Listeria monocytogenes and Ready-to-Eat Meats: Tackling a Wicked Problem using Grounded Theory

by

Steven Rebellato

A thesis
presented to the University of Waterloo
in fulfillment of the
thesis requirement for the degree of
Doctor of Philosophy
in
Health Studies and Gerontology

Waterloo, Ontario, Canada, 2012

AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

ABSTRACT

Background: *Listeria monocytogenes* and ready-to-eat meats have garnered considerable attention in Canada over the past decade as a result of foodborne outbreaks and product recalls that continue to transpire. A number of factors suggest that ready-to-eat meats and *Listeria monocytogenes* are a wicked problem. They include (among others) the number of stakeholders involved in the processing, distribution and inspection of ready-to-eat meats in Ontario, the ubiquitous and hardy nature of the organism and the challenges associated with eliminating it from ready-to-eat meat products and processing environments. Since Ontario public health units play an integral part in the inspection of ready-to-eat meats in the province, it is important to determine their current role in the wicked problem in order to identify possible solutions for change.

Purpose: The purposes of the study were: (1) to determine how Ontario public health units address the wicked problem of *Listeria monocytogenes* and ready-to-eat meats in their food safety inspection programs using the provincial regulatory framework in addition to the use of research, knowledge translation and innovation; and (2) to develop a theory that identifies gaps (if any) in public health unit inspection practices, provincial legislation or food safety research that serves to generate recommendations to reduce incidence of listeriosis resulting from consumption of RTE meat products.

Methodology: The research design used the principles of grounded theory to lead the interview and survey methodology and subsequent data analyses. The study was completed in three phases. Interviews were conducted in the first 2 phases of the study while a survey was conducted in the last phase. Interviews were conducted with public health unit 'food safety leads' that met pre-determined eligibility criteria. Following methods used in previous studies,

interview data were analyzed in 4 stages of theory development using a grounded theory approach. Through substantive coding and constant comparative methods, core categories were identified in each of the study phases. As a result, theoretical saturation was reached leading to the process of theoretical coding and the emergence of the study theory.

Results: In total, 27 public health units of 36 participated in the study. Eleven public health units participated in the first 2 phases of the interviews while 25 public health units (for a total of 45 participants) participated in the survey. The study core category, *reactive and regulatory practice* evolved from the results of the interviews and survey. As a result, it was determined that: (1) the Ontario provincial regulatory framework including the *Food Premises Regulation* is almost exclusively responsible for directing food safety inspection practices in food premises; (2) food safety inspection and investigation activities associated with listeriosis outbreaks are the focus of *Listeria monocytogenes* and ready-to-eat meat research; and (3) innovation and knowledge translation are not currently influenced by inspection practice as a result of the food safety framework which does not require or encourage it. Using the processes of theoretical integration and theoretical coding, the following theory emerged from the data analyses; *Ontario public health units manage ready-to-eat meats and Listeria monocytogenes through general population and reactive regulatory processes that focus on local-level, end-product, hazard reduction strategies for established risks in inspected food premises*.

Strengths and Limitations: The study had several strengths including being the first of its kind to associate ready-to-eat meats and *Listeria monocytogenes* as a part of a wicked problem. It was also the first study to use grounded theory to illuminate the function and role of Ontario public health units in managing *Listeria monocytogenes* and ready-to-eat meats. There are a number of limitations to the study including the study sample size, participant inclusion process

through provincial public health unit senior management, the generalizability of study results, and method of interviews conducted with participants.

Implications: The results of the study have implications for public health researchers and policy/regulatory makers in the province of Ontario. It stresses improved management of *Listeria monocytogenes* and ready-to-eat meats in food premises using a proactive approach.

Conclusions: Using a grounded theory approach, this study demonstrated that Ontario public health units manage ready-to-eat meats and *Listeria monocytogenes* through reactive and regulatory food safety inspection practices. Survey and interview results indicate that study participants aspire for evidence-based regulatory and program amendments that will allow for proactive and targeted microbial risk-reduction activities at the local level that focus on vulnerable populations. The study substantiates that amendments to the Ontario Food Safety program and in particular, the *Food Premises Regulation* are necessary.

ACKNOWLEDGEMENTS

I would like to thank my program supervisors including Dr. Stephen McColl and Dr. Phil Bigelow. Thank you for your guidance in navigating me through my research. In particular, thank you for your patience in taking me on as a graduate student and supporting me through this journey. I would also like to acknowledge and thank my committee members including Dr. Sharon Campbell and Dr. Shannon Majowicz. I am sincerely grateful for your support and tutelage in guiding my research. I would also like to express my gratitude to Dr. Jan Sargeant for being a part of my committee along with Dr. Robin Duncan.

I would like to acknowledge the Association for Supervisors of Public Health Inspector of Ontario (ASPHIO) and the Canadian Institute of Public Health Inspectors (CIPHI) for their support of my research. In particular, thanks to Christopher Munn as President of ASPHIO in connecting me with public health units across the province. I am particularly grateful to all public health units that willingly provided their time in completing the survey and interviews. Special thanks to the public health inspectors, managers, directors and Medical Officers of Health who graciously supported and participated in the study.

Thanks to Vahe Kehyayan and Andrew Costa for their assistance, encouragement and friendship throughout my years at the University. In particular, special thanks to Vahe for assisting me through the hurdles of doctoral research. I would also like to acknowledge Jeffrey Tong for his diligence in assisting with the analyses of research as a member of the research team. In addition, a special thank you to Tracy Taves for her assistance throughout my years in the program.

Special thanks to my mother and father for instilling in me the dedication and work ethic that is required to be successful in doctoral research. I would also like to thank my mother and father in-law for their support and encouragement throughout my time at the University of Waterloo.

DEDICATION

I dedicate this research to my wife, Sara-Jane, for her patience, love, and support in completing this research. Thank you for being the only motivation I will ever need to succeed and continue to improve myself. I will be forever grateful to you for seeing me through this time in my life when I needed your encouragement to persevere.

I also dedicate this study to my children, Brigitte and Bianca for being patient with their father when he was in front of the computer when he should have been with you on the playground.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1.0 Introduction

There has been a substantial increase in attention to the importance of food safety in Canada as population demographics evolve and food choices broaden. Consequently, research examining emerging pathogen-food combinations has increased (Farber, Kozak, & Duquette, 2011; Luber et al., 2011; Ruzante et al., 2010a; Todd, Greig, Bartleson, & Michaels, 2007). A pathogen-food combination that has garnered considerable attention in Canada over the past decade is *Listeria monocytogenes* (L. *monocytogenes*) and ready-to-eat (RTE) meats as a result of foodborne outbreaks and product recalls that continue to transpire (Batz, Hoffmann, & Morris, 2011). L. *monocytogenes* is a bacterium that occurs both in natural and anthropogenic environments including food processing settings. Ingestion of L. *monocytogenes* occurs mainly in food and can cause "listeriosis, which can be a serious human illness" (United States Food and Drug Administration [USDA], 2003, p. 5). Symptoms range from mild gastrointestinal effects such as vomiting and diarrhea to more serious health complications including nervous system problems and miscarriage in pregnant women. L. *monocytogenes* most often affects those who are immunocompromised, those with chronic conditions such as cancer and diabetes, children, and "pregnant women (including) unborn or newly delivered infants" (World Health Organization [WHO], 2004, P. 25).

Despite efforts to control its impact in food processing and preparation settings, research suggests that L. *monocytogenes* in RTE meats ranks as the "pathogen-food pair with the third highest disease burden" (Batz, Hoffmann, & Morris, 2011, p. 13) and remains a concern at the retail level where RTE meats are further processed through various means including slicing from larger cuts of meat (Gombas, Chen, Clavero, & Scott, 2003). Furthermore, Health Canada suggests that "Canadians are consuming foods contaminated with L. *monocytogenes* on a regular

basis" (Health Canada, 2011, p. 7) due to its ubiquitous nature in the food supply. Efforts to control for L. *monocytogenes* are required at all points in the farm-to-fork continuum as described by the Honourable Roland J. Haines who authored the 2004 report entitled 'Farm to Fork: a Strategy for Meat Safety in Ontario' (Haines, 2004). However, meat processing in the province of Ontario is a complex process. It involves a number of federal, provincial and local level government organizations with diverse regulatory requirements and responsibilities. It also involves a process where raw materials (e.g. animal carcasses) introduce foodborne pathogens including L. *monocytogenes* into the processing environment with no clear solutions to eliminating it from RTE products. As a result, the association between RTE meats and L. *monocytogenes* is a 'wicked problem' as described by Head and Alford (2008) and Kreuter et al., (2004).

Identifying risks associated with RTE meats is important to Ontario provincial public health units (from hereon in referred to as 'public health units') since they are principally involved with inspection in food premises. *Food premises,* as defined in RSO 1990, Health Protection and Promotion Act are locations where foods (including RTE meats) are "manufactured, processed, prepared, stored, handled, displayed, distributed, transported, sold or offered for sale" (sec. 1(1)) . However, despite the definition of food premises in the *Food Premises Regulation,* public health units and appointed public health inspectors are not involved with the inspection of provincially and federally licensed RTE meat processing plants as a result of a memorandum of understanding (MOU) with the Ontario Ministry of Agriculture and Food (OMAFRA) and the Canadian Food Inspection Agency (CFIA). As a result, public health units (through public health inspectors) inspect RTE meats in retail or food institutional (e.g. long term care facilities) settings where products are either pre-packaged or further processed (e.g. via

slicing) prior to sale or service. Thus, public health inspectors remain the last line of inspection and investigation for retailed RTE meat products including following up with incidence of listeriosis and participating in large-scale recalls involving RTE meats. Therefore, their role remains an integral part of the food safety continuum. As a result, an examination of the role of public health unit roles in addressing L. *monocytogenes* and RTE meats in food premises may substantially benefit the public health community.

1.1 Search Strategy – Listeria Monocytogenes and RTE Meats

The following databases were accessed prior to facilitation of the study methodology (see Section 3.0): MEDLINE (PubMed, CSA Illumina Version, OVID version), CSA Illumina, along with specialized databases including Ageline, Cochrane database, CINAHL, and Scopus. The following keywords were searched in the databases to locate research related to L. *monocytogenes* and RTE foods: '*Listeria monocytogenes*', OR '*Listeria*' OR '*Listeriosis*' AND 'ready-to-eat food', OR 'deli meat' OR 'processed food' OR 'food'. The databases were accessed using the following terms for research related to foodborne illness in relation to L. *monocytogenes*: 'Listeria', OR '*Listeria monocytogenes*' OR '*Listeriosis*' AND 'food illness' OR 'foodborne illness' OR 'illness'. The databases were accessed using the following terms for research related to L. *monocytogenes* and risk assessment: 'Listeria', OR '*Listeria monocytogenes*' AND 'risk' OR 'risk assessment'. The databases were accessed using the following terms for research related to L. *monocytogenes* and RTE meats and inspection: 'Listeria', OR '*Listeria monocytogenes*' OR '*Listeriosis*' AND 'ready-to-eat food', OR 'deli meat' OR 'processed food' OR 'food', AND 'inspection' OR 'audit' OR 'HACCP'. All terms were also used interchangeably and in combination with one another so as to increase search results.

The MeSH Database (through PubMed) was accessed using the following MeSH terms for research related to *Listeria monocytogenes*, RTE meat and risk assessment: 'Listeria'[Mesh], 'food preservation'[Mesh], 'risk assessment'[Mesh], 'food inspection'[Mesh], 'food safety'[Mesh], and 'meat'[Mesh]. The terms were used interchangeably and in combination with one another so as to increase search results. In addition to examination of those articles which were retrieved from literature searches from research databases, reference lists were reviewed in order to recover additional literature on the subject area of L. *monocytogenes*, RTE meats and inspection. Furthermore, a number of documents pertaining to food premises risk assessment were obtained through web-site retrieval at relevant agency websites including the Ontario Ministry of Health and Long Term Care (MOHLTC), OMAFRA, Public Health Ontario (PHO) and the CFIA.

Several studies were retrieved where abstracts were written and accessed in English, but full-text was unavailable or written in another language. Numerous attempts were made through various databases searched along with the Trellis inter-library access program through RACER at the University of Waterloo. If articles were not accessible in full-text English, they were excluded from the analyses. Searches were conducted from January, 2011 to December, 2011. Search results yielded 167 articles using the criteria mentioned in the search strategies for identification of studies relating to L. *monocytogenes* and RTE foods. Articles were included or excluded only after assessing the article abstract to determine appropriateness.

1.2 Purpose

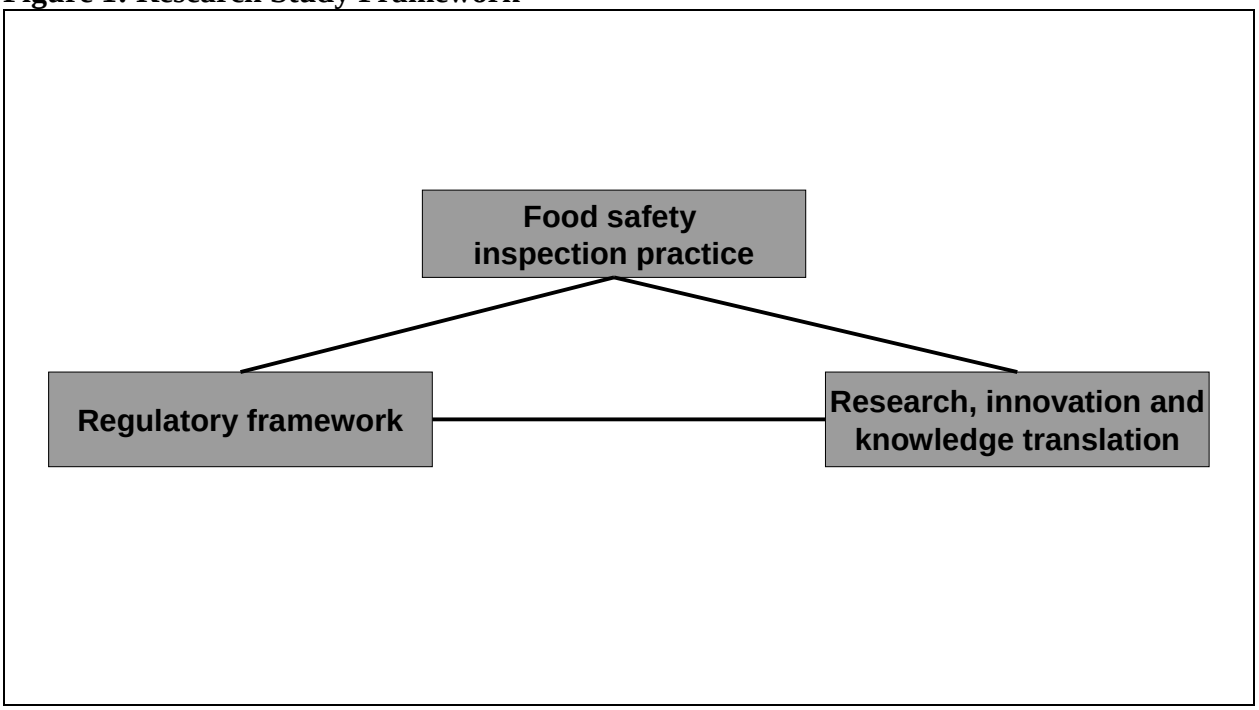
The purpose of the study is twofold:

(i) To determine how public health units manage L. *monocytogenes* and RTE meats in their food safety inspection programs using the provincial regulatory

framework in addition to the use of research, knowledge translation and innovation (see Figure 1); and

(ii) Using grounded theory methods, develop a theory that identifies gaps (if any) in public health unit inspection practice, provincial legislation or food safety research that serves to generate recommendations to reduce incidence of listeriosis resulting from consumption of RTE meat products.

Figure 1: Research Study Framework



1.3 Central Research Question

As a result of the study purpose, the central research question for the study is:

D*o Ontario public health unit inspection practices and food safety regulation use research, innovation and knowledge translation through experience to effectively address RTE meats in food premises and reduce the burden of listeriosis?*

Accordingly, the following research questions are proposed for this study.

1.3.1 Research Question 1

What is the current state of food safety research, knowledge translation and innovation related to L. *monocytogenes* and RTE meats and to what extent do public health units and provincial food safety standards incorporate these tenants into their food safety policies and inspection practices?

1.3.2 Research Question 2

To what extent do public health units view current food safety inspection programming examining RTE meats and L. *monocytogenes* as a 'wicked problem'?

1.3.3 Research Question 3

According to public health units, what additional or innovative components (if any) are required in RTE meat and L. *monocytogenes* research, policy and practice to reduce foodborne illness and to develop a comprehensive inspection program?

1.4 Benefits and Rationale

There are several benefits to this study. First, it explores RTE meats and L. *monocytogenes* in the context of a wicked problem. This is beneficial since defining the association between RTE meats and L. *monocytogenes* as a wicked problem allows qualitative methods (such as grounded theory) to begin the process of solution identification. Second, the study assists in determining the extent of research utilization occurring in public health units in both inspection practice and policy. Determining if research is being used for the purposes of inspection practice and food safety policy allows for the wicked problem to be addressed by a number of stakeholders including public health units (through practice), the MOHLTC and PHO

(through policy). It also assists in determining how the RTE meat and L. *monocytogenes* research framework functions (see Figure 1) and particularly, how inspection processes, regulation, and research interact with one another (if at all). Third, the study provides directions for future research in the field of L. *monocytogenes* and RTE foods given that the methodology for the study can be used by other stakeholders within their own organization for the same wicked problem. Lastly, the public may benefit from improved regulations given that public health inspectors may be able to perform their job more effectively and consequently reduce pathogen loading (e.g., L. *monocytogenes*) in foods (e.g., RTE meats).

As described in Figure 1, the study attempts to determine how policy, practice and research, innovation and knowledge translation interact in regards to RTE meats and L. *monocytogenes*. The study will benefit the MOHLTC and PHO to advance food safety inspection systems and future regulatory amendments to the *Food Premises Regulation*.

2.0 Listeria Monocytogenes and Ready-to-Eat Meats

RTE meats includes products such as ham, bacon, sausages, salamis, hot dogs, pate and delicatessen specialities (among others). According to the CFIA (2011b), RTE meats are defined as:

> Meat products that have been subjected to a process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and control spores of foodborne pathogenic bacteria so that the meat product does not require further preparation before consumption except washing, thawing or exposing the product to sufficient heat to warm the product without cooking it (para. 4).

L. *monocytogenes* presents a particular concern for RTE foods, including RTE meats for a number of reasons. First, L. *monocytogenes* is a "tenacious colonizer that favours moist, cool environments, such as food processing plants making eradication difficult" (Gottlieb et al., 2006, p. 5). The "psychrotrophic nature of the pathogen allows it to proliferate in foods and persist in the processing environment, making it a difficult pathogen to control" (Isonhood, Drake, & Jaykus, 2006, p. 1). Second, "although it is easily killed by cooking, L. *monocytogenes* multiplies readily at refrigeration temperatures" (Gottlieb et al., 2006, p. 5) at which RTE meats are normally stored when sold in food premises and when stored at home. Third, "it is more resistant than most foodborne pathogens to the treatments and conditions generally used to control microorganisms in food processing environments" (USDA, 2003, p. 6). The characteristics of L. *monocytogenes* allow it to "proliferate in foods and persist in the processing plant environment making it a difficult pathogen to control" (Isonhood et al., 2006, p. 1). Furthermore, its "persistence in biofilms" (Luber et al., 2011, p. 1536) in food processing environments is what usually leads to food "becoming contaminated with high levels of L.

monocytogenes" (Luber et al., 2011, p. 1536). For example, mechanical processing devices such as slicers and grinders can contribute to cross contamination as a result of inadequately cleaned and sanitized food contact surfaces. In addition, mechanical equipment usually requires disassembly in order to ensure that microorganisms are eliminated from surfaces which may contaminate food products.

RTE meat production is an important industry in Canada considering that "national consumption patterns of RTE meat in Canada is estimated at 912/g/person/year based on 5% of consumers eating approximately 50g daily" (WHO, 2004, p. 251). Canadians spend about 6% of their total retail food expenditures on RTE meats (Ruzante et al., 2010b). RTE "meat processors represent the largest sector of Canada's food processing industry, accounting for 10% of Canada's agri-food shipments and employing more than 63,000 Canadians" (Weatherhill, 2009, p. 14). RTE meat sales in Canada were slightly less than 978 million dollars in 2007 while the total value of the retail RTE meat industry is over 3 billion dollars (Ruzante et al., 2010b). RTE meats make up an important part of the Canadian meat industry. For example, 65% of Canadian wholesale pork and 25% of beef is used for the production of RTE meats (Ruzante et al., 2010b).

According to research, "the most important factors driving an increase in the burden of foodborne disease over the next few decades will be a significant increase in the consumption of certain high value commodities such as meat and poultry" (Quested, Cook, Gorris, & Cole, 2010, p. 29). Understanding the scope of the problem of listeriosis in Canada resulting from ingestion of RTE meats is difficult since a number of cases likely go unreported. In fact, research suggests that "the incidence of L. *monocytogenes* in RTE foods ranges from 0 to 10%" (Health Canada, 2011, p. 7). While incidence numbers may not appear to be significant, listeriosis is an on-going economic burden in Canada. For example, research by Ruzante et al. (2010b) put the cost-of-

illness (COI) associated with L. *monocytogenes* and RTE meats at 28.0 million dollars annually in Canada while disability-adjusted life years (DALY) at 178 years (Ruzante et al., 2010b). The COI and DALY figures for the study were calculated as an annual average over 3 years based on notifiable disease data from 2001 – 2003. The same research cited that 50.6% of listeriosis infections in Canada occurring from 1994 to 2003 were a result of RTE meats (Ruzante et al., 2010b). Furthermore, only 5% of disease incidence data collected represented non-invasive listeriosis infection while 95% represented invasive listeriosis with a case fatality rate of 25.23% (Ruzante et al., 2010b). In Canada, only "invasive infections (are reported) who are typically hospitalized" (Luber et al., 2011, p. 1537). However, Luber et al. (2011) suggest that "the milder cases, the non-invasive form of febrile gastroenteritis of listeriosis remains underreported" (p. 1537). Furthermore, "invasive listeriosis are cases (where) initial infections of the intestinal tissue by L. *monocytogenes* leads to 'invasion' of otherwise sterile body sites, such as the pregnant uterus, the central nervous system, the blood, or multiple organisms" (WHO, 2004, p. 1). Non-invasive listeriosis has been observed in a number of outbreaks internationally and in Canada (Clark et al., 2010) "where the majority of cases developed symptoms of gastroenteritis, such as diarrhea, fever, headache, and myalgia after a short period of time" (WHO, 2004, p. 25).

Despite surveillance statistics demonstrating that foodborne illness continues to plague the health care system, assessing the total number of individuals afflicted by illness poses a challenge for epidemiologists given that data on the extent of the problem are incomplete (Buzby & Roberts, 2009; Thomas, Majowicz, Pollari, & Sockett, 2008; Thomas et al., 2006). In particular, estimating the number of foodborne illness cases that do not require health care assistance is an on-going epidemiological challenge. Nonetheless, efforts for improving accuracy of foodborne illness incidence continues given that "most countries with systems for

reporting foodborne disease have documented significant increases" (Griffith, 2010, p. 416) citing actual and predicted cases based on population and age demographics. For example, Majowicz et al. (2007) found that "children under 10 years had the highest risk of acute gastrointestinal illness in Canada, followed by young adults aged 20 to 24 years old" (p. 1). Meanwhile, Thomas et al. (2006) found that "the average duration of illness resulting from acute gastrointestinal illness was 3.7 days" (Thomas et al., 2006, p. 1). Regardless of the approach, it is recognized that there are a number of factors involved in increasing worldwide cases of foodborne illness including improved reporting and diagnoses while research suggests that some of the increase is likely due to "poor food practice" (Griffith, Livesay, & Clayton, 2010, p. 451). For example, Health Canada has reported that a majority of Canadian foodborne illness "can be attributed to microbiological agents that can be traced back to poor food handling practices in the home" (Jacob & Powell, 2009, p. 1121). This trend is concerning in regards to RTE meats and L. *monocytogenes* when considering:

(i) RTE meats are permitted to be sold with L. *monocytogenes* whereby levels do not "exceed 100 CFU/g throughout the stated shelf life" (Health Canada, 2011, p. 8); and

(ii) An increasing movement towards processed foods such as RTE meats which require little intervention (e.g., cooking) from consumers and can be consumed directly from packaging.

This has resulted in the focus of recent studies on retail food processing environments and the safety associated with RTE food products for consumers (Govindaraju, Bebbington, & Wrathall, 2010; Griffith, Livesey, & Clayton, 2010; Lin et al., 2006; Morris, 2003; Newell et al., 2010; Pham, Jones, Sargeant, Marshall, & Dewey, 2010). Despite the pervasiveness of L.

monocytogenes in RTE meats, there are a number of hypotheses associated with its reported low incidence rate in comparison to other foodborne illnesses (e.g. salmonellosis) (Aureli et al., 2000; Gombas et al., 2003). These include;

(i) A small percentage of the population are "sensitive to L. *monocytogenes"* (Gombas et al., 2003, p. 559) including the immunocompromised and "exposure to high levels of L. *monocytogenes* (can cause) listeriosis" (Gombas et al., 2003, p. 559);

(ii) "Only certain subtypes of L. *monocytogenes* cause listeriosis" (Gombas et al., 2003, p. 559)*;*

(iii) "Symptoms can develop at any time from 2 to 70 days after eating contaminated food" (Bortolussi, 2008, p. 796)

(iv) There are a number of similarities in symptomatology of listeriosis to other foodborne illnesses;

(v) The mild nature of non-invasive listeriosis allows healthy individuals to recover quickly thus unlikely to report symptoms (if any) to physicians; and

(vi) There is a lack of testing facilities in the country to isolate the L. *monocytogenes* (Ontario samples are submitted to a federal laboratory for enumeration testing).

According to Health Canada (2011), "a definitive dose-response model for L. *monocytogenes* in humans has yet to be established" (p. 8). As a result, Health Canada's Policy on Listeria monocytogenes in Ready-to-Eat Foods (2011) suggests that a "lower priority with regards to industry verification and control…. should be placed on products in which the organism cannot grow, or, has the limited potential for growth whereby the levels do not exceed the 100 CFU/g limit throughout the stated shelf life" (Health Canada, 2011, p. 8). From limited outbreak data available in research, "exposures to L. *monocytogenes* seldom lead to listeriosis,

even among highly susceptible segments of the population" (USDA, 2003, p. 7). However, research findings suggest that "L. *monocytogenes* strains vary widely in virulence and confirm that large outbreaks can occur even when low levels of contamination are detected in sample foods" (Mead et al., 2006, p. 744). Consumption of contaminated RTE foods by vulnerable populations such as the elderly, infants, children and pregnant women is associated with a number of increased health risks including gastroenteritidis, meningitis and septicaemia. This is particularly concerning for the elderly. For example, "Canadian data shows that compared to healthy individuals aged 40-59, persons 65-69 years old have a 4-fold increased risk, while those 75-79 years of age have nearly a 9-fold increased risk of contracting listeriosis" (Luber et al., 2011, p. 1539).

Research suggests that "regulators are naturally conservative in their approach to food safety and, as many foods could on occasion become contaminated with L. *monocytogenes*, there is a natural inclination to consider that L. *monocytogenes* management should be universal" (Luber et al., 2011, p. 1537). Nevertheless, "without a focus on a country's specific high-risk foods and its high-risk consumers, the effectiveness of any control system is diluted" (Luber et al., 2011, p. 1537). As the Canadian and the global populations age, vulnerable populations such as the elderly have "an increased probability of developing debilitating chronic conditions (by) coming into contact with (L. *monocytogenes*) through food" (Luber et al., 2011, p. 1539) and subsequently have a greater probability of acquiring listeriosis. For example, in years 2000 and 2002, "a listeriosis outbreak associated with consumption of RTE turkey meat in the United States resulted in a combined 76 cases with eleven deaths, and 6 fetal miscarriages/stillbirths" (Peterson, Faith, & Czuprynski, 2008, p.112). As a result, the U.S Department of Agriculture (USDA) recommended that "elderly persons should avoid RTE meats (e.g., luncheon meats and

hot dogs) unless they were heated until steaming" or above 71 degrees Celsius (Nelson et al., 2008, p. 366). However, in spite of the USDA recommendations, a *FoodNet* survey of food use and practices in long-term care facilities in the United States found that most facilities served RTE meats at least once a week and products "were often not heated as prescribed" (Nelson et al., 2008, p. 6).

While the practices and policies used to reduce the incidence of L. *monocytogenes* and other foodborne pathogens are well described in programs such as *Hazard Analysis Critical Control Point* (HACCP), L. *monocytogenes* continues to be a challenge in the food industry. It is known that prevalence of L. *monocytogenes* in RTE meat products "is (most often) related to post-contamination after the cooking process" (Uyttendaele et al., 2009, p. 101). As a result, recalls involving RTE meats and L. *monocytogenes* continue to occur. For example, from 2008-2011, 470 individual RTE meat products were recalled by CFIA due to higher than acceptable levels of L. *monocytogenes* (see Table 1). The recall process is initiated federally through CFIA. However, in certain circumstances, public health units are invited to assist in recall activities to conduct 'effectiveness checks', to ensure that the product is not sold or distributed to the public.

Table 1: Ready-to-Eat Meat Products Recalled for *Listeria Monocytogenes* by the Canadian Food Inspection Agency

Year	Number of product recalls due to higher than acceptable levels of L. *monocytogenes*
2008	267
2009	51
2010	98
2011	54

Note. From "Food Recalls and Allergy Alerts," by Canadian Food Inspection Agency, 2012d, retrieved from http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recalls-and-allergy-alerts/eng/1299076382077/1299076493846

Recall statistics are not only alarming to the public, but also to retailers that purchase and, in many cases further process RTE meats. RTE meat contamination with L. *monocytogenes* is of particular concern since the perception is that the nature of these products (e.g., high salt content)

allows food to be "stored for longer periods of time at refrigerated temperatures which favours the growth of Listeria" (Bortolussi, 2008, p. 795). Unlike poultry products where the public tolerates a loading of *Salmonella spp*. and *Campylobacter spp*. since they can control for it (e.g., through cooking or methods to reduce cross-contamination), retail operators and the public may be unaware that the products they consume are contaminated with L. *monocytogenes.* This is likely since "consumers do not habitually read labels and are unaware of shelf lives and preparation requirements" (Havelaar et al., 2010, p. S84). For example, public survey research from 2006 in the United States suggested that "less than half of 1696 people surveyed were aware of L. *monocytogenes* or its vehicles while most stored RTE meats past the recommended packaging date" (Cates et al., 2006, p. 1630). Furthermore, according to Dufour (2011),

> The USDA predicted that 83% of illness and deaths from L. *monocytogenes* arising from deli meat consumption is attributed to deli meat sliced at retail facilities; this is because of increased handling by food preparers and improper storage of the product (p. 1492).

Microbiological and risk assessment research examining RTE meats and L. *monocytogenes* would suggest that the unique growth (e.g. in refrigeration temperatures) and processing characteristics (e.g. being ubiquitous in the environment) requires a heightened degree of attention at all levels from processing to sale (Farber, Ross, & Harwig, 1996; Norrung, 2000; Pradhan et al., 2009; Rocourt, BenEmbarek, Toyofuku, & Schlundt, 2003; Sheen & Hwang, 2008; USDA, 2008; WHO, 2004). Research suggests that food operators at the food premises level "may not fully understand the unique characteristics of L. *monocytogenes* and might assume that strategies aimed at controlling other pathogens may be equally applicable" (Crerar, Castle, Hassel, & Schumacher, 2011, p. 1511). For example, L. *monocytogenes* has the ability to grow in legislated (e.g. *Food Premises Regulation*) refrigeration storage temperatures and can

"persist in niches in the processing environment" (Crerar et al., 2011, p. 1511). As a result, food premises (as defined by the *Food Premises Regulation*) play "an important role in the contamination of foods with L. *monocytogenes* and interventions targeted at retail venues may help reduce sporadic infection" (Luber et al., 2011, p. 1537).

2.1 The Public Health Significance of Listeria Monocytogenes in Canada

According to Weatherhill (2009), "there has been a steady increase in listeriosis cases in Canada in recent years" (p. viii). Since 2005, "the number of cases of listeriosis reported annually has doubled" (Weatherhill, 2009, p. 63). The number of people who became seriously ill with listeriosis has been increasing steadily from 85 cases in 2003 to an estimated 239 cases in 2008. Research suggests that the "consumption of contaminated food is the major cause of listeriosis in Canada, and the number of reported listeriosis cases per million population between 2001 and 2007 were 2.7, 2.9, 3.4, 3.0, 3.3, 3.9, and 4.2 respectively" (Farber et al., 2011, p. 1506). In comparison, countries with similar "surveillance programs have reported rates of listeriosis infection from 0.6 to 6.2 cases per million with countries having active surveillance programs reporting the highest incidence" (Bortolussi, 2008, p. 796). From "2000 (to 2009), listeriosis was not a notifiable illness in Canada" (Farber et al., 2011, p. 1506) until after the outbreak of RTE meats in 2008 where it became notifiable once again. Bortolussi (2008) noted that while "case-fatality rates vary from country to country…the highest mortality is among newborns with infection acquired from their mothers (25%-50%) (while) mortality among those over 60 years of age is also high (10% - 20%)" (Bortolussi, 2008, p. 796). Attribution of foodborne illness and listeriosis continues to challenge public health agencies in Canada for a number of reasons. These include "inconsistencies in the traditional methods of gathering

outbreak data, lack of tracking of sporadic cases and challenges associated with conducting laboratory analysis on suspect food" (Luber et al., 2011, p. 1540). For example, the *Chief Medical Officer of Health's Report on the Management of the 2008 Listeriosis Outbreak in Ontario* (2009) indicated the source of listeriosis outbreaks is "particularly difficult to identify" (p. 4). In particular, human listeriosis samples including culture and molecular sampling takes 14 to 17 days while food samples typically take 14 to 15 days (Williams, 2009, p. 4). Culture and molecular identification of human and food samples assists investigators in confirming linkage of cases regardless of location. This time lapse in sampling results complicates investigations in particular to determining the source of illness. Research suggests that "accurate food-source attribution is vital to the establishment of a comprehensive food surveillance program, as well as better identification, control, prevention and response to foodborne disease outbreaks, including foodborne listeriosis" (Luber et al., 2011, p. 1540).

2.2 Ready-to-Eat Meats, Listeria Monocytogenes and Outbreak Research

The nature of L. *monocytogenes* "and the wide range in incubation periods between consumption of contaminated food and onset of (listeriosis) means that investigations to identify specific food vehicles are problematic" (Shetty et al., 2009, p. 333). Studies identify that outbreaks associated with L. *monocytogenes* and RTE meat processing were a result of a number of variables in relation to a general sanitation and time-temperature abuse of foods (Frye et al., 2002). It has also been identified that "an event which leads to some environmental change, such as construction in a plant, may subsequently result in the contamination of the food product" (Olsen et al., 2005, p. 965). For example, a large listeriosis outbreak of contaminated meat in the United States in 1998 affecting 24 people found that "a large refrigeration unit in the frankfurter

hopper room was cut into pieces with a chain saw and removed as a part of an equipment upgrade" (Mead et al., 2006, p. 748) which likely dispersed L. *monocytogenes* in the processing environment causing the outbreak.

According to Graves et al. (2005), "of the six species in the genus Listeria, only L. *monocytogenes* is almost exclusively associated with human disease" (p. 2350). Genetic mapping has assisted in determining that L. *monocytogenes* "strains may differ widely in virulence" (Mead et al., 2006, p. 749). Microbiological testing has demonstrated through various mechanisms using Listeria phages (listeriaphage) that specific strains of L. *monocytogenes* are better adapted to processing plant environments, "where relatively low temperatures prevail" (Kim & Kathariou, 2009, p. 2433). This information is valuable in determining the "potential of these organisms to contaminate food and become implicated in illness, including outbreaks since relatively low temperatures prevail in the processing environment as well as in cold-stored foods" (Kim & Kathariou, 2009, p. 2437).

Perhaps one of the more significant examples of RTE meat and listeriosis occurred in Canada in 2008, where a number of products were recalled from Maple Leaf Foods for L. *monocytogenes*. By the end of the 2008 outbreak, "57 cases of listeriosis were confirmed and L. *monocytogenes* was reported as the underlying or contributing cause of death for (23) individuals" (Weatherhill, 2009, p. 8). As a result, key conclusions (see Table 2) resulting from the outbreak were outlined by Weatherhill (2009) which addressed a number of the challenges associated with L. *monocytogenes* and RTE meat products that were previously documented in outbreak research (Aureli et al., 2000; Cairns & Payne, 2009; Centers for Disease Control and Prevention [CDC], 1999; CDC, 2002; Frye et al., 2002; Gottlieb et al., 2006; Graves et al., 2005; Kathariou et al., 2006; Koch, J., Stark, K, 2006; Mead et al., 2006; Meldrum & Smith, 2007;

Olsen et al., 2005; OzFoodNet Working Group, 2007; Stone & Shoenberger, 2001; Vaillant et al., 2005; Varma et al., 2007; Voelker, 2002)..

Table 2: 2008 Maple Leaf Foods Outbreak Investigation - Key Conclusions

Conclusion headings	Descriptions*
Product composition and packaging	1. The processing plant had created a recipe that uses less sodium, which was attractive to the institutional market due to reduced-sodium diets which increase the potential for L. *monocytogenes* to grow. 2. Maple Leaf Foods was producing larger packages of its RTE meat products for sale to institutions, including hospitals and long-term care facilities whose clientele are at higher risk of infection
Product testing	1. Food product tests which were taken by the plant were not analyzed for recurring L. *monocytogenes* issues 2. An environmental 'hold and test' approach was not in place at the plant
Most probable cause	1. Contamination of deli meat products by commercial meat slicers used within the plant production lines 2. Structural damage and maintenance issues in rooms where RTE meats were handled

*Note. From "Final report: Report of the Independent Investigator into the 2008 Listeriosis Outbreak", by Health Canada, 2011, retrieved from http://www.listeriosis-listeriose.investigation-enquete.gc.ca/lirs_rpt_e.pdf, p. xi - xiv.

The Weatherhill report (2009) (Report of the Independent Investigator into the 2008 Listeriosis Outbreak) was based on the national outbreak and described a number of key recommendations to all levels of government including public health units to reduce the risk of future outbreaks.

2.2.1 Federal Food Safety Framework and Ready-to-Eat Meats

The federal food safety framework in Canada focusing on meat processing, production and distribution includes a number of agencies; Agriculture and Agri-food Canada (AAFC), Health Canada, the Public Health Agency of Canada (PHAC) and predominantly, CFIA as it relates to RTE meats (See Figure 2).

AAFC, through the "*Growing Forward* policy framework, provides information and guidance to industry groups on food policy and regulatory issues" (Agriculture and Agri-Food Canada, 2010, para. 6). In particular to RTE meats, AAFC is the body to assist farmers in providing guidance for the transportation and safety of livestock on farms including water safety for human and livestock consumption. AAFC "helps the livestock industry to understand

regulatory processes and requirements and to set priorities with respect to health claims, novel foods and ingredients" (Agriculture and Agri-Food Canada, 2010, para. 6). AAFC works in conjunction with Health Canada in the development of policies, regulations and standards with respect to livestock health and also in conjunction with the CFIA with regards to the regulation and enforcement of statue pertaining to livestock welfare, which includes slaughter in federally registered plants.

Since the listeriosis and RTE meat outbreak involving Maple Leaf Foods in 2008, regulatory and policy amendments have been made by Health Canada to "provide guidance to industry and authorities regarding the verification and control of L. *monocytogenes* in RTE foods" (Health Canada, 2011, p. 4). Health Canada develops policies, regulations and standards related to the health, nutritional and safety aspects of foods governed under the Act and Regulations (Agriculture and Agri-Food Canada, 2010, para. 3). The "Federal Health Minister is responsible for establishing policies and standards relating to food quality along with the effectiveness of the CFIA's activities related to food safety" (Thompson, 2009, p. 6). Health Canada "also develops guidance documents to assist industry in compliance" (Agriculture and Agri-Food Canada, 2010, para. 4). For example, Health Canada recently updated the Policy on Listeria monocytogenes in Ready-to-Eat Foods in 2011. The policy includes "end-product compliance criteria… (that are) similar to the international Codex Alimentarius Commission standards" (Health Canada, 2011, p. 3). It also "provides categories of RTE foods according to risk, a detailed compliance-action decision tree, advice on including an environmental monitoring program in all processing plants and encouragement to use treatments that inhibit or eliminate the growth of L. *monocytogenes"* (CFIA, 2011a, para. 18). This policy is used by the food industry and CFIA as a "guide to action that can be taken to reduce the risk of L.

monocytogenes contamination in all RTE foods" (CFIA, 2011a, para. 27). Within the organization of Health Canada is "the Food Directorate, which is the federal health authority responsible for establishing policies, setting standards and providing advice and information on the safety of food" (Health Canada, 2005, para. 2). Within Health Canada's Food Directorate, "the Bureau of Microbial Hazards plays a major role in the study and prevention of foodborne listeriosis…through the Listeriosis Reference Service (LRS)" (Farber et al., 2011, p. 1507). The role of the service is to "assist physicians and provincial departments of health when foodborne illness is suspected, to examine suspect foods and clinical specimens submitted for analyses, and rapidly alert responsible agencies when commercial foods are involved" (Farber et al., 2011, p. 1507).

The Public Health Agency of Canada (PHAC) is the federal agency responsible for public health in Canada who's "mission is to protect the health of Canadians" (Public Health Agency of Canada, 2012, para. 1). Its mandate in the prevention of infectious diseases and responding to public health emergencies led to its role in the 2008 L. *monocytogenes* outbreak involving RTE meats. In general, "the usual first point of contact for notification of issues related to actual or potential food-borne illness outbreaks is the Centre for Food-borne, Environmental and Zoonotic Infectious Diseases, within the Infectious Disease Prevention and Control Branch at the PHAC" (Public Health Agency of Canada, 2010, para. 4). In providing guidance during foodborne emergencies, PHAC may "deploy field epidemiologists to assist local or provincial public health authorities during a foodborne illness outbreak investigation (while) the National Microbiology Laboratory provides related reference services such as bacterial strain identification" (Thompson, 2009, p. 7).

Compliance and enforcement of federal regulations pertaining to meat processing and distribution are the responsibility of the CFIA. The CFIA's inspection responsibility with processing and distribution of RTE meats is based on the tenants of its food safety and quality programming. The CFIA's mandate is to "enforce the food safety and nutritional quality standards set out by Health Canada for domestic and imported products" (Weatherhill, 2009, p. 16). The Agency "delivers inspection programs in food safety and quality, and plant and animal health across Canada, including food processing plants" (Weatherhill, 2009, p. 16). Food processing plants that are federally registered are inspected by CFIA inspectors. Inspections are completed in accordance with the plant HACCP plan which is consistent with the requirements under the Codex Alimentarius Commission standards. Products manufactured in these processing plants can be sold throughout the country or outside of Canada. CFIA also has the responsibility of ensuring that all food products meet "federal packaging and labeling requirements (while taking) enforcement action when food safety standards are not met or when health risks are identified" (Weatherhill, 2009, p. 16). The CFIA meat inspection regulations fall under the *Safe Food for Canadians Act* which will replace the *Meat Inspection Act RSC 1985, c. 25* and the *Consumer Packaging and Labeling Act RSC 1985, c. C-38*., in 2012 (CFIA, 2012b). The CFIA "conducts inspections at registered food processing plants to ensure firms comply with federal laws, regulations and its HACCP plan" (Weatherhill, 2009, p. 36). Although "the Agency has arm's length independence, it reports to the Minister of Agriculture and Agri-Food Canada" (Holley, 2010, p. 472).

The CFIA classification system categorizes RTE foods based on risk. A number of RTE meat products are categorized as Category 1 products (see Table 3) meaning they carry more risk than other categorized RTE products. Category 1 products include some RTE meats "in which

the growth of L. *monocytogenes* can occur" (Health Canada, 2011, p. 3). Category 1 products "should receive the highest priority for industry verification and control, as well as the regulatory

Table 3: Category 1 Ready-to-Eat Foods

Food category	Description of category 1 food products*
Deli meats	1. Deli meats that are sliced in the federal registered establishment 2. Deli meats shipped whole from the federal establishment. (This does not include cook-in-bag products; only those exposed post-lethality.)
Other products	1. Hotdog products 2. Deli salads, pates and meat spreads 3. Fermented products 4. Dried products 5. Salt-cured products 6. Products labeled as keep frozen

*Note. From "Policy on the control of Listeria monocytogenes in ready-to-eat (RTE) meat and poultry products", by Canadian Food Inspection Agency, 2011b, retrieved from http://www.listeriosis-listeriose.investigation-enquete.gc.ca/lirs_rpt_e.pdf, sec. 4.5.1.

oversight and compliance activities…(given that) the presence of L. *monocytogenes* in these Category 1 RTE foods will likely trigger a 'Health Risk 1' concern" (Health Canada, 2011, p. 3). 'Health Risk 1' "represents a situation where there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences, which are serious and life threatening or where the probability of a foodborne outbreak situation is considered high" (Farber et al., 2011, p. 1507). Category 2 products "include meats in which limited growth of L. *monocytogenes* to levels ≤ 100 CFU/g can occur throughout the stated shelf-life" (Health Canada, 2011, p. 4) or products where growth cannot occur. Category 2 parameters set by the CFIA are similar to guidelines set in the European Union and follow the recommendations of the Codex Alimentarius on Food Hygiene. However, research suggests that it is "difficult to predict with a high degree of certainty that the level will, or will not exceed 100 CFU/g during the shelf life" (Andersen & Norrung, 2011, p. 1496). Thus, "applying this approach may result in accepting the probability that foods with more than 100 CFU/g will be consumed" (Andersen & Norrung, 2011, p. 1496). Given that Health Canada does not require that producers sample products at the retail level, it is not possible to determine if a problem exists at a national retail

level. Therefore, risk of growth over the 100 CFU/g thresholds may increase in RTE meat products, which are distributed to retailers and further processed and sold to consumers with limited knowledge on product shelf stability.

2.2.2 Ontario Provincial Food Safety Framework and Ready-to-Eat Meats

In the province of Ontario, three provincial ministries and 36 public health units (boards of health) are responsible for food safety and thus the production, processing and distribution of RTE meat products to consumers in the province.

OMAFRA is responsible (among other programs) for meat inspection in the province. OMAFRA "administers and enforces a number of statutes established to minimize food safety risks (associated with meat products) including the production, quality, composition, safety, grading, packaging, labeling, advertising and sale (of meat products) in Ontario" (Ontario Ministry of Agriculture, Food and Rural Affairs [OMAFRA], 2011, para. 3). In addition, OMAFRA is responsible for developing and enforcing facility and operating standards for abattoirs in which meats are slaughtered and in some cases further processed (OMAFRA, 2011). Regulatory requirements pertaining to RTE meats fall primarily under the *Food Safety and Quality Act 2001, S.O. 2001, c. 20.*, which is managed within OMAFRA under the Food Inspection and the Food Safety Program Branches. Like the CFIA, OMAFRA is responsible for licensing and inspecting provincially registered food processing plants called free standing meat

Table 4: Ready-to-Eat Meat Inspection Requirements in Ontario

Criteria	CFIA	OMAFRA	Public health units
Environmental sampling	Food processing plants should carry out regular environmental sampling as required to verify the effectiveness of their sampling program for controlling L. *monocytogenes* in the plant environment and should increase sanitation efforts and control measures in areas where it is found*	Samples will be taken at random but each plant will be sampled at least once each year, and likely more often depending on their production volume of various types of RTE meats****	No requirement for food contact surface sampling required under the *Food Premises Regulation* or Ontario Food Safety Standard or Protocol
Product sampling before and after retail	End-product sampling schemes as a verification tool to demonstrate the efficacy of the control measures put in place to address L. *monocytogenes* are recommended but not required*	End-product sampling not required. RTE product testing after production is required under Ontario Regulation 31/05 (*Meat Regulation*) and is mandatory for meat plant operators****	No requirement for food contact surface sampling or end-product sampling for local processors required under the *Food Premises Regulation* or Ontario Food Safety Standard or Protocol
HACCP program requirements	Required through formal documentation and HACCP plan	Required through formal documentation and HACCP plan	No formal HACCP audit requirements. Critical control points should be monitored as a part of the inspection process
Inspection frequency	Risk based inspection frequency approach. The frequency and scope of the inspection activities would be based on risk level and would be adaptable, as required, to the size and complexity of the regulated parties' operation**	Abattoirs – Inspector is present during all slaughter activity FSMPs – Based on risk – Frequency of inspection is based on risk and can range from inspection every week (high risk) to once every six weeks (low risk)*****	Risk-based inspection frequency. Range = minimum of 3 times annually (High risk), 2 times annually (Moderate risk) and 1 time annually (low risk)
Labeling requirements	Core labeling requirements include common name, net quantity, name and address of manufacturer, nutritional labeling, durable life date, and have plant marking for inspected products***	Mandatory label information (inspection legend), common name, net quantity, name and address of manufacturer, list of ingredients, durable life date, production date or code, storage instructions, cooking instructions, nutritional labeling, declaration of percent protein******	Every manufactured meat product that is transported, handled, distributed, displayed, stored, sold or offered for sale at a food premises shall be identified as to the meat processing plant of origin by a tag, stamp or label affixed to the product*******

Note. *From "Policy on Listeria monocytogenes in ready-to-eat foods", by Health Canada, 2011, retrieved from http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/legislation/pol/policy_listeria_monocytogenes_2011-eng.pdf, sec .
Note. **From "The improved food safety inspection mode: the case for change", by Canadian Food Inspection Agency, 2012c, retrieved from http://www.inspection.gc.ca/about-the-cfia/accountability/inspection-modernization/case-for-change/eng/1337194116466/1337194257540, sec. 'inspection'.
Note. ***From *"Basic labelling requirements sections 2.1 – 2.9"*, by Canadian Food Inspection Agency, 2011c, retrieved from http://www.inspection.gc.ca/english/fssa/labeti/guide/ch2e.shtml, para. 1.
Note. ****From "Microbiological regulatory monitoring program for provincially licensed meat plants that process ready-to-eat meat products", by Ontario Ministry of Agriculture, Food and Rural Affairs, 2011, retrieved from http://www.omafra.gov.on.ca/english/food/inspection/meatinsp/samplingfollowup.htm,
Note. *****From "Ontario's Meat Inspection Program", by Ontario Ministry of Agriculture, Food and Rural Affairs, 2011c, retrieved from http://www.wrfoodsystem.ca/files/www/OMAFRA_Presentation_November_23_2011.pdf, slide 10
Note. ******From "Some feeding tips for tough times", by Ontario Ministry of Agriculture, Food and Rural Affairs, 2008, *Virtual Beef*, 7(18), p. 6.
Note. *******From "Health Protection and Promotion Act, R.R.O. 1990, Regulation 562, Food Premises", by Ontario Ministry of the Attorney General, 1990, sec. 39(1)

plants (FSMPs) in addition to slaughtering plants (abattoirs). In particular to RTE meats, FSMPs may include facilities that process and/or cook RTE products through various means including canning, curing, dehydrating, emulsifying, fermenting or smoking of a meat. OMAFRA inspectors are required to inspect these FSMPs within a frequency in accordance with a risk assessment of the plants activities.

The Ontario Ministry of Natural Resources (MNR) is "responsible for food safety and in particular, fish and fish plant inspection for products harvested and offered for sale in Ontario" (OMAFRA, 2011, para. 6). While its legislative mandate is not specifically focused on RTE meats and meat production and processing, it operates periodically under OMAFRA in providing enforcement services (e.g. investigation and prosecutions) under legislation pertaining to meat processing (e.g., *Meat Inspection Act*). For instance, MNR's role in resource and wildlife management has been used in investigating and prosecuting in cases of illegal slaughter and meat processing.

Working as an arm's-length government agency, PHO is "dedicated to protecting and promoting the health of all Ontarians" (Public Health Ontario, 2011, para. 1). PHO works with the provincial public health system including the MOHLTC to provide "expert scientific and

technical support" relating to various public health issues including food safety (Public Health Ontario, 2011, para. 2). PHO is also responsible for providing laboratory services for the province including food testing for samples submitted by public health units for bacteriological and virological results including presence/absence test for L. *monocytogenes*.

The MOHLTC is responsible for the protection of public health and setting food safety standards and policies for food premises. Inspection authority and legislative mandate related to eliminating or mitigating health hazards is provided under the provisions of the *Health Protection and Promotion Act, RSO 1990, c. H.7*., and more specifically, the *Food Premises Regulation*. The Ontario Food Safety program is guided by the Ontario Food Safety Standard (2008) and Ontario Food Safety Protocol (2008) that specify the mandatory food safety activities required by provincial boards of health. Food safety inspection is delegated to public health units and designated public health inspectors via the Medical Officer of Health under the authority of the *Health Protection and Promotion Act*. While the *Health Protection and Promotion Act* provides public health inspectors broad inspection powers and authorities for food premises in the province, federally (CFIA) or provincially (OMAFRA) regulated meat plant production areas are not inspected by public health unit staff due to a memorandum of understanding (MOU) between the agencies. As a result, public health unit inspectors are left with addressing RTE meat products in a food premises using a generalized food inspection approach dictated through the *Food Premises Regulation* and the Ontario Food Safety Standard and Food Safety Protocol (2008). There are a number of differences in regulatory requirements in regards to inspection of RTE meats as described in Table 4. For example, Health Canada has adopted the *Codex Alimentarius Guidelines for RTE foods and L. monocytogenes*. The guidelines recommend that there should be "no concessions for regulatory control of foods produced by

small or medium sized companies" (Luber, 2009, p. 1543). One regulatory control includes the sampling of food contact surfaces in food preparation areas on a frequent basis. However, despite this recommendation, there is no requirement for food premises under the *Food Premises Regulation* or the Food Safety Protocol (2008) to sample food contact surfaces.

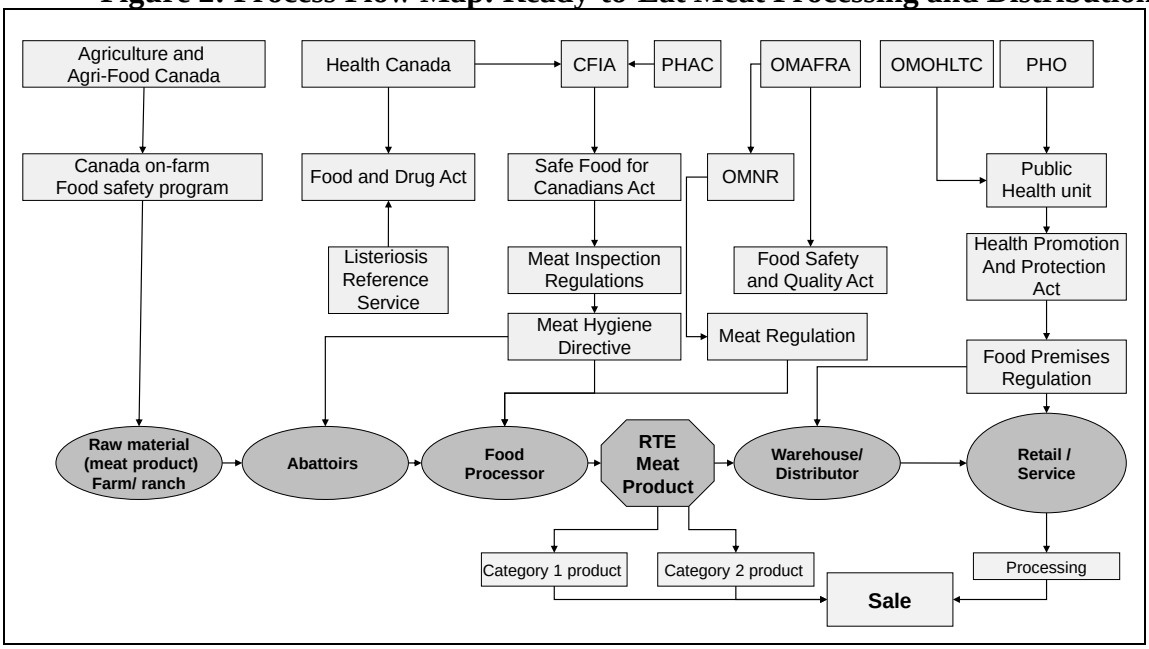
2.3 Listeria Monocytogenes, Ready-to-Eat Meats and Wicked Problems

Research suggests that foodborne illness statistics, including rates of listeriosis, remain significant in Canadian (Arthur, Gournis, McKeown D, & Yaffe, 2009; Flint, Doré, Majowicz, Edge, & Sockett, 2004; Henson et al., 2008; Luber et al., 2011; MacDougall et al., 2008; Majowicz et al., 2004; Majowicz et al., 2006; Majowicz et al., 2005; Sargeant, Majowicz, & Snelgrove, 2008; Thomas et al., 2008; Thomas et al., 2006). Furthermore, "each case of foodborne illness reported in the province of Ontario represents an estimated several hundred cases of infectious gastrointestinal illness in the community" (Majowicz et al., 2005, p. 178). According to models developed by Thomas et al., (2008), there are "an estimated eleven million episodes of foodborne disease in Canada annually" (p. 3). However, it is a challenging undertaking for epidemiologists to determine the number of illnesses associated with home-based consumption versus foods prepared outside of the home. While home food preparation has been a focus of recent amendments to the Ontario Food Safety Standard and Protocol (2008), the Ontario food supply principally originates from an inspected source. This emphasizes the importance of the food safety inspection program in the province given that most food prepared in a home environment has gone through some form of inspection by one or several agencies. Furthermore, in the case of an increasing trend towards low-sodium and RTE foods (Weatherhill, 2009, p. 34), the consumer should expect a higher degree of food safety given that no further

means of pathogen reduction steps (such as cooking) are required prior to consumption. It is therefore reasonable to suggest that the current framework for food safety inspection for RTE meats in the province of Ontario is not operating effectively given that episodes of foodborne illness and listeriosis remain significant and the economic costs associated with illness run in the hundreds of millions of dollars nationally (Ruzante et al. 2010a).

Compounded with issues surrounding illness statistics particularly in Canada and Ontario is the number of organizations currently involved with inspection of food safety systems and RTE meats. The processing and distribution of RTE meats in Ontario is also a complex process involving a number of agencies, their regulations and associated inspection activities for the processing and sale of manufactured meat products (see Figure 2). The process includes

Figure 2: Process Flow Map: Ready-to-Eat Meat Processing and Distribution



Federal (CFIA, Agriculture and Agri-food Canada, Health Canada), provincial (OMAFRA, MNR, PHO, MOHLTC) or local (public health unit) organizations. The mandate of these organizations in the distribution of RTE meats is to ensure or assist with ensuring a safe food supply and to reduce the incidence of foodborne illness. However, there are differences in

approach to food safety inspection and processes along with the regulatory administration in which they operate. As a result, a number of challenges pertaining to RTE meats and L. *monocytogenes* are noted as described in Table 5. They include issues associated with administration of product recalls, microbiological testing and analyses, attribution of listeriosis from RTE meats and product trends and labeling. While the study is intended to address only those challenges noted in Table 5 that are associated with public health units and their interaction with RTE meats and L. *monocytogenes*, study recommendations (see Section 5.7) address a number of issues shared by both provincial and federal agencies.

Table 5: Challenges Associated with Ready-to-Eat Meats and *Listeria Monocytogenes*

Challenge	Description
Regulatory framework	8 regulatory agencies involved with the processing and distribution of RTE meat products
Product recall process	Process can involve up to 6 agencies in the coordination of large-scale recall activities
Microbiological parameters	Federal and provincial discrepancy in microbiological allowances of L. *monocytogenes* in RTE foods
Vulnerable populations	No direct regulatory emphasis on communicating increased risk of RTE meats and L. *monocytogenes* to vulnerable populations at the provincial and public health unit level
Raw materials	Lack of regulatory framework for farm and feed processes with a focus on microbiological contamination and traceability
Consistency	Inconsistency in regulatory requirements for random product, food contact and non-food contact surface testing in food handling environments between the federal, provincial and public health unit agencies
Laboratory infrastructure	Limited number of dedicated testing facilities to isolate organism and perform PFGE pattern analyses to identify clusters for public health units
Product labeling	Best before dates do not communicate the potential hazards associated with consumption of the product after the posted package date. Packaging does not clearly delineate the use of product microbiological inhibitors which reduce total loading of the product related to shelf stability and product safety
Communication	Communication between public health units, OMAFRA, PHO, the MOHLTC and CFIA in regards to inspection results of facilities processing RTE meats is not required
Food attribution	Lack of policy in provincial protocols and guidelines dedicated towards improving attribution to specific pathogen-food combinations including listeriosis and RTE foods. Long incubation period increases difficulty associated with attributing listeriosis to foods
Product trends	Trend towards low-sodium, no/low preservative and extended shelf life products leads to challenges associated with appropriate categorization of foods and feasibility of meeting 100 CFU/g limit (CFIA standard for specific products)
Product sampling	Inconsistency in the requirements for food and food contact surface sampling Food premises that are not operated under OMAFRA or the CFIA and produce RTE meats are not required to sample surfaces for L. *monocytogenes*

As a result of the challenges outlined in Table 5, the current food safety system involved with the distribution and processing of RTE meats is considered a "wicked problem" (Agar, 1999; Head & Alford, 2008; Kreuter, De Rosa, Howze, & Baldwin, 2004; Leung, Middleton, & Morrison, 2012; Rogers, 2008). Wicked problems are characterized and defined as being elusive, difficult to solve and influenced by a constellation of factors which may "change during the process of solving the problem" (Kreuter et al., 2004, p. 442). Wicked problems have also been described as a system of related problems that have "technical, economic and political elements" (Hutchinson, English, & Mughal, 2002, p. 257). For example, research suggests that public administration's "hierarchical form of organization and system of control… (limits) opportunities to think expansively about policy issues such as food safety systems that might (arise) from wicked problems" (Head & Alford, 2008, p. 9). Wicked problems may also "involve many stakeholders who are likely to have differing ideas about what the 'real' problem is and what the causes are" (Kreuter et al., 2004, p. 443) as observed by the number of agencies who inspect or influence RTE meats in Ontario (see Figure 2). Wicked problems are seen as "linked to social pluralism (multiple stakeholder interests and values), institutional complexity and scientific uncertainty (leading to) fragmentation and gaps in knowledge" (Head & Alford, 2008, p. 5). Wicked problems are defined by a number of variables that are closely associated to RTE meats and L. *monocytogenes* as described in Table 6.

Table 6: Wicked Problem Variables and Associating Examples Examining Ready-to-Eat Meats and Listeriosis

Wicked problem variables*	Examples: ready-to-eat meats and listeriosis
Difficult to solve and clearly define*	Long incubation period and source of contamination in processing environments challenges validity of incidence rates and investigations
Many interdependencies and multi-causal aspects*	Process of investigating listeriosis cases involving RTE requires examination of retail and processing environment and may involve the federal, provincial and public health unit in order to determine the source of the product and contamination
No clear and correct solution*	There are a number of differences in inspection processes and regulatory requirements between the CFIA, OMAFRA and public health units in how RTE meats are inspected and regulated
Problems have many stakeholders*	There are up to 8 governmental agencies associated with the regulation, oversight and inspection of the production and distribution of federally inspected products
Responsibility stretches across many organizations*	Agencies share responsibility at some capacity in reducing introduction of the organism within processing environments and replication of the organism within RTE products after distribution and sale
Solutions may require behavioural changes from stakeholder groups*	A number of strategies for reducing loading of L. *monocytogenes* in RTE meat products are available, however, product recalls continue to occur
Problems may be unstable and continue evolving*	470 individual RTE meat products have been recalled by CFIA due to higher than acceptable levels of L. *monocytogenes* between 2008 – 2011
No agreement exists as to what problem is**	Presence of the organism in RTE meats may originate from the initial processing or via further processing (e.g., cross-contamination) after sale/distribution
Lack of stopping rule**	Rates of listeriosis in Canada has increased since 2007***

Note. *From "Wicked problems: the implication for public management", by B. Head, & J. Alford, 2008, *paper presented at the panel on public management in practice, International research society for public management*, Brisbane, Australia, p. 6.
Note. **From "Understanding wicked problems: a key to advancing environmental health promotion", by M. Kreuter, C. De Rosa, E. Howze, & G. Baldwin, 2004, *Health Education and Behaviour*, 31(4) p. 443.
Note. ***From "Changing regulation: Canada's new thinking on Listeria", by M. F. Farber, G. K. Kozak, & S. Duquette , *Food Control*, 22 p. 1506.

Research examining food safety inspection systems in relation to wicked problems, food safety systems and L. *monocytogenes* is sparse. A search of titles in Medline and Embase databases using search words 'wicked' OR 'wicked problems' AND 'food safety' OR 'food' from 1990 to 2012 provided just 5 results suggesting that additional research examining the relationship between the two concepts is required. Inclusion of the word 'Listeria' or 'Listeria *monocytogenes*' in conjunction with the words 'wicked' OR 'wicked problems' AND 'food safety' OR 'food' from 1990 to 2012 provided no results.

Despite the lack of peer reviewed research addressing wicked problems, L. *monocytogenes* and RTE meats, other agencies have used the concept of wicked problems to address similar complex issues. For example, the Joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization's (WHO) Food Safety Standards Program of the Codex Committee on Food labeling (2011) examined the wicked problem of another emerging food safety concern, biotechnology. In their study, they characterized wicked problems as problems with "ambiguity, uncertainty, several different perspectives on the issues and disagreement on goals and values" (Codex Alimentarius Commission, 2011, p. 2). Codex Alimentarius was also responsible for the development of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready to Eat Foods* in 2009 which also addressed the on-going concern with the microorganism in food settings.

Wicked problems, while extremely complex, "require practical resolutions and solutions that are realistic to implement" (Hutchinson, English, & Mughal, 2002, p. 258). Research suggests that "simple solutions that are technically feasible, economically sustainable and politically implementable are required to resolve wicked problems" (Hutchinson, English, & Mughal, 2002, p. 257). Furthermore, they require a "diverse group of public health actors, including individuals, communities, organizations, professional bodies and institutions from the state, civil society and private domains to solve" (Leung, Middleton, & Morrison, 2012, p. 3).

Defining the current provincial food safety system involving RTE meats and L. *monocytogenes* as a wicked problem is important to science for a number of reasons. First, it allows the problem to be addressed by more than one solution which is beneficial given the number of agencies involved (see Figure 2). Second, determining solutions to begin to tackle the problem becomes valuable to other related wicked problems in public health and food safety

systems including other pathogen-food combinations such as *Campylobacter spp*. in chicken; *Salmonella spp*. in chicken and spinach and *Escherichia coli* O157 in spinach and beef" (Ruzante et al., 2010a, p. 724). In this study, policy, practice, research, innovation and knowledge translation are examined with a focus on RTE meats and L. *monocytogenes* in the context of a wicked problem with the goal of reducing the burden of listeriosis in Ontario.

3.0 Research Design and Methods

The following research design and methodologies are based on the central research question and the three research questions described in Section 1.3. A qualitative research methodology was used for the purposes of the study for a number of reasons. First, given the complexity of the wicked problem (see Section 3.5), it would be exceptionally challenging to use methodologies which would quantify the extent of the complexities involved with the association between RTE meats and L. *monocytogenes* as described in Figure 2. Second, qualitative methods allow the study research questions to be addressed using an established qualitative method; grounded theory, which is intended to generate a theory to address components of the wicked problem.

3.1 Grounded Theory Research Design

The research design used the principles of grounded theory to lead the interview, survey methodology and data analyses. The study was completed in three phases. Interviews were conducted in phase 1 and phase 2 while a survey was conducted in phase 3. Phase 1 interviews were conducted with three public health units while phase 2 interviews were conducted with eight additional public health units. Phase 1 interview participants were selected after interested health units were grouped into three categories as described in Table 15. Once health units were grouped into the categories, three health units were randomly selected from each category (category 1,2 or 3) to be interviewed. Similarly, phase 2 interviews were randomly selected from each category group until theoretical saturation was achieved (see section 3.6.5). Interviews were conducted with public health unit 'food safety leads' that met eligibility criteria as specified in Section 3.4. Two interviews were conducted per public health unit for both phase 1 and phase

2 interviews. The first interview took place with a candidate representing 'food safety management' while the second interview took place with a candidate representing either a public health inspector or key informant. Interviews were either conducted in-person or over the telephone. In-person or telephone interviews were conducted separately and in a successive manner so as to reduce the likelihood of communication amongst interviewees. Phase 3 consisted of an internet-based survey, which was used for the purposes of data confirmation from interviews in phase 1 and 2. All participating public health units were given the opportunity to complete the phase 3 survey.

Data collection commenced in January, 2012 upon receiving approval from the University of Waterloo's Office of Research ethics on November 17, 2011. Research ethics clearance documentation was provided to two public health units based on formal requests for copies of the proposal in order to participate.

3.2 Sampling Strategy and Selection of Research Participants

The aim of the sampling strategy was to conduct interviews with public health unit food safety leads. Potential interview candidates included food safety management (e.g., Medical Officers of Health, directors, managers, and supervisors), public health inspectors or key informants (e.g., epidemiologists, policy analysts involved with the food safety program). In total, 23 directors/managers/supervisors represented the food safety management cohort. No Medical Officers of Health participated in the study. Furthermore, no key key informants (see Table 7) participated in the study. Twenty-two public health inspectors participated as the second study cohort.

3.3 Recruitment and Consent

In order to access food safety lead representatives from public health units, a letter (see Appendix A) was sent to the Association of Supervisors of Public Health Inspectors of Ontario (ASPHIO) to support the study. Since ASPHIO fully supported the research study, the Association agreed to send the letter on behalf of the principle investigator (see Appendix B) to encourage public health units to participate. The letter (see Appendix C) provided participation eligibility criteria for each position including the food safety manager and public health inspector or key informant in each respective public health unit. A copy of the consent forms were also provided as shown in Appendices D, E and F and were requested to be sent back (or agreed to) by the primary investigator.

3.4 Eligibility Criteria

Candidates eligible to participate in the interview and survey were required to meet the requirements as outlined in Table 7.

Table 7: Eligibility Criteria for Study Participants

Eligibility criteria	Food safety management	Public health inspectors	Key informants
Experience in position	Minimum 3 years experience in managing/supervising certified public health inspectors involved with the inspection of food premises	Minimum 3 years experience acting as a certified public health inspector involved with the inspection of food premises	Minimum 3 years experience in working with the food safety program in an epidemiology, policy or research capacity
Education	Certified public health inspector (Canada) or Medical Officer of Health	Certified public health inspector (Canada)	Minimum Bachelors degree for associated position in the public health unit
Program involvement	Involved with food safety program management in accordance with the Ontario Public Health Standards, *Health Protection and Promotion Act* and *Food Premises Regulation*	Involved with inspection of food premises in accordance with the *Health Protection and Promotion Act* and *Food Premises Regulation*	Involved with assisting the public health unit food safety program in reducing foodborne illness through various initiatives and activities
Association with *Food Premises Regulation*	Administrator of public health inspectors with direct application of the *Food Premises Regulation*	Administrator of regulation to food premises	Knowledge of the application of the *Food Premises Regulation* to the public health unit food safety program

Employment status	Currently employed with one of the 36 public health units in the province of Ontario	Currently employed with one of the 36 public health units in the province of Ontario	Currently employed with one of the 36 public health units in the province of Ontario
Consent	Has provided consent to be interviewed in accordance with ethics requirements and letter of consent	Has provided consent to be interviewed in accordance with ethics requirements and letter of consent	Has provided consent to be interviewed in accordance with ethics requirements and letter of consent

Experience in position was placed at three years for all interview and survey participants to ensure that that study would include candidates who may or may not have contributed in the 2008 listeriosis outbreak. Requiring ≥ four years of experience would likely have resulted in all candidates participating in the 2008 outbreak thus potentially biasing response. It also ensured that all cohorts had some experience in their respective position to provide breadth in answering interview questions in regards to inspection of food premises. Similarly, program involvement and association with the *Food Premises Regulation* included the requirement to be currently involved with the administration or application of the *Food Premises Regulation*. This ensured that the candidate had an adequate and working knowledge of the *Food Premises Regulation* taking into account its significance in survey and interview questions.

Education requirements for food safety management and public health inspectors were restricted to certification under the Canadian Institute for Public Health Inspectors. In addition, the food safety management group could include Medical Officers of Health which are appointed under the MOHLTC to administer the *Health Protection and Promotion Act* in public health units. Key informants were required to have a minimum of a Bachelors degree for their associated position in the public health unit. It was anticipated that key informants would have included epidemiologists or policy consultants that would have met the requirements. However, no key informants were selected by public health units to participate in the study

3.5 Wicked Problems, Grounded Theory and Complex Systems

In order to address the wicked problem identified for the research study as outlined in Section 3.5, grounded theory principles were used to frame the survey instrument for interviews with public health unit food safety leads. The principles of grounded theory are justified in this research area for a number of reasons. First, grounded theory is an effective method to employ when dealing with complex systems and wicked problems. Research suggests that the "properties of fit, relevance, control, workability, generalizability, and modifiability make grounded theory particularly well suited for studying complex systems" (Linden, 2006, p. 1). Grounded theory fits the "analysis of the wicked problem because the theory emerges from the analyses of data gathered from within the system" (Linden, 2006, p. 2). Research suggests that "once a grounded theory has been articulated, it is applied to a specific problem or issue, as discovered during the research process, thereby generating an operational theory that serves as a rationale and model for action for the wicked problem" (Simmons, 2006, p. 8). Second, grounded theory can be described as "innovative, systemic, and sophisticated enough to reveal the underlying complexities of systems" (Linden, 2006, p. 1). Identifying complexities allows for planned "actions that address their complex, dynamic nature while remaining grounded in what is occurring within the systems as they change over time" (Linden, 2006, p. 1). Lastly, "grounded theory is the study of a concept….where patterns are identified through core categories which have a direct impact on the field of study and the wicked problem" (Glaser, 2010, 0:38). These concepts can be used to generate a theory to improve the current environment and lead future research.

The study focuses on one agency within the system matrix (see Figure 2), public health units. Research would suggest that "a systematic research approach should involve not only

studying the parts of the system, but also the relationships and interactions between the parts and subsystems in order to understand the system as a whole" (Linden, 2006, p. 2). However, involving all responsible agencies would be too large for the purposes of a single study. Accordingly, this doctoral research study was categorized as exploratory and focused on a single agency in the larger framework of the RTE meat processing and distribution system for future research. Since in most cases, public health units and public health inspectors represent the final inspection step prior to consumer consumption, it can be argued that their role is significant in the epidemiological triangle of disease (host-pathogen-environment). However, despite the importance of public health units within the system, there is little research or theory to explain what public health units and public health inspectors can do as an organization to reduce the burden of listeriosis through inspection of RTE meats in food premises. As a result of a lack of tangible research, grounded theory allows all phases of interviews and survey instruments in the study to act as data and assist in theory generation.

3.5.1 Research Principles and Methodology

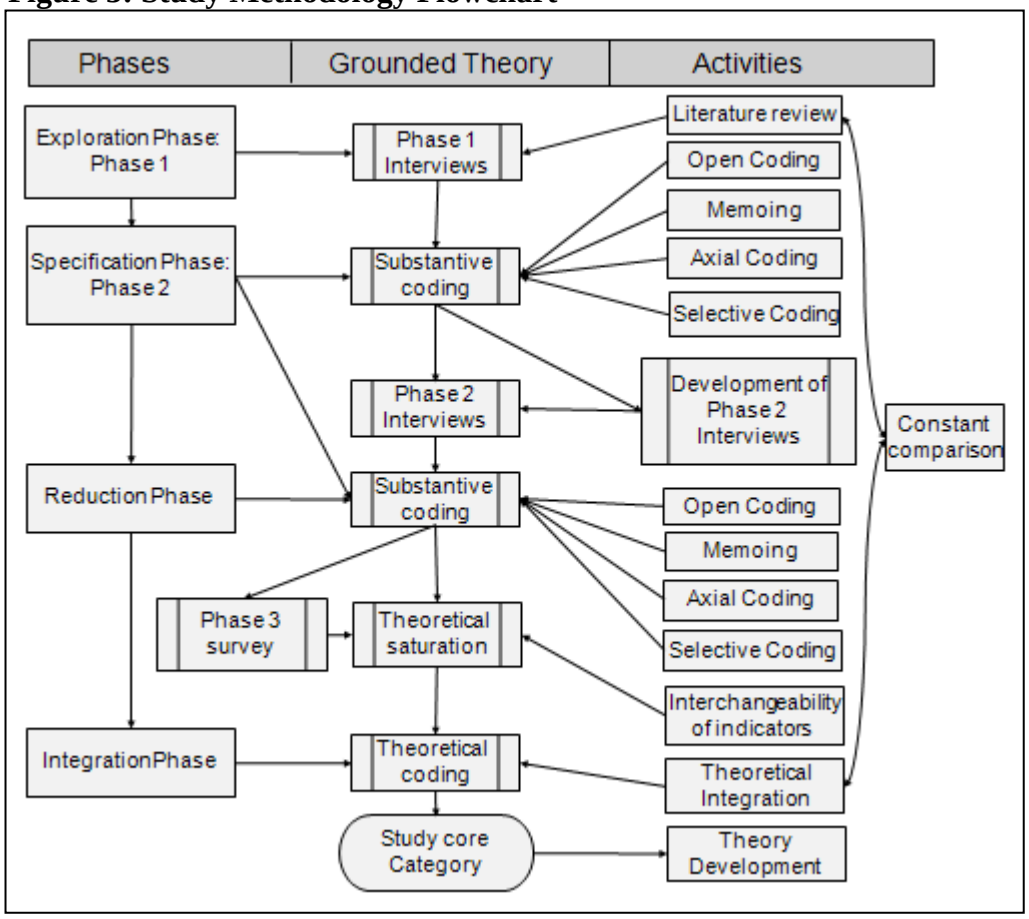
The framework for the grounded theory approach used in this study for data collection and analyses follows the grounded theory process steps adopted by Richardson and Kramer (2006) and includes four phases of theory development including exploration, specification, reduction and integration. Research activities involved in these processes are outlined in Figure 3 and include the use of a grounded theory approach to drive their study methodology:

I. **Exploration phase**: this phase "focused on becoming acquainted with the field of study" (Richardson and Kramer, 2006, p. 503). This entailed (a) conducting an initial literature review on the topic (see Sections 1.1), (b) developing process flow maps to identify gaps in process (see Figure 2), (c) developing free-style (Glaser, 2001) or open-ended research

questions for phase 1 questions to address the wicked problem and (d) conducting phase 1 interviews in order to develop a system of categories to frame the problem statement(s).

II. **Specification Phase**: this phase was focused on the "analyses of materials" (Richardson and Kramer, 2006, p. 503) gathered from phase 1 interviews using substantive coding (see Section 3.6.2). The transcribed interviews were analyzed using qualitative analyses and in particular the use of line-by-line *coding* from similar methods applied in other research studies (Broom, 2005; Charmaz, 2006; Glaser, 1992; Hale, Treharne, & Kitas, 2008; Meurer et al., 2007; Richardson & Kramer, 2006; Strauss, & Corbin, 1990; Verpy, Smith, & Reicks, 2003; Whitley & Crawford, 2005). In addition to completing line-by-line analyses of the data, phase 1 interviews were analyzed using qualitative data analysis software (Nvivo qualitative data analysis software; QSR International Pty Ltd. Version 10, 2012) to assist in identifying codes in the data. As a result of substantive coding exercises, 4 core categories emerged (see Section 4.2.1.1).

Figure 3: Study Methodology Flowchart



In association with the central research question, core categories identified in phase 1 were used in the development of interview questions for phase 2. In addition, an additional literature review was conducted (see Section 4.2.3.2) to ensure that the core categories identified in phase 1 and subsequently the questions developed for phase 2 would assist in addressing the study research questions (see Section 1.3). In order to support the method of question development, a grid was developed (see Appendix G) to ensure that questions developed for phase 2 were constructed in a manner that would address the central research question and study research questions (see Section 1.3). Consistent with the approach used in the phase 1 interviews, phase 2 questions were developed using a 'free-style' or 'open-ended' approach. Similarly, sub-questions were

also developed to elicit further dialogue on the subject area. Both the main question and the sub-questions (see Table 10) were asked of all 16 phase 2 interview participants.

III. **Reduction Phase**: this phase followed the specification phase and was aimed at "explicating the core of the study" (Richardson and Kramer, 2006, p. 504) and was focused on the identification and development of "core concepts that characterized the central processes in the field of study" (Richardson and Kramer, 2006, p. 504). Results of the transcribed phase 2 interviews were analyzed using substantive coding in order to explicate the core of the study to assist in answering the central research question. In addition to completing line-by-line analyses of the data, phase 2 interviews were analyzed using qualitative data analysis software as described in the specification phase. Prior to the development of the study's core category and navigating through the process of theoretical coding in the integration phase, a survey was developed (phase 3) to ensure that theoretical saturation had been met and that the answers provided in phase 1 and phase 2 were consistent with the remaining set of participating public health units . The phase 3 survey was also distributed to phase 1 and phase 2 public health units (n= 22 participants) in order to ensure data integrity and consistency of their interviews.

IV. **Integration Phase**: the phase in which the core concept identified in the reduction phase was used to "develop a substantive theory about the field of study" (Richardson and Kramer, 2006, p. 505) through identification of core categories and theoretical coding. The theory developed in this phase subsequently lead to:

    a. Addressing the central research question and study research questions through theory development and;

b. Addressing components of the wicked problem associated with public health units and their role with RTE meats and L. *monocytogenes.*

Interview data collection and analyses using the four-phased approach as described by Richardson and Kramer (2006) allowed the wicked problem to be best resolved "through a planned process with input from multiple sources" (Kreuter et al., 2004, p. 448). Richardson and Kramer (2006) argued that grounded theory is not strictly based on the constructs of Glaser or Strauss' "induction, deduction and verification" (p. 498) approach. Rather, Richardson and Kramer (2006) stress the use of abduction as a means of "grounded theorizing" (p.500). In its simplest form, abduction refers to the process of "studying facts and devising a theory to explain them" (Richardson & Kramer, 2006, p. 499). Furthermore, abduction is a type of inference that "operates bottom up (where) individual facts are collected and connected together to develop hypotheses" (Richardson & Kramer, 2006, p. 500).

3.5.1.1 Grounded Theory Approach - Benefits

Kramer and Richardson's (2006) grounded theory approach offered a number of benefits. First, it allowed for a phased-in approach for the research team allowing cohorts of groups to be categorized and identified in the early stages of the process. Cohorting also allowed for theory development to take place in a staged approach allowing for more information collection and subsequent analyses. Second, the process better conformed to the academic institutional ethics review processes as opposed to classic grounded theory inductivist models which would have required that the researcher know little about the population or topic area making the ethics process difficult.

3.5.1.2 Grounded Theory Method: 'Classic' vs. 'Compromised' Approach

In analyzing Richardson and Kramer's (2006) abductive grounded theory approach, it is evident that the theory generation process combines a number of different methodologies including:

I. 'Classic' grounded theory approach as described by Glaser and Strauss (1967) and Strauss (1992);
II. Constructivist view of grounded theory as described by Charmaz (2006); and
III. 'Straussian' grounded theory methodology as described by Corbin and Strauss (1999).

A number of strategies from the constructivist approach applied by Charmaz (2006) were employed in the research study (see Table 8). They included the method in which questions were developed, data were collected and analyzed, and the manner in which the study theory emerged and was constructed. Glaser (2001) referred to these types of "mixed-method grounded

Table 8: Charmaz Contructivist Principles and Associated Study Activities

Charmaz principles*	Study activity	Corresponding Section(s)
Structuring of inquiry*	Facilitation of semi-structured interviews using open-ended questions to generate dialogue and free-style response	3.6
Simultaneity of data collections and analyses*	Use of interview data, public health unit documentation, memoing and constant comparison approach to theory generation	3.6.2
Generation of a new theory rather than the verification of an existing theory*	Theory generation based on methods described in grounded theory research	4.2.3.2
Refinement and exhaustion of conceptual categories through theoretical sampling*	Through the process of triangulation and in implementing 3 phases of inquiry, conceptual categories were processed through a staged approach	4.2.2.1

*Note. From "Constructing grounded theory", by K. Charmaz, 2006, *3rd edition*, Thousand Oaks, CA, Sage

theory approaches as 'compromised' grounded theory" (Xie, 2009, p. 37). Glaser (2001) describes this type of grounded theory as "written in order to conform to the requirements of a standardized qualitative research proposal" (Xie, 2009, p. 35). It is thus important to identify the

fundamental differences in the approach used in this study in relation to Glaser's 'classic' grounded theory methodology since it originated from this author. They include:

(i) The use of literature review;

(ii) Pre-determined interview question development and candidate selection; and

(iii) The use of research questions.

Literature review process

Glaser's classic grounded theory approach to a research proposal "need only supply information on the area of interest, data source and a statement of method to the effect that the researcher begin to collect, code and analyse the data and let the theory emerge" (Xie, 2009, p. 1). Glaser's classic grounded theory approach would advise against conducting a literature review.

Unlike Glaser's approach, Strauss and Corbin (1990) argued that an "understanding of the research area through literature (review) will increase theoretical sensitivity of the researcher during data collection" (p. 45). As a result, a comprehensive literature approach was conducted prior to initiation of data collection to drive the research process in the area of RTE meats and L. *monocytogenes*. Given a general lack of process-related research pertaining specifically to public health units and RTE meats, research presented in Section 1.1 focused predominantly on microbiological and risk assessment processes associated with the microorganism and RTE food products. Furthermore, literature review topics focusing on research associated with wicked problems was also conducted (see Section 4.2.3.2) to assist in providing scope to the complex problem and to support the central and associated research questions. In order to reduce potential bias associated with the facilitation of a formal literature review as described by Glaser (1990), the literature review was treated as data and then constantly compared to the interview

responses for the purposes of analyses (Strauss, & Corbin, 1990). However, in keeping with the approaches used in similar studies (Adolph, Hall, & Kruchten, 2011; Deady, 2011), an additional literature review was conducted in the reduction phase for the purposes of constant comparison and theoretical coding after completion of phase 1 and phase 2 interviews and phase 3 surveys (see Section 4.2.3.2).

Pre-determined interview question development and candidate selection

To facilitate the free-style interview technique that reduces interview bias and leading questions, Glaser (1998) identified that there should be "no pre-conceived interviewing questions or identified informants" (Xie, 2009, p. 9). Furthermore, Glaser (1992) suggests that no direct questions should be asked during interviews to "guard against the preconception of emergence of data" (Mavetera, & Kroeze, 2009, p. 12). Glaser's recommendation, however, causes challenges in the ethics review and approval process since recruitment and consent requests along with sample questions are requirements for the Board of Ethics to rule our "privacy concerns" (Xie, 2009, p. 9). As a result, questions for the first phase of interviews were developed (see Section 3.6.1) in phase 1. However, the questions were developed in a format that left queries open-ended (see Table 10) to meet the spirit of Glaser's free-style approach to interviewing and to allow for participants to respond freely and not feel restricted to a specific area of response (Glaser, 2010).

Similarly, the selection process for interview candidates followed pre-determined processes and eligibility criteria to meet the requirements of ethics review. As described in Table 7, eligibility criteria were clearly defined. However, the selection process was internalized within the public health unit where the choice of participating candidates was left to the director or Medical Officers of Health who received the letter and were responsible for who would

participate from their public health unit based on the eligibility criteria. Thus, there was no intervention from the principle investigator in regards to who was chosen as long as candidates met minimum criteria.

Research Questions

As described in Section 1.3, both a central research question and three associated research questions were developed prior to commencement of the interviews and surveys. According to research, studies should "not consider a research question as a statement that focuses and identifies the unit under study…. (since) the research focus becomes clear during open coding, collection of data by theoretical sampling and analyses of the data through the constant comparison" (Mavetera, & Kroeze, 2009, p. 8). However, given the extent of the wicked problem and the research limitations associated with involving all agencies connected to the problem, it was determined that only public health units would be involved in the study. As a result, research questions were developed to guide the scope of study with a focus on the processes associated to the activities of public health units and L. *monocytogenes* and RTE meats (Strauss, & Corbin, 1990). Strauss and Corbin (1990) argued "the researcher would be faced with too many aspects to consider in a single research project" (Mavetera, & Kroeze, 2009, p. 8). Rather, Strauss and Corbin (1990) suggested development of a theory or research question "in a manner to facilitate flexibility and freedom for in-depth exploration" (Mavetera, & Kroeze, 2009, p. 8) while acting as a guide to focus the area of study.

3.6 Interview and Survey Instrument and Data Analyses

Requests for interviews with phase 1 and phase 2 participants were made via email after receiving acknowledgement of interest to participate in the study. No maximum or minimum time limits were allotted to interviews. Prior to each interview, a brief description of the research

was described to participants and written consent obtained in accordance with University of Waterloo requirements through research ethics clearance (see Section 3.1). Interviews were conducted either via telephone or in-person at the public health unit or preferred choice of location by the participant.

While research suggests that telephone interviewing is an "acceptable and valuable method of data collection" (Sturges & Hanrahan, 2004, p. 110), interviews were also conducted in-person where time and location (in proximity to the University of Waterloo) permitted. While in-person interviewing does have its disadvantages, such as increasing interview bias based on body language and cues, it provides a number of advantages. For example, in-person interviews reduced interviewee access to answers when asked questions (i.e., accessing a computer during the interview). Face-to-face interviews also increased the likelihood of spontaneous answers without delay in response. Face-to-face interviews allowed for the principle investigator to pick up on social cues (e.g., body language) which were noted in interview notes via *memoing*. *Memoing* refers to the practice of taking written notes ('memo') defined as "our abstract thinking about the data" (Green, & Thorogood, 2009, p. 205). *Memoing* included the process of creating "operational notes about data collection, but also theoretical memos, which are an essential step in the development of analytical ideas" (Green, & Thorogood, 2009, p. 205). In-person meetings were used in 12 of 22 interviews conducted.

Purposive and theoretical sampling was used for recruitment of food safety participant representatives given that all 36 public health units were requested to participate in interviews while those who asked to partake in the study participated in at least one phase of the research (see Section 3.1). The intent of interviews conducted in phase 1 and phase 2 was to attempt to reach theoretical saturation. Theoretical saturation (see Section 3.6.5) refers to the process of

terminating sampling and data collection when the researcher "concludes that new respondents are not adding anything significant" (Whitley & Crawford, 2005, p. 3). In total, 6 interviews were conducted in phase 1 and 16 interviews conducted in phase 2 (see Table 9).

Table 9: Research Phase Activities, Participants and Objectives

Research phase	Research activities	Number of interviews conducted: food safety management participants	Number of interviews conducted: public health inspector	Objectives
Exploration phase (phase 1)	Open-ended / free-style interviews	N = 3	N = 3	Using open, axial and selective coding along with memoing to develop themes (core categories) to create interview focus and questioning for phase 2
Specification phase (phase 2)	Semi-structured interviews (using open-ended and a free-style approach) based on system of categories identified in the exploration phase	N = 8	N = 8	Use of coding to assist in the identification of core concepts for the reduction and integration phase Completion of phase 2 interview stage based on reaching theoretical saturation
Specification phase (phase 3)	Confirmatory questionnaires via internet survey to all participating public health unit	N = 23	N =22	Based on interview responses provided in phase 2, provide survey to reinforce coding from phases 1 and 2 of the interviews

Upon reaching theoretical saturation, all participating public health units were asked to complete an internet survey for phase 3 of the study. This included those participants that were interviewed in phase 1 and in phase 2. Participants were provided with an introductory letter (via webpage) to introduce the survey and were provided instructions on completing it. The purpose of the use of the survey was confirmatory; that is, to ensure that responses provided in phase 1 and phase 2 interviews were consistent with the views of all participating public health units. Furthermore, the survey in conjunction with other materials served as a means of constant comparison in supporting the development of a theory in the integration phase of the

study. The survey was sent to participating public health units using Fluid surveys (www.fluidsurveys.com). Fluid surveys was chosen given that they have been used in other peer-reviewed research conducted in other Canadian Universities, including the University of Windsor (http://www.uwindsor.ca/web/fluidsurveys) and Canada's Advanced Research and Innovation Network (http://www.carl-abrc.ca/publications/elert/2011/elert416-e.html). In using fluid surveys, data were stored in Canada and thus not privy to the *Patriot Act* in the United States where data could be accessed without consent. A copy of the introductory letter provided to participants can be found in Appendix C.

3.6.1 Phase 1 and Phase 2 Interviews

Phase 1 and phase 2 questioning (see Tables 10 and 11) included *free-style* or *open ended* questions as described by research (Glaser, 1998; Strauss & Corbin, 1990). This method of questioning was critical to the generation of a theory and is based on addressing the components of the wicked problem as described in Section 3.5. The intent of phase 1 questioning was to identify core categories using grounded theory methods described by research to establish phase 2 questioning (Glaser, 1978; Glaser, 1998; Glaser, 2001; Glaser, 2005; Strauss, & Corbin, 1990). Questions were developed to address components of the central research and associated three research questions as described in Section 1.3.

Table 10: Phase 1 Interview Questions

Participants	Question	
-Food safety management **-Public health inspector**	What is your opinion in regards to the roles and responsibilities of public health units in inspection and investigation of RTE meats and L. *monocytogenes?*	
	Sub-questions (if necessary)	- What are your thoughts on provincial policies and regulation of RTE meats and L. *monocytogenes*? - How does your public health unit incorporate research, innovation and knowledge translation into your inspection program in relation to RTE meats and L. *monocytogenes*? - Does your public health unit face technical, economic and political issues in regards to RTE meats and L. *monocytogenes*?
	Tell me about a time when you addressed L. *monocytogenes* and RTE meats within your food safety program?	
	Sub-questions (if necessary)	- Did this result in a change to your policies and procedures related to RTE meats and L. *monocytogenes*? If so, what was the change? - Are there any other examples you can provide?
	What resources do you use for the purposes of the development of your food safety program in particular to RTE meats and L. *monocytogenes*?	
	Sub-questions (if necessary)	- Are there any best practice documents that you can reference that you have used in the past? - Are there any resources you would like to have developed for your food safety program in particular to RTE meats and L. *monocytogenes*? Who would you say is the best organization to develop these resources?
	What lessons has your food safety program drawn from outbreaks, recalls and investigations involving L. *monocytogenes* and RTE meats?	
	Sub-questions (if necessary)	- How did you address these outbreaks/recalls? - How would you have liked to have addressed these outbreaks/recalls?

Phase 1 questions were pilot-tested with a convenience sample of public health unit personnel who did not meet the participant eligibility requirements listed in Table 7. As a result of the test pilot, additional 'sub-questions' for each main question (see Table 10) were added in an attempt to elicit further dialogue on the subject area. Similar to the development of the main questions, the sub-questions were structured in a manner to address the study research questions. Both the main question and the sub-questions (see Table 10) were asked of all six phase 1 participants. The pilot group tested was not a part of the phase 1 or phase 2 interviews nor the phase 3 survey.

As a result of the themes identified through the substantive coding process in phase 1, four core categories emerged and were subsequently used to develop questioning for phase 2 interviews (see Table 11).

Table 11: Phase 2 Interview Questions

Core categories (phase I analyses)	**Questions and sub-questions**	
Prevention through collaboration	Based on your experience with the following agencies, describe your relationship in particular to L. *monocytogenes* and RTE meats with: (i) CFIA (ii) PHAC (iii) OMAFRA (iv) MOHLTC (v) PHO Is there any room for improvement in the relationship you currently have with each of these agencies that would support the manner in which you address L. *monocytogenes* and RTE meats? Please describe.	
	Sub-questions (if necessary)	- What are your thoughts in regards to the roles of provincial and federal agencies in providing knowledge and expertise to Ontario public health units? - To what extent is the current MOU between OMAFRA, CFIA and Ontario public health units where processing facilities are not inspected by public health inspectors beneficial or a detriment to the overall inspection process?
Population and product-based management	What do you think Ontario public health units' role in institutional settings should be where vulnerable populations such as the elderly or the immunocompromised are housed and are served RTE meats?	
	Sub-questions (if necessary)	- Should the manner in which inspections are conducted at these facilities in Ontario public health units differ from other retail establishments that serve RTE meats? - Has your public health unit established a different approach in regards to these populations and facilities? Please provide any examples.
Response driven research	- In what ways did the L. *monocytogenes* outbreak in 2008 (Maple Leaf Foods) lead to changes to the manner in which your health department addresses RTE meats and L. *monocytogenes*?	
	Sub-questions (if necessary)	- What is your opinion in regards to the use of scientific research or government publications in public health units for the purposes of inspection and investigation of listeriosis? - Have government publications or scientific research had any effect on the day-to-day operations of your public health unit? - Does your public health unit currently have a L. *monocytogenes* policy in place? (YES - why did you feel it necessary to have one in place? NO – are there reasons why your public health unit does not have a policy?)
Regulatory and microbiological limitations	What is your opinion in regards to the current provincial food safety program in Ontario including the *Food Premises Regulation*, Ontario Food Safety Standard and Food Safety Protocol (2008) as it relates to L. *monocytogenes* and RTE meats?	
	Sub-questions (if necessary)	- Do you believe that past outbreaks, recalls and research in regards to L. *monocytogenes* and RTE meats have had an impact on the *Food Premises Regulation* along with the Protocol and Standard? Please explain. - What components of your inspection program could use additional support in your investigations and inspection of RTE meats and L. *monocytogenes*?

		- What is your opinion in regards to the L. *monocytogenes* surveillance and management program in Ontario? Do you feel that the incidence of listeriosis related to consumption of RTE meats is sufficiently managed and controlled from a federal, provincial and public health unit level?

In addition to the interview questions (see Table 9), requests were made in all phases of interviews and survey for copies of inspection forms, risk assessment tools, and policies and procedures used by the public health unit in the food safety program. Lists of documents that were requested are provided in Table 12. These documents were used as data for the purposes of constant comparison (see Section 3.6.2) to inform the analyses.

Table 12: Examples of Documents Requested from Interview Participants

Document type	Description
Communication documents	- Public communication documents related to RTE meats and L. m*onocytogenes* - Food establishment communication documents related to RTE meats and L. *monocytogenes*
Risk assessment documents	- Food establishment inspection risk assessment tool - Food establishment inspection risk assessment policy
Inspection documents	- Food safety compliance inspection template - Food safety recall inspection template - Food safety foodborne illness inspection template
Policies and best practice documents	- Inspection policies - Food recall policies - Foodborne illness policies - External agency best practice documents (i.e., CFIA, MOHLTC, OAHPP, United States Centre for Disease Control)

Interviews were conducted with notes being recorded both in written and audio recorded format. All interviews were transcribed for analyses after cross-referencing interview notes with audio recorded notes. Transcriptions, field notes and documents collected were analyzed for emergent categories associated with the field of study using grounded theory methodology which is described in Figure 3.

In accordance with the process set out in Section 3.6 and from comparable research study methodologies, phase 1 and phase 2 data were coded in order to develop a theoretical construct to address the wicked problem (Broom, 2005; Glaser, 1992; Green, & Thorogood, 2009; Hale et

al., 2008; Holton, 2010; Strauss, A., Corbin, J., 1990; Verpy et al., 2003; Whitley & Crawford, 2005; Wuest, Ford-Gilboe, Merritt-Gray, & Lemire, 2006). Two types of coding were used; *substantive* coding in the exploration, specification and reduction phases, and *theoretical* coding used in the integration phase as described below.

3.6.2 Substantive Coding

Substantive coding included the use of open, axial and selective coding in conjunction with theoretical sampling to fracture phase 1 and phase 2 interview data to assist in identifying core variables. Core variables were identified through axial coding. *Substantive coding* included fracturing the interview data using open coding procedures and analyzing data initially for the emergence of a *core category* and related concepts. Open coding refers to the process whereby the interviews were analyzed line-by-line and comparing indicators in order to yield codes which ended up in the axes of the transcribed interview (Holton, 2010). The line-by-line analyses allowed for data to be scrutinized in a manner that provoked the research team to ask questions that sustained "the researcher's theoretical sensitivity...and encouraged a focus on patterns among incidents that (yielded) codes" (Holton, 2010, p. 24). After completing the first health unit interviews in phase 1 and phase 2 (with a management representative and a public health inspector), the research team (see section 3.6.6) met to develop "categories of codes" after open coding "in order to confirm methods for interpretation and extraction" (Sargeant et al., 2007, p. 179). After the research team agreed on terminology for open coding, axial coding was completed and lead to "theoretical sampling and selective coding of data to theoretically saturate the core categories" (Holton, 2010, p. 21). Theoretical sampling is the process by which "data are coded and constantly compared, while (theories) are generated about the emerging concepts and their relationships and additional data are collected to test the (theories)" (Wuest et al.,

2006, p. 494). Axial coding involved making connections or "relationships between categories" (Green, & Thorogood, 2009, p. 205) to create core variables. According to Brown et al., (2002), the "focus of axial coding is to create a model that details the specific conditions that give rise to the phenomenon's occurrence" (p. 5)

Selective coding followed open and axial coding. Selective coding only began after the core variables had been identified via the processes of open and axial coding. Through the identification of the core variables, core categories were identified to "form the basis of the emerging theory" (Holton, 2010, p. 11). The process of selective coding involved delimiting the core variables in order to identify the "emerging conceptual framework" (Holton, 2010, p. 31) to create core categories. This occurred by identifying uniformity in categories to reformulate the theory with "higher level concepts" (Holton, 2010, p. 11) which ultimately lead into the on-going process of theoretical saturation after the completion of the phase 3 survey (see Section 4.2.2.1).

3.6.3 Phase 3 Survey and Data analyses

The phase 3 survey (see Table 13) involved participants answering 7 content questions that were created based on the core variables from the phase 2 data analyses along with themes from the central research question (see Appendix H). All questions were followed using likert-scale levels of agreement including: *strongly disagree, disagree, neither agree nor disagree, agree,* and *strongly agree*. Participants were also free to provide open-field written text at the end of each question to allow additional insight or feedback.

Table 13: Phase 3 Questions

Core variables (Phase 2 Analyses)	Questions
Communication and collaboration	Question # 1: Please indicate your level of agreement with the following statement: "The 2008 L. *monocytogenes* outbreak, along with subsequent food recalls involving L. *monocytogenes*, have had an effect on my public health unit's food safety inspection program and inspection of RTE meats in food premises"
Knowledge and statistical relevance	Question # 2: Please indicate your level of agreement with the following statement: "Research and government publications are tools that my public health unit uses to address food safety risks, such as RTE meats and L. *monocytogenes*."
Responsibility and procedure	Question # 3: The current MOU between the OMAFRA, the CFIA and Ontario public health units states that licensed RTE meat processing plants are to be inspected by the licensing body (i.e., either by OMAFRA or the CFIA). Thus, typically, licensed facilities are not inspected by Ontario public health units. Based on your experience with this MOU, to what extent do you agree with the following statement: "Our public health unit rarely (if ever) communicates with OMAFRA or the CFIA in regards to their inspection of licensed RTE meat processing plants"
Responsibility and procedure	Question # 4: Please indicate your level of agreement with the following statement: "In order to address the risks of L. *monocytogenes*, Ontario public health units that inspect long term care facilities, homes for the aged, assisted living centres and retirement homes should have food safety requirements for food handlers who prepare RTE meats and serve to residents."
Regulatory focus	Question # 5: Please rate your level of agreement in regards to the following statement: "Our public health unit addresses L. *monocytogenes* and RTE as a part of the general inspection process. We do not currently have microorganism and product-specific policies and procedures in place that address L. *monocytogenes* and RTE meats explicitly"
Regulatory focus	Question # 6: Please indicate your level of agreement with the following statement: "The Ontario Food Safety program - including the Ontario Food Safety Standard, Ontario Food Safety Protocol (2008), and *Food Premises Regulation* -- has effectively incorporated recent research findings, and is using lessons from previous outbreaks (e.g., Maple Leaf Foods 2008) to better address L. *monocytogenes* in RTE foods"
Regulatory focus	Question # 7: Please indicate your level of agreement with the following statement in regards to *Food Premises Regulation*: "The *Food Premises Regulation* is sufficient for Ontario public health units to effectively address food safety risks, such as RTE meats and L. *monocytogenes*"

Upon receiving completed survey results, data were analyzed in two methods. First, open-field written text were analyzed using qualitative data analysis software (Nvivo qualitative data analysis software; QSR International Pty Ltd. Version 10, 2012) in order to quantify any potential new themes in the data associated with each research question. Second, levels of agreement among responses were analyzed for trends using chi-square tests with SPSS predictive analytics software (SPSS ® 19.0). Chi-square tests were carried out to determine if there were

significant differences between the study sample level of agreement and; (i) the respondent's public health unit category (1,2 or 3); and (ii) the participant cohort (food safety management and public health inspector). Confidence intervals were also calculated for reasons explained in Section 4.2.2.

3.6.4 Post-Interview and Survey Questionnaire

All candidates interviewed and surveyed were asked to answer a questionnaire provided in

Table 14: Post-Interview Questionnaire

Food Safety Management	**Questions**
Experience	Total number of years in management of public health programming
	Total number of outbreaks involving L. *monocytogenes* that public health unit has investigated in the past 3 years
Health unit	Total number of food premises in public health unit that serve/sell/produce RTE meats in public health unit
	Total number of staff devoted to the inspection of food premises
Collaboration	Has conducted training with the OMAFRA and/or the CFIA re: RTE meats and L. *monocytogenes* in the past 3 years?
	Has conducted joint inspections with OMAFRA/CFIA in provincially/federally regulated facilities producing RTE meats? If not, acquires inspection reports from OMAFRA/CFIA in their regulated facilities (if applicable)?
Public health inspector	**Questions**
Experience	Total number of years as a practicing public health inspector conducting inspections under the *Food Premises Regulation*?
	Total number of outbreaks involving L. *monocytogenes* that inspector has investigated in the past 3 years?
Training	Total number of trainings on HACCP and/or Codex processes in the past 3 years?
	Total number of trainings on best before dates and/or product labeling in the past 3 years?
	Has been trained by a professional institution (e.g., Institute, Organization, and College/University) in HACCP processes for RTE meat products?
Practice	Total number of full HACCP audits on RTE meat products that inspector has conducted since 2008 (implementation of the Ontario Food Safety Standard and Food Safety Protocol)?
	Total number of food premises in which inspector has conducted food and/or non-food contact surface testing in the past 3 years?

Table 14 after completion of the interview for the purpose of data analyses and cohort characterization of the food safety management, and public health inspectors groups.

3.6.5 Theoretical Saturation and Coding

Theoretical saturation was achieved in the reduction phase after completion of phase 1 and phase 2 interviews along with comments from the phase 3 survey. *Theoretical Saturation* "was achieved through constant comparisons of indicators in the data to elicit the properties and dimensions of each category (code)" (Holton, 2010, p. 21). This constant comparison of indicators continued until the process yielded "the *interchangeability of indicators*, meaning that no new properties or dimensions were emerging" (Holton, 2010, p. 32) from continued coding and comparison. Theoretical saturation could only be declared after interview and survey data were collected and analyzed by all members of the research team (see Section 3.6.6.).

Once theoretical saturation had taken place, all data provided to the principle investigator were revisited in order "to make sense of the patterns" (Broom, 2005, p. 71). This included revisiting and sorting of memos (via *memoing*), and re-examining the literature along with the documents supplied by food safety participants in Table 12. Memos were sorted to assist in generating the "emergent theoretical outline, or conceptual framework for full articulation of a grounded theory" (Holton, 2010, p. 15). The integration phase of the process focused on the development of the theory where each category and code identified through substantive coding and theoretical saturation accounted for "relationships between the concepts" (Holton, 2010, p. 17) through a process referred to as *theoretical coding*.

The purpose of theoretical coding in grounded theory is to "uncover the main problem in a substantive area, as well as the resolution to this problem...known as the core category" (Hernandez, 2009. p. 52). The core category was used to assist in the construction of the emerging study theory to account for the relationships "between concepts" (Holton, 2010, p. 28).

This theory explains the "pattern of behaviours" (Holton, 2010, p. 10) within the complex system examining L. *monocytogenes* and RTE meats.

3.6.6 Research Team

The research team consisted of the principle investigator along with a graduate student from the School of Applied Health Sciences (University of Waterloo). The graduate student participated principally in the substantive and theoretical coding process as described in Section 3.6 for the purposes of multiple coding and to reduce investigator bias. Coding was completed independently for phase 1 and phase 2 interviews after determining the 'categories of codes' collectively with the research team (see section 3.6.2). Expectations on the graduate student included a focus on the following phases of the research process:

> **(i) Exploration, Specification and Reduction phases:** In parallel with the principle investigator, coded interviews conducted in phase 1 and phase 2 along with free text comments in phase 3 surveys using substantive-coding methods to identify the core category; and
>
> **(ii) Reduction and integration phases**: In conjunction with the principle investigator, identify point of theoretical saturation and conducted theoretical coding in assisting the principle investigator in the development of a theory which characterized the central processes in the field of study and in particular, the wicked problem.

To participate in the analyses of the data in this study, the graduate student was required to have been enrolled in the Master of Public Health program (University of Waterloo). Prior to the analyses of data, the graduate student was provided with a copy of the research proposal along with a brief introduction describing expected duties and activities. The graduate student was chosen based on the selection criteria provided in Appendix I.

3.6.7 Supporting Coding Using Qualitative Data Analysis Software

In addition to the use of multiple coding to analyze transcripts, qualitative software programming (Nvivo) was used to provide additional data analyses support. Software programming allowed for efficient organizing and classification of data where findings were used to link back to original data. In addition, the software assisted in organizing and indexing codes to provide a conceptual framework for the study. Software analyses of transcripts assisted in identifying gaps in analyzed data. Data trends and analyses provided by the software were used primarily as a cross-reference to the coding exercises conducted by research team in order to support findings.

3.7 Addressing Study Bias

A number of processes were used to address potential qualitative research bias in the study. Identified biases included *investigator, moderator, sampling, interview, social desirability, and methodological perspective*. Processes involved in addressing bias in the study included:

(i) *Investigator bias*. In order to reduce bias attributed to the investigator completing the data analyses, research suggests multiple coding and triangulation methods be used to address "investigator bias" (Whitley & Crawford, 2005, p. 5). Multiple coding involved the research team analyzing the same data set and then comparing and discussing findings. Multiple coding involved the research team performing analyses on the interview data as described in Section 3.6. The processes of multiple coding "diminished investigator bias and can be (seen) as a qualitative form of interrater reliability" (Whitley & Crawford, 2005, p. 5). Triangulation was also used to assist in providing completeness and confirmation of research data and included the following

components which were used to support the analyses of the data (Risjord, Dunbar, & Moloney, 2002):

a) Phase 1 and phase 2 interviews;

b) Documentation (see Table 12); and

c) Phase 3 survey.

(ii) *Moderator Bias*. Includes bias involved in the interview process where the interviewer may provide subtle cues to the participant (e.g., facial expression, body language). In order to address moderator bias, phase 1 and phase 2 interviews were conducted both in-person and over the telephone. In phase 1, two of three interviews were conducted in person while four of eight interviews were conducted via telephone in phase 2 interviews.

(iii) *Sampling bias*. All provincial public health units were provided with an opportunity to participate in the study via written invitation (see Appendix C) and thus sampling bias is limited. However, the decision as to who would participate from each health unit was left to the Medical Officer of Health or public health unit director who received the email to participate in the study (see Appendix C). As a result, there may have been some bias introduced into the study based on who the Medical Officer of Health or public health unit director choose to participate from each health unit which was not within the control of the researcher.

The decision to conduct telephone or an in-person interview was based on interview candidate availability and based on proximity to the University of Waterloo and date availability. Public health unit selection for interviews conducted in phase 1 and phase 2 were based on criteria provided in Table 15 that placed each of the participating public health units into category 1, 2 or 3. Criteria listed in Table 15 were selected in an attempt to estimate the 'size' of the public health unit to ensure that interviews were completed with public health units that

represented urban, rural, and urban-rural mixed organizations. Category 1 public health units were described as 'urban-centred' units that likely had a large urban centre(s) with a number of food premises requiring inspection and subsequently requiring a large number of public health inspectors and managers to conduct these inspections. Category 2 public health units represented 'urban-rural' mixed units with a combination of urban centre(s) and rural geography. Lastly, category 3 public health units represented 'rural-centred' units that required a small number of public health inspectors and managers as a result of a small number of food premises requiring inspection. As a result, phase 1 interviews were conducted with public health units from each of the categories (1, 2 or 3) as described in section 3.1. Phase 2 interviews were conducted with three public health units representing category 1, three public health units representing category 2 and two public health units representing category 3 public health units.

Table 15: Public Health Unit Criteria Category Parameters

Category	Criteria
Category 1 public health units (urban)	> 15 public health inspectors within the food inspection program of the participating public health unit > 3000 food premises inspected annually within the food program of the public health unit > 10 managers dedicated to public health programming in the public health unit
Category 2 public health units (urban-rural)	≥5 and ≤15 public health inspectors within the food inspection program of the participating public health unit ≥ 1500 and ≤3000 food premises inspected annually within the food program of the public health unit ≥ 5 and ≤ 10 managers dedicated to public health programming in the public health unit
Category 3 public health units (rural)	< 5 public health inspectors within the food inspection program of the participating public health unit < 1500 food premises inspected annually within the food program of the public health unit < 5 managers dedicated to public health programming in the public health unit

(iv) *Interview Bias*. This group includes a host of survey-related biases such as *leading question bias*, and *question order bias*. The use of grounded theory as the interview methodology is effective in the management of biases associated with the lineage and process of

questioning. By adopting open-ended or a free-style methodology for interviews conducted in phases 1 and 2 (see Section 3.3.1), the interview participant was free to provide his/her opinions and thoughts on the issues discussed without being influenced by the questions. While phase 2 interviews focused on addressing the wicked problem based on the substantive coding process, the questions remained open-ended in order to remain consistent with the grounded theory processes described in Section 3.1.

(v) *Social desirability bias*. Bias which refers to "the systematic error in self-report measures that results from the desire of respondents to project a favorable image to the researcher" (Fisher & Tellis, 1998, p. 563). Social desirability "is one of the most common sources of bias affecting the validity of experimental and survey research findings" (Nederhof, 1985, p. 263). There are a number of ways in which social desirability bias was reduced in the study. For example, verification was used with interview responses in conjunction with documents provided to the interviewer (see Table 12) after the interview was completed. Other techniques included having in-person, telephone and survey candidates agree to the terms of the consent review (see Appendices D, E, F, J, and K), which informed the participant that the interview responses would remain confidential and anonymous.

(vi) *Methodological perspective bias*. This bias refers to the experiences and expertise that a researcher brings into a research study. In conducting a literature review prior to facilitating interviews using a grounded theory methodology, the researcher may introduce bias into their line of questioning and interpretation of the data (Deady, 2011). In order to reduce potential bias related to conducting a literature review, research was completed in 2 phases and used as a source of "data that (were) a part of the constant comparison analyses process" (Deady, 2011, p. 51). In addition, a subsequent literature review was conducted after construction of the

core categories (see Section 4.2.3.2.) for the purposes of constant comparison. This is completed, according to Glaser (1998) to avoid looking to the literature as a reference "for the authenticity and authority of the printed word and published author" (p. 72). *Methodological perspective bias* was reduced through the use of the research team concept in the analyses of interviews and associated documents. Qualitative data analysis software was also used to analyze the data thus further reducing the likelihood of bias in the research.

3.8 Privacy, Confidentiality and Participant Feedback

Privacy and confidentiality of interview and survey responses in phase 1, phase 2 and phase 3 were addressed prior to data collection and analyses phases of the research. Written consent forms were required to be signed by interview participants prior to conducting interviews in phase 1 and phase 2. After completing each telephone or in-person interview in phase 1 and phase 2, audio transcripts were transcribed using transcription software. Transcribed documents were reviewed and any reference to personal names or to names of public health units provided in the transcriptions were removed for the purposes of the analyses by the researcher. Public health unit names and/or personal names were replaced with a letter (e.g., 'public health unit A', 'person B') to produce a de-identified data set for the purposes of analyses. Direct identifiers including food safety management and public health inspector names, public health unit names, food establishment names, and elements of date related to an individual or investigation were eliminated. Indirect identifiers pointing to unique cases or investigations (e.g., larger listeriosis outbreaks) were de-identified so as to reduce any reference to location or variables which may have acknowledged a public health unit or participant involved.

3.8.1 Records Management

Paper and audible records of interviews with public health unit staff were kept using the University of Waterloo secured drive (M-drive server database). Paper records (.PDF) and audible records (.wav) were scanned and stored on the device and subsequently placed on the University of Waterloo secured drive (M-drive server database) after conducting interviews. Data are set to be destroyed within one (1) year of publication or three (3) years from completion of the data analyses, whichever comes first.

4.0 Results

4.1 Research Participant Overview

In total, 27 public health units participated in the study. Three public health units (for a total of six participants) participated in phase 1 interviews; eight public health units (for a total of 16 participants) participated in phase 2 interviews and 25 public health units (for a total of 45 participants) participated in the phase 3 survey. Of those public health units wishing to participate in the study, no participants declined after being provided with the interview/survey preamble (see Appendices D and K). On average, phase 1 interviews took 14.5 minutes to complete, phase 2 interviews took 19.5 minutes to complete and phase 3 surveys took 22 minutes and 37 seconds to complete.

Of the 45 study participants, 23 represented the food safety management group while 22 represented the public health inspector group. There were no representatives from 'key informants as described in Table 7. The average experience of the food safety management group was 10 years with a range from 3-26 years of experience as a public health manager, supervisor or director. The public health inspector group averaged 13 years of experience with a range from 3-34 years of practice. Based on post-survey data, both groups noted that they investigated an average of 1.25 cases of listeriosis in association with RTE meats per year in their public health unit since 2008. Just 4 participants from the food safety management group had received training from OMAFRA and CFIA on RTE meats and L. *monocytogenes* over the past 3 years. Furthermore, 4 participants from the food safety management group noted that their health unit public health inspectors regularly conduct inspections with the CFIA and OMAFRA in RTE meat processing plants. In regards to training, only 2 participants from the public health inspector group noted that they had some training related to HACCP since 2008

while 3 participants reported that they had received training in regards to product labeling including best before dates. Just 1 participant from the public health inspector group disclosed that their public health unit conducted complete (not modified) HACCP audits of RTE meats during their inspections while 6 participants reported that they had conducted food contact surface testing in conjunction with a L. *monocytogenes* and RTE meats investigation.

4.2 Research Findings

The following research findings are presented in a manner consistent with study methodology as depicted in Figure 3 in Section 3.0. The exploration phase is omitted from the results section since its activities were focused on the initial literature review, phase 1 interview questions (see Table 10) and the development of the process flow maps (see Figure 2).

4.2.1 Specification Phase

Results of phase 1 interviews are described in Table 16. Numerical values described in parentheses in Table 16 and in the results and discussion sections (see Section 4.0 and 5.0) are representative of the count of the number of times the code or phrase was referenced by the participants either directly or through analogous word(s) or phrase(s).

Table 16: Phase 1 Interview Results Summary

Open coding (n)	Axial coding (n)	Core variable (n)	Selective coding	Core categories
- Have support from other agencies (8) - Lack of communication (10)	Collaboration and partnership focus (18)	Communication and population-based focus (60): - agency collaboration, consistency and partnership - communication and information sharing - Crises management and response - prevention through communication - response - population-specific focus	Established process Evidence-based practice Targeted prevention and education Collaborative and partnership resourcing	Prevention through collaboration
Focus on education (4) Focus on vulnerable populations (13)	Prevention focus (17)			
Already have sufficient regulations (12) Enforce quality assurance by food premises (4) Insufficient regulations (9)	Regulatory focus (25)			Population and product-based management
Documentation is important (8) Need revision of internal policies and procedures (3)	Procedural focus (11)	Procedural, microorganism and epidemiological focus (122): - Outbreak and recall approach - procedural and risk based activities - regulatory and microbiological approach - microorganism limitations to case association - microbial prevention and reduction - regulatory and statistics based - regulatory-based control	Reactive and collaborative response Reactive and risk-based research Prevention in investigative restriction	Response driven research
Disconnect between inspection and responsibility (14) Lack of support (16)	Responsibility focus (30)			
- Effectiveness is a priority (1) - Efficiency is a priority (3) - Focus on credibility (5)	Results focus (9)			Regulatory and microbiological limitations
- Inspecting for microbiological hazards (29) - Involved with listeriosis-related cases or food recalls (19) - L. *monocytogenes* and RTE meats are a concern (3)	Outbreak and food recall focus (51)			
- Lack of evidence-based action (2) - Lack of relevant data (8) - Listeriosis not a burden of illness (11)	Statistical focus (21)			

4.2.1.1 Substantive Coding

Open coding using line-by-line analyses identified inconsistencies in organization response along with disparities in group response within a public health unit. For example, Table 16 describes that while a number of participants (n = 8) felt that they were adequately supported by OMAFRA and the CFIA, slightly more comments (n = 10) were noted where participants cited that there was an overall lack of agency communication to address the risk of RTE meat products at the retail level. Open coding also identified differences in opinions in regards to the sufficiency (n = 12) and insufficiency (n = 9) of the *Food Premises Regulation* to address RTE meat products and L. *monocytogenes*. Following axial coding, 2 principal core variables of focus were developed including:

(i) Communication and population-based focus; and

(ii) Procedural, microorganism and epidemiological focus.

After completing the process of selective coding based on the core variables, a number of recurring and substantive themes were identified throughout the analyses of phase 1 interviews that assisted in formation of the core categories. Key themes identified throughout phase 1 interviews included; *process*, *response* and *collaboration*. *Process* was referenced in relation to the existing regulatory and administrative framework. *Process* was referred to in the course of participant references to various recalls, outbreaks, and external organizations that impact the processing of RTE meat products throughout the province. *Process* was also referenced in relation to the existing regulatory infrastructure in place in the province. In particular, reference to the *Food Premises Regulation* was made extensively during the interviews in regards to its perceived sufficiency (or insufficiency) specific to RTE meat products and L. *monocytogenes*. Participants who noted that the regulatory framework was generally insufficient (n = 9) suggested that the microbiological characteristics of L. *monocytogenes* including its growth in

regulated cold-holding environments and its ubiquitous nature made the current iteration of the *Food Premises Regulation* inadequate. Conversely, participants who considered the regulatory framework as sufficient referenced that the general food safety principles and requirements in the regulation as adequate to control for L. *monocytogenes* growth in food preparation settings and did not consider it to represent a significant threat to the burden of illness (n = 11). For example, a food safety manager participant noted that "ready-to-eat meats are not an issue in our public health unit since we don't have a big issue with incidence of listeriosis".

Reference made to the theme of *response* was based on past (and present) recalls, outbreaks and investigations concerning RTE meats and L. *monocytogenes*. For example, *response* was used to illustrate participant risk assessments in regards to specific populations such as the elderly or pregnant women (n = 13) that they associated with being primarily affected by listeriosis. *Response* was also used to describe crises management and specifically, the 2008 L. *monocytogenes* outbreak (n = 19) associated with RTE meats. The 2008 outbreak seemed to elicit the theme of *response* in particular with the public health inspector cohort. References (n = 8) in regards to experience in addressing the microorganism in the field and reducing its impact using the tenants of the HACCP program were made throughout phase 1 interviews. Reference to *response* was also strongly associated with the food safety management cohort in particular with the use of public health unit foodborne illness statistics. Several participant references noted that a proactive risk reduction approach is not warranted for L. *monocytogenes* as a result of a lack of relevant data (n = 8) and burden of illness statistics related to listeriosis.

The theme of *collaboration* was referenced directly and indirectly by both groups of participants. *Collaboration* was used principally to describe the relationship of the public health unit with provincial (OMAFRA) and/or federal (CFIA) agencies and RTE meat processing

plants. In most cases, the food safety management cohort used the theme of collaboration to describe the MOU (n = 5) between public health units and provincial and federal agencies. References were made by both groups in regards to disengagement between inspection bodies as a result of an overall lack of communication (n = 10). Likewise, a number of references (n = 9) were made by the public health inspector cohort in regards to the infrequency of communication with federal and provincial agencies and an increase in collaborative efforts based on an event such as an outbreak. They noted that the infrequency of collaboration resulted in some cases to a lack of knowledge surrounding the processing of manufactured products that are eventually inspected by local public health unit staff. For example, one food safety management participant commented that "information including inspection sheets from the CFIA and OMAFRA for plants that they inspect would greatly assist our inspectors to identify some of the issues to look out for while in the field". Product best manufacturing processes and product characteristics (i.e., pH, aW) were noted (n = 5) as important information for public health inspector that would assist in improved risk assessments for products being sold and processed at the retail level.

4.2.2 Reduction Phase

Results of phase 2 interviews are described in Table 17. Similar to phase 1 interview results, numerical values described in parentheses in Table 16 and in the results and discussion sections (see Sections 3.0 and 4.0) are representative of the count of the number of times the code or variable was referenced by the participants either directly or through analogous word(s) or phrase(s).

Table 17: Phase 2 Interview Summary Results

Open coding (n)	Axial coding (n)	Core variable (n)	Selective coding	Core category
- Focus on operator and consumer education (24) - Have had L. *monocytogenes*-related training within PHU (2)	Knowledge and training (26)	Knowledge and statistical relevance (50)	Reactive-based practice	Reactive and regulatory practice
- Have research support within PHU to address risk (1) - Lack of evidence-based action (2) - Lack of relevant data to support proactive approach (12) - L. *monocytogenes* is currently not a focus of inspection program (9)	Statistical focus (24)			
- Changes already occurring to address risk (7) - Changes need to occur to address risk (29) - Focus on vulnerable population (12) - Not the responsibility of public health units (21) - Risk assessment-based product approach (10)	Procedural, population and product risk focus (79)	Responsibility and procedure (193)		
- Enforce quality assurance approach in food premises (22) - Inspecting for microbiological hazards (11) - Involvement strict to food recalls (20) - PHO has role in food-related outbreaks (5)	Inspection, outbreak and recall focus (58)			
- Disconnect between inspection agency and manufacturer responsibility (47) - Lack of support for public health units (9)	Agency and manufacturer responsibility (56)		Regulation through collaboration	
- Improved communication required from provincial and federal agencies (14) - Improved communication with public re: risk required (7)	Communication and risk-based approach (21)	Collaborative Communication (84)		
- Have financial support to address risk (2) - Lack of resources to address risk (4)	Resource focus (6)			
- Collaboration exists between inspection agencies (6) - Have direction from other agencies to address risk (6) - Have support to address risk (8) - Not much of a working relationship with other inspection agencies (27) - Resources are available to public health units (10)	Collaboration, resource and partnership focus (57)			
- Already have sufficient regulations (6) - Documentation is important (8) - Insufficient regulation to address food safety risk (22) - Regulation and guidance documents need to be amended (16) - Regulations are helpful but more is needed(13) - Food handlers should be certified (2)	Regulatory approach (67)	Regulatory focus (67)		

Core variables identified in phase 2 analyses included:

(i) Knowledge and statistical relevance;

(ii) Responsibility and procedure; and

(iii) Collaborative communication and regulatory focus.

The core variable, *knowledge and statistical relevance,* represented a number of topic areas associated with policy, practice and research. In particular, a number of references (n = 22) were made by both food safety management and public health inspector cohorts to propose that L. *monocytogenes* was not currently a threat to their food safety programming. Overall lack of concern by both cohorts focused predominantly on a lack of epidemiological data (n = 14) to suggest that listeriosis is a threat to their food safety programs. This trend is supported in data from the post-survey results which suggested the average number of outbreaks investigated for L. *monocytogenes* over the past 3 years by participating public health inspectors was 0.96. Both food safety management and public health inspector cohorts advised that general consumer and operator food safety education are their focus and not specific products such as RTE meats unless evidence (n = 12) supported a proactive approach. Nevertheless, participants acknowledged (n = 22) that the current food safety program in Ontario is insufficient in addressing the hazards associated with L. *monocytogenes*. Furthermore, participants noted (n = 16) that the *Food Premises Regulation* needs to be amended and that changes need to occur to address product risk (n = 26). For example, a participant in the food safety management cohort commented that:

> Listeria hasn't affected our public health unit really since the outbreak back a few years ago…but that doesn't mean that the *Food Premises Regulation* is meeting our needs currently…we have been asking for changes to the legislation for a number of years now to address these types of pathogens.

The core variable, r*esponsibility and procedure* focused primarily on the concepts of practice and research where agency responsibility, at-risk populations and mechanics of approach were addressed by participants. The mechanics of the relationship between public health units, OMAFRA and the CFIA was referenced (n = 18) in relation to responsibility of agencies involved with the RTE production and distribution processes. The consensus of participants focused on the perceived disconnect (n = 47) between public health unit's and provincial and federal agencies that inspect RTE meat products. Further, a number of references (n = 8) by the public health inspector cohort were made to associate the lack of public health unit inspection in provincial and federal RTE meat processing plants to a loss in product and process knowledge by public health inspectors. This was highlighted by the food safety management cohort who referenced that involvement with RTE meats and L. *monocytogenes* was strictly associated with CFIA issued food recalls (n = 14). When referencing recalls or investigations involving RTE meats and L. *monocytogenes,* both public health inspector and food safety management cohorts would associate with at-risk populations including the elderly and pregnant women (n = 12). This suggests recognition of product and population risk likely as a result of public health unit recall activities that are traditionally focused on institutional settings that house high risk populations.

The core variable *collaborative communication* addressed a number of themes that were associated with knowledge transfer and practice. There were a number of parallels between both the food safety management and public health inspector cohorts in regards to how they viewed their relationships with both OMAFRA and the CFIA. C*ollaborative communication* was focused on the manner in which public health units and the CFIA and OMAFRA interact during inspection and recall processes. A large number of respondents (n = 27) made reference to a lack of collaboration with OMAFRA and the CFIA. Both cohorts (n = 14) referenced the need to improve communication with OMAFRA and the CFIA in order to increase knowledge transfer to public health inspectors. These views were substantiated in the results of the post-survey, which demonstrated that just 4 public health units identified that they conducted joint inspections with the CFIA and OMAFRA in RTE meat processing plants. Furthermore, only 2 public health unit participants noted that they regularly requested copies of inspection reports from the CFIA and OMAFRA from inspected RTE meat processing plants.

The final core variable, *regulatory focus*, addressed a number of subjects associated with policy, practice and risk assessment. The food safety management cohort focused generally on the Ontario food safety regulatory framework and existing stakeholders, while the public health inspector cohort focused on product risk management and the *Food Premises Regulation*. For example, while a number of participants (n = 7) from the public health inspector cohort referenced that they used the *Food Premises Regulation* to assist generally in food safety inspections, a number of references (n = 19) were made to the lack of provisions within the requirements that were specific to RTE meats including cold holding, food handling and sanitizing requirements. References (n = 8) from the food safety management cohort were made in regards to general amendments and requirements under the *Food Premises Regulation* and

Food Safety Protocol pertaining to microbiological hazards including (among other pathogens) L. *monocytogenes* and culturally-diverse foods. For example, one participant from food safety management commented that:

> Listeria is just one of the issues that we need to keep an eye on in ready-to-eat foods… (however) we are constantly dealing with other microorganisms in new ready-to-eat foods from foreign cultures that we don't know anything about which has been a real challenge for us.

The food safety management cohort also cited (n = 14) the need to standardize the approach between public health units, the CFIA and OMAFRA in regards to inspection processes and requirements.

The process of selective coding identified two emerging codes from the data to frame the conceptual framework including:

(i) *Reactive-based practice;* and

(ii) *Regulation through collaboration*.

Reactive-based practice addressed the themes of *reaction* emerging from the data based on references to outbreaks associated with L. *monocytogenes* and RTE meats and in particular, the Maple Leaf Foods outbreak in 2008. For example, just 2 comments were received in regards to a proactive-based approach with operators and food processors using HACCP auditing and product or surface sampling. Rather, participant interviews suggested that public health inspection practice involving RTE meats and L. *monocytogenes* is driven by two distinct processes. First, public health units employ a general microbiological approach using the *Food Premises Regulation*. Second, a number of public health units (n = 21) suggested that they

believed that OMAFRA and the CFIA are solely responsible for adverse events associated with RTE meats and L. *monocytogenes*. For example, one participant from the public health inspector cohort commented that "public health units have little control with regards to these products since they enter food premises in a contaminated state that we (public health inspectors) can do little with". *Regulation through collaboration* addressed the emerging theme of *complexity* in particular to the wicked problem. Participants noted that the wicked problem is complex as a result of the number of stakeholders involved with the processing of RTE meats in conjunction with a complex regulatory structure at the provincial and federal level prior to public health unit involvement. Both cohorts acknowledged the difficulties associated with the multi-stakeholder engagement and referenced the weaknesses of the provincial regulatory framework (n = 22) in addressing specific microorganisms in association with specific products.

4.2.2.1 Phase 3 Survey Analyses and Results

The phase 3 survey was completed by 45 participants representing 26 public health units. The breakdown of participant public health unit categories included 13 category 1, three category 2, and 13 category 3 participants. In initiating the tabulation of phase 3 survey data, it was determined that the five levels of response categories provided to survey respondents could be collapsed to three as a result of sparse distribution of survey responses. Collapsed categories included;

(i) Strongly agree or agree;

(ii) Neither agree or disagree; and

(iii) Strongly disagree or disagree.

In collapsing the level of agreement, the number of respondents in each category increased slightly which assisted in reporting results. After completing the chi-square cross-tabulations

using both the collapsed and un-collapsed level of agreements, it was determined that results could not be used as a result of response rate values. In particular, a number of chi-square cross-tabulations involving statistically significant levels ($p < 0.05$) had more than 20% of the expected cells with less than 5 responses or with no responses (n=0). Research suggests that greater than 20% of cells with more than 5 responses are required to meet statistical significance (Yates, Moore, & McCabe, 1999, p.734). As a result, confidence intervals were used for the purposes of indicating the precision of the estimates and to note the numeric differences in the various study cohorts. All confidence intervals were calculated at the 95% level (alpha = 0.05). Confidence intervals (2-sided) listed for each proportion were based on the standard error of the proportion.

In total, 87 written text comments were received, with 32 comments received from 'return respondents' (respondents who participated in phase 1 or phase 2 interviews) and 55 comments received from 'new' participants (respondents who did not participate in phase 1 or phase 2 interviews). After the completion and analyses of phase 3 surveys, participant comments were entered into qualitative data software (see section 3.6.7) for the purposes of analyses. Analyses focused on the emergence of themes (core variables) in association with the research question and related topic. Core variables emerging from the phase 3 survey participant comments included; *population and product focus, agency responsibility and communication.*

As shown in Appendices M and N, the were a number of differences in the manner in which phase 3 survey results were distributed within the participant grouping based on the identified themes of

(i) Knowledge translation and communication;

(ii) Research and innovation; and

(iii) Regulation and policy.

4.2.2.1.1 Knowledge Translation and Communication

There was general consensus amongst phase 3 participants (71.1%, 95% CI: 57.86, 84.34) that communication between OMAFRA, CFIA and public health is limited in regards to RTE meat processing facilities. The majority of participating category 3 public health units agreed or strongly agreed (84.2%, 95% CI: 67.8, 100) that communication is lacking while 61.5% of category 1 and category 2 (61.5%, 95% CI: 35.05, 87.95) public health units felt similarly. Comments provided by participants focused on the theme of 'communication' and in particular, failed attempts to contact and subsequently maintain a consistent relationship with federal and provincial agencies to obtain inspection information. This leads to a decrease in knowledge translation for public health inspectors since information from provincial and federal agencies could be used in risk assessments in retail establishments where RTE meats are found. A number of comments (n = 6) focused on public health unit communication activities with OMAFRA and CFIA specific to product recalls. Within the cross-tabulations examining food safety management and the public health inspector cohort, participant comments suggested that communication with these agencies was conducted by food safety management and that few attempts to communicate with these agencies was made by front line inspection staff.

In regards to food handling requirements in institutional settings in association with RTE meats and vulnerable populations, less than half of respondents (42.2%, 95% CI: 27.77, 56.63) agreed or strongly agreed that food handlers should have requirements specific to RTE meat to address the risk of L. *monocytogenes*. Approximately one third of respondents (31.1%, 95% CI: 17.58, 44.62) neither agreed nor disagreed while a little more than a quarter of respondents (26.7%, 95% CI: 13.77, 39.63) disagreed or strongly disagreed. Those who agreed or strongly agreed stressed the need for additional training for food handlers who prepare RTE products for vulnerable populations in institutional settings. For example, one participant in the survey noted

that “the risks associated with RTE meats and their preparation can be dangerous for long term care facilities where vulnerable populations reside and therefore, there is a real need for food safety training for all food handlers in these facilities”.

4.2.2.1.2 Research and Innovation

A majority of phase 3 participants either agreed or strongly agreed (75.6%, 95% CI: 63.05, 88.15) that research, including government publications are tools that public health units use to address food safety risks including L. *monocytogenes* and RTE meats. There was, however some numeric difference in the manner in which phase 3 participants agreed or disagreed with the statement. For example, participating category 3 (84.2%, 95% CI: 67.8, 100) public health units agreed more so with the statement as opposed to category 2 public health units (53.8%, 95% CI: 26.7, 80.9). Numeric differences were also noted in regards to public health unit positions where 91.3% of the food safety management cohort (91.3%, 95% CI: 79.78, 100) agreed or strongly agreed while slightly more than half agreement was noted in the public health inspector cohort (54.5%, 95% CI: 33.69, 75.31). Comments provided by participants suggested that they rely on provincial and federal agencies to provide government publications and research in regards to RTE meats and L. *monocytogenes* to keep them up to date on risk management activities including population specific risks and product hazards. For example, one manager commented that “there is little time for health units to spend on the collection and analysis of research and other data that can assist us on the field….we need our provincial and federal counterparts to notify us is these products are a hazard”. Furthermore, a number of comments (n = 5) were made in reference to the lack of resources to read and interpret research in public health units. Further analyses of comments provided the theme (core variable) of population and product focus to describe references provided by participants.

Some variation in response was noted in regards to participant views on the use of research and lessons from previous outbreaks in changes to the Ontario food safety program including the *Food Premises Regulation*, Food Safety Standard and Food Safety Protocol. Nearly half of phase 3 participants (48.9%, 95% CI: 34.29, 63.51) noted that they disagreed or strongly disagreed that research and previous outbreaks have been incorporated to better address RTE meats and L. *monocytogenes*. Comments provided by participants focused primarily on a lack of change in the *Food Premises Regulation* as a result of the outbreak. For example, one participant commented that "the listeriosis outbreak from 2008 should have been a call to action for change to the food safety system including for local public health units… (however) no changes have been made as far as I know".

4.2.2.1.3 Regulation and Policy

More than half of participants (53.3%, 95% CI: 38.72, 67.88) disagreed or strongly disagreed with the statement that the *Food Premises Regulation* is sufficient to address RTE meats and L. *monocytogenes*. In particular, 57.9% of category 3 participants (57.9%, 95% CI: 35.7, 80.1) disagreed or strongly disagreed with the statement while approximately one third of category 2 participants provided the same level of agreement (30.8%, 95% CI: 5.7, 55.9). Furthermore, approximately 60% (59.1%, 95% CI: 38.56, 79.64) of phase 3 public health inspectors disagreed or strongly disagreed while slightly less than half (47.8%, 95% CI: 27.39, 68.21) of food safety management participants felt the same. Comments from participants ranged from a perceived lack of evidence-based regulation lending to the need for research to drive regulatory change that focuses on the dangers associated with L. *monocytogenes* and vulnerable populations. For example, a number of comments (n = 5) focused on a perceived lack of public health unit control in addressing the risks associated with RTE meats since they

believed that the regulation omitted them from eliminating the hazard (L. *monocytogenes*) up stream where they are produced and manufactured.

Little discrepancy was noted with participants' responses in regards to product and microorganism specific public health unit policies that address L. *monocytogenes* and RTE meats. In particular, an overwhelming majority of participants (97.7 %, 95% CI: 93.32, 100) agreed or strongly agreed that their public health units address RTE meats and L. *monocytogenes* as a part of the general inspection process. Comments (n = 5) focused on the use of general HACCP principles and the enforcement of *Food Premises Regulation* in addressing all food products and microorganisms in inspecting food premises along with the need for provincial and federal agencies to employ these techniques in production.

Over 40% (42.2 %, 95% CI: 27.77, 56.63) of participants agreed or strongly agreed that the 2008 outbreak involving L. *monocytogenes* and RTE meats had had an effect on their public health units food safety program. Approximately one quarter of participants (24.4 %, 95% CI: 11.85, 36.95) disagreed or strongly agreed that the outbreak had had an effect on their programming. However, a number of comments provided by participants indicated that they believed that change was not required as a result of the outbreak given the lack of control by local public health inspectors. For example, a public health inspector noted that "while the outbreak was extensive enough to get people's attention, the way that we (health units) inspect these products shouldn't change since the risk is something we cannot control for". As a result, the core variable of 'agency responsibility and policy' was used to describe comments provided by participants.

4.2.3 Integration Phase

4.2.3.1 Theoretical Saturation

After identifying the core variables resulting from the analyses of the phase 3 survey comments, themes were then compared (see Table 18) to the core categories and core variables provided in tables 16 and 17 for phase 1 and phase 2.

Table 18: Core Category and Variable Summary Chart

Theme	Phase 1 (core categories)	Phase 2 (core variables)	Phase 3 (core variables)
Ready-to-eat meat and population	Population and product-based management	Knowledge and statistical relevance	Population and product focus
Policy and procedure	Response driven research	Responsibility and procedure	Agency responsibility and policy
Collaboration and communication	Prevention through collaboration	Collaborative communication	Communication

Given that the focus of the themes was similar to those themes that had emerged from phase 1 and phase 2 (*interchangeability of indicators)* as illustrated in Table 18, it was determined that theoretical saturation had been reached and no subsequent interviews or analyses were required in order to proceed to the process of theoretical coding.

4.2.3.2 Theoretical Coding and Theory Development

In identifying the core variables in phase 2 and phase 3 in the reduction phase and in establishing theoretical saturation, theoretical coding was initiated in order to develop a theory about the field of study through the identification of core categories. The process involved revisiting sources of input in order to make sense of patterns and emerging theory. Sources of input included:

(i) Phase 1 and phase 2 coding charts (see tables 16 and 17);

(ii) Phase 3 results (see appendices M and N);

(iii) Interview memos (*memoing*);

(iv) Documents supplied by survey and interview participants (policies and procedures; MOHLTC documentation, inspection documents as described in Table 12); and

(v) Literature review processes.

As described in Section 4.2.3.2, an additional literature search was conducted in the integration phase. This allowed emerging themes as described through core variables and selective codes to be reviewed in the literature and used in the emergence of the core category and theory development. The MEDLINE (PubMed, CSA Illumina Version, OVID version) database was accessed during the months of May to June, 2012. Searches were restricted to publications in the English language between 1992 and 2012 and were also restricted to Canadian publications to ensure relevance to the processes involved in the integration phase. The following combinations of keywords were used: (*Listeria monocytogenes* OR Listeria OR listeriosis) AND (ready-to-eat food, OR deli meat OR processed food OR food) AND (immunocompromised OR aged OR older adults OR pregnancy) AND (agency OR federal OR provincial) AND (regulation OR policy OR statute OR legislation) AND (communication OR collaboration) AND (recall OR response) AND (knowledge translation OR KT). These terms were used interchangeably and in combination with one another to increase search results. Additional articles were identified through 'snowballing' or cross-checking citations in the listed references of the retrieved articles. The MeSH Database (through PubMed) was also accessed using the following MeSH terms for research related to L. *monocytogenes*, RTE meat and risk assessment: 'Listeria'[Mesh], 'food preservation'[Mesh], 'risk assessment'[Mesh], 'risk management'[Mesh], 'aged' [Mesh], 'government'[Mesh], 'legislation and jurisprudence'[Mesh] and 'knowledge' [Mesh]. The terms were used interchangeably and in combination with one another so as to increase search results. In total, 67 articles were retrieved as a result of

searching the databases. However, a majority of the articles had already been retrieved in the initial literature search (see Section 1.1) and thus, only a small number of articles were used for the purposes of theoretical coding.

After reviewing all sources of input, core variables and emerging themes were plotted within the matrix as described in Figure 1 to assist in processing the study core categories in order to address the central research question and three study research questions. Furthermore, direction was provided to arrows based on the core category and identified themes. As a result of the theoretical coding process and as described in Figure 4, it was determined that:

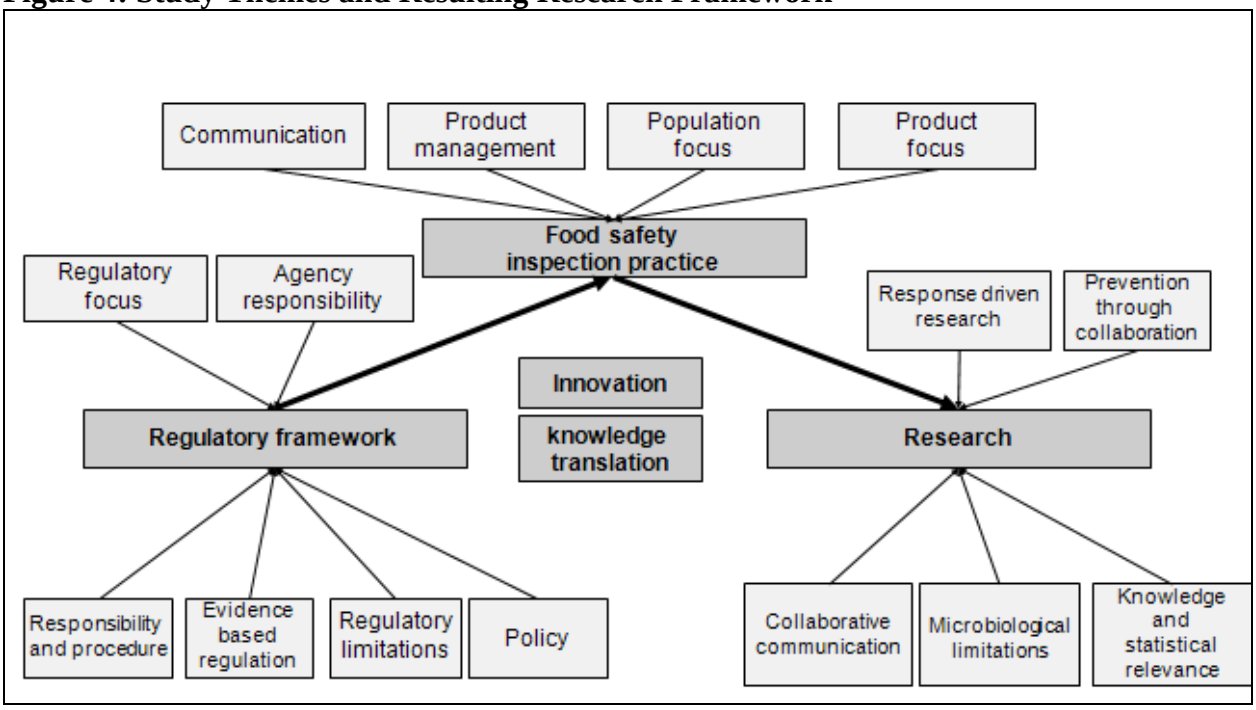
(i) The Ontario provincial regulatory framework and principally, the *Food Premises Regulation,* is responsible for directing food safety inspection practices for all food products and foodborne pathogens including RTE meats and L. *monocytogenes*;

(ii) L. *monocytogenes* and RTE meat research is influenced by food safety inspection practice. Research is primarily focused on microorganism growth characteristics, outbreak investigation and associated inspections that occur as a result. Additional research is required in associating public health unit inspection and regulatory processes on L. *monocytogenes* growth in foods. Research does not currently impact the Ontario food safety inspection program in regards to RTE meats and L. *monocytogenes*; and

(iii) Innovation and knowledge translation are not currently influenced by inspection practice as a result of the regulatory framework which does not require or encourage it.

As a result of the plotting exercise and in reviewing the sources of input, the emergent core category associated with the study is '**reactive and regulatory practice'.** Reactive and regulatory practice addresses the core variables and emerging themes in the central research question including inspection practice, regulatory framework, research, innovation and knowledge

Figure 4: Study Themes and Resulting Research Framework



translation. As a result of generating the core category, the following theory emerged from the data:

> **Ontario public health units manage RTE meats and L. monocytogenes through general population and reactive regulatory processes that focus on local-level, end-product, hazard reduction strategies for established risks in inspected food premises.**

Further discussion surrounding the core category and theory are provided in Section 5.0.

5.0 Discussion

As a result of the substantive and theoretical coding processes, the study's core category, 'reactive and regulatory practice', best characterized the association between the study framework including Ontario's food safety program, food safety inspection practices, research, innovation and knowledge translation. Accordingly, the core category and subsequent emerging theory informs the central and associated research questions for the study in order to provide clarity surrounding the management of RTE meats and L. *monocytogenes* in Ontario public health units.

5.1 Research, Knowledge Translation, Innovation and Ontario Public Health Units

The first research question for this study was; 'what is the current state of food safety research, knowledge translation and innovation related to L. monocytogenes and RTE meats and to what extent do Ontario health units and provincial food safety standards incorporate these tenants into their food safety policies and inspection practices?'

Interview and survey data suggests that research is not generally used in public health units to assist in the inspection process or to reduce the risks associated with L. *monocytogenes* and RTE meats. Participants suggested that this is primarily due to complacency associated with listeriosis as a result of perceived low provincial and public health unit population incidence rates. Furthermore, participant response suggests that research is not being used consistently as a result of the propensity of public health units to enforce the minimum requirements of the *Food Premises Regulation* as required by the MOHLTC.

5.1.1 Research

As described in Section 1.0, there is a wealth of both peer-reviewed research and gray literature describing the dynamics associated with L. *monocytogenes*, RTE meats and its morbidity and mortality. Similarly, there is a significant catalog of epidemiological data and research describing listeriosis, its incidence and its virulence. For example, laboratory research illustrating the L. *monocytogenes*-RTE meat environment and its associated growth characteristics aids in informing the inspection process and food establishment critical control points. Similarly, an equal amount of epidemiological and policy-focused research exists which describes listeriosis, its associated outbreak characteristics and inspection program impacts (e.g., Codex Alimentarius). Despite the wealth of available resources, few participants (n=8) acknowledged that research was used to assist organizational inspection policies. Research and government publications were rarely mentioned (n = 4) in conjunction with inspection processes or in relation to development of policies and procedures pertaining to RTE meats and L. *monocytogenes*. Participants citing the use of research from the public health inspector cohort noted that research exercises (i.e., database searches, report interpretation) are usually tasked by senior staff given that inspectors have little time to devote to such activities. For example, one participant commented that "there is an abundance of information available, however inspectors cannot read everything available and instead, we rely on senior staff and managers to sort through information and provide us with information". Furthermore, the food safety management cohort noted that their public health unit solicits the assistance of the MOHLTC or PHO to aid in obtaining and subsequently interpreting research. One participant noted "we use on-line provincial and federal food safety information and when we have questions, we use the research services of PHO".

Research capacity (or a lack thereof) was another common theme identified by study participants, especially in phase 2 where the topic of research was raised directly in questioning by the interviewer. For example, just one public health unit in phase 1 or phase 2 interviews suggested that there is sufficient research capacity within their public health unit to apply or conduct research within their food inspection program. However, both the food safety management and public health inspector representatives from the public health unit did not identify how research was used to improve their inspection programming in relation to RTE meats and L. *monocytogenes*.

5.1.2 Knowledge Translation and Innovation

Based on interview and survey response, knowledge translation stemming from research or experience that resulted in improvements to policy and practice related to RTE meats and L. *monocytogenes* was limited. This includes internal knowledge translation within public health units and external knowledge translation originating from OMAFRA and the CFIA to improve the method in which RTE meats are addressed by public health units in inspected facilities. For example, both cohorts noted that communication efforts and working relationships with processors (n=47) and provincial or federal agencies (n=27) were limited to reactive processes such as recalls (n = 20) or investigations associated with listeriosis. In particular, decreased communication was directly associated with the MOU between Ontario public health units and the CFIA and OMAFRA where inspections are conducted separately. One participant in the phase 3 survey noted that they "have minimal or no contact with either agency or the processing plants in regards to their inspections". Communication challenges were also noted internally and amongst food safety management and public health inspector cohorts. For example, one

participant commented that "management may communicate (with OMAFRA or the CFIA), but as a field public health inspector, I have limited interaction with these agencies".

Despite its impact on public health units and being referenced in examples in each phase of the study, a small number of participants (n=6) suggested that the Maple Leaf Foods outbreak in 2008 has impacted their public health units inspection processes pertaining to RTE meats and L. *monocytogenes*. A majority of phase 2 participants (n= 29) noted that regulatory or internal policy changes are required to address the risk associated with L. *monocytogenes* and RTE meats as a result of the outbreak. Changes focused on time-temperature abuse including storage requirements to slow the growth of L. *monocytogenes*. For example, one participant noted that "you would need to lower the 4 degrees Celsius requirement in the regulation in order to slow the growth of Listeria". Despite recommendations for policy and regulatory change, no public health units cited that they had amended their inspection processes resulting from the 2008 outbreak that might exceed the current requirements of *Food Premises Regulation*. Similarly, not a single reference was made to provincial or federal documents such as the Weatherhill report (CFIA, 2011a). A number of comments (n = 5) suggested that the most significant impact associated with the outbreak was perception associated with RTE meats that may increase inspection diligence in regards to these products. For example, one participant noted that "our inspection practices have not changed; however, the main impact was altering public health inspectors perceptions that RTE meats have almost no associated risk".

A lack of knowledge translation resulting from the 2008 Maple Leaf Foods outbreak was also likely associated with low incidence of listeriosis within provincial public health units. For example, complacency related to L. *monocytogenes* and RTE meats was referenced throughout phase 1 and phase 2 interviews. References were made in association with a lack of relevant

data to support a proactive approach (n = 20), insignificant burden of illness (n = 11), and subsequently a lack of L. *monocytogenes*-specific focus in the inspection program (n = 9). Comments associated with these open codes were abundant. In particular, one participant in phase 1 interviews noted that "public health units aren't likely heavily invested in concerning themselves with the microorganism (L. *monocytogenes*) since we rarely deal with cases of illness (listeriosis) and therefore, it isn't really on our radar".

Mention of 'innovation' as a general theme was lacking. In particular, little or no reference was made in regards to the use of research, new technology, or external policy and practice to improve the regulatory or public health unit policy framework for RTE meats and L. *monocytogenes*. For example, just one public health unit referenced the use of technology for the purposes of testing food contact surfaces in the event of an outbreak or where the method of food contact surface sanitizing was in question. Reference to information sharing amongst public health units in relation to policy improvements was discussed sparingly (n = 4) in phase 1 and phase 2 interviews. External agency inspection programming or policy was not referenced in regards to the use of research or practice from the CFIA, OMAFRA or international associations such as the Codex Alimentarius commission. Discussions involving 'innovative' practices were predominantly associated with references to meeting minimum requirements under the *Food Premises Regulation*. For example, a public health inspector noted that "following the requirements of the regulation is important to reduce the risk of L. *monocytogenes* since (L. *monocytogenes*) carries no added risk compared to other foodborne pathogens". Conversely, a number of participants suggest that the Ontario food safety program requires "extensive change" overall (n = 38).

5.2 Ontario Public Health Units, Wicked Problems and Ready-to-Eat Meats

The second research question for this study was; *to what extent do Ontario health units view current food safety inspection programming examining RTE meats and L. monocytogenes as a 'wicked problem'?*

Interview and survey responses suggest that Ontario public health units do not view RTE meats and L. *monocytogenes* as a 'wicked problem'. Interview and survey data suggests that public health units disassociate themselves as a part of the wicked problem. While they recognize the administration surrounding RTE meats and L. *monocytogenes* as 'wicked', such as the lack of communication and number of organizations involved in inspection, they do not recognize RTE meat products and L. *monocytogenes* as a foodborne pathogen as 'wicked'. Interview and survey data suggests that this is as a result of a lack of inspection mandate in processing facilities and a perceived lack of burden of illness. As a result, public health units themselves become a part of the wicked problem since they play a role in reducing foodborne illness through RTE meat inspection and investigation. Participant responses suggest that this lack of feeling of direct responsibility to the problem is a result of the 2008 Maple Leaf Foods outbreak which was not directly associated with an inspected facility or product from a public health unit. Comments from participants suggest the lack of involvement in product processing distances public health units from the (wicked) problem, thus decreasing their sense of responsibility to participating in the solution process.

5.2.1 Food Inspection Programming, Incidence and Wicked Problems

Survey data trends from phase 3 and participant feedback described in phase 1 and phase 2 interviews indicates that public health units do not necessarily view food inspection programming and their role with RTE meats and L. *monocytogenes* as a wicked problem. For

example, the majority of participants (97.7 %, 95% CI: 93.32, 100) agreed or strongly agreed that their public health unit addresses RTE meats and L. *monocytogenes* as a part of the general inspection process. This was supported by interviews in phase 2 where it was noted by one participant that "processed products such as RTE meats are treated no differently than other processed products that we see in retail settings…since we don't inspect the plants, we cannot determine the full extent of the risk associated with the product". Similar comments addressing the gap between product inspection and processing at the federal and provincial level versus end-product public health unit inspection were noted in phase 1. For example, one participant commented that "it is difficult to do a quality risk assessment on a RTE meat product since we don't have a stake in processing of the product". Similarly, another participant commented that the "*Food Premises Regulation* focuses primarily on food premises and food handler practices, and to a lesser extent on products since a majority of the products we inspect originate from another source".

A lack of engagement between provincial and federal inspection agencies and local public health units was also documented throughout the interviews and survey. For example, the phase 3 survey suggested that over 70% of participants (71.1%, 95% CI: 57.86, 84.34) identified that they have little contact with OMAFRA or the CFIA and rarely (if ever) communicate with them to obtain inspection reports at facilities where RTE meats are inspected. A number of hypotheses are formulated as a result. First, RTE meats are not viewed as products requiring additional risk reduction strategies outside of the regulatory requirements to reduce microbial risk. This observation was also reinforced in phase 2 interviews where participants indicated that no L. *monocytogenes* policy was currently in place in their public health unit. Second, though the MOU is prescriptive to who should inspect which type of RTE meat processing facility, the

Health Protection and Promotion Act suggests that there is nothing restricting public health units from participating in inspections of RTE processing plants or from requesting copies of inspection records from the CFIA or OMAFRA. For example, the Weatherhill report (2009) reported that that the Toronto Public Health unit participated in the inspection of the Maple Leaf Foods processing plant during the course of the listeriosis outbreak in 2008 (p. 45). However, the chronology of events from the listeriosis outbreak in 2008 suggests that several attempts were required by the Toronto Public Health unit to the CFIA before being permitted to participate in the plant inspection. The Weatherhill report (2009) suggests that the Toronto Public Health unit initially made a "verbal request to the CFIA to send a Toronto public health inspector to accompany the CFIA audit team at the Maple Leaf Foods processing facility" (p. 116) on August 26th, 2008, nearly 3 months after the emergence of the outbreak. The verbal request was followed up with a formal written request the following day "to the CFIA to send a Toronto public health inspector to accompany CFIA audit team at the Maple Leaf Foods facility" (Weatherhill, 2009, p. 116). As a result, the Toronto public health unit was "provided with a copy of Maple Leaf Foods action plan which outlining the steps necessary for the re-opening of the facility" (Weatherhill, 2009, p. 116). The Toronto public health unit was permitted to join the CFIA in-depth review team on September 2, 2008 (Weatherhill, 2009, p. 120). Despite the request for inspection records from the Toronto public health unit in 2008, phase 1 and phase 2 interviews suggest that the process of requesting inspection records and joint inspections with the CFIA and OMAFRA for RTE processing plants is rare. In fact, just 2 public health units indicated in the post-survey that they request inspection records and conduct joint inspections of processing plants. Thus, it is hypothesized that that public health units do not view these inspection reports as critical to their inspection program. A number of remarks made by study

participants would seem to validate this hypothesis. For example, one participant commented that "there have been no changes in the inspection of RTE meats (since 2008) where we have always focused on the source of product, refrigeration temperatures, sanitizing equipment and food contact surfaces". Similarly, another participant noted that "public health inspectors continue to address a wide variety of food safety issues during their inspections – RTE meats are just one aspect". In regards to communication with the CFIA and OMAFRA, one participant commented that they "rarely hear from CFIA or OMAFRA unless there is an issue and we haven't been successful in getting inspection records from these agencies".

5.2.2 Wicked Problem and Participant Response

Despite the perceived disconnect between product processing and the public health units' role in investigation of RTE meats and L. *monocytogenes*, participant feedback only serves to support the variables associated with wicked problems (see Table 6). For example, a number of participant comments (n = 43) suggested that a general approach to inspection of RTE meats is all that is required to control for product risks. However, this contradicts other phase 1, phase 2 and phase 3 remarks made with respect to the need for supplementary food safety requirements for vulnerable populations in regards to RTE meats and L. *monocytogenes*. Furthermore, while comments pertaining to risk associated with RTE meats and vulnerable populations were received in all phases of the research study, no specific public health unit activities targeting these groups were provided nor noted in the documents provided by public health units (see Table 12). As discussed in Section 1.0, risk assessment models focusing specifically on L. *monocytogenes* and RTE meats along with a number of research articles (Buchanan et al., 2004; Gallagher, Ebel, & Kause, 2003; USDA, 2008) suggest that risk is exponentially higher for these populations. Mention of vulnerable populations in the phase 3 survey resulted in 42.2% of

participants (42.2%, 95% CI: 27.77, 56.63) agreeing or strongly agreeing that facilities serving the vulnerable should have more stringent food safety requirements where RTE meats are served. This contradiction supports a number of different wicked problem variables including having 'no clear and correct solution' to the problem and that solutions require 'behavioural changes' from stakeholder groups. Furthermore, disengagement of public health unit participants from the inspection process as a result of provincial or federal inspection jurisdiction emphasizes that 'responsibility stretches across many organizations' and continues to be problematic. Interview and survey comments suggest that there is some degree of complacency amongst public health units in regards to inspection activities associated with L. *monocytogenes*. For example, phase 1 interviews suggest a lack of epidemiological data to support microbiological or product specific action. This lack of concern further supports the definition of a wicked problem given that public health units may not agree that L. *monocytogenes* and RTE is a significant public health issue despite a wealth of research suggesting the contrary. For example, post-survey data reported that public health units inspected less than one outbreak of L. *monocytogenes* on an annual basis since 2008. This despite continuing L. *monocytogenes* recalls which suggest that processing problems continue to occur in RTE meat processing plants and that research suggests that cases of foodborne illness including listeriosis go unreported as a result (Buzby & Roberts, 2009; Majowicz et al., 2005).

5.3 Policy, Practice and Ready-to-Eat Meats

The third research question for this study was; 'according to Ontario public health units, what additional or innovative components are required in RTE meats and L. monocytogenes research, policy and practice to reduce foodborne illness and to develop a comprehensive inspection program?'

When asked to comment on their views of the Ontario food safety program, a majority of interview and survey responses suggested that a change to the program, its regulatory framework and associated inspection practices is required to reduce the risks associated with L. *monocytogenes* and RTE meats. While participants did not reference the need for additional research to be completed, comments suggest that inspection practice and regulation should be evidence and risk-based. In particular, comments were made in reference to improving communication amongst federal and provincial agencies and focusing on vulnerable populations to improve knowledge sharing to reduce risk associated with RTE meats.

5.3.1 Ontario's Food Safety Program, Inspection Practice and Addressing the Hazards Associated with Listeria *Monocytogenes* and Ready-to-Eat Meats

The desire for regulatory change (n = 38) to mitigate risks associated with RTE meats in food premises is addressed by participants throughout the study and in particular in phase 1 and phase 2 interviews. For example, a lack of periodic updates to the regulation substantiates a number of comments from both cohorts. First, changes to the regulatory framework are required (n = 16) and the *Food Premises Regulation* is insufficient to meet the needs of public health inspectors at this time (n =22). Second, the *Food Premises Regulation* (and thus the MOHLTC) has not incorporated research or used innovation/knowledge translation to update the legislation since 1999. Despite participant comments and a lack of regulatory change, some inconsistency is noted with those participants who surmised that RTE meats and L. *monocytogenes* carries no additional risk in relation to other high risk products and foodborne pathogens. For example, one participant in phase 2 interviews noted that:

> The risks associated with RTE meats and L. *monocytogenes* are no different than other high-risk products and food pathogens that public health inspector's address in food

premises….however, with products changing constantly, the regulation may need to be updated to keep up to date with retailed products.

With respect to the use of research, nearly half of participants disagreed or strongly disagreed that the Ontario food safety program has effectively incorporated research to improve inspection processes focused on L. *monocytogenes* and RTE meats. For example, one participant noted that "it is unlikely that the *Food Premises Regulation* could possibly be based on the most up-to-date research given that it hasn't been update in years". Furthermore, another participant noted the "public health units have been waiting for years for the MOHLTC to update the regulation in order to address a number of new food safety hazards that are brought to our attention by outbreaks and research."

While participants recognized the importance of 'research' in addressing L. *monocytogenes* and RTE meats, no reference was made in regards to how research could be applied in public health unit food safety programs. Nor was there any mention of the use of any particular research or documents to influence regulatory change at the provincial level. As a result, it is hypothesized that a lack of research knowledge related to RTE meats and L. *monocytogenes* is likely associated with a lack of practice in dealing with the organism. This hypothesis is supported based on a number of study data sources. First, post-survey results with the food safety management cohort suggest that public health unit food safety programs have little experience in addressing incidence of L. *monocytogenes* since 2008. The food safety management cohort referenced 35 outbreaks of L. *monocytogenes* over the past 3 years, or an average of 0.48 outbreaks annually per participating health unit.

Innovation as a general theme was lacking in regards to participants identifying solutions to address the wicked problem and improving inspection practices associated with L.

monocytogenes and RTE. Notwithstanding, process improvements focused primarily on limiting vulnerable population exposure to L. *monocytogenes* (n = 25) along with improving agency collaboration (n = 41). In particular, participants suggested that improvements are required in risk messaging to vulnerable populations (n = 25) and improving communication between provincial public health units and the RTE meat processors (n = 47). For example, a participant in phase 2 interviews noted that:

> The Maple Leaf Foods outbreak highlighted that Listeria is an organism that vulnerable populations need to be aware of including the elderly and women who are pregnant. Furthermore, when inspecting institutional settings, it is important that food handlers are aware of the risks associated with RTE meat products and their association with Listeria which is why there is a real need for improving communication with OMAFRA and the CFIA to assist with assessing risk of these products on the field.

Comments provided in phase 3 surveys further supported the need for improved communication with provincial and federal agencies in conjunction with perceived barriers to information access. For example, one participant noted that they are "looking at improving communication with these agencies although (we) find that the CFIA has been somewhat reluctant to share information willingly with respect to inquiries we have had regarding licensed facilities which is likely due to privacy legislation".

5.4 Central Research Question

The central research question for the study is; 'do Ontario health unit inspection practices and food safety regulation use research, innovation and knowledge translation through experience to effectively address RTE meats in food premises and reduce the burden of listeriosis?'

Through the emergence of the core category, 'reactive and regulatory practice', a theory was developed to assist in answering the central research question for the research study. The theory describes the associations between core variables, selective codes and theories which emerged from data analyses conducted using a grounded theory approach. The study theory also assists in describing the manner in which inspection practice, regulation and research, innovation and knowledge translation interact within the core category (see Figure 4). The theory includes themes identified throughout the interview and survey phases including regulatory processes, local-level and end-product focus, and risk-reduction strategies that participants use to describe their involvement with RTE meats in inspected food premises. The themes describe components associated with the wicked problem while demonstrating associations that were identified and (not identified) by participants that assist in addressing the central research question.

5.4.1 Addressing the Central Research Question

The study theory; 'Ontario public health units manage RTE meats and L. monocytogenes through general population and reactive regulatory processes that focus on local-level, end-product, hazard reduction strategies for established risks in inspected food premises', describes a number of concepts based on results from the study. For example, participant analyses suggest that public health units address RTE meats and L. *monocytogenes* through reactive and general regulatory processes. This includes meeting minimum standards in accordance with the *Food Premises Regulation*. It also includes participating in product recall activities when formally requested to do so by the MOHLTC. The Ontario Food Safety Standard and Protocol requires public health units to use surveillance and HACCP-based methods. However, participant comments suggest that provincial food safety inspection programming is predominantly a regimented and reactive exercise with limited opportunities for proactive activities.

Furthermore, participants argued that while HACCP and CCP identification drives the food safety inspection agenda, only certain components of HACCP auditing can be used with RTE meats since only the 'end-product' is observed by public health inspectors with limited processing taking place in the retail environment. Therefore, 'complete' HACCP auditing, where processing of RTE foods is observed from 'farm-to-fork', does not likely occur in a majority of local public health units since; (i) the current provincial licensing inspection requirements by OMAFRA and the CFIA do not permit this to occur as a result of the MOU; and (ii) the Food Safety Protocol does not explicitly require public health units to conduct HACCP audits. Just one participant in the phase 3 survey noted that they have an active role in the inspection of RTE processing facilities. They suggested that they conduct joint inspections with their provincial and federal agencies with follow-up occurring via inspection record disclosure.

Just one participant acknowledged the significance of the MOHLTC performance management framework in administering the food safety program and its impact on inspection activities. The MOHLTC accountability agreements include specific, measurable results for public health units for the funding received by the province of Ontario. This includes "reporting requirements and any corrective action to achieve the indicator if results are not achieved" (Ontario Ministry of Health and Long Term Care, 2011, slide 13). The food safety accountability agreement requires that public health units meet minimum requirements for inspection of food premises. In particular, 'high risk' food premises are required to be inspected at least once every 4 months. One participant noted some of the difficulties associated with agreement given limited inspection resources:

> In rural public health units, we are expected to work with minimal human resources to meet the requirements of the high risk food safety accountability agreements which are tied

> to our on-going funding….(therefore), how can we concern ourselves with other inspection activities when we have funding-based targets to achieve the minimum requirements?

The comment suggests that; (i) the accountability agreements may be restrictive, especially for lower-resourced health units; and (ii) meeting the minimum inspection requirements of the *Food Premises Regulation* and the Food Safety Protocol (2008) may be the exclusive focus of some public health units hence the need for regulatory amendments. For example, one participant noted that:

> While I agree that the *Food Premises Regulation* requires updating, following the current version along with the general HACCP principles that are referenced in the (Ontario Food Safety) standard and (Ontario Food Safety) protocol is sufficient for inspectors to control for Listeria and RTE meats.

References to the employment of a reactive inspection approach to RTE meats and L. *monocytogenes* in food safety programming, including recall-focused activities were typically associated with comments noting low incidence of listeriosis in their public health unit. While this association is not unexpected given that the Ontario Food Safety Protocol (2008) requires surveillance to support the food safety inspection program for each unit, the approach fails to comprehensively identify a number of additional system inputs. First, quantitative evidence suggests that recalls associated with L. *monocytogenes* are common and frequent (see Table 1). Second, provincial and federal foodborne illness rates, including listeriosis, while infrequent in comparison to other pathogens are increasing and associated with significant rates of morbidity and mortality in the elderly (see Section 2.0). Thirdly, the 2008 Maple Leaf Foods outbreak occurred just 4 years ago. Lastly, an increase in sodium-reduced RTE foods in the marketplace aimed at reducing "sodium content in the diets of Canadians" (Health Canada, 2010, para. 1) is

subsequently leading to "decreased (product) storage times" (Stringer, & Pin, 2005, p. 27) and potentially increased risk to consumers and an aging Canadian population.

Participant references to local-level, end-product inspection focus serves to illustrate that risk-reduction strategies related to L. *monocytogenes* and RTE foods are lacking. Comments suggest that the lack of participation in inspection of federal or provincial processing could impact the approach of public health inspectors when inspecting RTE meat products in food premises. For example, one participant in phase 1 interviews commented that:

> Public health units feel disengaged in the inspection process as a result of RTE products being inspected by provincial and federal agencies…this is the case with RTE meats since labeling on these products gives public health inspectors little indication of its safety and in some cases, only a packaged-on date is provided which provides little information to consumers.

Similarly, a phase 2 participant noted:

> Previous outbreaks have made our inspection staff skeptical of RTE meat products. However, with limited information pertaining to the safety of these products and the loading of Listeria from plants we don't inspect, we are left to assume that while technically ready-to-eat, they may require some additional steps to reduce risk, especially with vulnerable populations….however, we need to follow the requirements of the *Food Premises Regulation*.

The comments suggest generally that public health units may be equipped with limited inspection information in order to enforce Section 13 of the *Health Protection and Promotion Act*, pertaining to health hazards. As a result, they rely on the general provisions of the *Food Premises Regulation* in conjunction with HACCP principles that will assist in mitigating risk.

5.5 Strength and Limitations

A significant strength of the research is the identification of the wicked problem for the purposes of examining RTE meats and L. *monocytogenes*. The research study was the first of its kind to associate RTE meats and L. *monocytogenes* as a part of a wicked problem and use grounded theory to illuminate the function and role of local public health inspection. An additional strength of the study was the use of cohorts in interpreting the study data. In particular, a number of disparities were noted within the participant group in regards to the public health unit categories along with the public health inspector and food safety management cohorts throughout the interviews and survey that provided for a more comprehensive approach to the data analyses.

There are a number of limitations to the study including sample size, participant inclusion process, wicked problem analyses, generalizability of results, and the method of interviews. First, small sample size limited the statistical significance of survey results in phase 3. While phase 1 and phase 2 interviews were based on a grounded theory approach, phase 3 interviews permitted quantitative analyses to take place based on the likert scale provided to participants. However, although overall public health unit participation was high (75%), the overall number of participants completing the survey was small (n = 45) for the purposes of the chi-square and cross-tabulation analyses that was conducted.

Second, invitation letters included the scope of study (see appendices A and C) and were provided to public health unit senior management contacts. Therefore, it is possible that communication, and potentially direction in regards to the study area and documentation provided to the interviewer may have occurred prior to initiation of the surveys or interviews leading to response bias. Furthermore, study participants may have been selected in a manner that potentially influences response despite study eligibility criteria. In order to reduce

preparation, survey and interview questions were not provided to candidates prior to initiation. In addition, as described in Section 3.6, interviews were conducted simultaneously to reduce communication between public health unit participants. However, it should be noted that the timing of phase 3 survey response could not be controlled by participants within a public health unit as a result of the surveys being distributed through email.

Thirdly, the study addresses only one organization involved with RTE meats and L. *monocytogenes* wicked problem, public health units. Addressing all organizations involved with the wicked problem was not feasible for the purposes of a single research study. Thus, additional research is required to address other components of the wicked problem, including the processing-end of the product stream (see Figure 2) in conjunction with the responsible provincial and federal agencies, product manufacturers, consumer groups, and the public.

The generalizability of the research findings is limited since the study was conducted using an exploratory qualitative method that was not intended to produce results that predict the behaviour of all public health units in regards to L. *monocytogenes* and RTE meats. The generation of the core category and the study theory is based on a grounded theory approach which assisted in explaining aspects of the wicked problem. Secondly, the study interviews were conducted with only certified public health inspectors which included the management cohort (see Table 7). Thus, the results cannot be generalized to Medical Officers of Health or 'key informants' (see Table 7) that were not selected by public health units to participate in the study.

Lastly, the method in which phase 1 and phase 2 interviews were conducted is also a potential limitation. While both in-person and telephone interviews have their advantages and disadvantages, it would have been beneficial to conduct all interviews in person. This would

ensure that assistance (e.g., via computers or documents) was not used during telephone interviews or that the second interview was listening in during the first.

5.6 Potential Implications and Future Research

The results of the study have implications for public health researchers and policy makers in the province of Ontario to address L. *monocytogenes* and RTE meats. In describing the current regulatory, inspection and research environment, policy makers and researchers can use the principles and results of the study theory to drive future research and improve the provincial food safety program through policy amendments (see Section 5.7). The emergence of the core category identifies that the current regulatory and inspection environment operates within a wicked problem, where the use of applied research and controls are limited. As a result, public health units operate reactively as opposed to proactively in an attempt to control for microbiological risks. The core category and study theory imply that a number of gaps exist in the provincial food safety system in particular to RTE meats and L. *monocytogenes*. These include regulatory, inspection, knowledge translation and research-based gaps that require the attention of regulators and researchers in order to improve food safety programming in the province.

The study substantiates that amendments to the Ontario Food Safety program and in particular, the *Food Premises Regulation* are necessary. In particular, regulators and researchers should work collaboratively to improve federal and provincial agency communication, training opportunities, and information sharing through knowledge translation to advance public health unit risk assessment practices. Furthermore, the updating or development of evidence-informed regulation is required to accommodate a changing and aging provincial demographic with specific nutritional and dietary needs that are driving product change including RTE foods

(Health Canada, 2010; Lenhart et al., 2008; Lupien, 2007). This would include embracing innovative methods to identify potential microbiological risks through non-traditional surveillance methods and use of technology in inspections of food processing environments. In addition, there is a need to improve provincial food safety programming to require that public health units engage in proactive inspection practices. In particular, this would include a renewed focus in HACCP programming and auditing that identifies and controls for hazards during the processing stage of product development. The 2008 version of the Ontario Food Safety Standard and Protocol does not explicitly require that public health units conduct HACCP audits. Rather, the only requirement is for public health units to incorporate HACCP-based principles and specifically critical control points (CCPs) in "assessing safe-food handling practices" (MOHLTC, 2008, p.3).

The results and associated grounded theory methods used in conducting the study have implications to the broader public health field and specifically food safety research. First, the literature review and participant analyses suggest a need for applied research associated with evaluating the effectiveness of the existing regulatory framework for public health units in reducing foodborne illness. This is a significant finding given that study participants stressed that the *Food Premises Regulation* directs the inspection activities of public health inspectors.

Finally, the use of qualitative methods, in particular grounded theory, was found to be effective in analyzing the wicked problem. Literature review exercises (see Section 1.1 and 4.2.3.2.) suggest that grounded theory has not been used extensively in addressing wicked problems, specifically in food safety. However, given the complexity of food safety systems as observed with L. *monocytogenes* and RTE meats, the grounded theory approach could be used to address other pathogen-food combinations referenced in research (Davidson, Ryks & Fazil,

2006; Ruzante et al., 2010a). Examples include "*Campylobacter spp*. in chicken; *Salmonella spp*. in chicken and spinach and *Escherichia coli* O157 in spinach and beef" (Ruzante et al., 2010a, p. 724)

5.7 Recommendations

Based on the core category and study theory, a number of recommendations are proposed to improve the Ontario Food Safety Program and reduce the risk of RTE meats and listeriosis. The recommendations address the study theory by focusing on the study framework (see Figure 1) including food safety inspection practice, program and regulation, and research, innovation and knowledge translation at the public health unit level. In particular, the recommendations include amending the Ontario food safety program by improving the use of research and innovative methods to improve knowledge translation and enhance proactive inspection activities by public health units. The intent of the recommendations is not to resolve the wicked problem associated with RTE meats and L. *monocytogenes* given the number of organizations connected to product processing and distribution. However, the recommendations will assist public health units in working within the current framework to improve the manner in which they address RTE meats and L. *monocytogenes* in food premises.

5.7.1 Recommendation # 1

The Ontario Food Safety Protocol (2008) should improve operational roles and responsibilities in particular to activities associated with food safety surveillance. Epidemiological analyses of surveillance data should include the development of baseline data for non-traditional food safety variables that assist in indicating potential processing and food handling deviations that may be associated with the growth of L. *monocytogenes*. Employing the use of baseline data and monitoring deviations from the established mean allows public health

units to address potential issues with proactive enforcement or increased operator food safety education initiatives. Examples of monitoring criteria include federal and provincial recall notices associated with L. *monocytogenes* and RTE foods in association with either confirmed or unconfirmed human illness. Increases in microorganism-specific recalls should be closely monitored with increases in foodborne illness specific to the associated incubation period. In particular, increases in RTE meat product recalls or elevated incidence of listeriosis should be associated with communications to long term care facilities, obstetricians, and community physicians with emphasis on the prolonged incubation period. As a result, public health units should be required to:

(i) Monitor and track seasonal violation frequencies related to time-temperature abuse and cross-contamination offences in inspected food premises. Violation rate increases should be linked with population-specific communication campaigns targeting vulnerable populations that may consume hazardous products; and

(ii) Expand criteria of surveillance activities in the Ontario Food Safety Protocol (2008) to include a focus on vulnerable populations, diet, and foodborne illness.

This recommendation addresses the study theory in ensuring that a proactive process is in place for food safety programming which assists both food safety management and public health inspectors focus on established (e.g., *Campylobacter spp*.) and novel (or underreported) organisms such as L. *monocytogenes* that directly impact vulnerable populations.

5.7.2 Recommendation # 2

The Ontario Food Safety Protocol (2008) should be amended to require additional program content related to L. *monocytogenes* and RTE meats in food premises for food handler

training courses. Minimum course program requirements for food handler training in the Ontario Food Safety Protocol (2008) should be amended to include content related to:

a) Food establishment design and maintenance. While this currently exists, it should be expanded to include a focus on reducing the introduction and harborage of L. *monocytogenes* in food contact and non-food contact surfaces along with safety associated with maintenance of equipment in food premises.;
b) Retrieving, analyzing and acting on provincial and federal recall notifications to ensure that products are removed promptly from food production; and
c) Product labeling and interpretation of best before dates to educate food handlers and the public on product shelf life requirements and the hazards associated with the use of RTE products after the stated date.

This recommendation addresses the study theory in ensuring that processes are in place at the retail level to proactively address hazards through system design while increasing pathogen-specific knowledge through labeling and active surveillance for food handlers.

5.7.3 Recommendation # 3

The *Food Premises Regulation* should be amended to require mandatory food handler training and certification for food handlers employed in institutional settings serving vulnerable populations. Ensuring that food handlers are certified in institutional food settings achieves a number of objectives. First, it meets the one of the 113 requirements from Justice Ronald J. Haines (2004) who recommended that:

> The provincial government amend the *Health Protection and Promotion Act* to require that the operator of a food premises and at least one staff member, present at a food

> premises during all hours of operation, be a certified safe food handler provincial food handlers be food safety trained and certified (p. 357).

Second, it ensures that food handlers in institutional settings are knowledgeable of the risks associated with RTE meat products and L. *monocytogenes* for the population they serve. Third, it harmonizes the *Food Premises Regulation* with the requirements of the *Retirement Home Act* 2010, S.O. 2010, c. 11. The *Retirement Home Act* requires that:

> At least one person involved in preparing the food holds a current certificate in food handling from the local public health unit or has recently successfully completed a food handling training program equivalent to that offered by public health units. (sec. 20(4))

Lastly, it is consistent with research that suggests that food handler training is associated with improvements in knowledge, and safe-food handling behaviours of food handlers who work in food premises (Cates et al., 2009; Cotterchio, Gunn, Coffill, Tormey, & Barry, 1998; Hedberg et al., 2006; Mathias et al., 1994; Rebellato, Cholewa, Chow, & Poon, 2012; Riben et al., 1994).

This recommendation addresses the study theory in ensuring that food handlers serving vulnerable populations are mandated to be trained in safe food handling and in conjunction with recommendation # 2, are aware of pathogen and product specific risks associated with the population they serve.

5.7.4 Recommendation # 4

The Ontario Food Safety Protocol (2008) should be amended to include sampling and HACCP program requirements for RTE meat manufacturers that are not licensed by OMAFRA or CFIA. Research suggests that there should be "no concession for regulatory control of foods produced by small- or medium-sized companies" (Luber et al., 2011, p. 1543). This would require small manufacturers of RTE meats to sample products, processing areas and equipment

for L. *monocytogenes* prior to sale and distribution thus harmonizing the requirements of both the CFIA and OMAFRA. Local manufacturers would be required to demonstrate that levels of L. *monocytogenes* do not exceed 100 CFU/g throughout the stated shelf life (Health Canada, 2011, p. 8). While this requirement could be met with some degree of resistance given potential costs, it could be disputed that the requirement for on-going source water sampling is equivalent to requirements under the *Safe Drinking Water Act, 2002, S.O. 2002, c. 32*., and Ontario Regulation 170/03 (*Drinking Water Systems*). Furthermore, implementation of a sampling and sanitation program would harmonize public health unit requirements with provincial and federal agencies that require manufacturers to test the products they sell along with the environments they produce them in. Product and environment testing should be conducted in conjunction with a detailed HACCP program since relying strictly on "performance testing (will) draw industry resources away from improving systems and monitoring activities" (Holley, 2010, p. 472) that proactive hazard identification systems like HACCP are based upon.

This recommendation addresses the study theory by requiring food operators to proactively test manufactured products to assist in the risk assessment and management aspect of the inspection and auditing process. Testing results also provide public health inspectors with data in regards to system performance and identify areas for improvement.

5.7.5 Recommendation # 5

The *Food Premises Regulation* should be amended to require the use of 'best before' date labels on re-processed foods based on the original product 'best before' date. This would replace 'packaged on' labels commonly used in deli meat counters in the province of Ontario. Currently, the only requirement for the use of 'best before' labeling is for the purpose of re-packaging of milk products which were not produced in food premises. Using RTE meats as an example,

'best before' labels would be affixed to deli meat products that are sliced from its original packaging. These would not include sliced products that originate from the processing level since provincial and federal labeling already includes this requirement. Affixing the date would improve the probability that customers would not consume the products past the provided date. Similarly, it is recommended that the CFIA re-examine date labeling for RTE meats and in particular, expanding the definition of the 'use-by' label. Communicating risk to vulnerable populations through product labels meets requirement 42 of the Weatherhill report (2009):

> To protect vulnerable populations, including the immunocompromised, older people and pregnant women, Health Canada should promote consumer education into the risks associated with Listeria. This could include targeted measures, such as precautionary labeling. This should be accomplished in collaboration with the Public Health Agency of Canada and in conjunction with provincial and territorial health partners. (p. xviii)

According to CFIA, "'Best before' dates do not guarantee product safety….however they do give you information about the freshness and potential shelf-life of the unopened foods (consumers purchase)" (CFIA, 2012a, para. 6). Furthermore, "the Food and Drug Regulations state that 'use-by' labeling may replace 'best-before' for pre-packaged fresh yeast only" (CFIA, 2012a, para. 12). Research suggests that "'use-by' statements are considered clearer and more helpful than 'sell-by' or 'best if used by' (best-before) labels" (Lenhart et al., 2008, p. 70). However, according to Health Canada (2011), the stated shelf life (i.e., the 'best-before' date on the package) is based on "L. *monocytogenes* growth parameters not greater than 100 CFU/g" (p. 9). As discussed in Section 2.0, consuming products that exceed 100 CFU/g is considered potentially hazardous for vulnerable populations. Accordingly, the *Food Premises Regulation* does not explicitly restrict RTE meat products that exceed the 'best-before' date from being sold.

However, studies note that consumers may be unaware of the hazards associated with RTE meats and L. *monocytogenes* (Cates et al., 2006; Lenhart et al., 2008). Furthermore, research suggests that RTE meat products are frequently consumed "longer than recommended" (Lenhart et al., 2008, p. 70). In addition, a study conducted by Luber et al. (2011) suggested that consumers may perceive that despite differences in L. *monocytogenes* inhibitors, "all deli meats should be treated equally" (p. 1542). As a result, the *Food Premises Regulation* should be amended to ensure that RTE meat products (or hazardous food products) that exceed the stated 'use-by' date should be considered a health hazard and subsequently be seized and destroyed as permitted under the *Health Protection and Promotion Act:*

> A public health inspector who is of the opinion, upon reasonable and probable grounds, that a condition of any substance, thing, plant or animal other than man is a health hazard may seize or cause the seizure of the substance, thing, plant or animal. (sec. 19(1))

This recommendation addresses the study theory through labeling which works proactively by communicating messaging both to food operators and to consumers. In amending messaging through the 'use-by' labeling, consumers are less likely to have access to potentially hazardous products since public health inspectors would subsequently remove them from sale.

5.7.6 Recommendation # 6

In order to improve agency communication to reduce incidence of listeriosis and foodborne illness, it is recommended that the CFIA, OMAFRA, PHO and public health units (through the MOHLTC) establish a network (portal) to share research, government publications, inspection records and product/surface sampling information for federal and provincial RTE meat processing plants. This would assist public health units in improving knowledge translation from all stakeholders involved in the wicked problem. Furthermore, it ensures that product and

site establishment risk assessment, surveillance, and foodborne illness investigations are provided to public health units and public health inspectors. The portal could also be used in sharing product, population and hazard –specific consumer information pertaining to L. *monocytogenes* and RTE meats. This aligns with Health Canada's (2011*)* Policy on Listeria monocytogenes in Ready-to-eat Foods which aimed to provide

> Science-based educational material to inform consumers and care providers about the hazards associated with L. *monocytogenes* in RTE food and how to minimize the risks of foodborne disease, with a particular focus on vulnerable populations and their families, as well as their care providers" (p. 6).

Product trends could also be discussed with examples including new product formulations (e.g., low-sodium formulations), L. *monocytogenes* inhibitors (e.g. sodium diacetate and sodium lactate) and extended shelf lives of new products.

This recommendation addresses the study theory by establishing communication channels to increase public health unit access to data that may assist in HACCP auditing and associated risk assessment activities at the retail level. It also improves knowledge translation in ensuring that research is available and accessible to public health units and public health inspectors.

5.8 Conclusions

Through the use of a grounded theory approach, this study demonstrated that public health units manage RTE meats and L. *monocytogenes* through reactive and regulatory food safety inspection practices. Survey and interview results indicate that public health unit food safety management and public health inspector participants aspire for evidence-based regulatory and program amendments that will allow for targeted microbial risk-reduction activities at the local level that focus on vulnerable populations. In addition, participants noted that despite previous outbreaks and recalls associated with manufactured RTE meat products, communication with federal and provincial licensing agencies are limited, resulting in a lack of knowledge translation to public health unit public health inspectors. Proactive education and inspection processes by public health units are required to reduce pathogen loading in foods in food premises. Furthermore, amendments are required in the Ontario food safety program to increase knowledge translation and innovative strategies that influence the regulatory framework and the inspection of RTE foods. Future studies should continue to address the wicked problem using grounded theory methods focusing on product processing and management to reduce contamination with L. *monocytogenes* prior to retail.

References

Adolph, S., Hall, W., & Kruchten P. (2011). Using grounded theory to study the experience of software development. *Empirical Software Engineering, 16*, 487-513.

Agar, M. (1999). Complexity theory: An exploration and overview based on John Holland's work. *Field Methods, 11*(2), 99-120.

Agriculture and Agri-Food Canada. (2010). *Food regulations.* Retrieved June 1, 2012, from http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1277744358829&lang=eng

Andersen, J. K., & Norrung, B. (2011). The challenge of setting risk-based microbiological criteria for Listeria monocytogenes. *Food Control, 22*, 1495-1497.

Arthur, A., Gournis, E., McKeown D, & Yaffe, B. (2009). *Toronto public health: Foodborne illness in Toronto*. Toronto, Ontario: Toronto Public Health.

Aureli, P., Fiorucci, G. C., Caroli, D., Marchiaro, G., Novara, O., Leone, L., et al. (2000). An outbreak of febrile gastroenteritis associated with corn contaminated by Listeria monocytogenes. *The New England Journal of Medicine, 342*(17), 1236-1241.

Batz, M. B., Hoffmann, S., & Morris, G. J. (2011). *Ranking the risks: The 10 pathogen-food combinations with the greatest impact on public health.* University of Florida: Emerging Pathogens Institute.

Bortolussi, R. (2008). Listeriosis: A primer. *Canadian Medical Association Journal, 179*(8), 795-797.

Broom, A. (2005). Using qualitative interviews in CAM research: A guide to study design, data collection and data analysis. *Complementary Therapies in Medicine, 13*(1), 65-73.

Brown, S. C., Stevens, R. A., Troiano, P. F., & Schneider, M. K. (2002). Exploring complex phenomenon: grounded theory in student affairs research. *Journal of College Student Development, 43*(2), 1-11.

Buzby, J. C., & Roberts, T. (2009). The economics of enteric infections: Human foodborne disease costs. *Gastroenterology, 136*(6), 1851-1862.

Cairns, B. J., & Payne, R. J. H. (2009). Sudden increases in listeriosis rates in England and Wales, 2001 and 2003. *Emerging Infectious Diseases, 15*(3), 465-468.

Canadian Food Inspection Agency. (2011a). Action *on Weatherhill report recommendations to strengthen the food safety system: Final report to Canadians.* Retrieved June 1, 2012, from http://www.inspection.gc.ca/english/fssa/transp/prog/final3e.shtml

Canadian Food Inspection Agency. (2011b). *Chapter 4 - annex H: Policy on the control of Listeria monocytogenes in ready-to-eat meat (RTE) and poultry products.* Retrieved April 11, 2012, from http://www.inspection.gc.ca/english/fssa/meavia/man/ch4/annexhe.shtml

Canadian Food Inspection Agency. (2011c). *Chapter 2 basic labelling requirements sections 2.1-2.9.* Retrieved April 15, 2012, from http://www.inspection.gc.ca/english/fssa/labeti/guide/ch2e.shtmlhttp://www.inspection.gc.ca/english/fssa/meavia/man/ch4/annexhe.shtml

Canadian Food Inspection Agency. (2012a). *Date labelling on pre-packaged foods.* Retrieved June 1, 2012, from http://www.inspection.gc.ca/food/consumer-centre/food-safety-tips/labelling-food-packaging-and-storage/date/eng/1332357469487/1332357545633

Canadian Food Inspection Agency. (2012b). *Safe food for Canadians act: What is means for Canadian industry.* Retrieved July 6, 2012, from http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/initiatives/sfca/industry/eng/1339045331689/1339045810466

Canadian Food Inspection Agency. (2012c). *The improved food safety inspection model.* Retrieved July 6, 2012, from http://www.inspection.gc.ca/about-the-cfia/accountability/inspection-modernization/case-for-change/eng/1337194116466/1337194257540

Canadian Food Inspection Agency. (2012d). *Food recalls and allergy alerts - high risk.* Retrieved August 22, 2012, from http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recalls-and-allergy-alerts/eng/1299076382077/1299076493846

Carroll, C. D., Alvarado, C. Z., Brashears, M. M., Thompson, L. D., & Boyce, J. (2007). Marination of turkey breast fillets to control the growth of Listeria monocytogenes and improve meat quality in deli loaves. *Poultry Science, 86*(1), 150-155.

Cates, S. C., Muth, M. K., Karns, S. A., Penne, M. A., Stone, C. N., Harrison, J. E., et al. (2009). Certified kitchen managers: Do they improve restaurant inspection outcomes? *Journal of Food Protection, 72*(2), 384-391.

Cates, S. C., Morales, R. A., Karns, S. A., Jaykus, L., Kosa, K. M., Teneyck, T., et al. (2006). Consumer knowledge, storage, and handling practices regarding Listeria in frankfurters and deli meats: Results of a web-based survey. *Journal of Food Protection, 69*(7), 1630-1639.

Centers for Disease Control and Prevention (CDC). (1999). Update: Multistate outbreak of listeriosis--United States, 1998-1999. *MMWR. Morbidity and Mortality Weekly Report, 47*(51-52), 1117-1118.

Centre for Disease Control. (2002). From the centers for disease control and prevention. Outbreak of listeriosis--northeastern United States, 2002. *The Journal of the American Medical Association, 288*(18), 2260.

Charmaz, K. (2006). *Constructing grounded theory: A practical guide through qualitative analysis* (3rd ed.). Thousand Oaks, CA: Sage.

Clark, C.G., Farber, J., Pagotto, F., Ciampa, N., Dore, K., Nadon, C., Bernard, K., Ng, L.-K & the CPHLN. (2010). Surveillance for listeria monocytogenes and listeriosis 1995-2004. *Epidemiology and Infection, 138*, 559-572.

Codex Alimentarius Commission. (2011). Labelling of Foods and Food Ingredients obtained through Certain Techniques of Genetic Modification / Genetic Engineering. *Proceeding of the thirty-ninth session of the codex committee on food labelling*, Canada, 1-53.

Cotterchio, M., Gunn, J., Coffill, T., Tormey, P., & Barry, M. A. (1998). Effect of a manager training program on sanitary conditions in restaurants. *Public Health Reports, 113*(4), 353-358.

Crerar, S. K., Castle, M., Hassel, S., & Schumacher, D. (2011). Recent experiences with Listeria monocytogenes in New Zealand and development of a food control risk-based strategy. *Food Control, 22*(9), 1510-1512.

Dagg, P. J., Butler, R. J., Murray, J. G., & Biddle, R. R. (2006). Meeting the requirements of importing countries: Practice and policy for on-farm approaches to food safety. *Revue Scientifique Et Technique (International Office of Epizootics), 25*(2), 685-700.

Davidson, V.J., Ryks J., & Fazil, A. (2006). Fuzzy risk assessment tool for microbial hazards in food systems. *Fuzzy Sets and Systems, 157*(9), 1201-1210.

Deady, R. (2011). Reading with methodological perspective bias: A journey into classic grounded theory. *The Grounded Theory Review, 10*(1), 41-57.

Dufour, C. (2011). Application of EC regulation no. 2073/2005 regarding Listeria monocytogenes in ready-to-eat foods in retail and catering sectors in Europe. *Food Control, 22*(9), 1491-1494.

Farber, J. M., Kozak, G. K., & Duquette, A. (2011). Changing regulation: Canada's new thinking on Listeria. *Food Control, 22*(9), 1506-1509.

Farber, J. M., Ross, W. H., & Harwig, J. (1996). Health risk assessment of Listeria monocytogenes in Canada. *International Journal of Food Microbiology, 30*(1-2), 145-156.

Fisher, R. J., & Tellis, G. J. (1998). Removing social desirability bias with indirect questioning: is the cure worse than the disease? *Advances in Consumer Research*, 25, 563-557.

Flint, J. A., Doré, K., Majowicz, S. E., Edge, V. L., & Sockett, P. (2004). From stool to statistics: Reporting of acute gastrointestinal illnesses in Canada. *Canadian Journal of Public Health, 95*(4), 309-313.

Francis, J. A., Abramsohn, E. M., & Park, H. Y. (2010). Policy-driven tobacco control. *Tobacco Control, 19 Suppl 1*, i16-i20.

Frye, D. M., Zweig, R., Sturgeon, J., Tormey, M., LeCavalier, M., Lee, I., et al. (2002). An outbreak of febrile gastroenteritis associated with delicatessen meat contaminated with Listeria monocytogenes. *Clinical Infectious Diseases, 35*(8), 943-949.

Gallagher, D. L., Ebel, E. D., & Kause, J. R. (2003). *FSIS risk assessment for Listeria monocytogenes in deli meats*. United States: United States Food Safety and Inspection Service.

Gibb, H., Anderson, J., & Forsyth, K. (2004). Developing support for remote nursing education through workplace culture that values learning. *The Australian Journal of Rural Health, 12*(5), 201-205.

Glaser, B. G. (1992). *Basics of grounded theory analysis*. Mill Valley, CA: Sociology Press.

Glaser, B. G. (1978). *Theoretical sensitivity*. Mill Valley, CA: Sociology Press.

Glaser, B. G. (1998). *Doing grounded theory: Issues and discussions*. Mill Valley, CA: Sociology Press.

Glaser, B. G. (2001). *The grounded theory perspective: Conceptualization contrasted with description.* Mill Valley, CA: Sociology Press.

Glaser, B. G. (2005). *The grounded theory perspective III: Theoretical coding*. Mill Valley, CA: Sociology Press.

Glaser, B. G. (2010, June 1). Grounded theory is the study of a concept [Video]. Retrieved from http://www.youtube.com/watch?v=OcpxaLQDnLk

Gombas, D. E., Chen, Y., Clavero, R. S., & Scott, V. N. (2003). Survey of Listeria monocytogenes in ready-to-eat foods. *Journal of Food Protection, 66*(4), 559-569.

Gottlieb, S. L., Newbern, E. C., Griffin, P. M., Graves, L. M., Hoekstra, R. M., Baker, N. L., et al. (2006). Multistate outbreak of listeriosis linked to turkey deli meat and subsequent changes in US regulatory policy. *Clinical Infectious Diseases, 42*(1), 29-36.

Govindaraju, K., Bebbington, M., & Wrathall, T. (2010). Statistical evaluation of the New Zealand food safety authority sampling protocol for imported food. *Risk Analysis, 30*(5), 817-826.

Graves, L. M., Hunter, S. B., Ong, A. R., Schoonmaker-Bopp, D., Hise, K., Kornstein, L., et al. (2005). Microbiological aspects of the investigation that traced the 1998 outbreak of listeriosis in the United States to contaminated hot dogs and establishment of molecular subtyping-based surveillance for Listeria monocytogenes in the PulseNet network. *Journal of Clinical Microbiology, 43*(5), 2350-2355.

Green, J., & Thorogood, N. (2009). *Qualitative methods for health research* (2nd ed.). Thousand Oaks, CA: SAGE Publications Inc.

Gregory, B. T., Harris, S. G., Armenakis, A. A., & Shook, C. L. (2009). Organizational culture and effectiveness: A study of values, attitudes, and organizational outcomes. *Journal of Business Research, 62*(7), 673-679.

Griffith, C. J., Livesey, K. M., & Clayton, D. (2010). The assessment of food safety culture. *British Food Journal, 112*(4), 439-456.

Griffith, C. J. (2010). Do businesses get the food poisoning they deserve? *British Food Journal, 112*(4), 416-425.

Haines, R. J. (2004). *Report of the meat regulatory and inspection review: Farm-to-fork, a strategy for meat safety in Ontario*. Ontario Ministry of the Attorney General. Retrieved from http://www.attorneygeneral.jus.gov.on.ca/english/about/pubs/meatinspectionreport/

Hale, E. D., Treharne, G. J., & Kitas, G. D. (2008). Qualitative methodologies II: A brief guide to applying interpretative phenomenological analysis in musculoskeletal care. *Musculoskeletal Care, 6*(2), 86-96.

Hammond, D. (2012). Tobacco packaging and labelling policies under the U.S. tobacco control act: Research needs and priorities. *Nicotine & Tobacco Research, 14*(1), 62-74.

Hammond, D., & Parkinson, C. (2009). The impact of cigarette package design on perceptions of risk. *Journal of Public Health (Oxford, England), 31*(3), 345-353.

Havelaar, A. H., Brul, S., de Jong, A., de Jonge, R., Zwietering, M. H., & Ter Kuile, B. H. (2010). Future challenges to microbial food safety. *International Journal of Food Microbiology, 139 Suppl 1*, S79-S94.

Head, B., & Alford, J. (2008). Wicked problems: The implications for public management. Paper presented at the *Panel on Public Management in Practice. International Research Society for Public Management*, Brisbane, Australia.

Health Canada. (2005). *Food directorate.* Retrieved June 3, 2012, from http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/fd-da/index-eng.php

Health Canada. (2010). *Sodium reduction strategy for Canada.* Retrieved June 12, 2012, from http://www.hc-sc.gc.ca/fn-an/nutrition/sodium/related-info-connexe/strateg/index-eng.php

Health Canada. (2011). *Policy on Listeria monocytogenes in ready-to-eat foods*. Ottawa, Canada: Bureau of Microbial Hazards. Retrieved June 1, 2012, from http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_2011-eng.php

Hedberg, C. W., Smith, S. J., Kirkland, E., Radke, V., Jones, T. F., Selman, C. A., et al. (2006). Systematic environmental evaluations to identify food safety differences between outbreak and non outbreak restaurants. *Journal of Food Protection, 69*(11), 2697-2702.

Henson, S. J., Majowicz, S. E., Masakure, O., Sockett, P. N., MacDougall, L., Edge, V. L., et al. (2008). Estimation of the costs of acute gastrointestinal illness in British Columbia, Canada. *International Journal of Food Microbiology, 127*(1-2), 43-52.

Hernandez, C. A. (2009). Theoretical coding in grounded theory methodology. *The Grounded Theory Review, 8*(3), 51-60.

Holley, R. A. (2010). Smarter inspection will improve food safety in Canada. *Canadian Medical Association Journal, 182*(5), 471-473.

Holton, J. A. (2010). The coding process and its challenges. *The Grounded Theory Review, 9*(1), 21-40.

Hutchinson, R.W., English, S.L., & Mughal, M.A. (2002). A general problem solving approach for wicked problems: Theory and application to chemical weapons verification and biological terrorism. *Group Decision and Negotiation, 11*(4), 257-279.

Isonhood, J., Drake, M., & Jaykus, L. (2006). Upstream sample processing facilitates PCR detection of Listeria monocytogenes in mayonnaise-based ready-to-eat (RTE) salads. *Food Microbiology, 23*(6), 584-590.

Jacob, C. J., & Powell, D. A. (2009). Where does foodborne illness happen - in the home, at foodservice, or elsewhere-and does it matter? *Foodborne Pathogens and Disease, 6*(9), 1121-1123.

Kathariou, S., Graves, L., Buchrieser, C., Glaser, P., Siletzky, R. M., & Swaminathan, B. (2006). Involvement of closely related strains of a new clonal group of Listeria monocytogenes in the 1998-99 and 2002 multistate outbreaks of foodborne listeriosis in the United States. *Foodborne Pathogens and Disease, 3*(3), 292-302.

Kirkham, C., & Berkowitz, J. (2010). Listeriosis in pregnancy. Survey of British Columbia practitioners' knowledge of risk factors, counselling practices and learning needs. *Canadian Family Physician, 56*(4), e158-e166.

Kim, J., & Kathariou, S. (2009). Temperature-dependent phage resistance of Listeria monocytogenes epidemic clone II. *Applied and Environmental Microbiology, 75*(8), 2433-2438.

Koch, J., & Stark, K. (2006). Significant increase of listeriosis in Germany - epidemiological patterns 2001-2005. *Euro Surveillance, 11*(6), 85-88.

Kreuter, M., De Rosa, C., Howze, E., & Baldwin, G. (2004). Understanding wicked problems: A key to advancing environmental health promotion. *Health Education & Behavior, 31*(4), 441-454.

Lenhart, J., Kendall, P., Medeiros, L., Doorn, J., Schroeder, M., & Sofos, J. (2008). Consumer assessment of safety and date labelling statements on ready-to-eat meat and poultry products designed to minimize risk of listeriosis. *Journal of Food Protection, 71*(1), 70-76.

Leung, L., Middleton, D., & Morrison, K. (2012). One health and EcoHealth in Ontario: A qualitative study exploring how holistic and integrative approaches are shaping public health practice in Ontario. *BMC Public Health, 12*(358), 1-15.

Lin, C., Takeuchi, K., Zhang, L., Dohm, C. B., Meyer, J. D., Hall, P. A., et al. (2006). Cross-contamination between processing equipment and deli meats by Listeria monocytogenes. *Journal of Food Protection, 69*(1), 71-79.

Linden, K.V. (2006). A grounded approach to the study of complex systems. *World Futures, 62*, 491-487.

Luber, P., Crerar, S. K., Dufour, C., Farber, J. M., Datta, A., & Todd, E. C. D. (2011). Controlling Listeria monocytogenes in ready-to-eat foods: Working towards global scientific consensus and harmonization - recommendations for improved prevention and control. *Food Control, 22*(9), 1535-1549.

Lupien, J. R. (2007). Prevention and control of food safety risks: The role of governments, food producers, marketers, and academia. *Asia Pacific Journal of Clinical Nutrition, 16 Suppl 1*, 74-79.

MacDougall, L., Majowicz, S., Doré, K., Flint, J., Thomas, K., Kovacs, S., et al. (2008). Under-reporting of infectious gastrointestinal illness in British Columbia, Canada: Who is counted in provincial communicable disease statistics? *Epidemiology and Infection, 136*(2), 248-256.

Majowicz, S. E., Doré, K., Flint, J. A., Edge, V. L., Read, S., Buffett, M. C., et al. (2004). Magnitude and distribution of acute, self-reported gastrointestinal illness in a Canadian community. *Epidemiology and Infection, 132*(4), 607-617.

Majowicz, S. E., McNab, W. B., Sockett, P., Henson, T. S., Doré, K., Edge, V. L., et al. (2006). Burden and cost of gastroenteritis in a Canadian community. *Journal of Food Protection, 69*(3), 651-659.

Majowicz, S. E., Edge, V. L., Fazil, A., McNab, W. B., Doré, K. A., Sockett, P. N., et al. (2005). Estimating the under-reporting rate for infectious gastrointestinal illness in Ontario. *Journal of Public Health, 96*(3), 178-181.

Majowicz, S. E., Horrocks, J., & Bocking, K. (2007). Demographic determinants of acute gastrointestinal illness in Canada: A population study. *BMC Public Health, 7*(162), 1-8.

Mathias, R. G., Riben, P. D., Campbell, E., Wiens, M., Cocksedge, W., Hazlewood, A., et al. (1994). The evaluation of the effectiveness of routine restaurant inspections and education of food handlers: Restaurant inspection survey. *Canadian Journal of Public Health. Revue Canadienne De Sante Publique, 85 Suppl 1*, S61-6.

Mavetera, N., & Kroeze, J.H. (2009). Practical Considerations in Grounded Theory Research. *Sprouts: working papers on information systems, 9*(32), 9-32.

McNeill, A., Hammond, D., & Gartner, C. (2012). Whither tobacco product regulation? *Tobacco Control, 21*(2), 221-226.

Mead, P. S., Dunne, E. F., Graves, L., Wiedmann, M., Patrick, M., Hunter, S., et al. (2006). Nationwide outbreak of listeriosis due to contaminated meat. *Epidemiology and Infection, 134*(4), 744-751.

Meldrum, R. J., & Smith, R. M. M. (2007). Occurrence of Listeria monocytogenes in sandwiches available to hospital patients in Wales, United Kingdom. *Journal of Food Protection, 70*(8), 1958-1960.

Meurer, W. J., Frederiksen, S. M., Majersik, J. J., Zhang, L., Sandretto, A., & Scott, P. A. (2007). Qualitative data collection and analysis methods: The INSTINCT trial. *Academic Emergency Medicine : Official Journal of the Society for Academic Emergency Medicine, 14*(11), 1064-1071.

Morris, J. G. (2003). The color of hamburger: Slow steps toward the development of a science-based food safety system in the United States. *Transactions of the American Clinical and Climatological Association, 114*, 191-202.

Nederhof, A. J. (1985). Methods of coping with social desirability bias: A review. *European Journal of Social Psychology, 15*(3), 263-280.

Nelson, J. M., Bednarczyk, R., Nadle, J., Clogher, P., Gillespie, J., Daniels, A., et al. (2008). FoodNet survey of food use and practices in long-term care facilities. *Journal of Food Protection, 71*(2), 365-372.

Newell, D. G., Koopmans, M., Verhoef, L., Duizer, E., Aidara-Kane, A., Sprong, H., et al. (2010). Food-borne diseases - the challenges of 20 years ago still persist while new ones continue to emerge. *International Journal of Food Microbiology, 139 Suppl 1*, S3-15.

Norrung, B. (2000). Microbiological criteria for Listeria monocytogenes in foods under special consideration of risk assessment approaches. *International Journal of Food Microbiology, 62*(3), 217-221.

Olsen, S. J., Patrick, M., Hunter, S. B., Reddy, V., Kornstein, L., MacKenzie, W. R., et al. (2005). Multistate outbreak of Listeria monocytogenes infection linked to delicatessen turkey meat. *Clinical Infectious Diseases, 40*(7), 962-967.

Ontario Ministry of Agriculture, Food and Rural Affairs. (2008). Some feeding tips for tough times. *Virtual Beef*, 7(18), 1-8.

Ontario Ministry of Agriculture, Food and Rural Affairs. (2011a). *Government roles and responsibilities for food safety in Ontario.* Retrieved June 5, 2012, from http://www.omafra.gov.on.ca/english/infores/foodsafe/rolesprov.html

Ontario Ministry of Agriculture, Food and Rural Affairs. (2011b). *Microbiological regulatory monitoring program for provincially licensed meat plants that process ready-to-eat meat products.* Retrieved June 7, 2012, from http://www.omafra.gov.on.ca/english/food/inspection/meatinsp/samplingfollowup.htmhttp://www.omafra.gov.on.ca/english/infores/foodsafe/rolesprov.html

Ontario Ministry of Agriculture, Food and Rural Affairs, (2011c). *Ontario's Meat Inspection Program*. Retrieved June 4, from http://www.wrfoodsystem.ca/files/www/OMAFRA_Presentation_November_23_2011.pdf

Ontario Ministry of Health and Long Term Care. (2008). *Ontario food safety protocol*. Ontario, Canada: Queen's Printer for Ontario.

Ontario Ministry of Health and Long Term Care. (2011). *Performance management framework for public health: Accountability agreements and performance indicators.* Retrieved April

17, 2012, from http://www.healthunit.com/(F(Lt05gK8SLOlxNYXIH1LUFkUrd3gxjXIapvK6J2cuMoK6L1A5GR0cae_pv26LgolSqTZEg3dPwyjXYoUzTezzABHAYoPEMEX9RS4jQgEpJZtGCTyYBH4VsiPyyt6J6PgmxEmrb_zC2oyG5vBAWdbHOy_aOIxmF-vhNRsVPr5H7TP7wvjN0))/articlesPDF/16794.pdf

OzFoodNet Working Group. (2007). Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual report of the ozfoodnet network, 2006. *Communicable Diseases Intelligence, 31*(4), 345-365.

Peterson, L. D., Faith, N. G., & Czuprynski, C. J. (2008). Growth of L. monocytogenes strain F2365 on ready-to-eat turkey meat does not enhance gastrointestinal listeriosis in intragastrically inoculated A/J mice. *International Journal of Food Microbiology, 126*(1-2), 112-115.

Pham, M. T., Jones, A. Q., Sargeant, J. M., Marshall, B. J., & Dewey, C. E. (2010). A qualitative exploration of the perceptions and information needs of public health inspectors responsible for food safety. *BMC Public Health, 10*(345), 1-9.

Pradhan, A. K., Ivanek, R., Gröhn, Y. T., Geornaras, I., Sofos, J. N., & Wiedmann, M. (2009). Quantitative risk assessment for Listeria monocytogenes in selected categories of deli meats: Impact of lactate and diacetate on listeriosis cases and deaths. *Journal of Food Protection, 72*(5), 978-989.

Public Health Agency of Canada. (2010). *Canada's foodborne illness outbreak response protocol (FIORP) 2010: To guide a multi-jurisdictional response.* Retrieved April 5, 2012, from http://www.phac-aspc.gc.ca/zoono/fiorp-pritioa/index-eng.php#a621

Public Health Agency of Canada. (2012). *Public health agency of Canada - about the agency.* Retrieved April 15, 2012, from http://www.phac-aspc.gc.ca/about_apropos/index-eng.phphttp://www.phac-aspc.gc.ca/zoono/fiorp-pritioa/index-eng.php#a621

Public Health Ontario. (2011). *Public health Ontario - about us.* Retrieved November 25, 2012, from http://www.oahpp.ca/about/index.html

Quested, T. E., Cook, P. E., Gorris, L. G., & Cole, M. B. (2010). Trends in technology, trade and consumption likely to impact on microbial food safety. *International Journal of Food Microbiology, 139*(Supplement 1), S29-S42.

Rebellato, S.R., Cholewa, S., Chow, J., & Poon, D. (2012). Impact of PROTON: A food handler certification course on food handlers' knowledge, attitudes and behaviour. *Journal of Food Safety*, *32*(1), 129-133.

Rhoades, J. R., Duffy, G., & Koutsoumanis, K. (2009). Prevalence and concentration of verocytotoxigenic escherichia coli, salmonella enterica and Listeria monocytogenes in the beef production chain: A review. *Food Microbiology*, *26*(4), 357-376.

Riben, P. D., Mathias, R. G., Wiens, M., Cocksedge, W., Hazelwood, A., Kirshner, B., et al. (1994). Routine restaurant inspections and education of food handlers: Recommendations based on critical appraisal of the literature and survey of Canadian jurisdictions on restaurant

inspections and education of food handlers. *Canadian Journal of Public Health, 85 Suppl 1*, S67-70.

Richardson, R., & Kramer, E. (2006). Abduction as the type of inference that characterizes the development of a grounded theory. *Qualitative Research, 6*(4), 497-513.

Risjord, M. W., Dunbar, S. B., & Moloney, M. F. (2002). A new foundation for methodological triangulation. *Journal of Nursing Scholarship, 34*(3), 269-275.

Rocourt, J., BenEmbarek, P., Toyofuku, H., & Schlundt, J. (2003). Quantitative risk assessment of Listeria monocytogenes in ready-to-eat foods: The FAO/WHO approach. *FEMS Immunology and Medical Microbiology, 35*(3), 263-267.

Rogers, P. (2008). Using programme theory to evaluate complicated and complex aspects of interventions. *Evaluation, 14*(1), 29-48.

Ruzante, J. M., Davidson, V. J., Caswell, J., Fazil, A., Cranfield, J. A. L., Henson, S. J., et al. (2010a). A multifactorial risk prioritization framework for foodborne pathogens. *Risk Analysis, 30*(5), 724-742.

Ruzante, J. M., Davidson, V. J., Caswell, J., Fazil, A., Cranfield, J. A. L., Henson, S. J., et al. (2010b). A multifactorial risk prioritization framework for foodborne pathogens - Information card: Listeriosis associated with ready-to-eat meat consumption. *Unpublished raw data*.

Sargeant, J. M., Majowicz, S. E., & Snelgrove, J. (2008). The burden of acute gastrointestinal illness in Ontario, Canada, 2005-2006. *Epidemiology and Infection, 136*(4), 451-460.

Sargeant, J. M., Ramsingh, B., Wilkins, A., Travis, R.G., Gavrus, D., & Snelgrove, J.W. (2007). Constraints to microbial food safety policy: opinions from stakeholder groups along the farm to fork continuum. *Zoonoses and Public Health, 54,* 177-184.

Sheen, S., & Hwang, C. (2008). Modeling transfer of Listeria monocytogenes from slicer to deli meat during mechanical slicing. *Foodborne Pathogens and Disease, 5*(2), 135-146.

Shetty, A., McLauchlin, J., Grant, K., O'Brien, D., Howard, T., & Davies, E. M. (2009). Outbreak of Listeria monocytogenes in an oncology unit associated with sandwiches consumed in hospital. *The Journal of Hospital Infection, 72*(4), 332-336.

Simmons, O. E. (2006). Some professional and personal notes on research methods, systems theory, and grounded action. *World Futures, 62*(7), 481-490.

Stone, S. C., & Shoenberger, J. (2001). Update: Multistate outbreak of listeriosis--United States, 2000. *Annals of Emergency Medicine, 38*(3), 339-341.

Strauss, A., Corbin, J. (1990). *Basics of qualitative research*. Newbury Park, CA: Sage Publications Inc.

Stringer, S.C., Pin, C. (2005). *Microbial risks associated with salt reduction in certain foods and alternative options for preservation*. United Kingdom: Institute of Food Research.

Sturges, J., & Hanrahan, K. (2004). Comparing telephone and face-to-face qualitative interviewing: A research note. *Qualitative Research, 4*(1), 107-118.

Succeeding with tobacco cessation takes perseverance and innovation.(1999). *Medical Management Network, 7*(11), 8-10.

Thomas, M. K., Majowicz, S. E., Pollari, F., & Sockett, P. N. (2008). Burden of acute gastrointestinal illness in Canada, 1999-2007: Interim summary of NSAGI activities. *Canada Communicable Disease Report, 34*(5), 8-15.

Thomas, M. K., Majowicz, S. E., MacDougall, L., Sockett, P. N., Kovacs, S. J., Fyfe, M., et al. (2006). Population distribution and burden of acute gastrointestinal illness in British Columbia, Canada. *BMC Public Health, 6*(307), 1-11.

Thompson, S. (2009). *Food safety in Toronto*. Toronto, Ontario: Toronto Public Health.

Todd, E. C., Greig, J. D., Bartleson, C. A., & Michaels, B. S. (2007). Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 3. Factors contributing to outbreaks and description of outbreak categories. *Journal of Food Protection, 70*(9), 2199-2217.

United States Food and Drug Administration. (2003). *Interpretive summary: Quantitative assessment of the relative risk to public health from foodborne Listeria monocytogenes among selected categories of ready-to-eat foods.* United States: Center for Food Safety and Applied Nutrition. Retrieved from http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/UCM197329.pdf

United States Food and Drug Administration. (2008). *Risk assessment of the public health impact from foodborne Listeria monocytogenes in some ready-to-eat foods sliced, prepared, and or packaged in retail facilities* No. FDA-2008-N-0658). United States: Department of Health and Human Services.

Uyttendaele, M., Busschaert, P., Valero, A., Geeraerd, A. H., Vermeulen, A., Jacxsens, L., et al. (2009). Prevalence and challenge tests of Listeria monocytogenes in Belgian produced and retailed mayonnaise-based deli-salads, cooked meat products and smoked fish between 2005 and 2007. *International Journal of Food Microbiology, 133*(1-2), 94-104.

Vaillant, V., de Valk, H., Baron, E., Ancelle, T., Colin, P., Delmas, M. C., et al. (2005). Foodborne infections in France. *Foodborne Pathogens and Disease, 2*(3), 221-232.

Varma, J. K., Samuel, M. C., Marcus, R., Hoekstra, R. M., Medus, C., Segler, S., et al. (2007). Listeria monocytogenes infection from foods prepared in a commercial establishment: A case-control study of potential sources of sporadic illness in the United States. *Clinical Infectious Diseases, 44*(4), 521-528.

Verpy, H., Smith, C., & Reicks, M. (2003). Attitudes and behaviors of food donors and perceived needs and wants of food shelf clients. *Journal of Nutrition Education and Behavior, 35*(1), 6-15.

Voelker, R. (2002). Listeriosis outbreak prompts action--finally. *JAMA: The Journal of the American Medical Association, 288*(21), 2675-2676.

Wagner, M., Melzner, D., Bagò, Z., Winter, P., Egerbacher, M., Schilcher, F., et al. (2005). Outbreak of clinical listeriosis in sheep: Evaluation from possible contamination routes from feed to raw produce and humans. *Journal of Veterinary Medicine.B, Infectious Diseases and Veterinary Public Health, 52*(6), 278-283.

Warner, K. E., & Mendez, D. (2010). Tobacco control policy in developed countries: Yesterday, today, and tomorrow. *Nicotine & Tobacco Research, 12*(9), 876-887.

Warner, K. E., & Tam, J. (2012). The impact of tobacco control research on policy: 20 years of progress. *Tobacco Control, 21*(2), 103-109.

Weatherhill, S. (2009). *Final report: Report of the independent investigator into the 2008 listeriosis outbreak*. Canada: Government of Canada. Retrieved from http://www.listeriosis-listeriose.investigation-enquete.gc.ca/lirs_rpt_e.pdf

Wegener, J. (2011). Multi-sectoral perspectives on regional food policy, planning and access to food: A case study of waterloo region. (Doctoral Dissertation, University of Waterloo, 2011). Retrieved from http://uwspace.uwaterloo.ca/handle/10012/6130

Whitley, R., & Crawford, M. (2005). Qualitative research in psychiatry. *Canadian Journal of Psychiatry.Revue Canadienne De Psychiatrie, 50*(2), 108-114.

Williams, D. (2009). *Chief medical officer of health's report on the management of the 2008 listeriosis outbreak in Ontario* No. 011774). Ontario: Ontario Ministry of Health and Long Term Care. Retrieved from http://www.health.gov.on.ca/en/public/publications/disease/docs/listeriosis_outbreak_rep.pdf

World Health Organization. (2004). *Risk assessment of Listeria monocytogenes in ready-to-eat foods*. Switzerland: World Health Organization. Retrieved from http://whqlibdoc.who.int/publications/2004/9241562625.pdf

World Health Organization. (2009). Joint FAO/WHO food standards programme codex Alimentarius commission: Thirty second session. Paper presented at the *Report of the Fortieth Session of the Codex Committee on Food Hygiene.* Rome, Italy. pp. 48-70.

Wuest, J., Ford-Gilboe, M., Merritt-Gray, M., & Lemire, S. (2006). Using grounded theory to generate a theoretical understanding of the effects of child custody policy on women's health promotion in the context of intimate partner violence. *Health Care for Women International, 27*(6), 490-512.

Xie, S. L. (2009). Striking a balance between program requirements and GT principles: Writing a compromised GT proposal. *Grounded Theory Review, 8*(2), 35-47.

Yates, D., Moore, M. D., & McCabe, G. (Eds.). (1999). *The practice of statistics* (1st ed.). New York: W.H. Freeman.

APPENDIX A: Support Letter to Association of Supervisors of Public Health Inspectors in Ontario

Grey Bruce Public Health Unit
101 17th Street East,
Owen Sound, ON N4K 0A5

August 20, 2011

Dear Chris Munn (ASPHIO President);

Please accept the following letter as an application of interest in using the ASPHIO list serve for the purposes of research being conducted beginning in the fall of 2011. A fourth year PhD student in the School of Public Health and Health Systems, I am requesting ASPHIO's support in a research study examining L. *monocytogenes* and ready-to-eat foods.

Please be advised that the purpose of this letter is to request that ASPHIO send the attached letters of request to all 36 public health units commencing in November 2011 on my behalf to support the research initiative. The purpose of the letter is to request interviews with food safety personnel (Medical Officers of Health, directors, managers, supervisors, public health inspectors, and key informants focused on food safety) in each public health unit. Interviews will be conducted in 2 phases. Phase 1 will take place either in person or over the telephone with a select amount of public health units. Similarly, phase 2 interviews will take place after completion of phase 1 interviews with another set of public health units in person or over the telephone. Those public health units who do not participate in telephone or in-person interviews in Phases 1 or 2 will be provided with an internet survey (phase 3) which will be sent out after completion of phase 2 interviews. Food safety personnel must meet eligibility criteria as specified in the research proposal. Eligibility criteria for participating public health units will

be shared within the body of the letter which will be addressed to the public health unit medical officer of health.

The study will examine L. *monocytogenes* and ready-to-eat meats. Qualitative-based grounded theory will be used to drive the research agenda through interviews with food safety participants. Using qualitative methods, the study will assist current provincial food safety initiatives in improving inspection activities aimed at reducing incidence of listeriosis. In addition, the study will serve to provide direction for future research in food safety inspection systems and will identify improvement opportunities for Public Health Ontario and the Ontario Ministry of Health and Long Term Care to improve their existing food safety programming and future amendments to the *Food Premises Regulation*. Interviews conducted with public health unit food safety participants will assist in determining to what extent L. *monocytogenes* and ready-to-eat meats research has influenced provincial legislation and food safety practice.

Results of the study will be shared with ASPHIO upon completion of the research. No identifiers will be included in study results in order to maintain confidentiality of interview responses. In order to reduce study bias, interviews will be recorded and transcribed. It is anticipated that the study will be completed by the end of 2012.

Please see my contact information below should you or members of ASPHIO have any question in regards to the study. Please also find attached a template of a letter to be sent by ASPHIO to public health unit contacts.

Regards,

Steven Rebellato, PhD Candidate
University of Waterloo. Faculty of Applied Health Sciences.
200 University Avenue West, Waterloo, Ontario, N2L 2G1
srebella@uwaterloo.ca

APPENDIX B: Acceptance Letter from the Association of Supervisors of Public Health Inspectors of Ontario

ASPHIO

The Association of Supervisors of Public Health Inspectors of Ontario (Incorporated 1982)

August 22, 2011

Steven Rebellato
University of Waterloo
Faculty of Applied Health Sciences
200 University Avenue West
Waterloo, Ontario, N2L 3G1

Dear Steven Rebellato:

Thank you for contacting ASPHIO in relation to your PhD dissertation proposal entitled: "*Listeria monocytogenes and ready-to-eat meats: tackling a wicked problem using grounded theory to create an improved inspection program for Ontario.*" Please be advised that ASPHIO supports the PhD research and has received your letter requesting support and distribution of research request letters to 36 Health Units in Ontario. In order to assist the research initiative, ASPHIO will assist in the distribution of the request letter to Ontario Public Health units to participate in the research study.

Please contact me directly when you are ready to distribute the letter to our members on your behalf.

Yours truly

Christopher Munn, B.A., CPHI(C)
President, ASPHIO
Phone: 519-376-9420 ext. 1235
Email: c.munn@publichealthgreybruce.on.ca

APPENDIX C: Email Request to Public Health Units for Study Participants

Dear public health unit director or Medical Officer of Health;

Please accept the following email to request your public health unit's participation in a research study being conducted by the University of Waterloo, School of Public Health and Health Systems. The study is being conducted by Steven Rebellato under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems at the University of Waterloo. The Association of Supervisors of Public Health Inspectors of Ontario (ASPHIO) fully supports the research study. The purpose of the proposed study is to determine the association between food safety inspection, the Ontario provincial regulatory framework and research, knowledge translation and innovation associated with L. *monocytogenes* and RTE meats.

The principle investigator is requesting that the attached information letter be sent to staff (Medical Officer of Health, managers, supervisors, public health inspectors, and key informants) in your respective public health unit who are currently working in the food safety program in order to determine interest in participating in the study. You may also participate in the study. The research study requires 2 participants from each public health unit including; (i) food safety manager/supervisor/director/Medical Officer of Health; and (ii) either a public health inspector or key informant to the food safety program. Details on time commitment requirements (15-30 minutes per study participant), participant eligibility criteria, and other information related to the study requirements are provided in the information letter attached.

The principle investigator is requesting that you (public health unit directors) indicate your interest in participating in the study by December 9, 2011 via email. The email to the principle investigator (Steven Rebellato) should include the names of the participants, their

position in the public health unit along with their contact information. Should you have questions about the research study, please direct them to Steven Rebellato in the contact information provided below.

Regards,

Steven Rebellato, PhD Candidate
University of Waterloo. Faculty of Applied Health Sciences.
200 University Avenue West, Waterloo, Ontario, N2L 2G1
srebella@uwaterloo.ca

Email Attachment [Microsoft Word document]

Dear public health unit staff;

Please accept the following letter to request your public health unit's participation in a research study being conducted by the University of Waterloo, School of Public Health and Health Systems. The study is being conducted by Steven Rebellato under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems at the University of Waterloo. The Association of Supervisors of public health inspectors in Ontario (ASPHIO) fully supports the research study. The purpose of the proposed study is to determine the association between food safety inspection, the Ontario provincial regulatory framework and research, knowledge translation and innovation associated with L. *monocytogenes* and RTE meats.

The purpose of the request is to appeal for the assistance of 2 food safety personnel in your public health unit. Food safety personnel could include directors, managers, supervisors, medical officer of health, public health inspectors, or 'key informants' (see chart below). Participating food safety personnel will be asked to participate in short interviews (e.g., 15-30 minutes) which will be facilitated by a member of the research group. Interviews will be

conducted in 2 phases. Phase 1 interviews will take place either in person or over the telephone with a group of selected public health units. Phase 2 interviews will be conducted either in person or by telephone with public health units not selected in phase 1. Public health units wishing to participate in the study but are not chosen to participate in phases 1 and 2 will be invited to participate in an internet survey in phase 3 to ensure the study findings are representative of all public health units in the province.

Study results will assist current provincial public health unit food safety initiatives in improving inspection activities aimed at reducing incidence of listeriosis. In addition, the study will serve to provide direction for future research in food safety inspection systems and will identify improvement opportunities for Public Health Ontario and the Ontario Ministry of Health and Long Term Care to improve their existing food safety programming and future regulatory amendments to the *Food Premises Regulation*.

For each public health unit interested in participating, one 'food safety management' participant and one of either a public health inspector or 'key informant' are required for a public health unit to participate in the study. The Table below defines the eligibility criteria for each position being sought by the principle investigator.

Eligibility criteria	**Food safety management (Medical Officers of Health, director, supervisors)**	**Public health inspectors**	**Key informants (researchers, policy analysts)**
Experience in position	Minimum 3 years in managing/supervising certified public health inspectors involved in the food safety program	Minimum 3 years acting as a certified public health inspector in food safety program.	Minimum 3 years in working with the food safety program in an epidemiology, planning or research capacity
Education	Certified public health inspector (Canada) or Medical Officer of Health.	Certified public health inspector (Canada)	Minimum Bachelors degree for associated position in the public health unit
Program involvement	Food safety program management in accordance with the Ontario Public Health Standards, and the *Health Protection and*	Involved with inspection of food premises in accordance with the *Health Protection and Promotion Act* and *Food Premises Regulation*	Involved with assisting the public health unit food safety program in reducing foodborne illness through various initiative and

	Promotion Act and *Food Premises Regulation*		activities
Association with the *Food Premises Regulation*	Administrator of staff with direct application of regulation to food premises (*Food Premises Regulation*)	Administrator of regulation to food premises	Knowledge of the application of the *Food Premises Regulation* to the public health unit food safety program

Your participation in the research study is voluntary. However, given the unique role in provincial food safety your public health unit plays, your perspectives are extremely valuable. Participating food safety interview personnel will also be asked to provide reference documents which assist their food safety programming in the area of research. Examples of requested documents are provided below:

Document type	Description
Communication documents	- Public communication documents related to RTE meats and L. m*onocytogenes* - Food establishment communication documents related to RTE meats and L. *monocytogenes*
Risk assessment documents	- Food establishment inspection risk assessment tool - Food establishment inspection risk assessment policy
Inspection documents	- Food safety compliance inspection template - Food safety recall inspection template - Food safety foodborne illness inspection template
Policies and best practice documents	- Inspection policies - Food recall policies - Foodborne illness policies - External agency best practice documents (i.e., CFIA, MOHLTC, OAHPP, United States Centre for Disease Control)

If you choose to participate in the study, you may decide to decline to answer any of the interview questions if you so wish. You may to decide to withdraw from this study at any time without negative consequences by advising the principle investigator. With participant permission, the interview will be recorded to facilitate collection of information and later transcribed for analyses. All information provided is considered completely confidential. Participant names will not appear in any publication resulting from this study; however, with permission, anonymous quotes may be used. The audio recordings from this study will be

securely stored at the University of Waterloo at the School of Public Health and Health Systems for 3 months following transcription and then confidentially destroyed. Transcripts will be de-identified with only the principle investigator knowing the identity of the participants' names. Only researchers associated with this research project will have access to the confidential data; with no report identifying what individuals or public health units participated in the study. Electronic data, with no personal or organization identifiers, will be kept for 1 year on a secure University of Waterloo server. There are no known or anticipated risks to you as a participant.

This study has been reviewed and received ethics clearance through the office of Research Ethics at the University of Waterloo. However, the final decision about participation is yours. If you have any comments or concerns resulting from your participation in this study, please contact Dr. Susan Sykes in the Office of research Ethics at 519-888-4567, Ext. 36005 or ssykes@uwaterloo.ca

If you would like to participate in the research study, please communicate your interest in participating with your public health unit director or Medical Officer of Health to coordinate a response to the principle investigator by December 9, 2011. Should you have questions or require further information on the research study, please direct questions to Steven Rebellato.

Regards,

Steven Rebellato, PhD Candidate
University of Waterloo. Faculty of Applied Health Sciences.
200 University Avenue West, Waterloo, Ontario, N2L 2G1
srebella@uwaterloo.ca

APPENDIX D: Interview Guide for In-Person Interviews

Preamble

Thank you [participant name] for agreeing to meet with me in person. I am here today to interview you regarding a research study examining L. *monocytogenes* and ready-to-eat meats. The study is being conducted by me [Steven Rebellato] under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems at the University of Waterloo. Before we begin, I want to go over some important information related to the study with you.

Consent Review: I wanted to remind you that your participation is completely voluntary; however, given your unique role with a public health unit in Ontario working in the food safety program, your perspective is extremely valuable to this research. You may decline to answer any of the interview questions or withdraw from the study at any time. With your permission, the interview will be recorded to facilitate collection of information, and later transcribed for analyses. All information you provide is considered completely confidential. Your name will not appear in any publication resulting from this study; however, with your permission anonymous quotations may be used.

Have you read the information letter provided about the interview (see Appendix B)?

□ yes □ no (if no, review contents of the letter)

Do you agree to have your comments audio-recorded?

□ Participant agrees □ Participant does not agree

Do you agree to the use of anonymous quotations from the interview in the evaluation report? Your organization will not be identified in any quotations.

□ Participant agrees □ Participant does not agree

Do you have any questions before we begin the interview? Please see a copy of the consent form in front of you which will need to be signed before we begin the interview

Once consent form is signed, begin interview

APPENDIX E: Consent Form: In-Person Interview

Dear _____

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

_____

I have read the information presented in the information letter about a study being conducted by Steven Rebellato under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems at the University of Waterloo. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted. I am aware that I may withdraw from the study without penalty at any time by advising the principle investigator of this decision.

I am aware that I have the option of allowing my interview to be audio recorded to ensure an accurate recording of my responses. I am also aware that excerpts from the interview may be included in the thesis and/or publications to come from this research, with the understanding that the quotations will be anonymous.

I was informed that I may withdraw my consent at any time without penalty by advising the principle investigator.

This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. I was informed that if I have any comments or concerns

resulting from my participation in this study, I may contact the Director, Office of Research Ethics at 519-888-4567 ext. 36005 or ssykes@uwaterloo.ca.

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

☐YES ☐NO

I agree to have my interview audio recorded.

☐YES ☐NO

I agree to the use of anonymous quotations from the interview in the evaluation report with the understanding that my organization will not be identified in any quotations in any thesis or publication that comes of this research.

☐YES ☐NO

Participant Name: _____ (Please print)

Participant Signature: _____

Witness Name: _____ (Please print)

Witness Signature: _____

APPENDIX F: Interview Guide for Telephone

December, 2011

Preamble

Hi [participant name], it is 'Steven Rebellato' calling from the University of Waterloo. As you may recall, I am conducting a research study under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems. I am following up regarding your participation in the 'L. *monocytogenes* and RTE meat' study. Is now still a good time for you to speak with me?

> Yes= Great, we will get started now. First, let me thank you for agreeing to participate in this important study.

Go to Consent Review (see below):

> No=Okay I understand and that is not a problem. When might be a better time for you to talk with me? Go to Schedule Next Interview

Consent Review: I wanted to remind you that your participation is completely voluntary; however, given your unique role with a public health unit in Ontario working in the food safety program, your perspective is extremely valuable to this research. You may decline to answer any of the interview questions or withdraw from the study at any time. With your permission, the interview will be recorded to facilitate collection of information, and later transcribed for analyses. All information you provide is considered completely confidential. Your name will

not appear in any publication resulting from this study; however, with your permission anonymous quotations may be used.

Have you read the information letter provided about the interview (see Appendix B)?

□ yes □ no (if no, review contents of the letter)

Do you agree to have your comments audio-recorded?

□ I agree □ I do not agree

Do you agree to the use of anonymous quotations from the interview in the evaluation report? Your organization will not be identified in any quotations.

□ I agree □ I do not agree

Do you have any questions before we begin the interview?

Begin interview

APPENDIX G: Phase 2 Question Justification Grid

Core categories **Phase 1 research questions**	**Prevention through collaboration**	**Population and product management**	**Response driven research**	**Regulatory and microbiological limitation**
Research question # 1 What is the current state of food safety research, knowledge translation and innovation related to L. *monocytogenes* and RTE meats and to what extent do Ontario public health units and provincial food safety standards incorporate these tenants into their food safety policies and inspection practices?	Based on your experience with the following agencies, describe your relationship in particular to L. *monocytogenes* and RTE meats with: (i) CFIA (ii) Public Health Agency of Canada (iii) OMAFRA (iv) MOHLTC (v) PHO	Has your public health unit established a different approach in regards to these populations and facilities? Please provide any examples.	Have government publications or scientific research had any effect on the day-to-day operations of your public health units? Why or why not? **For example, the *Report of the Independent Investigator into the 2008 Listeriosis outbreak* (Dec 2011)	Do you believe that past outbreaks, recalls and research in regards to L. *monocytogenes* and RTE meats have had an impact on the *Food Premises Regulation* along with the Protocol and Standard? Please explain.
Research Question # 2 To what extent do Ontario public health units view current food safety inspection programming examining RTE meats and L. *monocytogenes* as a 'wicked problem'?	To what extent is the current MOU between OMAFRA, CFIA and Ontario public health units where processing facilities are not inspected by Ontario public health inspectors beneficial or a detriment to the overall inspection process?	What do you think Ontario public health units' role in institutional settings should be where vulnerable populations such as the elderly or the immunocompromised are housed and are served RTE meats?	What is your opinion in regards to the use of scientific research or government publications in public health units for the purposes of inspection and investigation of listeriosis? Does your public health unit currently have a	What is your opinion in regards to the current provincial food safety program in Ontario including the *Food Premises Regulation*, Ontario Food Safety Standard and Food Safety Protocol (2008) as it relates to L. *monocytogenes* and RTE meats? What is your opinion in regards to the L. *monocytogenes* surveillance and management program in Ontario?

Core categories **Phase 1 research questions**	**Prevention through collaboration**	**Population and product management**	**Response driven research**	**Regulatory and microbiological limitation**
			L. *monocytogenes* policy in place? (YES - why did you feel it necessary to have one in place? NO – are there reasons why your public health unit does not have a policy?)	
Research Question # 3 According to Ontario public health units, what additional or innovative components are required in RTE meat and L. *monocytogenes* research, policy and practice to reduce foodborne illness and to develop a comprehensive inspection program?	Is there any room for improvement in the relationship you currently have with each of these agencies that would support the manner in which you address L. *monocytogenes* and RTE meats? Please describe. What are your thoughts in regards to the role of provincial and federal agencies in providing knowledge and expertise to Ontario public health units?	Should the manner in which inspections are conducted at institutional settings in Ontario public health units differ from other retail establishments that serve RTE meats?	In what ways did the L. *monocytogenes* outbreak in 2008 (Maple Leaf Foods) lead to changes to the manner in which your health department addresses RTE meats and Listeria?	Do you feel that the incidence of listeriosis related to consumption of RTE meats is sufficiently managed and controlled from a federal, provincial and public health unit level?

APPENDIX H: Phase 3 Selective Code and Central Research Question

Phase 2 selective codes	Central research question theme	Question
Reactive-based practice	Food safety inspection practice	Please indicate your level of agreement with the following statement: "The 2008 L. *monocytogenes* outbreak, along with subsequent food recalls involving L. *monocytogenes*, have had an effect on my public health unit's food safety inspection program and specifically, inspection of RTE meats in food premises"
Reactive-based practice	Research, innovation, and knowledge transition	Please indicate your level of agreement with the following statement: "Research and government publications are tools that my public health unit uses to address food safety risks, including RTE meats and L. *monocytogenes*."
Regulation through collaboration	Regulatory framework	The current MOU between OMAFRA, CFIA and Ontario public health units states that licensed RTE meat processing plants are to be inspected by the licensing body (i.e., either by OMAFRA or the CFIA). Thus, typically, licensed facilities are not inspected by Ontario public health units. Based on your experience with this MOU, to what extent do you agree with the following statement: "Our public health unit rarely (if ever) communicates with OMAFRA or the CFIA in regards to their inspections of licensed processing plants "
Reactive-based practice	Food safety inspection practice	Please indicate your level of agreement with the following statement: "In order to address the risks of L. *monocytogenes*, Ontario public health units that inspect long term care facilities, homes for the aged, assisted living centres and retirement homes should have specific food safety requirements for food handlers who prepare RTE meats and serve to residents."
Reactive-based practice	Research, innovation, and knowledge transition	Please rate your level of agreement in regards to the following statement: "Our public health unit addresses L. *monocytogenes* and RTE meats as a part of the general inspection process. We do not currently have microorganism and product-specific policies and procedures in place that address L. *monocytogenes* and RTE meats explicitly"
Regulation through collaboration	Regulatory framework, Research, innovation, and knowledge transition	Please indicate your level of agreement with the following statement: "The Ontario Food Safety program -- including the Ontario Food Safety Standard, Ontario Food Safety Protocol (2008), and *Food Premises Regulation* -- has effectively incorporated recent research findings, and is effectively using lessons from previous outbreaks (e.g., Maple Leaf Foods 2008) to better address L. *monocytogenes* in RTE foods"
Regulation through collaboration		Please indicate your level of agreement with the following statement in regards to The *Food Premises Regulation*: "The *Food Premises Regulation* is sufficient for Ontario public health units to effectively address food safety risks, specifically RTE meats and L. *monocytogenes*"
		Note: All questions were followed with varying levels of agreement including: Strongly disagree, Disagree, Neither agree nor disagree, Agree, and Strongly agree

APPENDIX I: Selection Criteria for Research Team Member

Category	Criteria	Met criteria (√)
Qualitative research analyses	Background (courses, practice) in qualitative methods, axial coding, software programming, etc.	
Public health policy	Knowledge/experience in development/research/evaluation of public health policy	
Research study experience	Has participated in other research studies at the Masters or PhD level	
Total		**/ 3**

APPENDIX J: Information Email to Introduce Phase 3 Internet Survey

[Email address]

Subject header: University of Waterloo research study: phase 3 survey

Research Study Title: ***Listeria monocytogenes and ready-to-eat meats: tackling a wicked problem using grounded theory***

December 9, 2011

Dear [ASPHIO member];

Thank you for agreeing to participate in a research study being conducted by the University of Waterloo, School of Public Health and Health Systems. The study is being conducted by Steven Rebellato under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems at the University of Waterloo. The Association of Supervisors of Public Health Inspectors of Ontario (ASPHIO) fully supports the research study. The purpose of the proposed study is to determine the association between food safety inspection, the Ontario provincial regulatory framework and research, knowledge translation and innovation associated with L. *monocytogenes* and RTE meats.

Phase 1 and phase 2 interviews have been completed with 11 other public health units participating to date. These interviews have assisted in the development of phase 3 of the study which you have been selected to participate in. Phase 3 of the research study will involve the completion of an internet survey.

If you decide to volunteer, you will be asked to complete a 10-minute online survey. Participation in this study is voluntary and confidential. You may decline to answer any

questions that you do not wish to answer and you can withdraw your participation at any time by not submitting your responses. There are no known or anticipated risks from participating in this study.

By agreeing to participate in the internet survey, you agree that as a participant, you meet the criteria for participation as outlined in the eligibility criteria provided in the Table below:

Eligibility criteria	**Food safety management**	**Public health inspector**	**Key informants**
Experience in position	Minimum 3 years in managing/supervising certified public health inspectors involved in the food safety program	Minimum 3 years acting as a certified public health inspector in food safety program.	Minimum 3 years in working with the food safety program in an epidemiology, planning or research capacity
Education	Certified public health inspector (Canada) or Medical Officer of Health.	Certified public health inspector (Canada)	Minimum Bachelors degree for associated position in the public health unit
Program involvement	Food safety program management in accordance with the Ontario Public Health Standards, and the *Health Protection and Promotion Act* and *Food Premises Regulation*	Involved with inspection of food premises in accordance with the *Health Protection and Promotion Act* and *Food Premises Regulation*	Involved with assisting the public health unit food safety program in reducing foodborne illness through various initiative and activities
Association with the *Food Premises Regulation*	Administrator of staff with direct application of regulation to food premises (*Food Premises Regulation*)	Administrator of regulation to food premises	Knowledge of the application of the *Food Premises Regulation* to the public health unit food safety program

It is important for you to know that any information that you provide will be confidential. All of the data will be summarized and no individual could be identified from these summarized results. Furthermore, the web site is programmed to collect responses alone and will not collect any information that could potentially identify you (such as machine identifiers).

Fluid surveys will be used for the purposes of the survey. If you prefer not to submit your data through *Fluid surveys*, please contact Steven Rebellato so you can participate using an alternative method (such as through an email or paper-based questionnaire). The alternate method may decrease anonymity but confidentiality will be maintained.

The data, with no personal identifiers, collected from this study will be maintained on a password-protected computer database in a restricted access area of the University of Waterloo. As well, the data will be electronically archived after completion of the study and maintained for 1 year and then erased.

Should you have any questions about the study or if you would like to receive a copy of the results after completion, please contact Steven Rebellato (srebella@uwaterloo.ca).

I would like to assure you that this study has been reviewed and received ethics clearance through the Office of Research Ethics at the University of Waterloo. However, the final decision about participation is yours. If you have any comments or concerns resulting from your participation in this study, please feel free to contact Dr. Susan Sykes, Director, Office of Research Ethics, at 1-519-888-4567 ext. 36005 or by email at ssykes@uwaterloo.ca .

Thank you for considering participation in this study.

'Begin survey.' [Hyperlink to Fluid survey Introductory Page – Appendix H]

APPENDIX K: Fluid Survey Introductory Page

Thank you for agreeing to participate in a research study being conducted by the University of Waterloo, School of Public Health and Health Systems. The study is being conducted by Steven Rebellato under the supervision of Professor Stephen McColl of the School of Public Health and Health Systems at the University of Waterloo.

Each question has a list of pre-determined responses which were provided by other food safety personnel (Medical Officers of Health, directors, managers, supervisors, public health inspectors, key informants focused on food safety) in provincial public health units in interviews conducted in November and December, 2011. Please fill in the most appropriate response for your public health unit and its research and inspection activities. Each question also provides the opportunity to fill in free-hand comments based on the content of the question. Upon completion of the survey, you will be asked to provide any supporting documents related to your responses. Examples of supporting documents include:

Document type	Description
Communication documents	- Public communication documents related to RTE meats and L. m*onocytogenes* - Food establishment communication documents related to RTE meats and L. *Monocytogenes*
Risk assessment documents	- Food establishment inspection risk assessment tool - Food establishment inspection risk assessment policy
Inspection documents	- Food safety compliance inspection template - Food safety recall inspection template - Food safety foodborne illness inspection template
Policies and best practice documents	- Inspection policies - Food recall policies - Foodborne illness policies - External agency best practice documents (i.e., CFIA, MOHLTC, OAHPP, United States Centre for Disease Control)

At the completion of the survey, you will be asked to provide your contact name and public health unit strictly for the purposes of tracking participation of public health units. Please note

that no identifiers will be included in study results in order to maintain confidentiality of interview responses.

Should you have questions or require further information on the research study being conducted, please send an email to Steven Rebellato (srebella@uwaterloo.ca).

Thank you for your participation, please click the link below to begin:

[Insert check box or radio button 'survey' – URL link to fluid survey page] 'I agree to participate.'

[Insert check box or radio button] 'I do not wish to participate (please close your web browser now).'

APPENDIX L: Acknowledgement Letter to Participating Public Health Units

[Name]
[Public health unit]
[Address]
[Email address]

November, 2011

Dear [participating public health unit contact];

Thank you for participating in the research study examining L. *monocytogenes* and ready-to-eat foods. The study is entitled: *Listeria monocytogenes and Ready-to-eat meats: Tackling a Wicked Problem using Grounded*. The purpose of the proposed study is to determine the association between food safety inspection, the Ontario provincial regulatory framework and research, knowledge translation and innovation associated with L. *monocytogenes* and RTE meats.

Data collected during interviews will contribute to a better understanding of *Listeria monocytogenes* and ready-to-eat meats in Ontario public health units. Interview data are currently being consolidated. Interview responses will be used to improve public health inspection practices in the Province of Ontario as it relates to research and legislation associated with L. *monocytogenes* and RTE meats.

Please remember that any data pertaining to you as an individual participant will be kept confidential. Once all the data are collected and analyzed for this project, I plan on sharing this information with the research community through seminars, conferences, presentations, and journal articles. If you are interested in receiving more information regarding the results of this study, or would like a summary of the results, please provide your email address, and when the

study is completed, anticipated by the end of 2012, I will send you the information. In the meantime, if you have any questions about the study, please do not hesitate to contact me by email or telephone as noted below. As with all University of Waterloo projects involving human participants, this project was reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. Should you have any comments or concerns resulting from your participation in this study, please contact Dr. Susan Sykes, Director, Office of Research Ethics at 519-888-4567, Ext., 36005 or ssykes@uwaterloo.ca.

Regards,

Steven Rebellato, PhD Candidate
University of Waterloo. Faculty of Applied Health Sciences.
200 University Avenue West, Waterloo, Ontario, N2L 2G1
srebella@uwaterloo.ca

APPENDIX M: Phase 3 Survey Results: Health Unit Categories

Question	Agree or strongly agree	Neither agree or disagree	Disagree or strongly disagree	Category 1 (trend)	Category 2 (trend)	Category 3 (trend)	Participant comments
Q1-1 derived effect of L. monocytogenes-related outbreaks * selection category based on respondent and respondent's PHU	42.2% (19)	33.3% (15)	24.4% (11)	61.5% (8) agreed or strongly agreed	30.1% (4) agreed or strongly agreed	36.8% (7) agreed or strongly agreed	"There have been no changes in the inspection which has always focused on source of product, refrigeration temperatures, sanitizing equipment and work surfaces, and personal hygiene"
Q1-2 derived research as tools * selection category based on respondent and respondent's PHU	71.1% (32)	15.6% (7)	13.6% (6)	69.2% (9) agreed or strongly agreed	53.8% (7) agreed or strongly agreed	84.2%(16) agreed or strongly agreed	"Food safety alerts and documentation from government agencies re: outbreaks/recalls etc. play a significant role in how my public health unit derives a plan of action - using this information to guide public health inspectors"
Q1-3 derived MOU * selection category based on respondent and respondent's PHU	71.1% (32)	8.9% (4)	20.0% (9)	61.5% (8) strongly agree or agree	61.5% (8) strongly agree or agree	84.2% (16) strongly agree or agree	"We have minimal/no contact with either agency about their plant inspections. We have tried unsuccessfully to get them to inspect sites which we believe are under their jurisdiction."
Q1-4 derived vulnerable populations * selection category based on respondent and respondent's PHU	42.2% (19)	31.1% (14)	26.7% (12)	38.5% (5) neither disagree or agree	23.1% (3) strongly disagree or disagree	36.8% (7) strongly agree or agree	"I'm not sure the requirements are any different for this population. You just need to make sure food safety is followed appropriately."
Q1-5 derived policy and procedures * selection category based on respondent and respondent's PHU	97.7% (44)	2.3% (1)	0	100% (13) strongly agree or agree	92.3% (12) strongly agree or agree	100% (19) strongly agree or agree	"HACCP is the focus and not product specific"
Q1-6 derived Ontario Food Safety program * selection category based on respondent and respondent's PHU	15.6% (7)	35.6% (16)	48.9% (22)	46.2% (6) strongly disagree or disagree	46.2% (6) neither disagree or agree	68.4% (13) strongly disagree or disagree	"There has been minimal change in the Ontario food safety program through the OPHS, Protocol and FPR that are used by local public health units as it relates to lessons learned from previous outbreaks."

Q1-7 derived *Food Premises Regulation* * selection category based on respondent and respondent's PHU	24.4% (11)	22.2% (10)	53.3% (24)	61.5% (8) strongly disagree or disagree	30.8% (4) strongly agree or agree	57.9% (11) strongly disagree or disagree	"There is an inherent risk in serving ready to eat foods because quality control is out of the hands of the retail operator.

APPENDIX N: Phase 3 Survey Results – Management and Public Health Inspector

Question	Agree or strongly agree	Neither agree or disagree	Disagree or strongly disagree	Management (trend)	Public health inspector (trend)	Participant comments
Q1-1 derived effect of L. *monocytogenes*-related outbreaks * derived respondent position	42.2% (19)	33.3% (15)	24.4% (11)	39.1% (9) strongly agree or agree	45.5% (10) strongly agree or agree	"Apply the *Food Premises Regulation* to the inspection of public food premises as applicable and recognize priority populations (pregnant women, the elderly, children) relating to Listeria."
Q1-2 derived research as tools * derived respondent position	75% (33)	15.6% (7)	13.6% (6)	91.3% (21) strongly agree or agree	54.5% (12) strongly agree or agree	"We use on-line provincial and federal food safety information. When we have questions, we use the research services of PHO."
Q1-3 derived MOU * derived respondent position	71.1% (32)	8.9% (4)	20.0% (9)	65.2% (15) strongly agree or agree	77.3% (17) strongly agree or agree	"Management may, but as a field PHI, I have had limited interaction with the above noted agencies."
Q1-4 derived vulnerable populations * derived respondent position	42.2% (19)	31.1% (14)	26.7% (12)	43.5% (10) strongly agree or agree	40.9% (9) strongly agree or agree	"This product is generally safe and should follow routine food handling practices. Raw vegetable have also been linked to illness and recalls and there is no special requirements for them."
Q1-5 derived policy and procedures * derived respondent position	97.8% (44)	2.2% (1)	0	95.6% (22) strongly agree or agree	100% (22) strongly agree or agree	"We do not currently have microorganism and product-specific policies and procedures in place that address Listeria and RTE meats explicitly."
Q1-6 derived Ontario Food Safety program * derived respondent position	15.6% (7)	35.6 (16)	48.9% (22)	43.5% (10) strongly disagree or disagree	13.6% (3) strongly agree or agree	"The *Food Premises Regulation* needs to be re-written to address major gaps in food safety issues."

Q1-7 derived *Food Premises Regulation* * derived respondent position	24.4% (11)	22.2% (10)	53.3% (24)	47.8% (11) strongly disagree or disagree	59.1% (13) strongly disagree or disagree	"I think that legislation typically does not incorporate the latest research in a timely fashion and so it is quite possible that much evidence-based information may not be reflected in the *Food Premises Regulation*."

APPENDIX O: Descriptive Observations

A number of observations were noted throughout the facilitation of the research study. These observations were not included in the results (see Section 4.0) and discussion sections (see Section 5.0) given that the grounded theory analyses did not identify these as substantive themes or codes that merited inclusion in the theory development process. Accordingly, they are provided below as a subset of reflections based on the interview and survey processes that may be used for the purposes of future research.

(i) Workplace and Organizational Culture

Workplace culture plays an important role in the success of an organization in achieving its operational goals and objectives. An effective workplace culture includes organizational cohesiveness where "common values and a derivation of common principles for practice" (Gibb, Anderson, & Forsyth, 2004, p. 202) are identified and achieved. Workplace culture is significant to public health units given its importance to "organization effectiveness" (Gregory, Harris, Armenakis, & Shook, 2009, p. 673) such as the provincial food safety program which strives to reduce the incidence of foodborne illness in a complex environment.

The study interviews and surveys provide some insight into the workplace culture in public health units in particular to L. *monocytogenes* and RTE meat products. As described in Section 5, public health units establish their inspection programming based on food premises meeting the 'minimum requirements' of the *Food Premises Regulation*. In adopting a regulatory approach, public health units work within a culture of compliance that addresses food pathogens broadly under the authority of the *Food Premises Regulation*. Furthermore, the study interviews and survey identified that the workplace culture addressing RTE meats and L. *monocytogenes* is supported by incomplete, and in some cases, inaccurate incidence data and a perception of a lack

of control for processed products that are inspected by federal and provincial agencies. As a result, public health units work within a reactive-based organizational culture. This culture operates with limited data input (e.g. epidemiological data and manufactured product information) under the requirements of a regulatory structure to frame the provincial food safety inspection program. A cursory examination of a number of the provisions of the *Food Premises Regulation* would indicate that the requirements are proactive in nature (e.g. cooking temperatures, practices preventing cross-contamination) with the intention of reducing future health hazards. However, the regulation fails to provide a comprehensive food safety programming focus that requires a 'farm-to-fork' auditing HACCP approach that proactively works to prevent microorganisms from entering the food processing environment. Furthermore, while the *Food Premises Regulation* does not preclude a public health inspector from providing education to food handlers, it does not explicitly require it. This regulatory-focused approach and workplace culture minimizes innovative strategies and knowledge-translation opportunities and programs (e.g. HACCP) aimed at proactively addressing foodborne pathogens prior to becoming problematic in a food processing environment. Reference to insignificant rates of listeriosis, a lack of product control and a focus on the *Food Premises Regulation* was consistent amongst the management and public health inspection cohorts and health unit categories (see Section 5.0). No discernible differences between groups indicated a clear rationale for the current workplace culture. However, it is hypothesized that the impetus of this 'minimum-requirement' approach and associated organizational workplace culture stems from variables such as organizational reporting requirements (e.g. provincial accountability agreements) that are based upon a regulatory structure that has not been amended or adapted to current research and policy documents (e.g. the Weatherhill report*, 2009).*

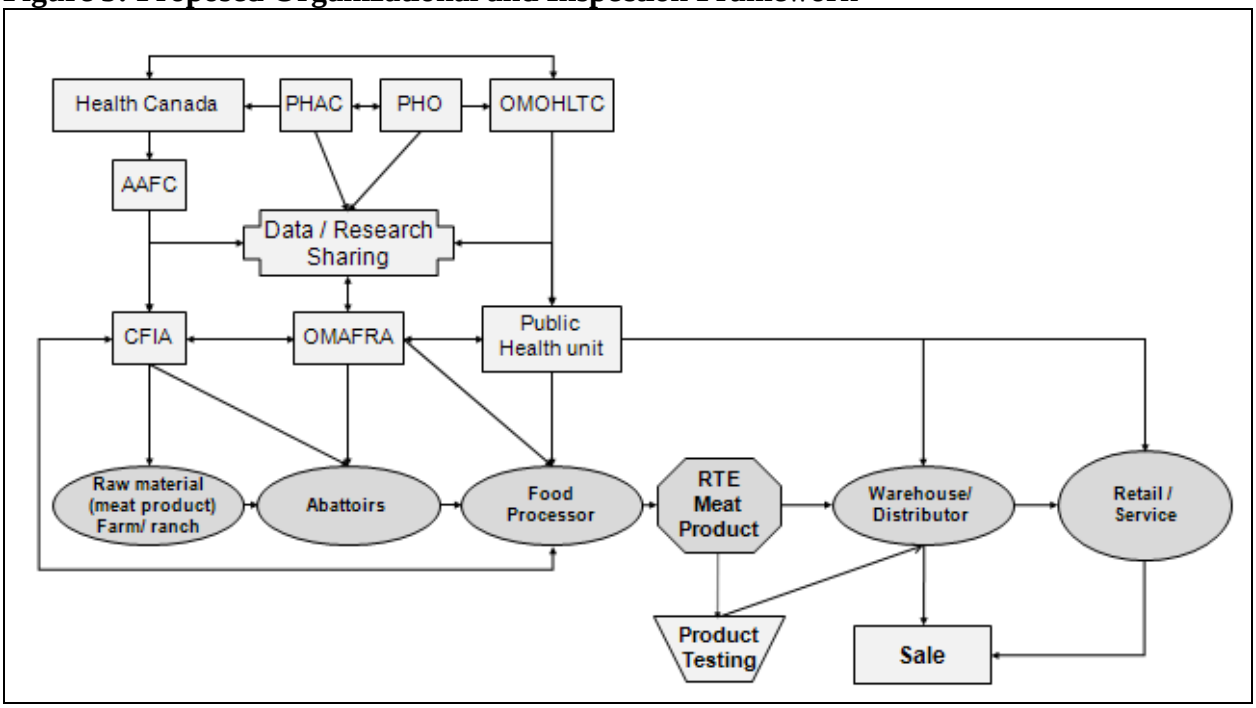
The Ontario accountability agreements were referenced only once in the research study (see Section 5.4.1) despite their importance to organizational performance management that drives inspection activities in public health units. In particular to food safety inspection activities, the accountability agreement focuses on statistical compliance based on identified 'high risk' facilities. Thus, the accountability agreement stresses resource allocation to compliance management activities and meeting mandated inspection frequencies based on a regulatory structure which supports the culture of minimum requirements. Coincidentally, public health units with limited resourcing are likely to have a decreased capacity to deliver a proactive inspection agenda focusing on lengthy food manufacturing processes using a HACCP-based approach that a RTE meat product requires. Furthermore, compliance-focused health unit activities aimed at meeting accountability agreement indicators could potentially decrease public health inspector capacity in resource-stressed public health units to maintain and subsequently implement current research into inspection practices. In addition, it may impact the likelihood that the public health unit will actively engage provincial and federal agencies to share inspection records or request for joint-inspections of processing facilities to improve local product risk assessment activities since this is not a mandated activity.

(ii) Inconsistency in Health Unit Approach

As described in Section 5.2, a number of inconsistencies were observed in the manner in which public health units approached the MOU between OMAFRA and the CFIA. Post-survey data indicated that a majority of public health units participating in the study do not actively engage processing facilities that are licensed (and inspected) by provincial and federal agencies. However, inconsistency in health unit approach was observed. For example, the Toronto Public Health unit (see Section 5.2) actively participated in the 2008 Maple Leaf Foods outbreak despite

the provisions of the MOU between agencies. The definition of *food premises* under the *Health Protection and Promotion Act* allows public health units to inspect any location where food is manufactured or processed. While it is unclear how many public health units inspect provincial or federal processors where outbreaks are declared and manufactured processed products are identified, the *Health Protection and Promotion Act* permits all food premises to be inspected by public health inspectors acting under the local Medical Officer of Health. Engaging all levels of inspection in the manufacturing process as described in Figure 5 increases communication amongst responsible agencies and pools resources to improve research, data sharing and knowledge translation. Under the proposed framework, the CFIA would take a more active

Figure 5: Proposed Organizational and Inspection Framework



role in the farm-to-fork continuum in conjunction with the AAFC and focus on raw material inputs into the processing system prior to the product entering provincial or federal abattoirs (slaughter houses). Research suggests that raw material microbial loading is an important component to food safety systems in reducing product contamination (Dagg, Butler, Murray, &

Biddle, 2006; Rhoades, Duffy, & Koutsoumanis, 2009; Wagner et al., 2005). Under the proposed framework, PHAC and PHO would work collaboratively to identify relevant research and data sources and work in conjunction with their respective ministerial agencies to provide support for field and organizational queries based on best-practices. PHAC and PHO would work with Health Canada and the MOHLTC to assist in knowledge translation and guidance for revisions to applicable food safety legislation. Public health units would actively participate in annual audits with the CFIA and OMAFRA at RTE meat plants and conduct demand inspections based on consumer complaints or cases of confirmed foodborne illness. It would also require that OMAFRA and the CFIA provide expertise, guidance and sampling assistance to public health units for unlicensed manufacturers of RTE meat products in the development of HACCP plans for smaller producers. The knowledge transfer between agencies could potentially allow for local public health units to lead the inspection program for licensed facilities in future years. In this scenario, CFIA and OMAFRA inspectors would continue to conduct periodic audits of plants inspected by public health inspectors. However, the audits would be concentrated on identified high risk facilities that epidemiological and inspection data indicate are problematic. It would also allow for CFIA and OMAFRA to focus on program oversight, product labeling and inter-provincial and federal product distribution that contributes to the existing wicked problem. The framework ensures that organizational capacity is maximized and that proactive strategies are in place in all sectors of RTE meat distribution, regardless of the size of the operation. While it is acknowledged that this would require additional resourcing in its infancy stages, a review of the CFIA and OMAFRA registered plants (2011) that produce RTE products in Ontario reveals that the number of facilities (194 federally inspected processing plants and 393 provincially inspected FSMPs) is not insurmountable. Assuming equal distribution of facilities within the

province, this would equate to an additional 16.3 processing facilities per health unit in the province for manufacturers of RTE meat products. It should be noted however that in many cases, these plants have retail facilities that are currently inspected by public health inspectors. Thus, visits to several of these facilities are already taking place under the provisions of the current MOU.

(iii) Nutrition, pregnancy, RTE Foods and Future research

It was notable, but not unexpected, that product formulation and trending (e.g. sodium-reduced products) was not referenced by participants in either the interviews or survey phases of the study. Despite its importance in the outcome of the 2008 Maple Leaf Foods outbreak, nutrition and food safety programs are addressed as separate program entities in the Ontario Public Health Standards. No formal requirements are in place for public health units to integrate food safety and nutrition knowledge and expertise despite (in some circumstances) competing program goals and objectives. For example, based on Health Canada sodium reduction strategy, RTE food formulations are encouraged to use sodium-reduced formulations while food safety research suggests that increasing sodium concentrations "improves shelf life and reduces L. *monocytogenes* growth" (Carroll, Alvarado, Brashears, Thompson, & Boyce, 2007, p. 150). However, product manufacturers are diversifying and improving product shelf stability ingredients for RTE foods that both nutritionists and public health inspectors should be knowledgeable of when advising clients and inspecting products in retail settings. However, as product formulations become more complex and meet the needs of consumers (e.g. low sodium formulas), it is unlikely that public health units would have the capacity to adequately assess product safety and shelf stability. This is likely as a result of a general lack of experience that public health inspectors have in addressing these products as a result of the MOU structure with

provincial and federal processing plants. As a result, public health units, including public health inspectors and nutritionists, should be increasing collaborative communication efforts with OMAFRA and the CFIA in order to ensure that product formulations are consistent with industry best practice for unlicensed RTE food manufacturers. Collaboration efforts are also required with local physicians in regards to the risk associated with L. monocytogenes and pregnant women. For example, while the importance of L. *monocytogenes* to pregnancy was noted a number of times by participants (n = 5), there was no indication that messaging to women or physicians was being conducted. Research by Kirkham and Birkowitz (2010) suggests that few (18%) midwives and physicians "were aware that infection (Listeriosis) was more common during pregnancy" (p. e158). Furthermore, physicians and midwives suggested that "the main reasons for not providing counseling (to their patients) were lack of knowledge and the perception that listeriosis was rare and not important to pregnant women" (Kikrham & Birkowitz, 2010, p. e158).

(iv) Importance of Research

As described in Section 5.2, an overall lack of identification of the importance of research to the field of food safety and specifically L. *monocytogenes* and RTE meats by study participants was observed. It was anticipated that study interview and survey participants would not likely reference specific peer-reviewed journal articles that speak to studies addressing the efficacy of RTE product formulations or the optimal growth rates of L. *monocytogenes* in laboratory settings. However, it was expected that documents arising from provincial or federal-based outbreaks such as the 2004 report from Justice Ronald J. Haines 'Farm to Fork: a Strategy for Meat Safety in Ontario' or the 2009 Weatherhill report would be referenced given their impact to the field of inspection and specifically L. *monocytogenes*. In particular, both reports provide recommendations that speak directly to a number of the current issues that were

addressed by the study participants and the study framework that directly contribute to the current wicked problem. They include public health unit inspection, food handler behaviour, regulation, RTE product formulations, innovation, knowledge translation, labeling, inter-agency collaboration and communication. This is noteworthy given the success of another public health program, tobacco control; that has used research, innovation, knowledge translation and regulation to reduce smoking uptake. For example, in the province of Ontario, research has influenced the use of innovative strategies such as product packaging and subsequent amendments to the *Ontario Smoke Free Ontario Act S.O. 1994, c. 10*., to limit access to tobacco products and smoking uptake in the province (Succeeding with tobacco cessation takes perseverance and innovation.1999; Francis, Abramsohn, & Park, 2010; Hammond & Parkinson, 2009; Hammond, 2012; McNeill, Hammond, & Gartner, 2012; Warner & Mendez, 2010; Warner & Tam, 2012).