short time (Batz et al., 2012) and is different across geographical boundaries. Thomas et al. (2013) developed recent estimates of the burden of foodborne illness in Canada based on a new definition of gastroenteritis. In addition, incidence data (Canadian and international) were asymmetrically drawn from 2000-2010 and were felt to represent the situation in 2006. The present work will estimate food attribution data using the most recently available evidence and use that information to develop a risk assessment model.

2.5. Review of Microbial Risk Assessment

Several research studies have been conducted involving MRA of different pathogens in various food processing operations. Danyluk & Schaffner (2011) conducted a quantitative risk assessment of the microbial risk of leafy greens from farm to consumption. Their assessment was conducted in response to the occurrence of *Escherichia coli* O157:H7 in spinach (2006) which caused more than 200 illnesses in the United States. The model assumed that all *E. coli* present on contaminated spinach originated from the field. Using Monte Carlo simulations, the model predicted temperature abuse would result in a 1 log CFU/day increase of *E. coli* on spinach. Furthermore, assuming an initial contamination rate of 0.1% this would have been

sufficient for an outbreak approximately the size of the one that occurred in 2006 (Danyluk & Schaffner, 2011). Therefore, in this instance for a RBI, temperature control would have been of the utmost priority.

Using predictive microbiology, Puerta-Gomez et al. (2013) developed a quantitative risk assessment model to predict the effect of cross-contamination on the levels of *Salmonella* on baby spinach. They also used the model to determine the effectiveness of each mitigation step in processing to avoid possible foodborne illness. The model indicated that, for low levels of cross-contamination (1 CFU/g), sanitizing steps including chlorine washing would be an effective method of hazard control. However, at *Salmonella* concentrations of more than 3 CFU/g, these steps would be inadequate and alternate processing techniques such as irradiation should be considered (Puerta-Gomez et al., 2013).

Mataragas et al. (2010) also performed a risk analysis for *Listeria monocytogenes* in ready-to-eat meat products (since they are considered high risk foods). The growth kinetics of the model constructed indicated that *L. monocytogenes* growth was a function of temperature. At temperatures higher than 7 ^{o}C to 9 ^{o}C, there was a significant increase in *L. monocytogenes* on the ready-to-eat meat products. The model indicated that in order to reduce listeriosis, industry needed to have better control of product temperatures and where possible reformulate products such that they could no longer support pathogen growth (Mataragas et al., 2010).

A scientific opinion regarding Quantitative Microbial Risk Assessment (QMRA) by the European Union (EU) evaluated the prevalence of *Salmonella* in pigs and *Campylobacter*

in broiler chickens from the farm to the point of consumption (Romero-Barrios et al., 2013). The model showed that reduction of *Salmonella* in the lymph nodes of pigs by 80% – 90% would reduce the number of salmonellosis cases traced back to pork products by the same rate. Furthermore, even though transport and lairage interventions had no significant effect on the level of salmonellosis, at slaughter a 2 log reduction of *Salmonella* would result in a 90% reduction in illness (Romero-Barrios et al., 2013). Therefore, in this case RBI emphasis should be placed on slaughtering conditions. For *Campylobacter*, it was concluded that strict implementation of biosecurity controls on the farm and implementation of HACCP and Good Manufacturing Practices (GMP) would be sufficient to reduce the number of contaminated carcasses. The effects of different interventions could not be fully quantified since they were dependent on each other. However, the authors proposed that reduction of *Campylobacter* prevalence to 5% in flocks would reduce public health risk up to 90% (Romero-Barrios et al., 2013).

Lindqvist et al. (2002) assessed the risk associated with the consumption of unripened raw milk cheese containing toxigenic *Staphylococcus aureus*. Using a structured approach, the hazard was characterized as causing acute effects 1-7 hours after ingestion of 10^6 CFU/g, resulting in symptoms that included nausea, vomiting, abdominal pain and diarrhea. However, no dose-response relationship was found in the literature and data were only related to numbers of *S. aureus* bacteria present in the food and not the amount of toxin per gram (Lindqvist et al. 2002). Exposure assessment was conducted for prevalence at the point of sale and at the time of consumption (using predictive microbiology). Since the authors did not have a dose-response model, this assessment was not complete. A scenario analysis indicated that for both high and low pH cheese, the

initial level of *S. aureus*, storage temperature and time all contributed to levels of *S. aureus* above 6 log CFU/g which was considered the threshold for intoxication in this study.

Walls (2006) also conducted a quantitative risk assessment of *Listeria monocytogenes* in ready-to-eat products. The hazard (*L. monocytogenes*), is a foodborne pathogen that causes listeriosis resulting in an estimated fatality rate of 20 - 40%. Dose-response models could not be determined since using humans for such trials is not ethical; therefore, mice models were used and then extrapolated to humans. Exposure assessment was estimated based on the prevalence and extent of contamination, and the amount of growth that could occur before consumption (predictive microbiology). Risk characterization was based on risk per serving to an individual and the risk per annum to different populations. In the United States, deli meats, frankfurters, pâté and meat spreads posed greater threats to the population than hard cheeses, cultured or processed milk products. For risk management options, the authors proposed that strategies that reduce the likelihood of contamination and growth of *Listeria* should be implemented. They recommended GMP's, HACCP and Food Safety Objectives (FSO) as risk management tools.

Duffy et al. (2006) reviewed a series of QMRA studies on the management of *Escherichia coli* O157:H7 on beef. Cassin et al. (1998) developed a QMRA for *E. coli* O157:H7 in ground beef in Canada/North America. Exposure assessment was initiated by evaluating the prevalence and concentration of *E. coli* O157:H7 in cattle feces. Processing was characterized as the operations that occurred between slaughter and packaging of beef trim in 5 kg vacuum packs. This was conducted to evaluate the

behavior of *E. coli* O157:H7 during carcass dressing operations. The model calculated a mean prevalence rate of *E. coli* O157:H7 at 2.9% in retail packages. The dose-response model was modified from feeding studies of *Shigella* with the assumption that both *E. coli* O157:H7 and *Shigella* possessed the same infectivity. Increased risks for the elderly and children were also considered based on epidemiological results. The QMRA model indicated that the concentration of *E. coli* in feces and host susceptibility had the most impact on predicted occurrence of illness. Moreover, lowering the maximum temperature of storage from 10 ^{o}C to 8 ^{o}C resulted in an 80% reduction of predicted illness. Lammerding et al. (1999) also conducted a QMRA for *Shiga* toxin-producing *E. coli* (STEC) in ground beef from beef trimmings in Australia and modelled dose response as well as exposure assessment similar to Cassin et al. (1998). The prevalence of STEC in feces of Australian cattle ranged from 35.4% to 53.4%. Risk analysis indicated that the concentration of STEC in feces and host susceptibility were the most important factors when predicting illness outcomes. Hypothetical use of mitigation factors such as hot water decontamination and irradiation of boxed beef trimmings could reduce predicted illness by up to 99.7% and 97%, respectively.

Nauta et al. (2001) estimated the risk associated with the consumption of steak tartar patties in the Netherlands. The model covered the farm to fork chain and differentiated between the size of slaughter operations, industrial and traditional processing, and traditional butcher versus industrial preparation. Data used to describe the prevalence of *E. coli* O157:H7 at primary production was based on studies conducted in the Netherlands. Expert opinion was used to estimate fecal contamination of carcasses. A dose-response model was based on results from a single outbreak that occurred in Japan

and this was similar to the feed trials with *Shigella*. This model predicted that for ground beef there was higher prevalence of *E. coli* O157:H7 from industrial production compared to traditional facilities, however, for steak tartar there was no difference noted. Pathogen numbers were, however, reduced in industrially produced tartar which the authors attributed to diluting of pathogens due to the higher volume of production. The most important factors that affected the risk estimate was prevalence on the farm, concentration of the pathogen in feces and growth and/inactivation during carcass processing. The factor that was deemed most likely to result in a significant decrease in risk was lowering the prevalence on farms and improving slaughter hygiene.

Nauta et al. (2009) evaluated different MRA models of *Campylobacter* in broiler meat. The review indicated that for primary production, two models were appropriate to assess risk. The aim of both models was to describe the between-flock and within-flock prevalence of colonization in slaughter-age birds. The United Kingdom (UK) model was the first one to be developed. In this instance, the sources of the infections were not explicitly modelled. The first stage assumed that one or more birds became colonized on the first day of infection. From there the organism subsequently spread through the oral-fecal route within birds within the same social cluster of initially-infected birds. The second stage assumed that the contamination of the broiler house equipment was sufficient to transmit infection beyond the social cluster. Parameters for both stages of this model were based on published literature and expert opinion. This model was also able to separate uncertainty and variability using second order modelling techniques. The Netherlands model incorporated two independent sub-models on within-flock and between-flock transmission. This model did not account for social structures; therefore,

once *Campylobacter* entered the flock each broiler would have an equal probability of colonization. In this model, variability within and between flocks was included, however, uncertainty was not quantified but was explored by the "specific scenario" analysis. The two models generated point estimates of 69% and 44%, respectively. Since the UK has traditionally been known to have higher prevalence rates, this result was not surprising.

The results of these risk assessments provide a vehicle where hazards associated with different processing facilities and food categories could be identified. For instance, from the above, temperature control, prevalence rates of pathogens, initial contamination, volume of production and size of facility are all important criteria in developing a risk assessment model for the CFIA.

2.6. Risk Ranking Using a Multi-criterion Approach

Several risk ranking tools have been identified as being useful in microbial risk analysis. These ranking systems can involve qualitative, semi-qualitative and quantitative analyses of risk. Risk ranking models can be developed for either food categories or food-pathogen pair combinations.

FAO-WHO (2013), during an expert committee meeting, developed qualitative criteria to rank hazards in fresh produce. The six criteria agreed upon were: frequency and severity of disease; size and scope of production; diversity and complexity of the production chain and industry; potential for amplification of hazards through the food chain; potential for control; and the extent of international trade and economic impact. Based on these criteria, leafy green vegetables were given the highest priority followed by berries, green

onions, melons, sprouted seeds and tomatoes. Carrots, cucumbers, almonds, baby corn, sesame seeds, onions, garlic, mango, paw paw and celery were classified as having the lowest priority based on information available.

However, Anderson et al. (2011) pointed out that even though this technique was intuitive, it was not quantitative and therefore comparisons of risks with similar probabilities of occurrence were not possible. They proposed a Pathogen-Produce Pair Attribution Risk Ranking Tool (P^3ARRT), which is a semi-quantitative risk analysis method. In this instance, the relative public health impacts of pathogen-produce combinations are ranked based completely on data-driven criteria. This system ranked enterohemorrhagic *Escherichia coli* on leafy vegetables as the highest risk followed by *Salmonella* spp. on tomatoes. The limitations of this risk ranking tool are that (i) it is not predictive and only prioritises known risks (ii) it must be updated frequently to stay relevant and (iii) inadequate data may also lead to bias since higher risk values are assigned.

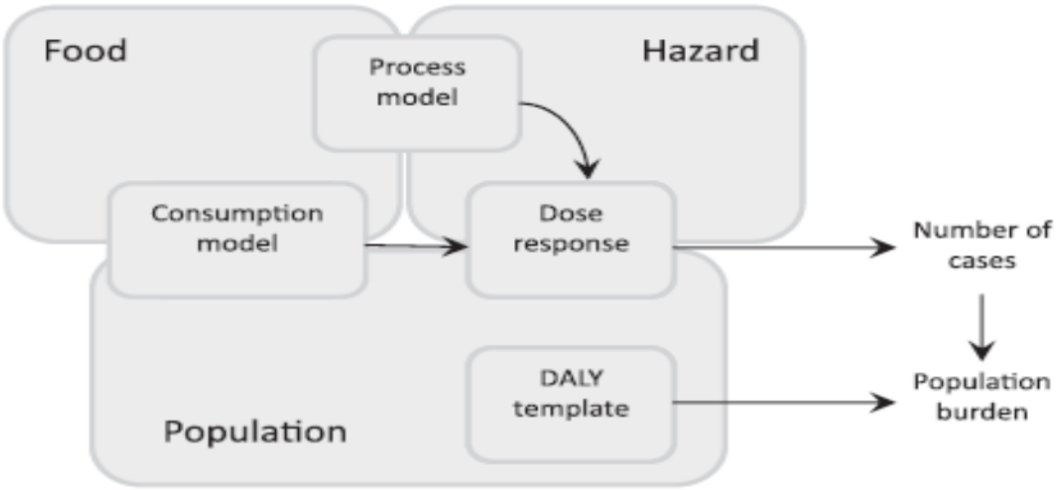
Alternatively, the EFSA developed a risk ranking method based on seven criteria. These criteria were related to consumption, dose-response relationships, prevalence of contamination, burden of disease, strengths of association between foods and pathogens, pathogen growth potential during shelf life and incidence of illness (EFSA, 2013a). For each criterion, intervals were selected and for each interval, a score usually ranging between 1 to 4 was assigned. Using this model, rankings of food-pathogen pairs for foods of non-animal origin were developed. The top three food-pathogen pairs in decreasing in order of priority were:

- *Salmonella* spp. and leafy greens eaten raw as salads;
- *Salmonella* spp. and bulb and stem vegetables; *Salmonella* spp. and tomatoes; *Salmonella* spp. and melons; and pathogenic *Escherichia coli* and fresh pods, legumes or grain;
- Norovirus and leafy greens eaten raw as salads; *Salmonella* spp. and sprouted seeds; and *Shigella* spp. and fresh pods, legumes or grain.

Kirezieva et al. (2013) also developed a method to assess the implementation of a Food Safety Management System (FSMS) in the fresh produce food chain independent of current quality control measures used by the industries studied. This assessment tool addressed critical controls for primary production, processing and trading companies. A panel of experts was used and they found that sanitation programs, control of incoming materials, packaging (type and quality) and water control were the most important risk assessment criteria in primary production. However, overall, processing was considered by experts as the most important criterion in FSMS (Kirezieva et al. 2013).

The US FDA developed a quantitative comparative risk assessment model for ranking food-pathogen hazard pairs known as FDA-iRISK (Chen et al., 2013). The elements identified as being essential in the risk analysis included the food, hazards, population risks, models of processes, consumption and dose response (Fig. 2.2). Using iRisk, assessors generated a DALY template that could be used to estimate the population burden of a food-pathogen pair.

Figure 2. 2. Seven Elements of a Generic Risk Scenario in iRisk and their Relationships.



(adapted from Chen et al., 2013)

2.7. Objective

From the literature review, it is evident that MRA is an important tool in estimating the risk associated with specific food-pathogen pairs. Relating this risk to human health, especially in terms of public health estimates is critical in developing policies aimed at providing safer food for consumers. The objective of this study is to provide a comprehensive RBI framework to define the initial biological risk for fruits, vegetables and animal products that will be generic in nature and applicable uniformly to food processing facilities and pathogens.

This was to be achieved by:

i. Identifying hazards associated with all food categories identified in the model
ii. Providing an assessment of exposure and a hazard characterization of the model

iii. Characterizing the risk associated with food categories by

    a. developing attribution for food-pathogen pairs

    b. developing a risk ranking of food-pathogen pairs using a multi-criterion approach

iv. Including a list of data used to develop and rank hazards

v. Including a list of gaps in the scientific literature pertaining to either the criteria or the data used to develop the criteria

CHAPTER 3: A Generic Model for Risk-Based Food Inspection in Canada: Assessment of Initial Biological Hazards

ABSTRACT

Risk-based inspection provides a framework whereby inspection resources can be prioritized and targeted towards foods that pose the highest risk to human health. To provide a risk assessment of the initial biological hazards associated with foods consumed, criteria related to hazard identification, hazard characterization and exposure assessment were developed for all foods (dairy, eggs, meat [beef, poultry, pork and game], fats and oils, honey and maple, grains and bakery products, fruits and vegetables, and aquatic animals [fish, crustaceans and mollusks]) inspected by the Canadian Food Inspection Agency (CFIA). Identifying hazards, then characterizing them and estimating exposure associated with the initial risks were conducted through an extensive scientific literature review, including examination of surveillance reports and epidemiological studies. It was found that a comprehensive assessment of hazards required inclusion of foodborne illness outbreak and product recall data related to both the product and facility, an examination of environmental conditions that might affect the initial contamination of the food product, the nature of the source of the food or its components used in production, and the implementation of a comprehensive food safety program in the processing facility. During the literature review, considerable scientific information was found for meats (beef, poultry, pork and game), eggs and fresh produce. However, for the other food categories including honey and maple products, and fats and oils, there were significant gaps. In order to bridge those gaps, information from other countries

was used. Hazard characterization examined the adverse effects of the biological hazards identified in this study. Infectious doses for all relevant foodborne pathogens were also included in this work. However, there was no information on infectious doses for vulnerable sub-populations and, therefore, this was a limitation in the accuracy of illness burden estimates. Specific characteristics of the pathogens (virulence, infectivity, and end-point of illness) were identified as being critical in hazard characterization. For exposure assessment, consumption, potential of the pathogen to grow in food, and the viability of pathogens in the food matrix were identified as important.

3.1. Introduction

Risk-Based Inspection (RBI) has been recommended by the Codex Alimentarius Commission (CAC, 1999) as a standardized tool for food safety inspections globally. RBI inspection prioritizes risks such that more resources are directed towards foods that pose the highest burden to human health. In order to achieve a RBI in Canada, a structured approach recommended by the World Health Organization (WHO) and Codex Alimentarius Commission (CAC) for microbial risk assessment (MRA) of food (CAC, 1999) was followed. This approach encompasses the separate but inter-connected modules of risk assessment, risk management and risk communication as tools for risk analysis. To provide a risk assessment model, four basic principles that are traditionally established for MRA were used. These criteria were: hazard identification, hazard characterization and dose response, exposure assessment and risk characterization.

Hazard identification is mainly a qualitative evaluation of risk and involves an initial examination of factors that determine risks which are analysed further in assessments. Biological hazards in foods can be identified through national surveillance reporting, epidemiological, clinical and laboratory studies of pathogens and their interactions in the food chain (Lammerding & Todd, 2006).

Hazard characterization examines the degree of adverse effects associated with biological hazards and can be assessed using qualitative and quantitative analyses (WHO, 2013a). For biological hazards, this can be done by through a dose-response model using available data (Lammerding & Todd, 2006). It should also be recognized that for each food environment the internal ecological system of the food (e.g. water activity, temperature and pH) influences the ability of pathogens to cause disease. Also important in hazard characterization is an estimate of the prevalence of food contamination by pathogens.

Exposure assessment predicts the probable extent of exposure to a hazard and the magnitude of that exposure (i.e., the number of pathogens likely to be ingested) (EC, 2013). Since it is unlikely that the numbers of microorganisms present in a contaminated food are measured at the time of consumption, the use of models and accurate assumptions are essential in conducting exposure assessments (Lammerding & Fazil, 2000). The initial contamination of raw material, growth rate of the pathogen, effects of processing steps on pathogen viability and patterns of consumption are important factors used in assessing exposure (Lammerding & Fazil, 2000).

MRA can be either quantitative, qualitative or both based on sources of reliable information available. MRA have been performed for a variety of foods and food processing facilities (Nauta et al., 2001; Lindqvist et al., 2002; Duffy et al., 2006; Walls, 2006; Mataragas et al., 2010; Danyluk & Schaffner, 2011; Puerta-Gomez et al., 2013; Romero-Barrios et al., 2013). Importantly, it was noted in all of the risk assessments that identifying areas in the food safety system where mitigation factors can be directly targeted was the most effective in reducing foodborne illnesses associated with food-pathogen pairs and processing environments. For instance Danyluk & Schaffner (2011) concluded that temperature control would have been critical in preventing the 2006 *Escherichia coli* O157:H7 outbreak in the United States that was linked to the consumption of spinach. Mataragas et al. (2010) also showed the importance of temperature control in a food processing environment. Their risk assessment model indicated that at temperatures higher than 7 ^{o}C to 9 ^{o}C, there was a significant increase in *L. monocytogenes* on ready-to-eat meat products; therefore, to reduce listeriosis, industry needed to have better control of product temperatures or formulate products whereby pathogen growth would be further limited. Puerta-Gomez et al. (2013) developed a model which indicated that, for low levels of cross-contamination (1 CFU/g), sanitizing steps including chlorine washing of baby spinach would be an effective method of hazard control. However, at *Salmonella* concentrations of more than 3 CFU/g, these steps would be inadequate and alternate processing techniques such as irradiation should be considered (Puerta-Gomez et al., 2013). Walls (2006) recommended, after conducting a MRA for *Listeria monocytogenes* in ready-to-eat meat products, that policies associated with Good Manufacturing Practices (GMP's), Hazard Analysis Critical Control Points

(HACCP) and Food Safety Objectives (FSO) should be used as effective management tools to minimize risks. Health Canada conducted a risk assessment of *Salmonella* associated with cracked eggs in Canada (Todd, 1996). It was concluded that cracked shell eggs were 3 to 93 more times likely to cause foodborne illness than uncracked shell eggs. It was recommended that all cracked eggs be broken and pasteurized. But since this was unlikely to happen in certain parts of the country, a management approach which included sales to GMP operating facilities were recommended (Todd, 1996). Opsteegh et al. (2011) conducted a QMRA for the risk posed by meat-borne *Toxoplasma gondii* infections in the Netherlands. From their model, although various uncertainties were noted, results indicated 40% of all predicted infections were related to consumption of unheated meat products and sensitivity analysis showed heating temperature had the single strongest influence in reducing infections.

The above risk assessments are specific to each food category and not applicable across the board to all foods. However, it can be noted that identifying hazards in processing models would be an effective process to generate an RBI framework in Canada. In developing criteria for RBI, a decision was made to initially develop criteria for each of the separate major food commodities regulated by the Canadian Food Inspection Agency (CFIA) which will be outlined in the Safe Food for Canadians Act. These food commodities include dairy, eggs, meat (beef, poultry, pork and game), fats and oils, honey and maple, grains and bakery products, fruits and vegetables, and aquatic animals (fish, crustaceans and mollusks). The rationale for this choice was three-fold. First, it was important to develop criteria that were specific to each food category and yet uniformly applicable for each type of food production. Second, these product-specific criteria were

to be used to develop a generic risk assessment model to inform modernized inspection procedures to be used by the CFIA. Last, developing hazard identification criteria based on the initial, unprocessed material is considered of greater value because it enables earlier and more efficient targeting and mitigation of hazards.

The first part of this work was to identify hazards associated with all food categories identified in the model and to provide an assessment of the exposure and hazard characterization. This information would then be utilized to develop a model where biological risks associated with food categories would be assessed and ranked. The objective was to provide information that would improve food safety control systems (food inspection prioritization), identify gaps that exist in the current scientific literature and contribute to the overall development of international and domestic food trade.

3.2. Method

Literature reviews were conducted for all of the major food commodities to identify and determine hazards. Hazards associated with each food commodity were identified by consulting scientific databases such as ScienceDirect, Web of Knowledge, ProQuest Dialog, PubMed and Agricola. Key words such as “food safety”, “food outbreaks”, “foodborne pathogens” “hazard identification”, “microbial risk assessments” with combinations of pathogens such as *Salmonella*, *Escherichia coli* O157:H7, *Campylobacter, Shigella*, *Listeria monocytogenes*, *Clostridium*, *Toxoplasma*, *Cryptosporidium*, *Giardia*, and Norovirus; and food categories (dairy, eggs, meat [beef, poultry, pork and game], fats and oils, honey and maple products, grains and bakery

products, fruits and vegetables, and aquatic animals [fish, crustaceans and mollusks]) were used to identify reports of interest. In order to include only credible information, articles selected were peer-reviewed research reports and reviews from journals, published manuals, scientific opinion reports, and texts.

To identify the overall hazards from each food category and pathogens of interest, articles by Batz et al. (2011 & 2012) and Painter et al. (2013) were three primary sources utilized. These papers identified and ranked food-pathogen pairs that represented the greatest public health burden in the United States. Poultry, pork, produce, and complex foods were responsible for approximately 60% of the total cost of illness and loss of Quality-Adjusted Life Years (QALYs). To determine which pathogens in Canada represented the greatest public health risk, the work by Thomas et al. (2013) which identified the top 30 pathogens responsible for foodborne illnesses in Canada, and the occurrence of each pathogen were examined. Infectious doses of pathogens were identified by review of the scientific literature and government publications.

The predominant pathogens present in each commodity were identified and these represented the important biological hazards. These hazards were used to develop an overall generic model for RBI. For instance, hazards associated with fruits and vegetables were subdivided into two categories: pre-and post-harvest. Two reports, one by Olaimat & Holley (2012) which reviewed the microbial safety of fresh produce and identified key hazards associated with this commodity, and another by Kozak et al. (2013) which provided a summary of foodborne disease outbreaks in Canada linked to fresh produce from 2001-2009, were the primary references used for produce-related information.

Information related to hazard identification was obtained from various government enteric and infectious foodborne illness surveillance networks. The Public Health Agency of Canada (PHAC) compiles information from the Canadian Notifiable Diseases Surveillance System (CNDSS) which summarizes infectious disease reports from provincial health authorities. From this system information was acquired on infectious diseases from 2005 – 2008 (CNDSS, 2012). In addition, the annual (both long and short) reports of the C-EnterNet (now FoodNet Canada) surveillance program from 2005 – 2011 were obtained and this information was used to identify pathogens of relevance to Canada (PHAC, 2006; PHAC, 2007; PHAC, 2009; PHAC, 2010a; PHAC, 2010b, PHAC, 2011 & PHAC, 2012). From the National Laboratory for Enteric Pathogens (NLEP) the annual reports of Laboratory Surveillance Data for Enteric Pathogens in Canada (LSDEPC) for the years 2000 – 2006 (Health Canada, 2001; Health Canada, 2004; Health Canada, 2005; Health Canada, 2006; Health Canada, 2007a; Health Canada, 2007b; Health Canada, 2007c; & Health Canada, 2008) were obtained. Pathogens of interest included non-typhoidal *Salmonella*, pathogenic *Escherichia coli*, *Campylobacter* spp., *Shigella* spp., *Yersinia* and parasites (*Cryptosporidium, Cyclospora, Entamoeba* and *Giardia*). In 2005, *Vibrio* spp. was added to the list of pathogens included in these reports. More importantly, the LSDEPC provided information on major outbreaks that had occurred in Canada during the period for which the annual reports were written. From 2007–2012, the annual report summary of the National Enteric Surveillance Program (NESP) (which provides information on laboratory-confirmed isolations of enteric pathogens in Canada) was also used to identify potential food hazards (NESP, 2009; NESP, 2010; NESP, 2011 & NESP, 2012).

In order to complete the data and fill gaps where necessary, information from countries with more comprehensive foodborne illness surveillance and reporting systems was included. From the Centers for Disease Control and Prevention (CDC), US, information related to foodborne outbreaks from 2001 – 2011 was obtained (CDC, 2013a). From the surveillance program of the European Union, annual reports of the European Food Safety Authority (EFSA) (which contains a summary report on trends and sources of zoonoses, zoonotic agents and foodborne outbreaks) from 2009–2012, information related to hazard identification (EFSA, 2010; EFSA, 2011; EFSA, 2012B; EFSA, 2013b & EFSA, 2014) was identified. Scientific opinions that were published by the EFSA related to microbial hazards in foods of animal and non-animal origin based on surveillance reports (EFSA, 2013a; Helwigh et al. 2012) were included in the assessment presented in this report. To provide a framework for the microbial risk assessment, a joint report by the United States Department of Agriculture (USDA) and the U.S. Environmental Protection Agency (EPA) was used as a guide for the current work (USDA/FSIS-EPA, 2012).

Epidemiological studies are important tools necessary to identify hazards. In Canada, few epidemiological studies have examined the link between food and foodborne illnesses. The National Studies on Acute Gastrointestinal Illness (NSAGI) provided some information on hazard identification in food in Canada (Flint, 2002). However, since no distinction was made between foodborne and waterborne illnesses in this study, its usefulness was limited.

The methods used in developing hazard identification above were utilized for characterizing hazards/pathogens in all food categories. Pathogens that have been involved in foodborne illness were listed for each food category and an infectious dose

included. It should be noted that dose-responses for pathogens were estimated from foodborne illnesses and clinical as well as laboratory studies. Through PHAC surveillance, C-EnterNet provides a snap-shot of food contamination rates at two sentinel sites in Canada. This surveillance is conducted to provide estimates for the prevalence of pathogens in selected foods and is available from 2005–2011 (PHAC, 2006-2012). In addition, reviews of scientific reports including the EFSA reports on trends and sources of zoonoses, zoonotic agents and foodborne outbreaks from 2009–2012 (EFSA, 2011–2014) provided additional data on estimates of prevalence. Tables of data comprehensively identifying hazards applicable to each food commodity (Tables AI.1. to A1.8.) plus a table summarizing results from characterization of hazards for all food categories were created which encompassed all critical elements in one model (Table AI.9.). Due to a lack of information on infectious doses for vulnerable population sub-groups (immune-compromised and pregnant women, stage of life [young and old], in addition to those with pre-existing conditions), this model did not include these elements as factors. Infectious doses for all food categories used in this model are shown in Tables AI.10. to AI.20.

As described in the development of criteria for hazard identification, extensive literature reviews were used to characterize hazards which involved describing the exposure of individuals to contaminated food vehicles and these data for all food categories are included in Table AI.21. Of importance to this work was data from Statistics Canada on consumption rates of foods per capita; however, such data were last published in 2009 (Statistics Canada, 2009). The data obtained from an examination of criteria identifying hazards related to food production, processing and distribution activities specific to food

commodities regulated by the CFIA were developed independently of the Scientific Advisory Committee (SAC, CFIA). These data (Tables AI.1. to AI.21.) were used to update the criteria lists developed by the SAC for use in the CFIA Inspection Pilot Study conducted in early 2014.

3.3. Results and Discussion

In general, hazards identified could be summarized into two categories (Tables AI.1. to AI.8.); those applicable uniformly to all foods (general) and those specific to each food category. General hazards identified include, but are not limited to, the following:

- Foodborne outbreak and recall history related to product and facility
- Estimates of foodborne illness related to product
- Environmental conditions that affect initial contamination (soil & water)
- Nutrient source for production of food commodity (manure & feed)

Hazards specifically identified for produce included an assessment of pre-and post-harvest conditions imposing biological risks on produce (Beuchat & Ryu, 1997; Buck et al., 2003; Harris et al., 2003; James, 2008; Olaimat & Holley 2012). Such hazards included the probability of contamination of incoming materials by biological hazards (e.g. *Escherichia coli* O157:H7 and *Salmonella* in seeds for sprouting) (Mahon et al., 1997; Harris et al., 2003; Rimhanen-Finne et al., 20011; Ding et al., 2013) and effects of post-harvest conditions and processing steps in increasing/ decreasing pathogens

(sanitation, storage, transportation and scale of geographical distribution) (Beuchat, 1996; Tauxe et al., 1997; Lund & Snowdon, 2000; Kozak et al., 2013).

Meat hazard identification included assessing the risk at the farm level, transport, slaughter, processing, and at the wholesale/retail level (Pearson & Dutson, 1995; Ahl & Buntain, 1997; Crump et al., 2002; EFSA, 2012a).

Aquatic animal products hazard identification focused primarily on the environment, on-board ship handling practices and presence of toxin-forming microorganisms (e.g. scombrotoxin, ciguatoxin) (Gibson et al., 1988; Dillon & Patel, 1992; FAO/WHO, 2005a & 2005b; FDA, 2011).

Hazard identification associated with eggs touched upon hazards related to the hatchery and layers as well as an overall general hazards associated eggs which included storage conditions (i.e. temperature at 10 ºC to 13 ºC and humidity at 70% to 85%) (Curtis et al., 1996; New Zealand Food Safety Authority, 2002; Gantios et al., 2009; Botey-Saló et al., 2012; EFSA, 2009) wash water (i.e. wash water temperature, water quality characteristics (i.e. hardness, pH), detergent type and concentration. Evidence of implementation of biosecurity measures (e.g. pest control), and potential for cross-contamination (e.g. type of housing) with fecal matter were also identified (Rose & Slifko, 1999; Thorns, 2000; Namata et al., 2008; Carrique-Mas et al., 2009; van Hoorebeke et al., 2010b; Holt et al., 2011; Howard et al., 2012).

Hazards associated specifically with dairy were sub-categorized into two processes, hazards that could develop during production of raw milk and those that could occur during value-added processes (during pasteurization, butter and fermented milk

products). Factors related to primary production include bedding, animal husbandry practices (stress of animal impacts natural defense mechanisms) including appropriate farm design and effective biosecurity (Faith et al., 1996; McEvoy et al., 2004; Nightingale et al., 2004; EFSA, 2009; Oliver et al., 2009; Papademas & Bintsis, 2010).

Pasteurization time and temperature, raw milk storage, and the use of unpasteurized milk for cheese production (allotting a time for a minimal 60 day aging) were identified as potential sources of hazards post-primary production (Morgan et al., 2001; Jorgensen et al., 2005; Chambers & Surapat, 2006; FDA, 2006; BCCDC, 2013).

From the literature research it was evident that for fats and oils, chemical composition of water phase in products (e.g. mayonnaise and salad dressings) related to pH, oil content, aqueous salt content, sugar content and water activity were important components in identifying hazards. Fat continuous systems were recognized as being more stable than water continuous systems. Also, possible anaerobic sites for growth of toxin producing pathogens (e.g. addition of fresh garlic to oil) were found as being a significant source of concern (Hathcox et al., 1995; Smittle, 2000; CDC, 2013).

The type of processing steps used (e.g. preparing dough at warm temperatures) increase the potential risk from *Staphylococcus aureus*. Frying, baking and boiling remove moisture and destroy *S. aureus* cells but not toxins that are produced since they are thermally stable. Final water activity (a_w) of products (this typically ranges from 0.94-0.95), addition of ingredients that increase safety (e.g. humectants, preservatives, acids, spices, gums & starches) were all part of the complexity associated with hazards in grains and baked products (FDA, 2013; Hackla et al., 2013).

Since honey and maple products are mostly shelf-stable products, hazards were mainly related to the presence of spore forming bacteria (*Bacillus cereus, Clostridium botulinum, Clostridium perfringens*), the water content of the final product (ideally it should be below 18%) and the effectiveness of heat treatment (e.g. pasteurization at 77 ºC for 2 min) (Du et al., 1991; Nakano & Sakaguchi, 1991; Nevas et al., 2002; Nevas et al., 2005; Nevas et al., 2006; Kuplulu et al., 2006; Koluman et al., 2013).

For hazard characterization, dose-responses were identified for all pathogens that were shown to cause foodborne disease in Canada attributed to each food category. A table of data comprehensively characterizing hazards applicable to all food categories was created which encompassed all the critical elements in one model and is included in Table AI. 9. Infectious doses associated with pathogens that were responsible for foodborne illness for each food category are included in Tables AI.10. to AI.20.

For pathogens where a dose response was identified, infectious doses were for pure cultures and not for food environments. It is therefore critical to note that the food environment could change/affect infectious doses and this limitation must be noted during the final risk ranking process. An examination of the specific characteristics related to a pathogen which included virulence, infectivity and the end point of the illness (death or related sequela) is critical in establishing the level of risk associated with the food product. It was also recognized that environmental factors such as pH, desiccation and the food matrix would also either adversely or otherwise affect the pathogenicity (survival, reproduction, production of toxins) of organisms.

Thus for each food, predictive microbiology including modeling of pathogen growth/decline through the processing and consumption cycle is essential in characterizing hazards. Therefore, external factors such as prevalence rates of contamination, diagnostic tests and methodological approaches to quantify and identify microorganisms are essential.

Criteria related to exposure assessment included estimates of probable exposure to pathogens through consumption of food. This is related to hazard characterization since potential for pathogen growth and survival in the food matrix is critical. Also, in this instance, consumer manipulation of food, including storage conditions and cooking would affect exposure. In addition, probability of cross contamination (by consumers) and geographical scale of distribution were identified as important parameters. Finally, probability of exposure to pathogens (either cells or their toxins) through consumption of a serving of food is necessary in constructing risk assessments. In Canada, information from statistics Canada (2009) provided information for food consumption. However, this information is purely theoretical and must be used with caution.

It must be noted that there was limited scientific data available for some food categories, both in Canada and worldwide. These included honey and maple, fats and oils, and grain and baked goods. However, because biological hazards were being identified, this was acceptable since these products are not considered major sources of biological hazards. In addition, the scientific literature for dairy, and especially pasteurization processes were for the most part predominantly over 20 years old, and therefore, newer studies are needed to validate these processes.

3.4. Conclusion

Overall, hazards were identified for all food categories that are inspected by the CFIA. It was noted that previous risk assessments provided a framework for identifying hazards associated with the different food categories. These criteria and mitigation factors were combined with the work conducted to provide a comprehensive list of hazards. The criteria provided by the University of Manitoba were then broadened and generalized into a minimum number that could be used by the CFIA in inspection activities. Furthermore, this work was then used as a foundation to develop risk ranking for food-pathogen pairs. However, the above work was a purely qualitative approach and a quantitative method that would be able to evaluate the relative risks associated with foods so that inspection efforts would be improved was needed. Therefore, in the subsequent chapter, risk characterization was performed based on a semi-quantitative approach to rank the relative risks associated with food-pathogen pairs.

CHAPTER 4: A Generic Model for Risk-Based Food Inspection in Canada: Risk Ranking for Inspection

ABSTRACT

Risk-based inspection utilizes food-pathogen pair attribution as a risk ranking tool to estimate risk and allocate resources for inspection. In part one of this study, ranking of food-pathogen pair attribution was developed using the proportion of food specific attribution of selected gastrointestinal illnesses and estimates of Canadian foodborne illnesses from the scientific literature. Nine selected pathogens (*Campylobacter* spp., non-typhoidal *Salmonella* spp., *Escherichia coli*, *Bacillus cereus*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Yersinia enterocolitica*, *Vibrio* spp. and *Shigella* spp.) and foods grouped in 9 categories (aquatic animals/seafood, beef, pork, poultry, eggs, dairy, produce, grains and bakery products, and other meats) as sources of these organism, were paired and ranked in order of causing illness. *Campylobacter* spp. and poultry, *Campylobacter* spp. and dairy, *Salmonella* spp. and poultry, *Salmonella* spp. and eggs, *Escherichia coli* and beef were the top five food-pathogen pairs (in descending order) implicated in Canada. To more fully characterize the risk, the overall burden of these food-pathogen pairs in terms of cost and impact on the population was estimated using a multi-criterion model adapted from the European Food Safety Authority (EFSA). This approach incorporated criteria related to pathogen characteristics and probability of exposure of humans to pathogens by food. The 6 criteria included in the model were: strength of associations between food and pathogen based on food-pathogen attribution data, incidence of illness, burden of disease, dose-response relationships, prevalence of contamination and food consumption. The top risk-ranked food-pathogen pairs were

Campylobacter spp. and poultry, pathogenic *Escherichia coli* and beef, *Salmonella* spp. and poultry, *Salmonella* spp. and produce, and *Campylobacter* spp. and dairy. Limitations of the model and gaps identified in the scientific literature were also discussed.

4.1. Introduction

Illnesses caused by the consumption of food are still prevalent in developed countries including the United States, the European Union and Canada. In the United States in particular, estimates show that there are 9.4 million cases of foodborne illness annually attributable to 31 pathogens with 38.4 million cases linked to unspecified agents (Scallan et al. 2011a & 2011b). In Canada, 1.6 million cases of foodborne illnesses are attributed to 30 pathogens with a further 2.4 million cases of unknown etiology (Thomas et al. 2013). In the European Union, there were 5,363 foodborne illness outbreaks reported in 2012 with 55,453 illnesses, 5,118 hospitalizations and 41 deaths (EFSA, 2014). Increasingly, it has become apparent that these pathogens are transmitted from zoonotic sources and include pathogens like *Campylobacter* spp., *Escherichia coli* and non-typhoidal *Salmonella* spp. The impact of these pathogens in the food safety system and their burden on public health differs greatly. Also, from reports of foodborne illness outbreaks, it is evident that issues associated with food safety and pathogens that cause foodborne illnesses are dynamic in nature. Currently, the profile of zoonotic diseases traditionally caused by foods of animal origin is changing and becoming more frequently associated with foods of non-animal origin.

To quantify the risk associated with specific food pathogens and the foods that cause illness, food-pathogen pair attribution methods have been developed. Food attribution

and its related impact can then be used in decision making to improve food safety. Various approaches have been used to provide estimates of food-pathogen pair attribution (Batz et al. 2012; EFSA, 2013a; Painter et al. 2013; Ravel et al. 2009). These include the use of outbreak data, epidemiological studies and expert elicitation. The approach and usefulness of each method have also been justified by the respective researchers. Outbreak data provides relevant information on the current food safety system. However, because they represent only a small fraction (10%) of illness associated with foods, these data are not truly representative. Epidemiological studies provide information on foodborne illness outbreaks but there are problems associated with uncertainty and assumptions inherent with the methodology. Also, with the above two methods, there is a lag in time between when the information is collected and when it is published. Thus food-pathogen attribution data that are generated is a few years old before being used in policy making. Expert elicitation has the ability to cover gaps in the system resulting from inadequate foodborne outbreak illness and epidemiological data; however, identifying experts who are sufficiently knowledgeable on the topics of relevance is critical in generating useful data by this approach.

In developing a MRA using food-pathogen attribution, since there are no guidelines in terms of what can be used, each team utilizes information that is accessible and data that are available. There are therefore difficulties in extrapolating data from one country to another and even in comparing countries. This problem is mostly associated with the manner used for food category classification whereby food attribution is made either product specific (for instance for only fruits and vegetables) or is far more broadly

defined. Food categories can also be grouped as raw products (eg. grains) or be end product specific (eg. bread).

There are different methods by which these estimates can be quantified. These include using the number of illnesses, a disease burden matrix or a multi-criterion approach (Batz et al. 2012; EFSA, 2013; Painter et al., 2013; Ravel et al. 2009). On a population basis, a calculation of risk can predict the expected number of specific illnesses or deaths per 100,000 persons per year attributable to the food/pathogen in question (Lammerding & Fazil, 2000). Health-adjusted life years (HALYs), which are summary measures that concurrently combine the effect of death and morbidity, have been developed to provide estimates of the overall population burden of illness (Gold et al., 2002). Disability-adjusted life years (DALYs) are HALYs which measure the sum of years of life lost by premature mortality and years lived with disability (Lindqvist et al., 2002). A DALY per-case value is used to measure the average burden of disease per illness including the relative frequency of each potential health impact (Chen et al., 2013). This relative burden is weighted between a factor of 0 and 1 for the severity of illness (Lindqvist et al., 2002). Quality-adjusted life years (QALYs) is another measurement which uses HALYs to estimate the public health costs associated with foodborne diseases. QALYs measure the retention of quality of life features and provide a means for comparing health outcomes that differ in survivability (Ponce et al. 2001). QALYs are calculated based on several standardized instruments which enable the input of parameters consisting of five health domains obtained from a EuroQoL (EQ-5D) standardized survey (Hoffmann et al., 2012).

Risk characterization combines hazard identification, hazard characterization and exposure assessment into a quantitative and/or qualitative estimate of the probability of the occurrence and severity of health effects in a given population (WHO, 2013b). The degree of uncertainty in risk assessment must be recognized by the assessor and included in the risk analysis (Manning & Soon, 2013). This should be estimated, and where possible, quantified to reduce errors with risk ranking (Walls, 2006). The main aim of developing a model to characterize risk in this work was to provide a framework that would be adaptable such that as new information was obtained, it could be used to update the model. The first part of this risk characterization process involved developing a risk ranking model of food-pathogen combinations. To achieve this objective, parameters for this model were organized, and then food-pathogen combinations based on previously published Canadian data were generated. However, it was evident from the literature that simple food-pathogen combinations were not by themselves a true reflection of the overall burden of disease in the population. In response, a multi-criterion approach developed by the EFSA (2013a) was used to rank the risk associated with food-pathogen combinations, which is discussed further in the next section.

4.2. Part I. Food Attribution

4.2.1. Method

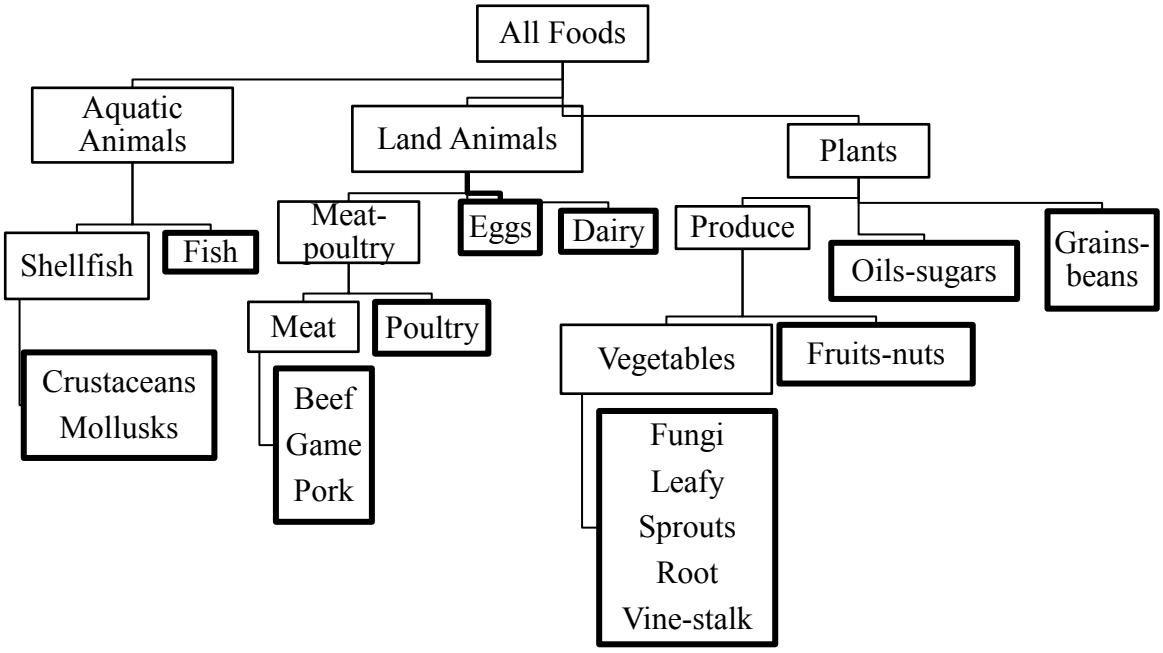
4.2.1.1. Parameters for Risk Ranking

4.2.1.1.1. Food Categories

The first parameter required that categories of foods to be used in this model be established. Numerous considerations were necessary before choosing the final food categories. First, since the task was to develop a model that would be utilized by the

CFIA to inspect food processing plants, food categories had to be consistent with those defined by the SFCA. In addition, to provide a model that would be useful during inspection for identifying the "initial biological hazards" associated with foods, it was deemed valuable to categorize foods according to the raw materials that would be used in food processing. Therefore, the hierarchical classification of food developed by Painter et al. (2013) and presented in Fig. 4.1 was used as a starting point. Since this classification embodied 17 different food categories which were difficult to replicate using Canadian data, these were reorganized to form 9 groups. The categories used were: aquatic animals/seafood (including crustaceans, mollusks, and fish), beef, pork, poultry, eggs, dairy, produce (fruits and vegetables), and grains and bakery products. Since it was necessary to use many different sources of information for estimates, an additional category of "other meats" (game and luncheon meats) was used in this work. It must be noted that two food categories (fats and oils, and honey and maple products) were not included in the risk ranking process because there was limited information on foodborne illnesses caused by these food categories. It should also be noted that in the present work, a cross-commodity, "mixed or complex food" category was not included for attribution analysis to avoid the ambiguity associated with this type of group. Its inclusion would require doubtful assumptions regarding the initial contaminated component in the mixture responsible for the illness reported (Batz et al. 2012) and further, since the task was to develop an assessment for initial biological hazards, "complex foods" did not fit that framework.

Figure 4. 1. Hierarchy of food commodities.



(adapted from Painter et al. 2013)

4.2.1.1.2. Pathogens

To provide a risk characterization that would be comprehensive and support the inspection initiative, the number of pathogens used in the final assessment was reduced. First, noroviruses were eliminated since it is known that transmission of these viruses occurs mainly via human to human contact. *Clostridium botulinum* was also not used for the risk characterization because the numbers of foodborne illnesses caused by this pathogen are extremely low (Thomas et al. 2013). Since the impact of *Clostridium perfringens* on foodborne illness cannot be controlled by inspection of a food processing plant other than by than assuring good sanitation practices, this organism was also

eliminated from further ranking. In addition, protozoan parasites (*Cryptosporidium parvum, Giardia* and *Cyclospora cayetanensis*) were not included since it is fairly certain that most of their involvement in causing foodborne illness results from contaminated water. Due to the incomplete nature of information available in Canada for *Toxoplasma gondii*, this pathogen was not included in the risk ranking. Therefore pathogens selected for risk ranking were limited to *Campylobacter* spp., non-typhoidal *Salmonella* spp., *Escherichia coli* (including *Escherichia coli* O157, non-O157 verotoxigenic *Escherichia coli* and enterotoxigenic *Escherichia coli*), *Bacillus cereus*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Yersinia enterocolitica*, *Vibrio* spp. and *Shigella* spp.

4.2.1.2. Methodology for Food-pathogen Attribution

Food-pathogen attribution estimates have been made by correlating incidence of illness with foods implicated in both the US and in Canada (Painter et al. 2013, Ravel et al. 2009 & CSPI, 2013). In reference to Canadian attribution, this was conducted using data from over a 30 year period (1976-2005) and therefore is not directly applicable to the present day (Ravel et al. 2009). To provide estimates of attribution, a variety of information from different sources was utilized. In attempting to perform this task, it was recognized that simple food-pathogen pair attribution would identify what food-pathogen pair caused the most disease, but would not include the relative health impacts that these pairs have. First, data from the work by Thomas et al. (2013) which provided estimates for foodborne illnesses in Canada caused by 30 specified pathogens was utilized as the source of estimates for numbers of illnesses in Canada per year. In order to provide source attribution for Canada, two types of studies, one an expert elicitation study (A)

(Greig & Ravel, 2009) and the other an epidemiological study (B) (Davidson et al. 2011), were combined (by averaging) to provide proportions of attribution in Canada. To provide an idea of the incidence of illnesses per food-pathogen combinations in Canada, estimates of foodborne illness developed by Thomas et al. (2013) were then multiplied by the average proportions obtained from Davidson et al. (2011) and Greig & Ravel (2009) to provide numbers of illnesses from a specific pathogen attributable to each food category in Canada.

The formula below was utilised to calculate these food-pathogen pairs:

Food-pathogen pair attribution = $\left(\frac{A+B}{2}\right) \times numbers\ of\ illnesses$

It must be noted that, since the two studies above were done by different groups, there was some overlap in food categories. Consequently, all poultry including chicken and turkey were included as one category. Also, where there was only one estimate for attribution, this was used in the calculation. For instance, proportions of attribution for *S. aureus* and *B. cereus* were only obtained from the Greig & Ravel (2009) study and a proportion of attribution for *Y. enterocolitica* was only obtained from Davidson et al. (2011). Tables 4.1a and 4.1b show the proportion of illnesses attributed to each food-pathogen pair from the two sources described above.

4.2.2. Results and Discussion

Poultry, dairy, beef and produce accounted for 70% of foodborne illnesses attributable to food in Canada (Fig. 4.2). In contrast, grains and bakery, seafood and other meats contributed to only 10.5% of all foodborne illnesses (Figs. 4.3 to 4.11). Poultry alone accounted for 31.1% of all illnesses showing its impact on the Canadian food safety system. Dairy represented 15.4% of all illnesses, beef (13%) and produce (11.25%). This can be compared to U.S. data from Hoffmann et al. (2007) where produce, seafood and poultry were reported to cause 70% of foodborne illnesses. Table 4.2 shows the numbers of illness attributable to the top 15 food-pathogen pairs. This group represented 77.7% of all foodborne illnesses with *Campylobacter* spp., and *Salmonella* spp. dominating the ranking. This can be compared to the EFSA (2013b) annual report where most illnesses were attributable to non-typhoidal *Salmonella* spp. (28.6%) bacterial toxins (14.5%), viruses (14.1%) and *Campylobacter* spp. (9.3%). Specifically, in Canada the breakdown includes non-typhoidal *Salmonella* spp. (26%) bacterial toxins (11.1%), and *Campylobacter* spp. (42%).

For food-pathogen attribution, poultry-*Campylobacte*r spp. was ranked as causing the most number of illnesses (Table 4.2). This was then followed by dairy-*Campylobacter* spp., poultry-*Salmonella* spp. (non-typhoidal), eggs-*Salmonella* spp. (non-typhoidal) and beef-*E. coli* (in descending order). Over the same time period, attribution studies have been conducted with varying results. In the study by Hoffmann et al. (2007)

Table 4. 1a. Proportion (%)[1] of food-specific attribution of selected gastrointestinal illnesses: estimates from a Canadian expert elicitation survey[2] (A) and food-pathogen attribution using international outbreak data from 1988 -2007[3] (B).

Food Categories		*Campylobacter* spp.		*Escherichia coli*		*L. monocytogenes*		*Salmonella* spp.	
Painter et al.	**Davidson et al.**	**A[2]**	**B[3]**	**A**	**B**	**A**	**B**	**A**	**B**
Beef	**Beef**	7.5	4.7	54	44.2	2.2	5.7	5.8	7.73
Grain and baked goods	**Bread and bakery**	0	0.5	0.1	1	0	0	2.1	7.63
Dairy	**Dairy**	9.2	34.6	5.7	9.8	27	41.5	7.1	8.17
Eggs	**Eggs**	4.5	1.6	0.4	0	0.1	0	21	25.07
Other meats[4] (game and luncheon meats)	**Other meats[4] (game and luncheon meats)**	3.2	2.1	4.9	6.9	51.5	13.2	6.3	3.63
Pork	**Pork**	4.7	0.5	1.4	0.5	2.5	11.3	7.2	4.6
Poultry[5]	**Poultry[5]**	59	34.5	0.2	1.3	2.4	9.5	34.2	14.3
Vegetables/fruits	**Produce**	6.1	4.7	28.8	19.5	8.4	1.9	17.8	9.4
Aquatic animals	**Seafood**	0.8	2.6	0.2	0.5	6.1	11.3	1.6	3.87

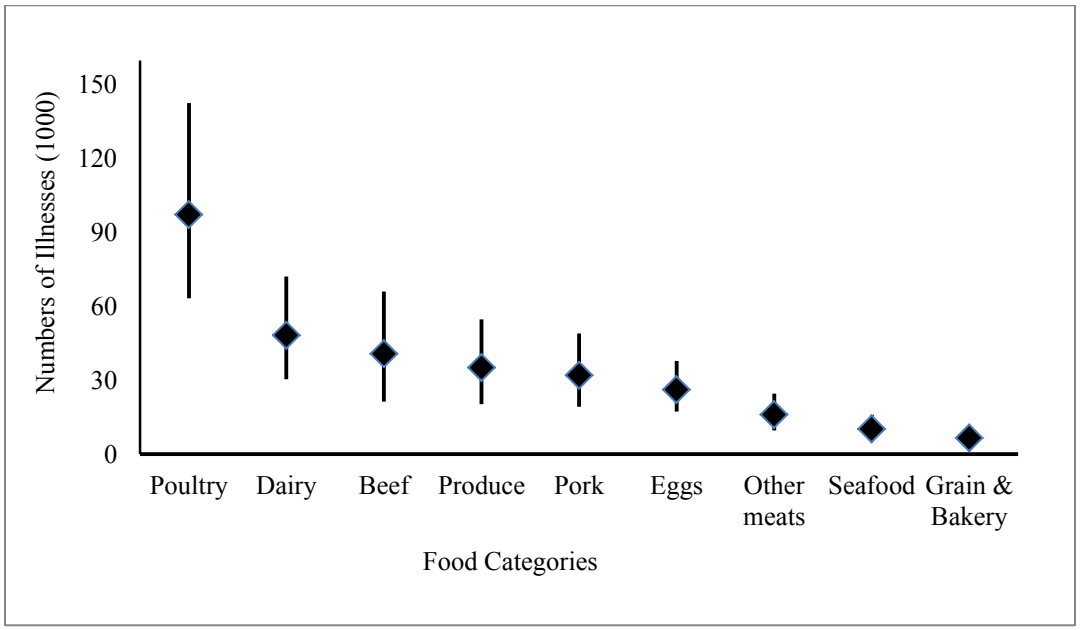
1. Estimates were calculated from the total foodborne illness across food categories.
2. (A) Estimates adapted from: Davidson, V.J., Ravel, A., Nguyen, N., Fazil A. & Ruzante J.M. (2011). Food specific attribution of selected gastrointestinal illnesses: estimates from a Canadian expert elicitation survey. *Foodborne Pathogens & Disease*, **8**: 983-995.
3. (B) Estimates adapted from Greig, J.D. & Ravel, A. (2009). Analysis of foodborne outbreak data reported internationally for source attribution. *International Journal of Food Microbiology*, **130**: 77-87.
4. In Greig & Ravel (2009) and the above work, game and luncheon meats are classified together as "other meats"
5. In Greig & Ravel (2009), turkey and other poultry are differentiated from chicken, but these have been combined in the same category.

Table 4.1b. Proportion (%)[1] of food-specific attribution of selected gastrointestinal illnesses: estimates from a Canadian expert elicitation survey[2] (A) and food-pathogen attribution using international outbreak data from 1988 -2007[3] (B).

Food Categories		*Shigella* spp.		*Vibrio* spp.		*Y. enterocolitica*	*B. cereus*	*S. aureus*
Painter et al.	**Davidson et al.**	**A**[2]	**B**[3]	**A**	**B**	**A**	**B**	**B**
Beef	**Beef**	5.6	6	0	0	2.2	6.7	13.7
Grain and baked goods	**Bread and bakery**	2	0	0	0	0	1.4	5
Dairy	**Dairy**	6.9	14.5	0	0	9.1	4.1	11
Eggs	**Eggs**	0.9	0	0	0	0	1.4	3.9
Other meats[4] (game and luncheon meats)	**Other meats[4] (game and luncheon meats)**	6.1	0	0.8	0	16.6	0	4.4
Pork	**Pork**	2.6	2.4	0	0	63.3	2.7	21.4
Poultry[5]	**Poultry[5]**	2.9	6	0	1.9	0.5	13.5	11.5
Vegetables/fruits	**Produce**	40.5	28.9	0.9	3.7	6.3	8.1	3.3
Aquatic animals	**Seafood**	13	9.6	89.4	90.7	0.4	4.1	3.3

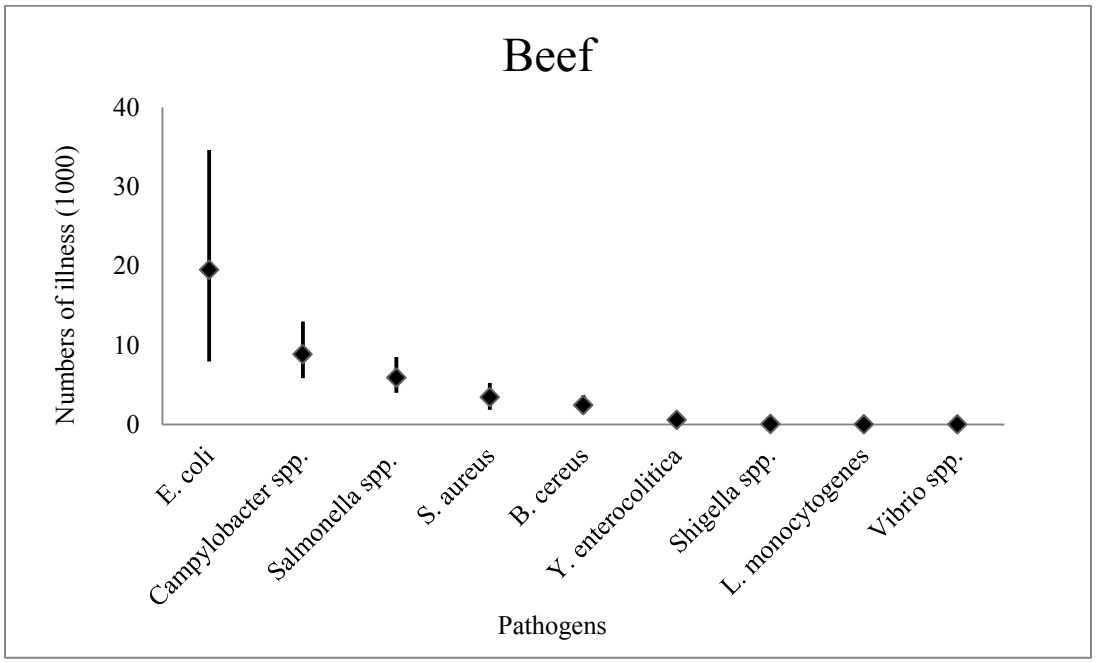
1. Estimates were calculated from the total foodborne illness across food categories.
2. (A) Estimates adapted from: Davidson, V.J., Ravel, A., Nguyen, N., Fazil A. & Ruzante J.M. (2011). Food specific attribution of selected gastrointestinal illnesses: estimates from a Canadian expert elicitation survey. *Foodborne Pathogens & Disease*, **8**: 983-995.
3. (B) Estimates adapted from: Greig, J.D. & Ravel, A. (2009). Analysis of foodborne outbreak data reported internationally for source attribution. *International Journal of Food Microbiology*, **130**: 77-87.
4. In Greig & Ravel (2009) and the above work, game and luncheon meats are classified together as "other meats"
5. In Greig & Ravel (2009), turkey and other poultry are differentiated from chicken, but these have been combined in the same category.

Figure 4. 2. Total numbers of illnesses attributable to each food category for all 9 selected pathogens[1].



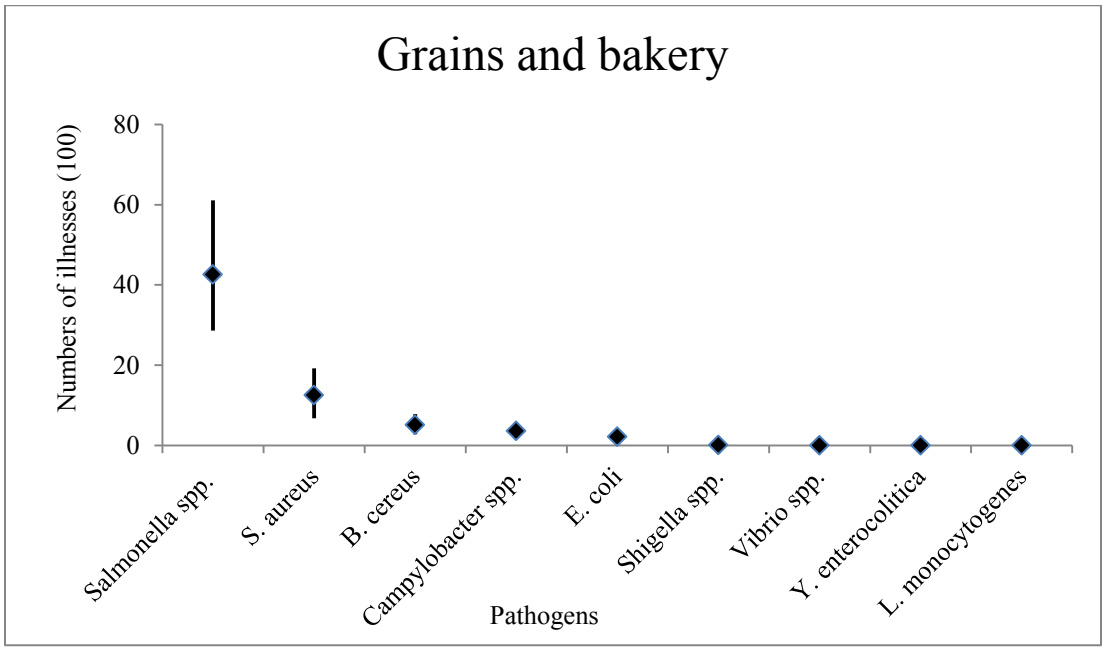
1. Estimates showing the 90% low and high confidence interval

Figure 4. 3. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of beef[1].



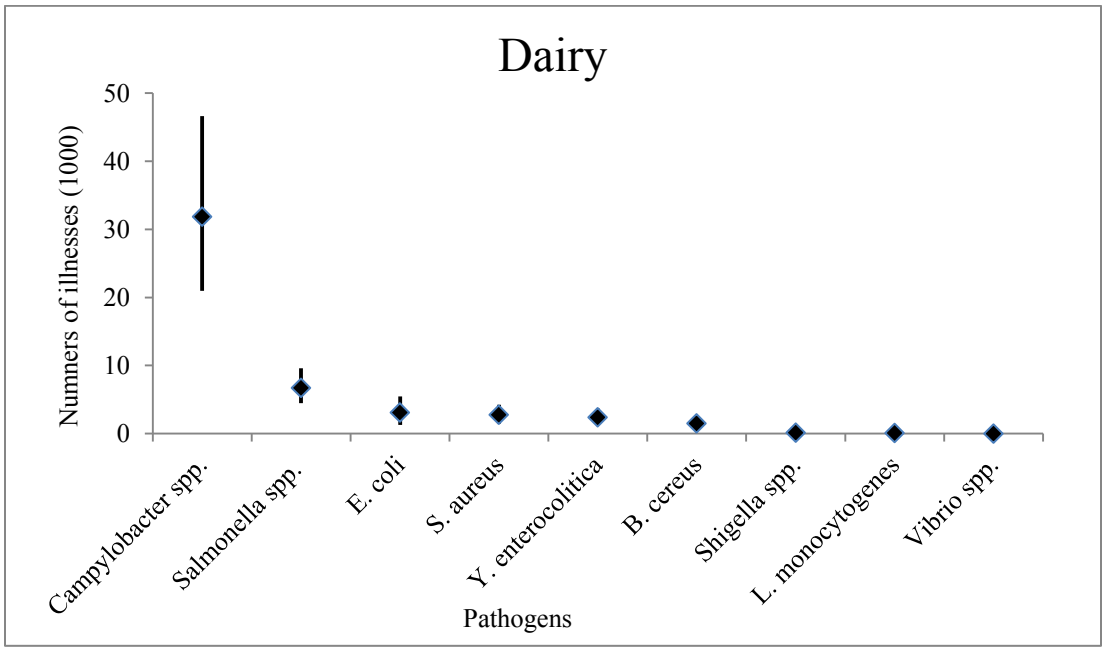
1. Estimates showing the 90% low and high confidence interval

Figure 4. 4. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of grains and bakery products[1].



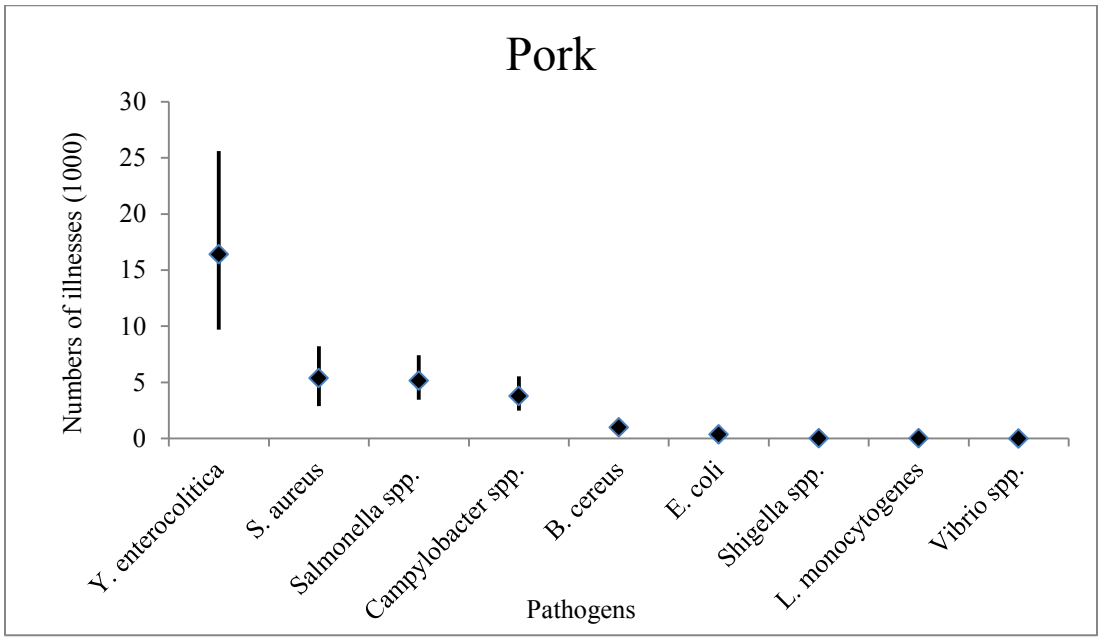
1. Estimates showing the 90% low and high confidence interval

Figure 4. 5. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of dairy and dairy products[1].



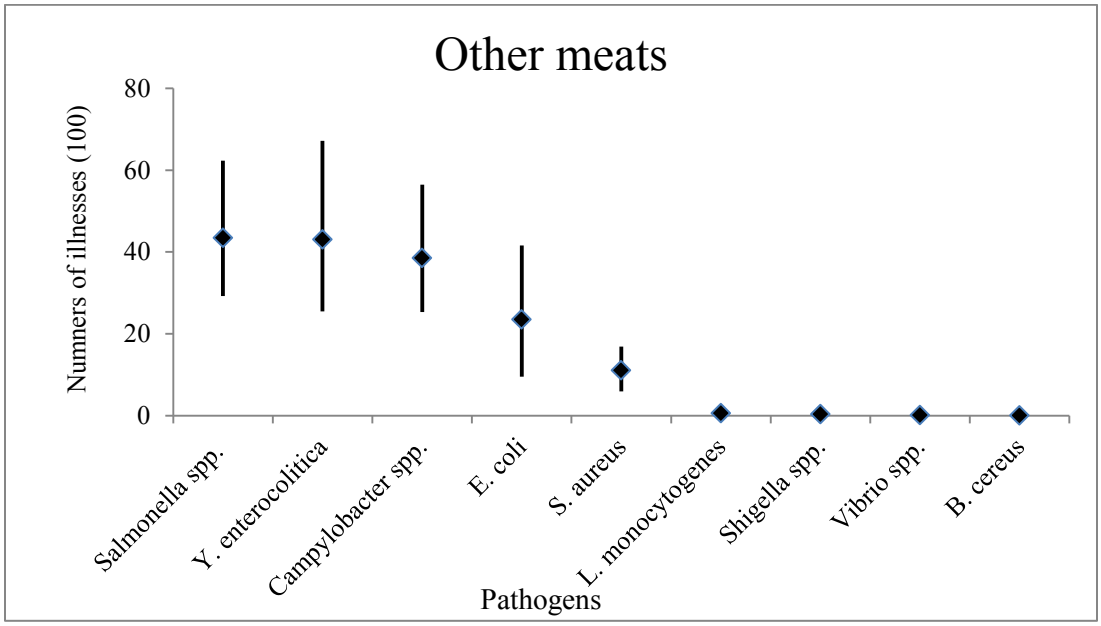
1. Estimates showing the 90% low and high confidence interval

Figure 4. 6. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of pork[1].



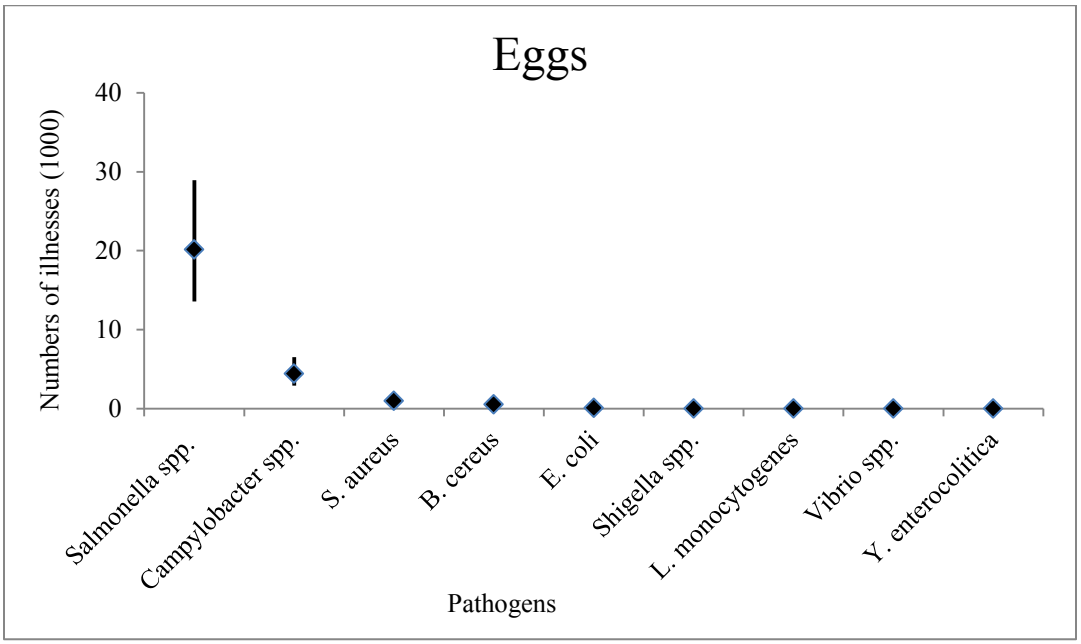
1. Estimates showing the 90% low and high confidence interval

Figure 4. 7. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of other meats[1].



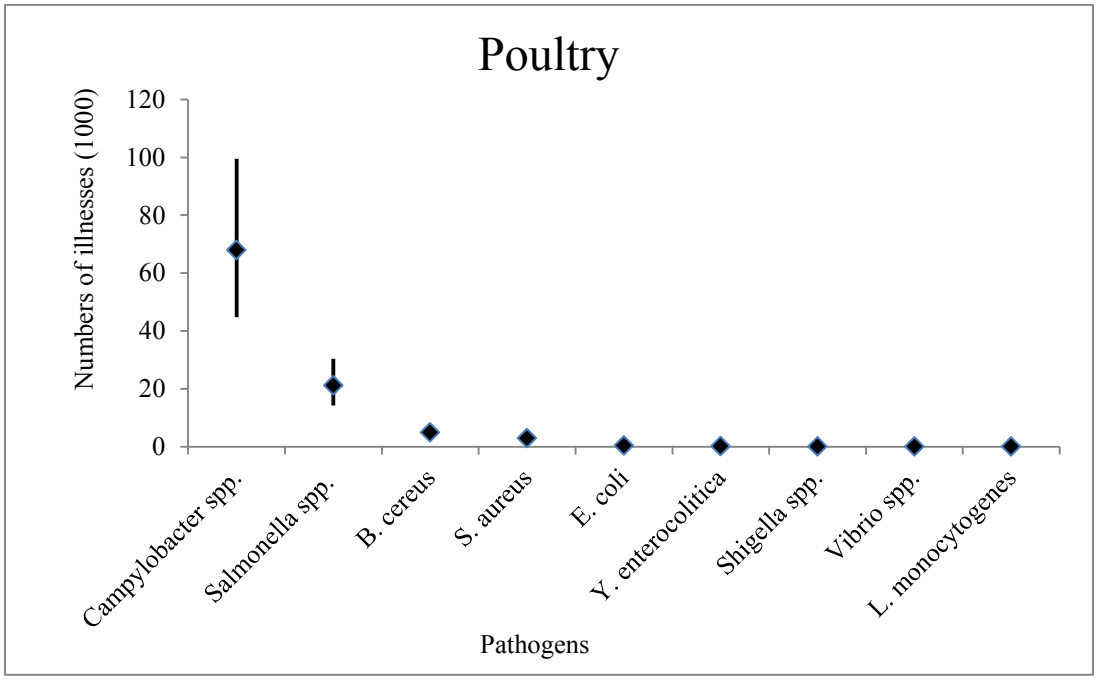
1. Estimates showing the 90% low and high confidence interval

Figure 4. 8. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of eggs and egg products[1].



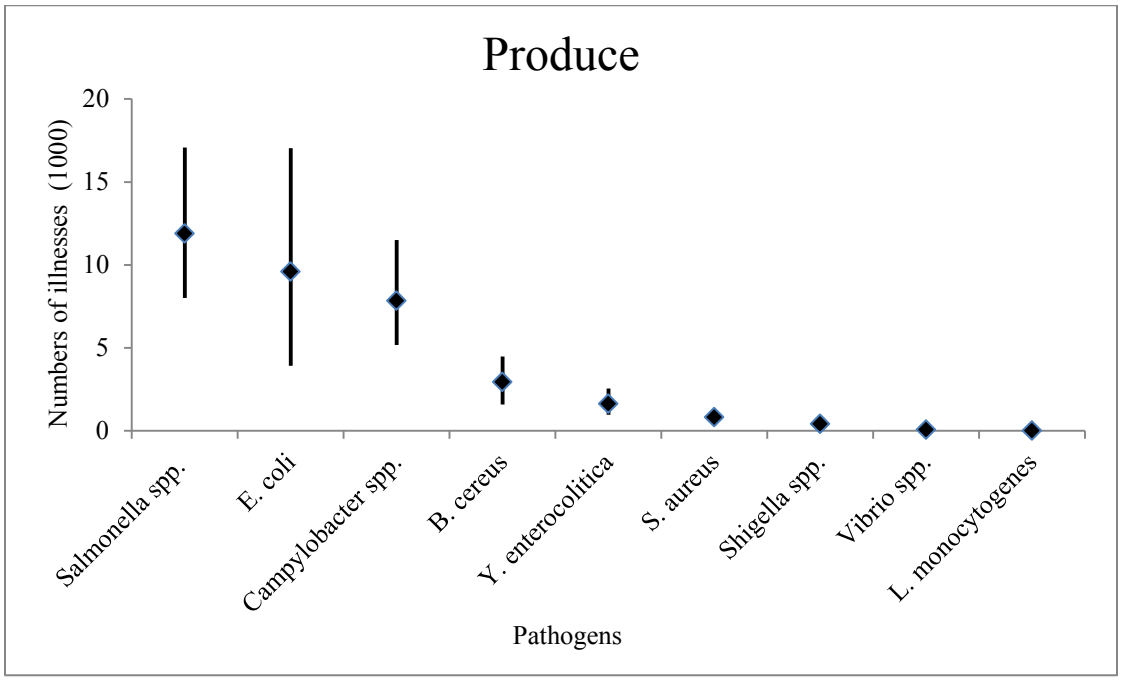
1. Estimates showing the 90% low and high confidence interval

Figure 4. 9.Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of poultry[1.]



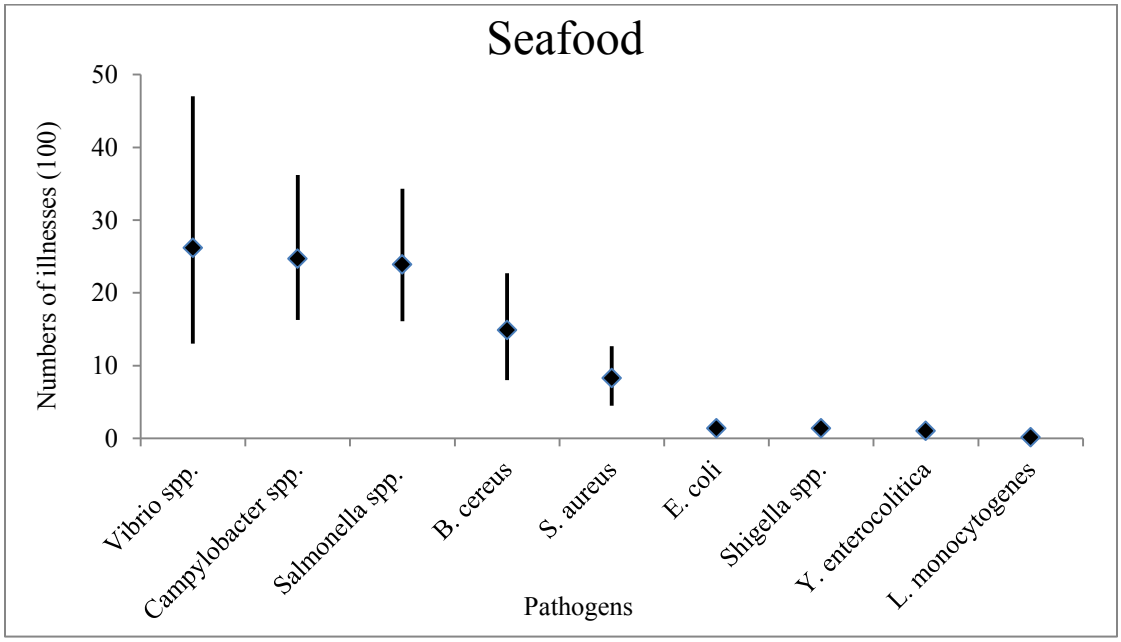
1. Estimates showing the 90% low and high confidence interval

Figure 4. 10. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of produce[1].



1. Estimates showing the 90% low and high confidence interval

Figure 4. 11. Numbers of foodborne illnesses attributable to 9 pathogens from the consumption of seafood[1].



1. Estimates showing the 90% low and high confidence interval

Table 4. 2. Estimated annual cases of foodborne illnesses attributed to the top 15 food-pathogen pairs causing disease in Canada[1].

Food-pathogen Pair	Mean Numbers of illnesses	90% CI (low)	90% High CI (high)
Poultry-*Campylobacter* spp.	67951	44733	99564
Dairy-*Campylobacter* spp.	31832	20955	46641
Poultry-*Salmonella* spp.[2]	21148	14218	30335
Eggs-*Salmonella* spp.[2]	20156	13551	28913
Beef-*E. coli*	19524	7954	34628
Pork-*Y. enterocolitica*	16404	9713	25609
Produce- *Salmonella* spp.[2]	11901	8001	17071
Produce- *E. coli*	9603	3912	17032
Beef-*Campylobacter* spp.	8866	5837	12991
Produce-*Campylobacter* spp.	7849	5167	11500
Dairy-*Salmonella* spp.	6680	4491	9582
Beef- *Salmonella* spp.[2]	5922	3981	8494
Pork-*S. aureus*	5374	2892	8203
Pork-*Salmonella* spp.[2]	5163	3471	7406
Poultry-*B. cereus*	4896	2635	7475

1. Food-pathogen pairs arranged in descending order.
2. Non-typhoidal *Salmonella*

Campylobacter-poultry, *E. coli*-beef, and *Listeria monocytogenes*-luncheon and other meats were shown to be important pairs for food attribution. Batz et al. (2012) also concluded that *Campylobacter* spp.-poultry, *Toxoplasma gondii*-pork and *Listeria monocytogenes*-deli meats were the three food-pathogen pairs of most importance in the United States. It must be noted that the work by Hoffmann et al. (2007) was based solely on expert elicitation using numbers of illnesses to produce rankings. However, Batz et al. (2012) used both foodborne outbreaks and expert elicitation to rank attribution. In

addition, QALYs and cost of illness were generated and used as the basis for ranking in the Batz et al. (2012) study. DeWaal & Glassman (2013) also analysed and produced food-pathogen pair attribution rankings for foods inspected by the United States Department of Agriculture (USDA) and Food and Drug Administration (FDA). For USDA-inspected foods, non-typhoidal *Salmonella* spp. in poultry; *C. perfringens* and *E. coli* O157:H7 in beef; *Staphylococcus aureus*, *C. perfringens* and non-typhoidal *Salmonella* spp. in pork; and C. *perfringens,* non-typhoidal *Salmonella* spp. and Norovirus in luncheon and other meats were indicated as important food-pathogen pairs. Norovirus in produce, scombrotoxin and ciguatoxin in seafood, *Campylobacter* spp. in dairy, and non-typhoidal *Salmonella* in eggs were classified as significant food-pathogen pairs for FDA-inspected foods (DeWaal & Glassman, 2013). The Center for Science in the Public Interest (CSPI) also published a report ranking meat products according to risk associated with foodborne illness over 12 years (1998-2010). In this work ranking was developed by multiplying the number of illnesses by the hospitalization rates characteristic of specific pathogens, thereby providing an index of severity for each meat product (CSPI, 2013). Using this process, the highest risk was associated with chicken and ground beef, followed by beef (other), steak and turkey.

Interestingly, for each food category, results in the present study for pathogen attribution followed what has mainly been identified as the most probable attribution by previous studies (Figs. 4.2 to 4.11). For beef, *E. coli* was the most important pathogen, with *Campylobacter* in dairy, *Y. enterocolitica* in pork, *Salmonella* spp. in eggs, *Campylobacter* spp. in poultry, *Salmonella* in produce and *Vibrio* spp. in seafood. However, in the other meats food category *Salmonella* spp. was ranked as being the most

important pathogen whilst *L. monocytogenes* was ranked sixth (Fig. 4.7). This may reveal a short-coming in the methodology which caused *L. monocytogenes* to be ranked low because the numbers of illnesses it causes are small, but ignores the serious health risk this organism represents in processed meats. Surprisingly, for grains and baked products, *Salmonella* spp. were associated with the most number of illnesses and this may be due to pastry/dairy product-filled baked goods (Fig. 4.4). Overall, grains and bakery products caused the least number of illnesses compared to other food categories in this study.

Since there were significant differences in methods used for the above mentioned studies, and these differences were mainly due to parameters used to define food categories and pathogens considered, it was presumed that there would be differences in the source attribution identified. However, a general trend was noticed in all food-pathogen pairs where illnesses were attributable to three main pathogens; *Salmonella* spp., *Campylobacter* spp. and *E. coli*. However, when ranking methods were changed from numbers of illnesses to other measures such as HALYs, then the pathogens of most significance were identified as being *L. monocytogenes*, *Toxoplasma gondii* and *Salmonella* spp. Addition of Norovirus and *C. perfringens* to this study would have significantly changed these rankings as large numbers of illnesses were presumed associated with these two pathogens in a study conducted by the PHAC (Thomas et al. 2013). However, because information on source attribution was largely estimated for these pathogens, the usefulness of these data is limited. As stated earlier, a simple food-pathogen pair attribution does not provide an overall public health estimate of the burden of illnesses. In the present study, in order to include illness burden in the ranking, an

approach developed and utilized by the EFSA (2013a) for estimating the risks posed by pathogens in foods of non-animal origin was modified and utilized.

4.3. Part II. Risk Ranking Using a Multi-criterion Approach

4.3.1. Method

Parameters used for defining the risk assessment for food categories and food pathogens were the same as described above in the food-pathogen pair attribution. The EFSA (2013a) developed a multi-criterion approach for risk ranking that included both a hazard characterization and exposure/consumption assessment based on 7 criteria. These criteria were divided into two groups. The first 3 were related to pathogen characteristics and consequences of human disease and the last 4 were related to criteria that describe the probability of exposure to that particular hazard.

1. Strength of associations between food and pathogen based on food-pathogen attribution data
2. Incidence of illness
3. Burden of disease
4. Dose-response relationship
5. Prevalence of contamination
6. Consumption
7. Pathogen growth potential during shelf-life

4.3.1.1. Methodology for Risk Ranking Using a Multi-criterion Approach

For a complete justification of this approach, it is suggested that the EFSA (2013a) report be consulted. In summary, for each of the 6 criteria utilized (pathogen growth potential

during shelf-life was not used): annual per capita consumption of specific foods in Canada; strength of association between a pathogen and food and in terms of percent of illnesses caused by that combination; annual incidence of illness per pathogen; the pathogen dose-response relationship; the prevalence of each pathogen in 9 food categories, and the burden of illness by pathogen represented by disability adjusted life-years (DALYs), the available data were grouped into scoring categories which were defined and assigned a numerical, ordinal score. For each food-pathogen combination, the scores of each of the 6 criteria were multiplied together to give a total final risk score, thus providing a ranking of all combinations. This procedure differed from that used by the (EFSA 2013a) where scores were added together. The highest value represented the greatest food safety risk. Below, each criterion is defined and justification for scoring criteria indicated.

4.3.1.1.1. Criterion 1. Consumption

Food consumption records were obtained from Statistics Canada (2009) food statistics report. Consumption was defined as food available in Canada for which losses (from retail, household, cooking and plate loss) had been adjusted. It must, however, be noted that these values are experimental and should be used with caution. In Canada, there was no information on consumption of “other meats” (luncheon meats and game) and therefore, data from the United States were used as substitutes (Daniel et al. 2011). Scores for per capita consumption ranging from 1 to 4 were used to represent consumption rates. These scores and their respective ranges are represented in Table 4.3. Based on these intervals, scoring of foods utilized in this study are shown in Table 4.4.

Table 4. 3. Scoring of food available (per capita consumption) in Canada adjusted for losses[1].

Score[1]	Category	Consumption per capita
1	low	0 – 5 kg/person
2	medium	>5 – 10 kg/person
3	high	>10 – 30 kg/person
4	very high	>30 kg/person

1. Scores and intervals were arbitrarily determined for this study.

Table 4. 4. Food available in 2009 (per capita consumption) in Canada adjusted for losses[1].

Food Category	Consumption (kg/person)	Score
Poultry	13.4	3
Eggs	12.68 dozen/year (7.6 kg/person)[2]	2
Dairy	15.96	3
Grains/cereals	57.46	4
beef & veal	12.54	3
Pork	9.66	2
Fish & shellfish	5.43	2
Fresh fruits and vegetables	80.04	4
Other meats	8.5	2

1. Experimental, use with caution. The data have been adjusted for retail, household, cooking and plate loss.
2. An average large egg without a shell is 50 grams, therefore 12.68 dozen eggs is 12.68 * 12 * 50g = 7.6 kg, Egg Farmers of Alberta (2014).

4.3.1.1.2. Criterion 2. Strength of Associations

The EFSA (2013a) created ranges for strengths of associations by defining situations where foods have been linked to outbreaks of illnesses. However, in Canada there is no central outbreak surveillance system and therefore this approach could not be employed. The strengths between food-pathogen combinations were scored by making the incidence

of illness for each food-pathogen combination a proportion of all incidences of illnesses used in this model. A score range from 1-5 was developed by creating discrete intervals that would reflect the incidence between very low to very high proportions of illnesses attributable to each food-pathogen combination (Tables 4.5 and 4.6).

Table 4. 5. Scoring for strength of associations between food-pathogen combinations.

Score[1]	Category	Percentage of illnesses attributed to food-pathogen combinations
1	Very low	0 % - 1 %
2	Low	>1 % - 2 %
3	Medium	>2 % - 5 %
4	High	>5% - 10%
5	Very high	>10%

1. Scores and intervals were arbitrarily determined for this study.

4.3.1.1.3. Criterion 3. Incidence of Illness

Incidence of illness for each pathogen was obtained from Thomas et al. (2013). Scores were then allotted for each range based on the spread of the distribution (lowest and highest incidence of illnesses) (Table 4.7). For pathogens such as *Vibrio* spp. and *E. coli*, all serotypes classified separately by Thomas et al. (2013) were considered as one group in this study (Table 4.8).

Table 4. 6. Strength of association scores based on proportions (%) of illnesses attributed to food-pathogen combinations.

Pathogens	**Food Categories**								
	Beef	Grains & bakery	Dairy	Eggs	Other meats	Pork	Poultry	Produce	Seafood
***Salmonella* spp.**	1.89%	1.36%	2.13%	6.44%	1.39%	1.65%	6.76%	3.80%	0.76%
Score	2	2	3	4	2	2	4	3	1
***Campylobacter* spp.**	2.83%	0.12%	10.17%	1.42%	1.23%	1.21%	21.71%	2.51%	0.79%
Score	3	1	5	2	2	2	5	3	1
S. aureus	1.10%	0.40%	0.88%	0.31%	0.35%	1.72%	0.92%	0.26%	0.26%
Score	2	1	1	1	1	2	1	1	1
B. cereus	0.78%	0.16%	0.48%	0.16%	0.00%	0.31%	1.56%	0.94%	0.48%
Score	1	1	1	1	1	1	2	1	1
E. coli	6.24%	0.07%	0.98%	0.03%	0.75%	0.12%	0.10%	3.07%	0.04%
Score	4	1	1	1	1	1	1	3	1
***Shigella* spp.**	0.02%	0.00%	0.04%	0.00%	0.01%	0.01%	0.02%	0.13%	0.04%
Score	1	1	1	1	1	1	1	1	1
L. monocytogenes	0.00%	0.00%	0.02%	0.00%	0.02%	0.00%	0.00%	0.00%	0.00%
Score	1	1	1	1	1	1	1	1	1
***Vibrio* spp.**	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.02%	0.84%
Score	1	1	1	1	1	1	1	1	1
Y. enterocolitica	0.18%	0.00%	0.75%	0.00%	1.37%	5.24%	0.04%	0.52%	0.03%
Score	1	1	1	1	2	4	1	1	1

Table 4. 7. Scoring intervals for incidence of illness in Canada.

Score[1]	Category	Score intervals (No. illnesses/year)
1	Low	< 1000
2	Medium	1000 – 25,000
3	High	25,000 – 50,000
4	Very High	> 50,000

1. Scores and intervals were arbitrarily determined for this study.

Table 4. 8. Estimates and scoring for incidence of illness/year in Canada[1].

Pathogen	Numbers of Illness	Scores
Salmonella spp.	87,510	4
Campylobacter spp.	145,350	4
S. aureus	25,110	3
B. cereus	36,269	3
E. coli	39,763	3
Shigella spp.	1,202	2
L. monocytogenes	178	1
Vibrio spp.	2,911	2
Y. enterocolitica	25,915	3

1. Estimates adapted from Thomas et al. (2013)

4.3.1.1.4. Criterion 4. Dose-response Relationships

These dose response relationships were adapted from EFSA (2013a). However, for this work slight modifications were made. *Yersinia enterocolitica* was assigned a score of 1 since it was determined previously that high numbers were required to cause disease

(Bottone, 1999) (Table 4.9). Below in Table 4.10 are the doses and their respective score value for all pathogens used in the model.

Table 4. 9. Scoring for dose-response relationships[1].

Score	Dose-response relationship
1	Pathogen growth to high numbers (>10^5 CFU/g) is needed for toxin production and initiation of disease.
2	Pathogen growth is needed to initiate disease in humans (*e.g. Clostridium botulinum).*
3	Low numbers can cause disease (e.g. *Salmonella* spp.*, Shigella* spp., virus, protozoa).

1. Parameters adapted from EFSA (2013a).

Table 4. 10. Infectious doses and attributed scores for dose-response relationships for all pathogens used in this model.

Pathogen	Infectious dose[1]	Score
***Salmonella* spp.**	10^3 cells	3
Campylobacter spp.	500 cells	3
***S. aureus* (enterotoxin)**	0.1 μg^3	1
B. cereus	10^{6-8} cells/g	1
E. coli	10-100 cells	3
Shigella spp.	10 cells	3
L. monocytogenes	1000 cells	3
Vibrio spp.	10^3 to 10^7 cells	1
Y. enterocolitica	10^7cells	1

1. Infectious doses for all pathogens and corresponding references are listed in Appendix I.

4.3.1.1.5. Criterion 5. Prevalence of Contamination

Scores were allotted based on the criteria described by EFSA (2013a) (Table 4.11). Prevalence rates for contamination of foods were obtained from surveillance records from C-EnterNet which provided a snap-shot of contamination rates in sentinel sites. In addition, the EFSA summary report on trends and sources of zoonoses, zoonotic agents and foodborne outbreaks from 2009 – 2012 (EFSA, 2011 - 2014) provided additional sources for estimates of prevalence. Where there was uncertainty due to geographical differences between the sources of information, a score of 2 was allotted to reflect that, and scores allocated for prevalence of contamination of foods are shown in Table 4.12.

Table 4. 11. Scoring intervals for prevalence of contamination[1].

Score	Category	Explanation
1	Zero prevalence	Available prevalence studies indicate 0 prevalence
2	Unknown prevalence	Not possible to draw any conclusions on the prevalence based on the available data.
3	Low prevalence (< 1%)	Pathogens occur in foods and cause disease, and are likely to have an origin from human or animal contamination
4	High prevalence (> 1%)	Would also include e.g. *Bacillus* spp. and *Listeria monocytogenes*, which originate from the environment and may in some instances be underestimated.

1. Parameters adapted from EFSA (2013a)

Table 4. 12. Attributed scores for prevalence of contamination for all pathogens considered in this model[1].

Pathogens	Food Categories								
	Beef	**Grains & bakery**	**Dairy**	**Eggs**	**Other meats**	**Pork**	**Poultry**	**Produce**	**Seafood**
***Salmonella* spp.**	3	2	2	3	2	4	4	4	4
***Campylobacter* spp.**	3	2	2	3	2	4	4	1	2
S. aureus	2	2	2	2	2	2	2	2	2
B. cereus	4	4	4	4	4	4	4	4	4
E. coli	4	2	2	2	2	1	1	2	2
***Shigella* spp.**	3	2	2	2	2	2	2	3	2
L. monocytogenes	4	4	4	4	4	4	4	4	4
***Vibrio* spp.**	2	2	2	2	2	2	2	2	4
Y. enterocolitica	2	2	2	2	2	4	2	2	2

1. Prevalence rates adapted from Bohaychuk et al. (2006), EFSA (2013a, 2014), PHAC (2011, 2012), Olaimat & Holley (2012).

4.3.1.1.6. Criterion 6. Burden of Disease

Estimates for burdens of disease are important to provide a comprehensive risk assessment for public policy purposes. After consultations with the Scientific Advisory Committee, disability adjusted life years (DALYs) were employed in this work. The rationale behind this approach was two-fold. First, DALYs are more globally used as an estimate in comparison to QALYs, therefore, any estimates generated would be comparable to current work. Also, within the scope of this work, DALYs could not be generated, thus, it was necessary to use results from previous work. Havelaar et al. (2012), using European data, generated a comprehensive set of DALYs for selected pathogens in the Netherlands and these were used. However, this choice of data adds uncertainty because there are differences between countries, although differences were modulated by conversion of DALYs to scores based on DALY magnitude. The criteria developed by the EFSA (2013a) were utilized to generate a scoring system as shown in Table 4.13. Scores for intervals and rank assignments generated for burden of illness are shown in Tables 4.14 and 4.15, respectively.

Table 4. 13. Overall disease burden, disease burden per 100,000 persons and mean disease burden per case of illness in the Netherlands, 2009.

Pathogen	DALY[1] per year		DALY per 100,000 persons		DALY per 1000 cases of illness	
Discount rate	0%	1.5%	0%	1.5%	0%	1.5%
Bacteria — infectious						
***Campylobacter* spp.**	3250	2890	19.8	17.5	41	36
STEC O157	125	98	0.7	0.6	143	113
***Salmonella* spp.**	1270	1100	7.7	6.7	49	41
***Listeria monocytogenes* (perinatal)**	27	16	0.16	0.09	9190	5460
***Listeria monocytogenes* (acquired)**	87	80	0.53	0.49	1140	1050
***Listeria monocytogenes* (total)**	114	96	0.69	0.58	1450	1220
Bacteria-toxin-producing						
Bacillus cereus	112	112	0.7	0.7	2.3	2.3
Clostridium perfringens	536	531	3.3	3.2	3.2	3.2
Staphylococcus aureus	770	761	4.7	4.6	2.6	2.6
Viruses						
Norovirus	1480	1310	8.9	7.9	2.4	2.1
Rotavirus	1820	1630	11.0	9.9	4.9	4.4
Hepatitis A virus	142	123	0.86	0.75	167	145
Hepatitis E virus	24	20	0.15	0.12	460	380
Protozoa						
***Cryptosporidium* spp.**	69	67	0.4	0.4	2.9	2.8
***Giardia* spp.**	162	159	1.0	1.0	2.1	2.1
***Toxoplasma gondii* (congenital)**	2270	1330	13.8	8.1	6360	3730
***Toxoplasma gondii* (acquired)**	1350	1020	8.2	6.2	3170	2400
***Toxoplasma gondii* (total)**	3620	2350	23.0	14.3	4610	2990

1. Disability adjusted life-year

Adapted from Havelaar et al. (2012).

Table 4. 14. Scoring intervals for burden of disease[1].

Score	DALY	DALY per 1,000 cases score intervals
1	Low	< 10
2	Medium	10-99
3	High	100-999
4	Very high	> 999

1. Parameters adapted from EFSA (2013a)

Table 4. 15. Attributed scores for DALYs for all pathogens considered in this model.

Hazard	DALY per 1000 cases	Score based on DALYs
Bacillus cereus	2.3	1
***Listeria monocytogenes* (acquired)**	1140	4
***Campylobacter* spp.**	41	2
***Salmonella* spp.**	49	2
***Shigella* spp.[2]**	N/A[1]	2
Staphylococcus aureus	2.6	1
VTEC O157 [3]	143	3
***Yersinia enterocolitica*[4,5]**	N/A[1]	1
***Vibrio* spp.[6]**	N/A[1]	4

1. N/A are for pathogens for which no estimated available from Havelaar et al. (2012).
2. For *Shigella* spp. no estimates were available, but due to the nature and outcomes of the disease these pathogens cause, it was assumed that their DALYs would fall within the same category as *Salmonella* spp.
3. Similar values have been assumed for all VTEC, although this may represent an overestimation for some non- O157 VTEC serotypes.
4. Similar values have been assumed for all *Yersinia* spp.
5. For *Yersinia enterocolitica*, no estimates were available, but due to the nature and outcomes of the disease this pathogen causes, it was presumed its DALYs would fall into the same category as *Clostridium perfringens.*
6. For *Vibrio* spp. no estimates were available but due to the nature and outcomes of the disease this pathogen causes, it was presumed that their DALYs would fall within the same category as *L. monocytogenes*.

4.3.2. Results and Discussion

This risk ranking was developed by modifying the model published by the EFSA (2013a) which was aimed at quantifying and ranking the risks posed by foods of non-animal origin. Of the 7 criteria developed by the EFSA (2013a), 6 were utilized in the present work. Table AII.1. contains the rankings of all 81 food-pathogen combinations used to develop this model. Using the 6 criteria, the 10 top ranked food-pathogen pairs (which included 6 more pairs that had identical scores) in decreasing order of priority were:

1. *Campylobacter* spp. and poultry;
2. *Escherichia coli* and beef;
3. *Salmonella* spp. and poultry; and *Salmonella* spp. and produce (fresh fruits and vegetables);
4. *Campylobacter* spp. and dairy;
5. *Campylobacter* spp. and beef; and *Escherichia coli* and produce;
6. *Salmonella* and eggs;
7. *Salmonella* and beef; and *Salmonella* and dairy;
8. C*ampylobacter* spp. and pork; *Salmonella* and grains and bakery; and *Salmonella* and pork;
9. *Campylobacter* spp. and produce; and *Campylobacter* spp. and eggs;
10. *Escherichia coli* and grains and bakery

It must be noted that criterion 7, which is related to pathogen growth during shelf-life, was not included in this model. This would affect the rankings of foods such as grains and bakery products where potential for growth during shelf-life would be low; however, levels of uncertainty with respect to other foods caused distortion in the ranking when criterion 7 was included. It is difficult to compare the results of this study to previous attribution studies since this model incorporated all elements of the risk assessment

model (exposure assessment and hazard characterization) instead of using one criterion. The only similar study that has been conducted was by the EFSA (2013a), however, their assessment focused entirely on foods of non-animal origin. It is interesting to note that poultry-*Campylobacter* spp. was risk-ranked in the present work as the food-pathogen pair with the highest burden of illness on the Canadian population. This result is likely due to the relationship between numbers of illnesses, consumption and the prevalence of *Campylobacter* spp. in poultry (which can be as high as 90%). However, compared to simple food-pathogen attribution (which is based solely on the numbers of illness caused), *Campylobacter* spp. were not as important as *E. coli* in beef and *Salmonella* spp. in produce on the overall health of the Canadian population. Results also indicated that food intoxication caused by *B. cereus* and *S. aureus* was not as important as they ranked low in the food-pathogen attribution pair risk assessment. It is important to note that *L. monocytogenes* was not ranked highly in this work. This indicated that though the severity of illness of was high in terms of DALYs, when other criteria of the model were taken into consideration, especially the low incidence of illness, its relative importance was reduced. However, this does not imply this pathogen is not important because an outbreak of foodborne illness caused by this organism, with attendant seriousness, is important to prevent.

A sensitivity analysis was conducted to examine the impact of each criterion on the rankings of the food-pathogen pairs. Results indicated that when each single criterion related to consumption, strengths of associations, prevalence rates, dose-response and burden of illness was eliminated, there were slight changes in the top ten food pathogens pairs. However, when the criterion related to incidence of illness was eliminated, *Listeria*

monocytogenes and associated food categories of grains and bakery, produce, beef, dairy, poultry, other meats, pork, eggs and seafood were in the top ten food pathogen-pairs. This reflects the severity of *L. monocytogenes* on the burden of illness in the population. However, because the incidence of listeriosis in Canada is low, its overall impact for risk ranking using the multi-criterion approach was reduced.

4.4. Conclusion

The importance of food-pathogen attribution data in establishing policy for food safety cannot be overestimated. In this work it was shown that *Campylobacter* spp. in poultry should be a major food safety concern. *Salmonella* spp. and *E. coli* also represent a significant burden of illnesses for the Canadian population. The data used in the present work were based on foodborne illness cases (sporadic plus outbreak–related cases), and it should be recognized that outbreaks of illness can influence perceptions of illness burden. The goal of this model was to generate risk ranking of food-pathogen pairs which would give an indication of where inspection resources should be best targeted. Inherent in the model is the ability of input data to be changed easily whenever new and validated information becomes available.

GAPS IDENTIFIED IN THE SCIENTIFIC LITERATURE

As part of the present work, it was intended that gaps be identified that are present in the Canadian food safety system which prevent accurate analysis of specific food safety issues. In order to provide better evidence to define criteria for more accurate risk ranking, the following gaps need to be addressed:

- Improvement in collection of data on incidence of outbreaks, sporadic illnesses, and severity of human diseases caused by hazards in food.
- A system for collecting data for source attribution needs to be developed and used.
- Development of national guidelines and a framework for Microbial Risk Assessments (MRA) must be undertaken.
- Epidemiological and cohort studies to provide a baseline for current foodborne illnesses related to pathogens of interest in food in Canada need to be conducted on a yearly basis.
- Studies generating public health estimates of the burden of foodborne pathogens in Canada (Disability adjusted Life Years (DALYs) and Quality Adjusted Life Years (QALYs) are needed.
- Information from the National Studies on Acute Gastrointestinal Illness (NSAGI) should be collected in a manner that will distinguish illness caused by food from those caused by water. Importantly, results should be made available in a more timely manner, enabling their use in setting public health policy that is relevant.

- Epidemiological information and food analytical results collected by agencies that have a mandate to ensure the safety of food in Canada should be shared regularly and a single agency should be charged with analysis of these data as well as generation of annual reports that can evaluate the effectiveness of interventions to improve the safety of food.
- Information from hospitals on foodborne illnesses is consistently incomplete and this issue as well as the reporting of foodborne illnesses by the Provinces and Territories to Health Canada needs to be raised to a higher level of priority.
- To more accurately assess the burden of illness, further study of the dose-response relationships between foodborne pathogens and vulnerable sub-populations must be undertaken.

GENERAL CONCLUSIONS AND RECOMMENDATIONS

- Microbial Risk Assessment (MRA) using multiple criteria provided a risk ranking of foods and pathogens which involved some subjectivity because of gaps in the data, but it enabled generation of an overall estimate of the societal burden associated with food-pathogen combinations on a reasonably strong scientific basis.
- Development of an MRA in Canada required the use of a number of international sets of data, resulting in assumptions that do not necessarily reflect the Canadian situation. Therefore, there is a level of uncertainty in the results obtained which must be recognized and which can only be minimized when adequate Canadian data become available.
- The model used for risk ranking is structured in such a way that new data can be incorporated with minimal difficulty to update the ranking in response to changes in the food safety environment.

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Appendix I.

Table AI. 1. Criteria for hazard identification related to fruits and vegetables consumption.

Criteria Related to Hazard Identification for Fruits and Vegetables	Reference
Pre-harvest conditions	CFIA (2013); EFSA (2013); Olaimat & Holley (2012); FDA (2001); James (2008); Beuchat (1996); Buck et al. (2003); Harris et al. (2003)
Agricultural source of water	Islam et al. (2005); Islam et al. (2004a); Solomon et al. (2002); Islam et al. (2004b); Garcia-Villanova et al. (1987)
Soil conditions and land usage	Garcia-Villanova et al. (1987)
Feed and/ manure source	Islam et al. (2005); Nicholson et al. (2005); Islam et al. (2004a) Solomon et al. (2002); Islam et al. (2004b)
Environmental conditions (that may be favorable for pathogen growth) for instance location, prone to flooding etc.	Islam et al. (2004b)
Worker hygiene and harvesting conditions	Hutin et al. (1999); Kozak et al. (2013)
The probability of contamination of incoming materials by biological hazards (e.g. *E. coli* O157:H7 and *Salmonella* in seeds for sprouting)	Harris et al. (2003); Mahon et al. (1997); Rimhanen-Finne et al. (2011); Ding et al. (2013)
Post-harvest conditions	
Foodborne gastroenteritis and outbreak data related to product	Thomas et al.(2013), CDC (2013), CNDSS, NSAGI
Food-pathogen pair attribution data	Batz et al. (2012) Painter et al. (2013), EFSA (2013a)
Effects of post harvesting conditions and processing steps in increasing/ decreasing pathogens (sanitation, storage, transportation and scale of geographical distribution)	CFIA (2013), Tauxe et al. (1997); Beuchat (1996); Lund & Snowdon (2000); Kozak et al. (2013)
Level of complexity associated with the production of the final food material (e.g. time, temperature, slicing, sanitation)	Harris et al. (2003)
Changes in processing steps that could exacerbate risk	Beuchat & Ryu (1997)
Recall history related to this product	CFIA internal data
Volume of production	
Further manipulation required by consumers	
Distribution to vulnerable sub populations	

Table AI. 2. Criteria for hazard identification related to dairy products consumption.

Criteria related to Hazard Identification Dairy	References
Environment	
Water source- water quality/contamination; storage; distribution system	Linton & Hinton (1987); Sofos (2002); McEvoy et al. (2004); Faith et al. (1996); LeJune et al. (2001); Shere et al. (1998); Food Standards Australia New Zealand (2009)
Feed/pasture	Hinton (2000); Notermans & Beumer (2002); McEvoy et al. (2004); Buncic (2006); Crielly et al. (1994); Oliver et al. (2009); Nightingale et al. (2004); Food Standards Australia New Zealand (2009)
Bedding and soil	Crielly et al. (1994);); Murinda et al. (2004); Food Standards Australia New Zealand (2009)
Farm	
Quality assurance system related to primary production (HACCP, GMP's, FSEP)	Papademas & Bintsis (2010)
Facility management (e.g. equipment including regular cleaning and disinfection of water troughs	Buncic (2006)
Management practices to reduce spread of pathogens (e.g. exposure of calves to cows and their feces, manure handling, exposure of pre-weaned calves to other calves, not cleaning calf hutches/pens before use)	Wells (2000)
Animals with clinical signs of disease or illness are identified and managed	Wells (2000)
Animal husbandry practices- stress of animal impacts natural defense mechanisms including appropriate farm design and effective biosecurity	McEvoy et al. (2004)
Contact with vermin, wild or other farm animals	McEvoy et al. (2004) ; Buncic (2006)
Vaccination program in place	Buncic (2006)
Milking machine design and operations	Visers & Driehuis (2009)
Bulk tank design and operations	
Personnel	
Good personal hygiene including boot sanitation	Buncic (2006); Callon et al. (2008)
Animal Transport	
Potential for cross contamination by pathogens and parasites (e.g. *E. coli* can be shed by cattle)	McEvoy et al. (2004)
Disinfection of vehicles	Buncic (2006)
Proper implementation of safety guidelines during truck unloading of milk	
Milk Products	
Liquid and frozen milk products	Chambers & Surapat (2006); FDA (2006)

Criteria related to Hazard Identification Dairy	**References**
Acidity/pH of milk before receiving (i.e. high pH indicates possible contamination)	
Proper temperature control during all stages of production (i.e. transportation, storage, post-pasteurization, packaging etc.)	
Pasteurization time and temperature	
Tests for microbial pathogens (e.g. coliforms, *Escherichia coli*, Standard plate counts)	Notermans et al. (1997)
Equipment for transporting milk in plant must be easy to clean	Murinda et al. (2004)
Cooling of raw, skim and cream milk	
Handling and storage of raw, liquid, whey and condensed milk products	
Packaging of liquid, condensed, bulk dry milk and whey milk products (for both pasteurized and sterilized milk products)	
Aseptic product processing and storage (bulk)	
Use of water reclaimed from condensing or membrane processing of milk or whey Products	
Addition of reworked or reclaimed product	
Fermented/Cultured milk products (cheese and yogurt)	
Use of post pasteurized ingredients	
Proper acid development (for both cheese and yogurt products)	Morgan et al. (2001); Jorgensen et al. (2005)
Minimum aging time for unpasteurized milk cheese (i.e. minimum of 60 days)	
Liquid cultures must be produced under hygienic conditions (i.e. pasteurization of media, positive air flow etc.) and verified for the presence of pathogenic bacteria (*Salmonella*, *E. coli, S. aureus* and *L. monocytogenes*)	
Cheese (soft), cultured products and butter must be stored below 4ºC Hard cheeses can be stored at higher temperatures during the ripening stage	
Monitoring of fresh ingredients added to the final product (e.g. addition of fresh puree in yogurt)	
Procedure for salting and maximum reuse time of brine	
General Hazards	
Consumption of raw milk products	BCCDC (2013)
Outbreak history related to product	Kousta et al. (2010); Evenson et al. (1988)
Recall history related to facility/product	CFIA internal data
Food pathogen-pair attribution	Painter et al. (2013), Batz et al. (2012)

Table AI. 3. Criteria for hazard identification related to aquatic animals consumption.

Criteria Related to Hazard Identification	Reference
Recall history related to plant	CFIA internal data
Outbreak history related to product	CFIA internal data; CDC (2013a); Dillon & Patel (1992)
Maximum cumulative exposure times and temperatures for which pathogenic bacteria would grow during processing, transportation and storage	FDA (2011); FAO/WHO (2005a &2005b); Gibson et al. (1988)
On-board-ship handling practices	FDA (2011)
Method, season and geographical location of harvesting site	FAO/WHO (2005a & 2005b)
Sanitation processes and pasteurization times-temperature combinations	FDA (2011)
Potential for cross-contamination	
pH/acidity and salt concentration of aquatic animals during processing, transportation and storage	
Food handling and employee hygiene	
Bacterial load on raw material	FAO/WHO (2005a & 2005b)
Time aquatic animals is exposed to air (harvest or receding tide)	FAO/WHO (2005a)
Environment where aquatic animal is raised (may contain larvae of parasites that can enter into the fish through skin)	
Part consumed (e.g. liver)	
Presence of toxin-forming microorganisms (e.g. scombrotoxin, ciguatoxin)	FDA (2011)
Changes in processing steps that might increase risk	
Level of complexity associated with final product	
Temperature of product during processing (e.g. if at any time the product is held at internal temperatures above 70°F (21.1°C), exposure time (i.e., time at internal temperatures above 50°F (10°C) but below 135ºF (57.2ºC) should be limited to 2 hours (3 hours if *Staphylococcus aureus* is the only pathogen of concern)	FDA (2011); Dillon et al. (1994); Dillon & Patel, (1993)

Table AI. 4. Criteria for hazard identification related to fats and oils consumption.

Criteria Related to Hazard Identification	**Reference**
Outbreak history related to product	CDC (2013a), CFIA internal data
Outbreak history related to plant	CFIA internal data
Chemical composition of water phase in products (e.g. mayonnaise and salad dressings) related to pH, oil content, aqueous salt content, sugar content and water activity. Fat continuous systems are more stable than water continuous systems	Hathcox et al. (1995)
Possible anaerobic sites for growth of toxin producing pathogens (e.g. addition of fresh garlic to oil)	Smittle (2000)
Storage environment of products	
Sanitary conditions of the environment during handling and packaging	
Product modifications (reducing fat level and increasing water content)	
Acid/pH of mayonnaise and dressings (acetic acid essential in inhibiting a variety of pathogens usually between 3.0 – 4.2)	Smittle (2000)

Table AI. 5. Criteria for hazard identification related to maple and honey consumption.

Criteria Related to Hazard Identification for Maple and Honey	**References**
Outbreak history associated with product	CDC (2013)
Recall history related to plant	CFIA internal data
Evidence of a food safety program (GMP, HACCP, FSEP etc.)	
Presence of spore forming bacteria (*Bacillus cereus, Clostridium botulinum, Clostridium perfringens*)	Dumen et al. (2013); Koluman et al. (2013); Snowden & Cliver (1996); Sumner (2002)
Prevalence of contamination rates in product (10% of honey contained is *C. botulinum* spores)	Du et al. (1991); Koluman et al. (2013); Kuplulu et al. (2006); Nakano & Sakaguchi (1991); Nevas et al. (2002); Nevas et al. (2005); Nevas et al. (2006) ;
Water content of the final product (ideally should be below 18% water content)	
Level of complexity associated with final product	
Food-pathogen pair attribution data	Batz et al. (2012)
Changes in processing steps that might increase risk	
Potential for cross-contamination	Gilbert et al. (2006); Snowden & Cliver (1996);
Effect of hygienic conditions from environment, equipment and storage conditions	Nevas et al. (2006)
Effectiveness of heat treatment (e.g. pasteurization at 77ºC for 2 min)	European Commission (2002)
Possible sources of secondary contamination (e.g. equipment, environment, sanitation practices etc.)	Al-Waili et al. (2012)
Risk associated with product processing (e.g. maple syrup and honey are considered low-risk activity)	FDA (2012b)

Table AI. 6. Criteria for hazard identification related to egg consumption.

Criteria related to hazard identification for eggs	References
Hazards related to egg quality	
Equipment (i.e. grading tables, rollers, conveyor belts)	New Zealand Food Safety Authority (2002); Curtis et al. (1996); Davison et al. (1997); EFSA (2009); Davies & Breslin (2003); De Reu et al. (2005)
Personnel	New Zealand Food Safety Authority (2002); Curtis et al. (1996); Foley et al. (2011); EFSA (2009)
Non-food grade oils used to seal washed eggs.	New Zealand Food Safety Authority (2002)
Transport conditions (e.g. temperature control)	New Zealand Food Safety Authority (2002); EFSA (2009)
Storage conditions (i.e. temperature 10 ºC to13 ºC and humidity at 70% to 85%)	Botey-Saló et al. (2012); Gantios et al. (2009); New Zealand Food Safety Authority (2002); Curtis et al. (1996); EFSA (2009)
Wash water (i.e. wash water temperature, water quality characteristics (i.e. hardness, pH), detergent type and concentration, iron content and de-foamer) for eggs	Van Immerseel et al. (2009); New Zealand Food Safety Authority (2002); Curtis et al. (1996); Knape et al. (2001)
Hazards related to hatchery	
Vertical transmission from breeder flocks (breeder farms)	Thorns (2000); Howard et al. (2012)
Presence of pests	Namata et al (2008); Carrique-Mas et al. (2009)
Screening of breeder chicks	Edel (1994)
Controlled introduction of stock, litter and feed	Poppe et al. (1992)
Hazards related to layers	
Consumption of contaminated feed	Crump et al. (2002); Wales et al. (2010)
Presence of host-adapted and non-host adapted *Salmonella* serovars in environment	Martelli & Davies (2012);
Age of birds	Jones et al. (2002); Van Hoorebeke et al. (2010a)
Type of housing and size of the farm	Rose & Slifko (1999); Holt et al (2011); Carrique-Mas et al. (2009); Van Hoorebeke et al. (2010b); Mollenhorst et al. (2005)
Evidence of *Salmonella* control programs for chicks	Davies & Breslin (2004)
Evidence of implementation of biosecurity measures (e.g. pest control)	New Zealand Food Safety Authority (2002); Curtis et al. (1996); Davison et al. (1997); Crippen et al. (2009); Henzler & Opitz (1992); Davies & Wray (1995)
Potential for cross-contamination (e.g. type of housing) with fecal matter	Davison et al. (1997); Henzler & Opitz (1992); Foley et al. (2011);
Source of poultry feed and water	Guard-Petter et al. (1997); Crump et al. (2002); EFSA (2008); Bucher et

Criteria related to hazard identification for eggs	**References**
	al. (2007); Foley et al. (2011); Wales et al. (2010); Torres et al. (2011)
Presence of vaccination program	Foley et al. (2011); Cogan & Humphrey (2003); Zhang-Barber et al. (1999)
Results of environmental and egg sampling	Davison et al. (1997); Davies & Wray (1996); Hogue et al. (1997); Henzler et al. (1998).
Molting	Bell (2003); Holt (1995); Murase et al. (2001); Golden et al. (2008)
General hazards related to egg production	
Outbreak history related to product, volume of eggs produced, geographical distribution of product	Perry & Yousef (2012); Nesbit et al. (2012); Bermúdez-Aguirre & Corradini (2012); Bean & Griffin (1990); Hennessy et al. (1996); Chittick et al. (2006); Schroeder et al. (2005); Guard-Petter (2001); Hoffmann et al. (2012); Martelli & Davies (2012)
Prevalence and/incidence of pathogens in egg products	Cogan & Humphrey (2003); Martelli & Davies (2012); Favier et al. (2013); Fearnley et al. (2011); Arsenault et al. (2007); Ebel & Schlosser (2000); Martelli & Davies (2012); Chemaly et al. (2009)
Presence of reservoirs to spread pathogens (e.g. rodents in the case of *Salmonella* spp.) and pest control	Henzler & Opitz (1992); Umali et al.(2012); Lapuz et al. (2012); Carrique-Mas et al. (2009); Davison et al. (1997); Davies and Wray, (1995) ; Kinde et al., (1996); Olsen & Hammack (2000); EFSA (2009)
Presence of serovars that most frequently cause human salmonellosis	EFSA (2010) ; NARMS (2014)

Table AI. 7. Criteria for hazard identification related to meat consumption.

Criteria related to Hazard Identification for Meat	References
Primary Production	
Environment	Ahl & Buntain (1997)
Pasture	
Water source- water quality/contamination; storage; distribution system	Horchner et al. (2006)
Farm Inputs	Ahl & Buntain, 1997
Feeding practices and Feed source	Lynn et al. (1998); Crump et al. (2002); Ellis (1968); Clark et al. (1973); Danish Zoonoses Center (1999); Gray (1958); Hacking (1978); Srivastava et al. (1971); Selim & Cullor (1997); Kidd et al. (2002); McChesney et al. (1995)
Environmental contamination of farming equipment	Thompson et al. (1980); Ellis-Iversen et al. (2012)
Disposal of manure	Kudva et al. (1998)
Farm	Ahl & Buntain (1997)
Quality assurance system related to primary production (HACCP, GMP's, FSEP)	Pearson & Dutson (1995)
Animals with clinical signs of disease or illness are identified and managed	
Animal husbandry practices- stress of animal impacts natural defense mechanisms	Veterinary services (2009)
Flock prevalence of pathogens (e.g. *Campylobacter* on poultry is 71.2%)	EFSA (2012)
Recall history related to plant	CFIA internal data
Animal Transport	Ahl & Buntain (1997)
Potential for cross contamination by pathogens and parasites (e.g *E. coli* can be shed by cattle)	
Slaughter	Ahl & Buntain (1997)
Worker hygiene	
Potential for cross-contamination (e.g. live animals, processing procedures, equipment and the environment)	FSIS (1999); Bertolatti et al. (1996); Chaffey et al. (1991)
Recall history related to plant	
Sanitation method in place (e.g. for poultry air chilling or chlorine wash)	
Scale of slaughtering operation (e.g. automated or manual)	
Cross-contamination during evisceration (e.g. by equipment, contamination from employee and contamination from bladder, stomach and intestines	

Criteria related to Hazard Identification for Meat	**References**
contents of animal)	
Processing	Ahl & Buntain (1997)
Level of complexity associated with final product	
Changes in processing that might increase risk	
Complete separation of ready-to-eat and not ready-to-eat meat	
Parameters that restrict the potential for growth (e.g. control of temperature, acidity, and salting and drying)	FSIS (1999)
Parameters that destroy potential pathogens (e.g. maintaining a minimum temperature for a time - 130 ºF to 165 ºF or higher thermal treatments that destroy spores and toxins 240 ºF)	FSIS (1999)
Type of product (fresh, frozen, ready-to-eat or processed meat)	
Recall history related to processing plant	
Results of microbial tests for presence of ubiquitous pathogens (e.g. *L. monocytogenes*) and effectiveness of sanitation	
Employee hygiene, air, traffic and equipment flow between ready-to-eat and not-ready-to-eat environment	
Type of end product (ground beef, mechanically tenderized meat, refrigerated meat product, frozen meat product or ready-to-eat meat product or commercially sterile product)	
Compliance of producers to government standards (e.g. zero tolerance of *Listeria monocytogenes* in ready-to-eat meat products where pathogen can grow)	
Wholesale/Retail	Ahl & Buntain, 1997
Recall history related to product and facility	
Storage time and temperature, pH and Water Activity (Aw) of final product	
Storage requirements of final product (e.g. frozen, refrigerated or room-temperature stable)	
Volume of production	
Consumer	Ahl & Buntain (1997)
Further manipulation before consumption	
Storage time and temperature	
Human Health	Ahl & Buntain (1997)

Criteria related to Hazard Identification for Meat	**References**
Foodborne gastroenteritis and outbreak related to meat products (beef, poultry and pork)	EFSA (2012); Thomas et al. (2013),
Incidence and severity of illness (DALYs) including case fatality ratios	EFSA (2012)
Presence of antibiotic resistance strains of pathogens (e.g. *Salmonella* DT104)	
Food-pathogen pair attribution (e.g. 20-30% of *Campylobacter* in the EU is caused by broiler meat)	EFSA (2012); Batz et al. (2012); Painter et al. (2013)

Table AI. 8. Criteria for hazard identification related to grains and baked goods consumption.

Hazard Identification for grains and bakery products	**References**
Outbreak history related to the product	Thomas et al. (2013)
Food-pathogen pair attribution data	Painter et al. (2013)
Level of complexity associated with the final product	FDA (2013)
Changes in processing steps that might increase risk	
Prevalence rate of microorganisms on product (e.g. coliforms)	
Effect of processing steps (e.g. preparing dough at warm temperatures increases potential of *Staphylococcus aureus* but frying, baking and boiling removes moisture and destroys pathogens)	FDA (2013)
Addition of raw materials as part of ingredients (e.g. eggs, meat and dairy can increase risk of hazards)	FDA (2013)
Final water activity (A_w) of product (this typically ranges from 0.94-0.95)	Hackla et al. (2013)
Addition of ingredients that increase safety (e.g. humectants, preservatives, acids, spices, gums & starches)	
Nature of final product (e.g. dough enrobed in other products – cream-cheese croissant compared to cream-filled éclair)	
Multiple factors related to production (manure, harvesting, processing, drying, equipment, storage, water,	Hackla et al. (2013)
Temperature and time control before and after processing	FDA (2013)

Table AI. 9. Criteria for hazard characterization for all food categories.

Criteria Related to Hazard Characterization	Reference
Estimates of incidence of foodborne illnesses and outbreak history	Thomas et al. (2013); Kozak et al. (2013)
Estimates of burden and severity of food-pathogen pairs using DALYs	Batz et al. (2012)
What are the characteristics of the pathogen that affect its ability to cause disease in a host (e.g. pathogenicity, virulence, infectivity)	WHO (2003)
What are the adverse effects could be associated with the pathogen (endpoint of illness – mild to severe and death)	WHO (2003)
How does the response to environmental stress (pH, heat, desiccation etc.) affect the ability of the pathogen to cause infection and illness	
Who is susceptible to the pathogen or infection?	
Host range of pathogen (zoonotic, virus or parasite)	
Are multiple exposures independent or is a form of immune response likely?	
Possibility of secondary transmission	
Replication (in food conditions)	
Resistance to processing conditions	
Dose-response of pathogen in different populations	
- Age or stage of life	
- Pregnancy and immune-compromised individuals	
- Presence of pre-existing conditions	
Product characteristics and physical conditions that might enhance survival of pathogen	
- rough or smooth surface	
- Parts of the food consumed	
- Water activity, pH, temperature, presence of disinfectants and antimicrobials, refrigerated storage	
Rates or prevalence of contamination by pathogens in product.	
Length of time for disease to show symptoms in humans after consumption	
Length of time for results to be received after diagnostic tests. Are foods held until results are received or shipped prior to obtaining results?	
Methodological approaches available to quantify and identify microorganisms (are there concerns regarding these detection methods)	

Table AI. 10. Infectious doses for biological hazards related to poultry consumption.

Microbial agent	Author and year	Infectious Dose
***Salmonella* spp.**	Ryan & Ray (2004)	10^3 cells
Listeria monocytogenes	FDA (2012a)	1000 cells
***Campylobacter* spp.**	van Vliet & Ketley (2001)	500 cells
Clostridium perfringens	FDA (2012a)	10^6/g vegetative cells or spores
Clostridium botulinum	Foster (1986)	1 ng/kg body weight toxin production
Staphylococcus aureus	Schmid-Hempel & Frank (2007)	100,000 organisms
***Bacillus cereus* emetic form**	Logan & Rodrigez-Diaz (2006)	10^5-10^8 cells
***Bacillus cereus* diarrheal form**	Logan & Rodrigez-Diaz (2006)	10^4-10^9 cells

Table AI. 11. Infectious doses for biological hazards related to pork consumption.

Microbial agent	Author and year	Infectious Dose
Salmonella spp.	Ryan & Ray (2004)	10^3 cells
Listeria monocytogenes	FDA (2012a)	1000 cells
Campylobacter spp.	van Vliet & Ketley (2001)	500 cells
Yersina enterocolitica	Bottone (1999)	10^7cells
Toxoplasma gondii		Unknown
Trichinella spp.[1]	Teunis et al. (2012)	60-750 larvae
Clostridium perfringens	FDA (2012a)	10^6/g vegetative cells or spores
Bacillus cereus diarrheal form	Logan & Rodrigez-Diaz (2006)	10^4-10^9 cells
Bacillus cereus emetic form	Logan & Rodrigez-Diaz (2006)	10^5-10^8 cells
Staphylococcus aureus	Schmid-Hempel & Frank (2007)	100,000 organisms

1. A statistical analysis of disease outbreak data estimated that ingestion of 5 larvae resulted in a mean 1% chance of observable disease symptoms; ingestion of 10 larvae resulted in a 7.5% chance; and ingestion of 100 larvae resulted in a 45% chance.

Table AI. 12. Infectious doses for biological hazards related to beef consumption.

Microbial agent	Author and year	Infectious Dose
***Salmonella* spp.**	Ryan & Ray (2004)	10^3 cells
Verotoxigenic *E. coli* (VTEC) 0157	Ray and Bhunia (2008)	10-100 cells
Listeria monocytogenes	FDA (2012a)	1000 cells
***Campylobacter* spp.**	Van Vliet and Ketley (2001)	500 cells
Clostridium perfringens	FDA (2012a)	10^6/g vegetative cells or spores
Yersina enterocolitica	Bottone (1999)	10^7cells
***Shigella* spp.**	Kurjak& Chervenak (2006)	10-200 organisms
Staphylococcus aureus	FDA (2012a)	10^5
***Bacillus cereus* (diarrheal form)**	Logan & Rodrigez-Diaz (2006)	10^4-10^9 cells
***Bacillus cereus* emetic form**	Logan & Rodrigez-Diaz (2006)	10^5-10^8 cells

Table AI. 13. Infectious doses for biological hazards related to maple and honey product consumption

Microbial agent	Author and year	Infectious Dose
Clostridium perfringens	FDA (2012a)	10^6/g vegetative cells or spores
***Bacillus cereus* diarrheal form**	Logan & Rodrigez-Diaz (2006)	10^4-10^9 cells
***Bacillus cereus* emetic form**	Logan & Rodrigez-Diaz (2006)	10^5-10^8 cells

Table AI. 14. Infectious doses for biological hazards related to egg consumption.

Microbial Agent	Author and Year	Infectious dose
non-typhoidal *Salmonella (Salmonella enterica* subsp. *enterica* serotypes)	Ryan & Ray (2004)	$>10^3$ cells
***S.* Typhimurium**	Bronze & Greenfield (2005)	10^5 cells
***S.* Heidelberg**		
***S.* Enteritidis**		
Norovirus	Teunis et al. (2008)	18 viruses
***Campylobacter* spp.**	van Vliet & Ketley (2001)	500 cells
***Staphylococcus aureus*[1]**	FDA (2012a)	10^5
Listeria monocytogenes	FDA (2012a)	1000 cells

1. Infectious dose for *Staphylococcus enterotoxin is* 0.1 µg (Evenson et al., 1988)

Table AI. 15. Infectious doses for biological hazards related to fruit and vegetable consumption.

Microbial agent	Author and year	Infectious Dose
***Salmonella* spp[1].**	Ryan & Ray (2004)	10^3 cells
Cryptosporidium parvum	Tauxe et al. (1997)	10 oocysts
Norovirus	Teunis et al. (2008)	18 viruses
***E. coli* O157:H7**	Ray & Bhunia (2008)	10-100 cells
Bacillus cereus	Schoeni & Wong (2005)	10^{6-8} cells/g
Listeria monocytogenes	FDA (2012a)	1000 cells
***Campylobacter* spp.**	van Vliet & Ketley (2001)	500 cells
Clostridium perfringens	Heymann (2008)	10^5/g
Clostridium botulinum	Foster (1986)	1 ng/kg body weight toxin production
***Shigella* spp.**	Bean & Griffin (1990)	10 cells
Yersina enterocolitica	Bottone (1999)	10^7cells
Cyclospora	Rose & Slifko (1999)	unknown

1. *Salmonella* 10-20% probability for infection with a dose of 100 organisms and a 60%-80% probability for infection at 1,000,000 organisms.

Table AI. 16. Infectious doses for biological hazards related to aquatic animal consumption.

Microbial agent	Author and year	Infectious Dose
***Salmonella* spp.**	Ryan & Ray (2004)	10^3 cells
Listeria monocytogenes	FDA (2012a)	1000 cells
Clostridium botulinum	Foster (1986)	1 ng/kg body weight toxin production
***Shigella* spp.**	Bean & Griffin (1990)	10 cells
Staphylococcus aureus		
***Staphylococcus* enterotoxin**	Evenson et al. (1988)	0.1 µg[2]
Vibrio vulnificus	FAO/WHO (2005b)	1000 cells[1]
Vibrio parahaemoliticus	Ray & Bhunia (2008)	10^5-10^7 cells (Kanagawa strain)
Vibrio cholera	FDA (2012a)	10^6 cells

1. 10^6 the risk of disease for susceptible people is 1:50,000
2. 100 to 200 ng- highly susceptible populations.

Table AI. 17. Infectious doses for selected toxins related to aquatic animal consumption.

Toxins	Author and year	Infectious Dose
Scomboid	FDA (2011)	$>10^5$ cells
Ciguatoxin	FDA (2011)	$10^{8\text{-}10}$ cells immune-compromised 100 -1000 cells
Maitotoxin	FDA (2011)	1 ng/kg body weight toxin production
Paralytic shellfish poisoning	FDA (2011)	0.8 ppm saxitoxin equivalents
Neurotoxic shellfish poisoning	FDA (2011)	0.8ppm brevetoxin-2 equivalents
Diarrhetic shellfish poisoning	FDA (2011)	0.16 ppm total okadaic acid equivalents
Amnesic shellfish poisoning	FDA (2011)	20 ppm domoic acid

Table AI. 18. Infectious doses for biological hazards related to fats and oils consumption.

Microbial agent	Author and year	Infectious Dose
Salmonella spp.	Ryan & Ray (2004)	10^3 cells
Cryptosporidium parvum	Tauxe et al. (1997)	10 oocysts
Norovirus	Teunis et al. (2008)	18 viruses
E. coli O157:H7	Ray & Bhunia (2008)	10-100 cells
Bacillus cereus	Schoeni & Wong (2005)	10^{6-8} cells/g
Listeria monocytogenes	FDA (2012a)	1000 cells
Clostridium botulinum	Foster (1986)	1 ng/kg body weight toxin production
Yersina enterocolitica	Bottone (1999)	10^7cells
Staphylococcus aureus	FDA (2012a)	10^5

Table AI. 19. Infectious doses for biological hazards related to dairy product consumption.

Microbial agent	Author and year	Infectious Dose
***Salmonella* spp.**	Ryan & Ray (2004)	10^3 cells
Verotoxigenic *E. coli* (VTEC) O157	Ray and Bhunia (2008)	10-100 cells
Listeria monocytogenes	FDA (2012a)	1000 cells
Campylobacter jejuni	van Vliet and Ketley (2001)	500 cells
Clostridium botulinum	Foster (1986)	1 ng/kg body weight toxin production
Staphylococcus aureus	FDA (2012a)	10^5
***Bacillus cereus* diarrheal form**	Logan & Rodrigez-Diaz (2006)	10^4-10^9 cells
***Bacillus cereus* emetic form**	Logan & Rodrigez-Diaz (2006)	10^5-10^8 cells
***Shigella* spp.**	Bean & Griffin (1990)	10 cells
Clostridium perfringens	Heymann (2008)	10^5/g
Yersinia enterocolitica	Bottone (1999)	10^7cells

Table AI. 20. Infectious doses for biological hazards related to grains and baked goods consumption.

Microbial agent	Author and year	Infectious Dose
***Salmonella* spp.**	Ryan & Ray (2004)	10^3 cells
Verotoxigenic *E. coli* (VTEC) 0157	Ray and Bhunia (2008)	10-100 cells
Listeria monocytogenes	FDA (2012a)	1000 cells
***Shigella* spp.**	Kurjak& Chervenak (2006)	10-200 organisms
Staphylococcus aureus	FDA (2012a)	10^5
***Bacillus cereus* (diarrheal form)**	Logan & Rodrigez-Diaz (2006)	10^4-10^9 cells
***Bacillus cereus* (emetic form)**	Logan & Rodrigez-Diaz (2006)	10^5-10^8 cells
Clostridium botulinum	Foster (1986)	1 ng/kg body weight toxin production

Table AI. 21. Criteria for exposure assessment for all food categories.

Criteria Related to Exposure Assessment	References
Matrix characteristics of produce	
How many viable pathogens are initially present in food?	
Dose of microorganisms/toxin per unit of intake (serving) of food	
Amount of food consumed per individual (specifically at-risk populations)	Stats Canada (2009)
Exposure of individuals to food across time (frequency of intake)	Stats Canada (2009)
Is the product consumed raw, cooked or either by consumers?	
Invasiveness, pathogenicity and virulence of pathogen	
Possibility for horizontal transfer of genetic material	
Are there further manipulations by the consumer before consumption	
Differences in consumption between different geographical regions or populations	Consumer groups
Geographical scale of distribution (provincial, inter-provincial and export or import)	CFIA internal data
Is the process a continuous one or batch?	CFIA internal data
What is the form of the release – fomites, spray equipment, waste water and animal slaughter	
Processes by which microorganisms move through different scenarios (using predictive microbiology)	
Morbidity and mortality rates following exposure to hazard	Weekly reports from CDC (Morbidity and mortality weekly)
Recall history associated with the hazard and food product	CFIA
Probability of cross-contamination (from consumers and processors)	Harris et al. (2003)

Appendix II.

Table AII. 1. Risk ranking of food-pathogen combinations for 9 selected pathogens with food categories.

	Criteria for risk ranking						
		Consequence of human disease		Probability of illness			
Pathogen-food combinations	**Burden of illness**	**Strength of associations**	**Incidence of illness**	**Dose response**	**Prevalence of contamination**	**Consumption**	**Results of risk characterization[1]**
***Campylobacter* spp.-poultry**	2	5	4	3	4	3	1440
***Escherichia coli*-beef**	3	4	3	3	4	3	1296
***Salmonella* spp.-poultry**	2	4	4	3	4	3	1152
***Salmonella* spp.-produce**	2	3	4	3	4	4	1152
***Campylobacter* spp.-dairy**	2	5	4	3	2	3	720
***Campylobacter* spp.-beef**	2	3	4	3	3	3	648
***Escherichia coli*-produce**	3	3	3	3	2	4	648
***Salmonella* spp.-eggs**	2	4	4	3	3	2	576
***Salmonella* spp.-beef**	2	2	4	3	3	3	432
***Salmonella* spp.-dairy**	2	3	4	3	2	3	432
***Campylobacter* spp.-pork**	2	2	4	3	4	2	384
***Salmonella* spp.-grains & bakery**	2	2	4	3	2	4	384
***Salmonella* spp.-pork**	2	2	4	3	4	2	384
***Campylobacter* spp.-produce**	2	3	4	3	1	4	288
***Campylobacter* spp.-eggs**	2	2	4	3	3	2	288
***Escherichia coli*-**	3	1	3	3	2	4	216

Criteria for risk ranking							
	Consequence of human disease			Probability of illness			
Pathogen-food combinations	**Burden of illness**	**Strength of associations**	**Incidence of illness**	**Dose response**	**Prevalence of contamination**	**Consumption**	**Results of risk characterization[1]**
grains & bakery							
***Y. enterocolitica*-pork**	2	4	3	1	4	2	192
***Campylobacter* spp.-grains & bakery**	2	1	4	3	2	4	192
***Salmonella* spp.-seafood**	2	1	4	3	4	2	192
***Campylobacter* spp.-other meats**	2	2	4	3	2	2	192
***Salmonella* spp.-other meats**	2	2	4	3	2	2	192
***L. monocytogenes*-grains & bakery**	4	1	1	3	4	4	192
***L. monocytogenes*-produce**	4	1	1	3	4	4	192
***Escherichia coli*-dairy**	3	1	3	3	2	3	162
***L. monocytogenes*-beef**	4	1	1	3	4	3	144
***L. monocytogenes*-dairy**	4	1	1	3	4	3	144
***L. monocytogenes*-poultry**	4	1	1	3	4	3	144
***Shigella* spp.-beef**	2	1	2	3	3	3	108
***Escherichia coli*-eggs**	3	1	3	3	2	2	108
***Escherichia coli*-other meats**	3	1	3	3	2	2	108
***Escherichia coli*-seafood**	3	1	3	3	2	2	108
***Shigella* spp.-grains & bakery**	2	1	2	3	2	4	96
***Shigella* spp.-produce**	2	1	2	3	2	4	96

Criteria for risk ranking							
	Consequence of human disease			Probability of illness			
Pathogen-food combinations	**Burden of illness**	**Strength of associations**	**Incidence of illness**	**Dose response**	**Prevalence of contamination**	**Consumption**	**Results of risk characterization[1]**
***Campylobacter* spp.-seafood**	2	1	4	3	2	2	96
***L. monocytogenes*-eggs**	4	1	1	3	4	2	96
***L. monocytogenes*-other meats**	4	1	1	3	4	2	96
***L. monocytogenes*-pork**	4	1	1	3	4	2	96
***L. monocytogenes*-seafood**	4	1	1	3	4	2	96
***Escherichia coli*-poultry**	3	1	3	3	1	3	81
***B. cereus*-poultry**	1	2	3	1	4	3	72
***Shigella* spp.-dairy**	2	1	2	3	2	3	72
***Shigella* spp.-poultry**	2	1	2	3	2	3	72
***Vibrio* spp.-grains & bakery**	4	1	2	1	2	4	64
***Vibrio* spp.-produce**	4	1	2	1	2	4	64
***Vibrio* spp.-seafood**	4	1	2	1	4	2	64
***Escherichia coli*-pork**	3	1	3	3	1	2	54
***Vibrio* spp.-beef**	4	1	2	1	2	3	48
***Vibrio* spp.-dairy**	4	1	2	1	2	3	48
***Vibrio* spp.-poultry**	4	1	2	1	2	3	48
***B. cereus*-grains & bakery**	1	1	3	1	4	4	48
***B. cereus*-produce**	1	1	3	1	4	4	48
***Y. enterocolitica*-grains & bakery**	2	1	3	1	2	4	48

Criteria for risk ranking							
	Consequence of human disease			Probability of illness			
Pathogen-food combinations	**Burden of illness**	**Strength of associations**	**Incidence of illness**	**Dose response**	**Prevalence of contamination**	**Consumption**	**Results of risk characterization[1]**
***Y. enterocolitica*-produce**	2	1	3	1	2	4	48
***Shigella* spp.-eggs**	2	1	2	3	2	2	48
***Shigella* spp.-other meats**	2	1	2	3	2	2	48
***Shigella* spp.-pork**	2	1	2	3	2	2	48
***Shigella* spp.-seafood**	2	1	2	3	2	2	48
***Y. enterocolitica*-other meats**	2	2	3	1	2	2	48
***B. cereus*-beef**	1	1	3	1	4	3	36
***B. cereus*-dairy**	1	1	3	1	4	3	36
***Y. enterocolitica*-beef**	2	1	3	1	2	3	36
***Y. enterocolitica*-dairy**	2	1	3	1	2	3	36
***Y. enterocolitica*-poultry**	2	1	3	1	2	3	36
***S. aureus*-beef**	1	2	3	1	2	3	36
***Vibrio* spp.-eggs**	4	1	2	1	2	2	32
***Vibrio* spp.-other meats**	4	1	2	1	2	2	32
***Vibrio* spp.-pork**	4	1	2	1	2	2	32
***B. cereus*-eggs**	1	1	3	1	4	2	24
***B. cereus*-other meats**	1	1	3	1	4	2	24
***B. cereus*-pork**	1	1	3	1	4	2	24
***B. cereus*-seafood**	1	1	3	1	4	2	24
***S. aureus*-grains & bakery**	1	1	3	1	2	4	24
***S. aureus*-produce**	1	1	3	1	2	4	24

Criteria for risk ranking							
	Consequence of human disease			Probability of illness			
Pathogen-food combinations	**Burden of illness**	**Strength of associations**	**Incidence of illness**	**Dose response**	**Prevalence of contamination**	**Consumption**	**Results of risk characterization[1]**
***Y. enterocolitica*-eggs**	2	1	3	1	2	2	24
***Y. enterocolitica*-seafood**	2	1	3	1	2	2	24
***S. aureus*-pork**	1	2	3	1	2	2	24
***S. aureus*-dairy**	1	1	3	1	2	3	18
***S. aureus*-poultry**	1	1	3	1	2	3	18
***S. aureus*-eggs**	1	1	3	1	2	2	12
***S. aureus*-other meats**	1	1	3	1	2	2	12

1. A higher score represents a larger/greater relative food safety risk.