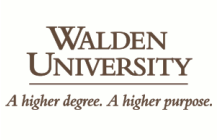

2017

Predictors of Compliance with the Food Safety and Inspection Service's Listeria Rule, 2012-2015

Amadou Samb
Walden University

Walden University

College of Health Sciences

This is to certify that the doctoral dissertation by

Amadou Samb

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Kourtney Nieves, Committee Chairperson, Health Services Faculty
Dr. Michael Furukawa, Committee Member, Health Services Faculty
Dr. James Rohrer, University Reviewer, Health Services Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
2017

Abstract

Predictors of Compliance with the Food Safety and Inspection Service's *Listeria* Rule, 2012-2015

by

Amadou Samb

MPH, Kaplan University, 2012

BA, Cheikh A. Diop University, 1994

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Ph.D. in Health Services

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Abstract

Since 1987, the Food Safety and Inspection Service (FSIS) has implemented a zero-tolerance policy for *Listeria monocytogenes* (*Lm*) in ready-to-eat (RTE) meat and poultry products, which culminated with the implementation of the *Listeria* rule in 2003. While researchers have extensively examined human listeriosis and its causative agent, *Lm*, there remained a significant gap in the current literature regarding how, singly or in combination, establishment size, RTE product type, *Listeria* alternative used, and FSIS district of production predict compliance with the *Listeria* rule. Therefore, the purpose of this quantitative study was to investigate the relationship between establishment size, RTE product type, *Listeria* alternative used, FSIS district of production, and compliance with the *Listeria* rule. The deterrence theory was used to explain the relationships and associations between variables. Archival *Lm* sampling data collected between 2012 and 2015 by FSIS was used to analyze the relationships. Chi-square tests showed no significant statistical relationship between establishment size, *Listeria* alternative used, FSIS district, and compliance, but they did show a significant association between compliance, RTE salt-cured products, and fully cooked products. Additionally, logistic regression analysis showed that the odds of an *Lm*-positive sample was higher for salt-cured products than for fully-cooked products. This study's findings indicate the need for a reevaluation of FSIS *Listeria* prevention policy, with a focus on salt-cured products. These results can influence positive social change if used in a targeted public health outreach/education program that focuses on the food safety risks associated with salt-cured products.

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Dedication

I dedicate this once-in-a-lifetime work to my late beloved mother *Sokhna Niang*, who instilled in me self-confidence, resilience, hard work and perseverance. I wish you were here to see me graduate, mummy. I cannot leave out my late uncle *Amadou Bineta Niang* who had always believed in me and treated me like his own son. I am sure I made him proud up there. I also dedicate this work to my lovely wife *Ndèye Maty Cissé* and my adorable children *Abdullah Dame Samb*, *Muhammad Samb*, and *Rahmatoullah Samb*. I am blessed to have you as family members.

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It would be an aberration to leave out Dr. John Johnston, the research coordinator for FSIS, who facilitated this enterprise and directed me to the resources I needed to complete the project.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

The burden of Foodborne illnesses is a worldwide public health challenge. In fact, the World Health Organization (WHO) estimates that, every year, 1 in 10 people get sick from the contaminated food they ingested, while 420,000 others die from it (WHO, 2015). Furthermore, children under the age of 5 remain the most vulnerable, with 125,000 of them dying from foodborne illness every year. The most affected areas around the world include the WHO African and South-East Asia regions (WHO, 2015).

In the United States, the Centers for Disease Control and Prevention (CDC) reports that, every year, 31 known foodborne pathogens cause 48 million cases of foodborne illness affecting 1 in 6 citizens, and causing 128,000 hospitalizations, and 3,000 deaths (CDC, 2016a). It is noteworthy that many cases of foodborne illnesses are either not reported at all or under-reported. As such, the CDC data may not be telling the whole story on the morbidity and mortality associated with foodborne pathogens (CDC, 2016a; Means, 2010). Moreover, the CDC recognized the existence of "unspecified agents" (CDC, 2014, para. 2), those emerging, unknown, and unidentified foodborne pathogens that compound and exacerbate the foodborne illness conundrum. As an illustration, in an interview with CNN, the top outgoing Obama administration counterterrorism advisor L. Monaco (2016) cited emerging infectious diseases as a national security threat at the same level as terrorist threats and cyber threats. Therefore, it is safe to argue that the foodborne illness burden ranks high on the agenda of both public health and national security leaders in the United States.

Human listeriosis, a foodborne disease caused by the *Listeria monocytogenes* (*Lm*) pathogen, is at the same time a rare but deadly disease and a global public health scourge. De Noordhout et al. (2014) reported that, in 2010 alone, there were 23,150 cases of listeriosis, 5,463 fatalities, and 172,823 disability-adjusted life years (DALYs) due to listeriosis around the world. DALYs are a measure of the overall disease burden in terms of number of years lost due to bad health, disability, or early death. In 2015, 2,200 persons contracted human listeriosis, while 270 died from it in the European Union between 2008 and 2015 (European Food Safety Agency, 2016). In Europe, the number of listeriosis cases among people over age 64 increased from 56% to 64%, while the case count nearly doubled for people over age 84 during the same time period (European Food Safety Agency, 2016). Cartwright et al. (2013) and Dhama et al. (2013) postulated that listeriosis may cause septicemia, encephalitis, febrile gastroenteritis, fatal bacteremia, and meningitis among the elderly, pregnant women, newborns, and adults with impaired immune systems. Therefore, public health initiatives and resources should be directed toward protecting those vulnerable populations and the general population at-large. That was the intent of the United States Department of Agriculture's (USDA) *Listeria* rule.

The Food Safety and Inspection Service (FSIS) is the public health agency within the USDA with regulatory oversight over the wholesomeness, safety, and proper packaging and labeling of the domestic meat, poultry, and egg supply. FSIS has 10 district offices that cover all 50 states and territories, and assigns full time inspection personnel to slaughter and processing federally inspected establishments (FIEs) to carry out daily inspection/enforcement duties and oversee the safety of the meat and poultry

products FIEs produce. It is notable that, of the approximately 6,000 FIEs that FSIS regulates, only 300 (10%) are large establishments, while 5,700 (90%) are either small or very small establishments (FSIS, 2016a).

In 2003, FSIS published the *Listeria* rule in the Code of Federal Regulations (CFR) under 9 CFR 430. The *Listeria* rule mandated that FIEs producing ready-to-eat (RTE) meat and poultry products exposed to the environment after the lethality treatment (post-lethality exposed or PLE products), choose from one of three alternatives to prevent, control, or suppress *Lm* in their products (*Listeria* rule, 2003). The three alternatives included Alternative 1; Alternative 2 (which included Alternative 2-Choice 1, and Alternative 2-Choice 2), and Alternative 3 (see the *Listeria* rule section in chapter 2 for a more detailed explanation of the alternatives). The rule reinforced FSIS's zero-tolerance policy for the presence of *Lm* in RTE meat and poultry products (*Listeria* rule, 2003).

It is important to note that 14 years after the publication of the *Listeria* rule, no researchers have empirically examined whether (a) the FIEs' size, (b) the RTE product type, (c) the alternative used, and (d) the FSIS districts where the RTE products were produced had any bearing on regulatory compliance with the rule. Therefore, it is essential to explain whether those four predictor variables constitute determinants of compliance or not. Doing so would have important social change implications because it would provide FSIS policy-makers with evidence-based knowledge regarding compliance with the rule, and it would allow them to have an empirical explanation of the riskiest RTE products, the size of the FIEs that are grappling with the rule, the usefulness

of the *Listeria* alternatives, the districts with the most noncompliant FIEs, and the general usefulness of the regulation (the *Listeria* rule). Equipped with that empirical information, FSIS policy-makers may decide to leave the rule as is, and/or determine ways to streamline, adjust, or amend it in order to make it a responsive regulation. Nielsen and Parker (2009) described responsive regulation as a regulation that is effective, efficient and legitimate, and strikes a balance between deterrence and cooperation on the part of the regulator.

In the remainder of this chapter, I provided the background of the study, followed by the problem statement. Afterwards, I described the purpose of the study, stated the research questions and hypotheses, and identified the study's theoretical foundation. After that, I explained the nature of the study, provided an operational definition of the variables and other special terms, stated the study's assumptions, delineated the research scope and study delimitations, and finally, outlined the limitations and significance of the study.

Background

Scientists have extensively studied the history, characteristics, taxonomy, detection/serotyping, and control/prevention of *Lm* on foods (Adzitey & Huda, 2010; Amenu, 2013; Ghandi & Chikindas, 2007; Gibbons, 1972; Graves, Swaminathan, & Hunter, 2007; Jadhav, Bhave, & Palombo, 2012; Lomonaco, Nucera, & Filipello, 2015; Lucy, Chukwuezi, & Ozougwu, 2014; Montville & Matthews, 2008; Law, Ab Mutalib, Chan, & Lee, 2015; Quendera, Varela, Barreto, & Semedo-Lemsaddek, 2016; Rocourt & Buhrieser, 2007; Saha, Denath, & Pramanik, 2015; Murray, Webb, & Swan, 1926).

Similarly, researchers have produced a large body of literature examining human listeriosis in terms of epidemiology, pathogenicity, outbreaks, and treatment (Cartwright et al., 2013; Disson & Lecuit, 2012; Donovan, 2015; Gaul et al., 2013; Gottlieb et al., 2006; Goulet, King, Vaillant, & de Valk, 2013; Lecuit, 2007; Olsen et al., 2005). What remained to be studied was whether and how variables such as establishment size, product type, *Listeria* alternative used, and FSIS district, affected compliance with FSIS's *Listeria* rule. Therefore, this study was needed to help explain whether large, small, and very small FIEs fared equally and uniformly in dealing with regulations, and whether some RTE product types were more likely to be contaminated with *Lm* than others. Finally, the study also helped me determine whether the *Listeria* alternatives that FIEs used, and the FIEs'district location in the United States, had a statistically significant relationship with their compliance or noncompliance with the *Listeria* rule.

Problem Statement

In the United States, the CDC estimates that, every year, 1,600 cases of listeriosis occur, resulting in 260 deaths (CDC, 2014). In 2013, the average incidence rate was 0.26 per 100,000 population (CDC, 2014). Even though the incidence of listeriosis declined by 42% between 1998 and 2012 (CDC, 2014), the national incidence rate has not yet reached the 0.2 case per 100,000 target set by the U.S. Department of Health and Human Services (USDHHS) in *Healthy People 2020* (USDHHS, 2016). Furthermore, Painter et al. (2013) reported that, between 1998 and 2008, poultry products contaminated with *Listeria* and *Salmonella* species caused more deaths than any other food items in the United States. Hoffmann, Batz, and Morris (2012) estimated the annual cost of illnesses

and quality adjusted life years (QALYs) losses due to *Lm* to be $2.6 billion and 9,400 respectively. QALYs are defined as a generic measure of disease burden, including both the quality and quantity of life lived. Bending the curve of human listeriosis has been and remains a herculean task in many parts of the world due to the unique characteristics of its disease-causing agent, *Lm*.

The causative agent of listeriosis, *Lm*, is an opportunistic, gram-positive, facultatively anaerobic, psychotropic, catalase positive, and non-spore-forming bacterium that is highly tolerant to heat and salt, and unlike other foodborne pathogens, it can survive and grow under refrigeration temperature (Li et al., 2011). Gómez, Iguàcel, Rota, and Carramiñana (2015) and Tompkin (2002) contended that the *Lm* pathogen is frequently found in food processing environments because of the favorable survival and growth conditions (moisture, organic material, equipment design, etc.) in those settings. Listeriosis was first recognized as a foodborne illness in 1981 when, in an outbreak investigation, epidemiologists conclusively associated the disease with the ingestion of Lm-contaminated coleslaw in Canada (Cartwright et al., 2013; Schlech et al., 1983).

The U.S. federal regulatory agencies (FDA and FSIS) have a zero-tolerance policy on the presence of *Lm* in ready-to-eat (RTE) foods. In other words, an RTE food item would be considered adulterated (unfit for human consumption) if it contains ≥ 1 colony forming unit (CFU) in a 25-gram sample (Ivanek, Gröhn, Tauer, & Wiedmann, 2004; Todd, 2007; Warriner & Namvar, 2009). This science-based policy was predicated upon the *Lm* organism's inclination to cause human listeriosis, its ability to grow at refrigeration temperatures, and the mystery surrounding its infectious dose (Shank, Elliot,

Wachsmuth, & Losikoff, 1996). Ivanek et al. (2004) took issue with the U.S. federal agencies' (the Food Safety and Inspection Service [FSIS] and the Food and Drug Administration [FDA]) *Listeria* policy, claiming that "increasing evidence has been accumulated that low numbers of *L. monocytogenes* represent no considerable health risk for the vast majority of consumers" (p. 2). This viewpoint found its manifestation in the unsuccessful citizen's petition (by which anyone can ask the U.S. government to change its policy) that was filed against the United States' *Listeria* policy a few years ago (Montville & Matthews, 2008).

Given that *Lm* is considered an adulterant in food, when FIEs Operators and owners believe that foods in commerce are contaminated with *Lm*, they will voluntarily recall the product, or FSIS will request that they do so. FSIS (2013) has classified recalls as Class I (when there is a probability that consuming the food would cause a serious adverse health effect), Class II (when there is a remote probability of adverse health effect from the ingesting the food), and Class III (when consuming the food will not cause an adverse health effect). It is almost unnecessary to mention that compliance with the *Listeria* rule would eliminate the need for a recall. Nevertheless, no empirical research had been conducted about how establishment size, product type, the *Listeria* alternative used, and the FSIS district where the RTE product was produced, affected compliance with the *Listeria* rule between 2012 and 2015.

The research problem originated from the empirical need to determine whether a statistically significant relationship (correlation) existed between compliance with the rule and establishment size, RTE product type, the *Listeria* alternative used, and the FSIS

districts between 2012 and 2015. This study also contributes to the broader debate about whether government regulations, in general, hurt businesses, especially small and very small ones, or helped alleviate the burden of foodborne illness and thereby protect public health in the United States. The study's scientifically solid and valid findings might be used to shape future food safety policies.

One school of thought holds the view that *social regulations* are needed to: promote social and economic good; prevent environmental disasters; curtail accidents in mines, transportation, and factories; avert foodborne illness and ill health; ensure social justice and inclusion for the vulnerable segment of the population; and keep society safe from man-made wrongdoing (Means, 2010; Parker & Nielsen, 2011). From a food safety standpoint, Means (2010) posited that foodborne illnesses continued to occur, despite science-based food safety regulations. Therefore, Means (2010) argued that, "it does not make sense, from a scientific perspective, to allow processing and sale of potentially hazardous foods without regulation and inspection" (p. 2). *Economic regulation*, on the other hand, is meant to level the economic playing field by preventing monopoly, fostering competition, and ensuring that economic agents comply with the market rule of offer and demand (Parker & Nielsen, 2011). Other scholars have opined that regulations are unreasonable and result in economic inefficiency (Bardach & Kagan, 2010); "From Crop to Beer," 2016). For example, Bardach and Kagan (2010) dichotomized the unreasonableness of regulations into (a) "rule-level unreasonableness" (p. 7) related to aggregate economic inefficiency, and (b) "site-level unreasonableness" (p. 7), which related to particular interactions between regulators and regulatees. In the same vein, R.

A. Williams, in a hearing testimony at the U.S. Senate Committee on Homeland Security and Government Affairs, took issue with the current U.S. food safety regulatory process which, in his opinion, is not science-based and leaves out the main stakeholders (farmers, retailers, manufacturers, warehousers, packers, and shippers), resulting in food regulations that "cost far too much and accomplish far too little, far too often" (From "Crop to Craft Beer," 2016, p. 1). To remedy what he considered an economic inefficiency, R. A. Williams recommended that federal regulators conduct a better risk analysis and benefit-cost-analysis before issuing food regulations, while stakeholders should be allowed to sue the regulators "when this analysis is absent, ignored, or just poorly done" ("From Crop to Beer," 2016, p. 5). Thus, these scholars believe that the *Listeria* rule is just another government regulation with limited usefulness meant to stifle economic growth. In support of such arguments, the U.S. Small Business Administration (SBA) estimated that, in 2008, federal regulations in the United States cost a staggering $1.75 trillion (SBA, 2010). In the same year, the SBA also reported that small businesses employing fewer than 20 employees had an "annual regulatory cost of $10,585 per employee, which is 36 percent higher than the regulatory cost facing large firms (defined as firms with 500 or more employees)" (p. iv). In this study, I sought to contribute to the scholarly debate about whether regulations constitute a burden to the regulated industry, or validate the goal of the *Listeria* rule, which is to protect public health by preventing human listeriosis in RTE foods.

Purpose of the Study

The purpose of this quantitative, nonexperimental, cross-sectional study was to investigate the significance, if any, of the statistical relationship between the independent variables (IVs) of establishment size, product type, *Listeria* alternative used, and FSIS district, and compliance with the *Listeria* rule (dependent variable [DV]) for FIEs producing RTE post-lethality exposed (PLE) meat and poultry products under the regulatory oversight of FSIS in the 50 states as well as in the U.S. territories, between 2012 and 2015.

Research Questions and Hypotheses

Research questions and hypotheses play a quintessential role in quantitative inquiries (Kumar, 2011). Creswell (2009) has noted that research questions and hypotheses mold and focus the purpose of quantitative inquiries. While researchers develop quantitative research questions to find answers about the relationships between and among variables, their research hypotheses constitute predictions that they make about the expected relationship among and between variables (Creswell, 2009; Frankfort-Nachmias & Nachmias, 2008; Kumar, 2011). Hypotheses are tested using statistical procedures that allow the researcher to make inferences from a unit of analysis (sample), and those inferences may then be generalized to the population from which the sample was drawn (Creswell, 2009). The underpinning of this research study was the empirical need to explain whether, between 2012 and 2015, a statistically significant relationship (correlation) existed between compliance with the *Listeria* rule and establishment size,

product type, *Listeria* alternative, and FSIS district. Accordingly, I designed the following research questions:

Research Question 1: Is there a statistically significant relationship between establishment size and compliance with the *Listeria* rule?

$H_0$1: There is no statistically significant relationship between establishment size and compliance with the *Listeria* rule.

H_a1: There is a statistically significant relationship between establishment size and compliance with the *Listeria* rule.

Research Question 2: Is there a statistically significant relationship between RTE product type and compliance with the *Listeria* rule?

$H_0$2: There is no statistically significant relationship between RTE product type and compliance with the *Listeria* rule.

H_a2: There is a statistically significant relationship between RTE product type and compliance with the *Listeria* rule.

Research Question 3: Is there a statistically significant relationship between the *Listeria* alternative used by FIEs and compliance with the *Listeria* rule?

$H_0$3: There is no statistically significant relationship between the *Listeria* alternative used by FIEs and compliance with the *Listeria* rule.

H_a3: There is a statistically significant relationship between the *Listeria* alternative used by FIEs and compliance with the *Listeria* rule.

Research Question 4: Is there a statistically significant relationship between the FSIS district where the RTE products were produced and compliance with the *Listeria* rule?

$H_0$4: There is no statistically significant relationship between the FSIS district where the RTE products were produced and compliance with the *Listeria* rule.

H_a4: There is a statistically significant relationship between the FSIS district where the RTE products were produced and compliance with the *Listeria* rule.

Theoretical Base

The theoretical foundation of this quantitative study was Paternoster's (2010) deterrence theory (DT). Paternoster claimed that, under classical deterrence theory, individuals and firms try to maximize utility by complying with laws and regulations. Parker and Nielsen (2011) argued that individuals and firms comply only if "the probability of swift detection and sanction by the regulator in combination with the amount of the penalty outweighs the benefits of noncompliance" (p. 10). The main constructs of DT are: (a) certainly of punishment, (b) severity of punishment, and, to a lesser extent, (c) celerity (swiftness) of punishment (Gray, 2010; Kennedy, 1983; Parker & Nielsen, 2011; Paternoster, 2010). In the context of this study, I theorized that FIEs would comply with the *Listeria* rule if they knew that the punishment of noncompliance was severe, certain, and swift, and if compliance outweighed the benefits of noncompliance. The deterrents that the FSIS has at its disposal include (a) the Rules of Practice (See Appendix A), (b) an arsenal of enforcement tools (see definition of terms for more details), and (c) the naming and shaming of noncompliant FIEs (FSIS publishes

the names on a press release posted on its website of FIEs that recall products for any reason). Other deterrents include loss of sales by FIEs due to Internet publicity, and costly lawsuits by consumers resulting from consuming contaminated foods.

According to Paternoster (2010), the precursors to the DT came in the work of Enlightenment philosophers C. Beccaria and J. Bentham. C. Beccaria published a treatise entitled, *Dei Delitti e delle Pene* (*On Crimes and Punishment*), challenging the rights of states to sanction crimes, and advocating a proportionality between crime and punishment (Paternoster, 2010). In 1780, C. Bentham published *An Introduction to the Principles of Morals and Legislations,* in which, like Beccaria, he denounced the arbitrary nature of crime punishment in England at the time (Paternoster, 2010). Bentham (1948) was credited with the famous principle of utility when he argued that "nature has placed mankind under the governance of two sovereign masters, pain and pleasure" (p. 125). Said another way, he claimed that humans behaved in a certain way if the pleasure they derived from their behavior exceeded the pain they might have experienced due to the behavior. Paternoster argued that deterrence theory is "a theory of crime that presumes that human beings are rational to consider the consequences of their actions and to be influenced by those consequences" (p. 782). Hence, this notion of certainty and severity of punishment in crime deterrence is the foundation of the criminal justice system in the United States (Paternoster, 2010).

Thornton, Gunningham, and Kagan (2005) tested the DT to explore the relationship between general deterrence and enhanced compliance with regulatory requirements in the environmental industry using a survey of 233 companies from several

U.S. environmental firms. The purpose of their study was to find out (a) whether environmental businesses knew about "signal cases" (p. 267) or environmental firms that were legally punished for violating environmental regulation, and (b) whether a change of behavior occurs just because other companies know about "signal cases." The researchers found that only 42% of participants could name a signal case, while 89% could name some form of enforcement against other companies. and 63% of the respondents reported having changed their behaviors after learning about signal cases. The authors then inferred that, since most companies were already compliant, the explicit general deterrence did not enhance the perceived threat of legal sanction, but rather confirmed the relevance of enforcement/compliance and the need to critically review the current compliance regimes. In the context of this study, Thornton et al.'s (2005) findings support the view that the *Listeria* rule might be an effective deterrent that might compel the regulated industry to comply.

Patrignani (2014) also tested the DT to determine whether the 2009 change of the Federal Acquisition Regulation (FAR, 2009) led to a reduction of reported government contractor misconduct (DV) and government contractor ethics business process (DV). The IVs consisted of the top 100 government contractors over two separate 3-year time periods. The unit of analysis consisted of annual contract awards (n = 600), contractor misconduct reports (n = 600), and contractor ethics business process records (n = 600). The author found that (a) no statistically significant reduction occurred in the rate of reported government contractor misconduct after the change of the FAR in 2009; but (b) there was a statistically significant impact of the change to the FAR regulations on the

government contractor ethics business processes. Patrignani's (2014) study confirmed deterrence theory and "indicated the effectiveness of the change to the FAR in 2009 in deterring misconduct" (p. 12).

Critics of the DT such as Kennedy (1983) have claimed that (a) some crimes are spontaneous and emotional in nature, and individuals committing the crime do not think of their crime rationally by assessing and weighing its benefits or costs; (b) the large number of criminal cases awaiting processing and trial in the court system indicated that deterrence by itself was not effective; and (c) the DT did not have a solid moral basis, conceptualized as social legitimacy in the criminal justice system or justness of the social order. In support of this view, Kennedy (1983) noted that most members of society abided by the law because they accepted the advantages of social order, but not because they feared a certain, swift, and severe punishment resulting from a violation of the criminal law. The author clearly contended that other motives of compliance, such as the regulator's perceived legitimacy, needed to be factored in to describe the determinants of compliance. I covered deterrence theory in detail in Chapter 2.

Nature of the Study

In this study, I used a quantitative methodology, with a cross-sectional, nonexperimental, and retrospective design. As Frankfort-Nachmias and Nachmias (2008) put it, cross-sectional designs are the most common designs used in social sciences. Furthermore, Creswell (2009) argued that the research design or the "*plan or proposal to conduct research* involves the intersection of philosophy, strategies of inquiry, and specific methods" (p. 5). In this quantitative study, I maintained a postpositivist

worldview which is consonant with my ontological views. Also known as the scientific method or science research, postpositivism took issue with the positivist maxim of the absolute truth of knowledge (Creswell, 2009). Postpositivists hold the view that "cause probably determines effects and outcomes" (Creswell, 2009, p. 7). Ryan (2006) described postpositivist research as having the following attributes:

- Research is broad rather than specialized – lots of different things qualify as research.
- Theory and practice cannot be kept separate. We cannot afford to ignore theory for the sake of 'just the fact'
- The researcher's motivations for and commitment to research are central and crucial to the enterprise.
- The idea that research is concerned only with correct techniques for collecting and categorizing information is now inadequate. (pp. 12-13)

In a word, the postpositivist approach or scientific method requires that the researcher starts with a theory, collects and analyzes data that either confirms or disconfirms the theory, and makes the required revisions before the theory is retested (Creswell, 2009). I used this approach in this study.

After a Freedom of Information Act (FOIA) request, I obtained secondary data from FSIS about the establishment size, product type, alternative used, FSIS districts, and *Lm* sampling results from 2012 through 2015. I believed that using more recent data was more appropriate because they represented the most current trend of (non)compliance in FSIS-regulated establishments, and made the *Listeria* policy recommendations more

relevant. I developed the research questions to address the underlying research problem. Using secondary data, I examined the significance of the statistical relationship (correlation) between establishment size, product type, alternative used, and FSIS district (IVs), and compliance with the FSIS' *Listeria* rule (DV) between 2012 and 2015.

I operationalized the DV (regulatory) *compliance* as obedience/conformance by a target FIE with the *Listeria* rule materialized by an Lm-negative product sample. An Lm-positive result was considered noncompliant with the rule.

I operationally defined the IVs as follows:

Establishment size: Refers to the three categories of establishment, which are:

- *Large establishments*: Which have 500 or more employees.
- *Small establishments*: Which have 10 or more employees, but fewer than 500.
- *Very small establishments:* Which have fewer than 10 employees, or annual sales of less than $2.5 million.

Alternative: A method of control for *Lm* adopted by an establishment to meet the requirements of the *Listeria* rule.

- *Alternative 1 (Alt. 1)*: Requires the use of a post-lethality treatment (PLT) that reduces or eliminates microorganisms on the product, and an antimicrobial agent that suppresses or limits *Lm* growth.
- *Alternative 2*; *Choice 1 (Alt. 2a)*: Requires the use of a post-lethality treatment (PLT) that reduces or eliminates microorganisms on the product.

- *Alternative 2*; *Choice 2 (Alt. 2b)*: Requires the use of an antimicrobial agent or process that suppresses or limits *Lm* growth.
- *Alternative 3 (Atl. 3)*: Requires the use of sanitation measures only.

Ready-to-eat (RTE) product types: An RTE product is a meat or poultry product that is edible and needing no additional preparation to achieve food safety. RTE products are products that may be contaminated with *Lm* after the lethality treatment due to their exposure to the environments (or post-lethality exposed products or PLEs). The different RTE product types are:

- *RTE fully-cooked meat and poultry-PLE*: Other fully cooked sliced products; hot dog products; salad/spread/pate products; RTE products with meat and nonmeat components; sausage products; patties/nuggets products; and other fully cooked not sliced RTE products.
- *RTE acidified/fermented meat and poultry without cooking-PLE*: RTE fermented meat and poultry (sliced or not sliced); acidified/fermented meat/poultry products.
- *RTE dried meat and poultry*-PLE: RTE dried meat and poultry (sliced or not sliced).
- *RTE salt-cured meat and poultry-PLE*: RTE salt cured meat and poultry, sliced or not sliced (FSIS, 2016).

FSIS District: One of the 10 districts that fulfill FSIS's mission in the 50 U.S. states and territories. The FSIS districts are:

- *District 05* (Alameda, CA District), which covers the states of Arizona, California, and Nevada.
- *District 85* (Atlanta, GA District), which covers the states of Florida, Georgia, Puerto Rico, South Carolina, and the U.S. Virgin Islands.
- *District 50* (Chicago, IL District), which covers the states of Illinois, Indiana, Michigan, and Ohio.
- *District 40* (Dallas, TX District), which covers the states of Louisiana, New Mexico, Oklahoma, and Texas.
- *District 15* (Denver, CO District), which covers the states of Alaska, American Samoa, Colorado, Guam, Hawaii, Idaho, Northern Mariana Islands, Montana, Nebraska, Oregon, Utah, Washington, and Wyoming.
- *District 25* (Des Moines, IA District), which covers the states of Iowa, Minnesota, North Dakota, South Dakota, and Wisconsin.
- *District 90* (Jackson, MS District) which covers the states of Alabama, Kentucky, Mississippi, and Tennessee.
- *District 60* (Philadelphia, PA District), which covers the states of Connecticut, Massachusetts, Maine, New Hampshire, New York, Pennsylvania, Rhode Island, and Vermont.
- *District 80* (Raleigh, NC District), which covers the states of Delaware, District of Columbia, Maryland, North Carolina, New Jersey, Virginia, and West Virginia.

- *District 35* (Springdale, AR District), which covers the states of Arkansas, Kansas, ad Missouri. (FSIS, 2016c)

I analyzed the data using IBM's SPSS software, version 21. All statistical analysis was performed with **α** = .05 significance level. I first ran a chi-square test to investigate the individual correlation between the DV and the IVs. A chi-square test is a nonparametric test that allows investigators to determine the relationship between two categorical (nominal) variables through contingency table analysis or cross-tabulation (Trochim & Donnelly, 2008). After that, I ran a multiple logistic regression test to investigate the correlation between the DV and the IVs combined. As Burns and Burns (2012) put it, multiple regression is a statistical test that allows researchers to estimate the value of the criterion variable from values on two or more other variables. I discuss the research method further in Chapter 3.

Definition of Terms

Federally inspected establishments (*FIEs*): Large, small, or very small plants that produce FSIS-regulated products under the regulatory oversight of FSIS inspectors.

Deli product: A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption (FSIS, 2014).

Food contact surface (*FCS*): A surface in the post-lethality setting that comes in direct contact with RTE products (FSIS, 2014).

Hotdog product: A RTE meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181 (FSIS, 2014).

Listeria monocytogenes (Lm): A foodborne pathogen that can cause the disease listeriosis in humans (FSIS, 2014).

Listeriosis: A disease caused by *Lm*.

Post-lethality exposed product: An RTE product that comes into direct contact with an FCS after the lethality treatment (e.g., cooking) in a post-lethality processing environment (FSIS, 2014).

Antimicrobial Agent (*AMA*): A substance in or added to an RTE product (such as potassium lactate or and sodium diacetate) that reduces or eliminates *Lm*, or suppresses/limits *Lm* growth in the product throughout the shelf life of the product (FSIS, 2014).

Antimicrobial Process (*AMP*): An operation/intervention (such as drying or freezing) that is applied to an RTE product, which suppresses/limits *Lm* growth in the product throughout the shelf life of the product. Additional examples include processes resulting in a pH or water activity that suppresses or limits microbial growth (FSIS, 2014).

Post-lethality processing environment: The area in an establishment where RTE product is conveyed after an initial lethality treatment. Access that may cause *Lm* recontamination include slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, etc. (FSIS, 2014).

Post-lethality treatment (*PLT*): A lethality treatment that is applied to the final product or sealed package of product to reduce or eliminate *Lm* after post-lethality exposure (FSIS, 2014).

Hazard Analysis and Critical Control Points (HACCP): A risk-based scientific system for process control that that consists of identifying, evaluating, and establishing controls for biological, chemical, and physical food safety hazard at points in a food production process where hazards could be controlled, reduced, or eliminated (FSIS, 2015a).

HACCP system: The HACCP plan in operation, including the HACCP plan itself. The HACCP plan in operation includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records (FSIS, 2015a).

Corrective actions: Remedial procedures taken as a result of a deviation (FSIS, 2002).

Critical control point (*CCP*): A point, step, or procedure in a food process where control can be established to prevent, eliminate, or reduce a food safety hazard to acceptable levels (FSIS, 2002).

Critical limit (*CL*): The maximum or minimum value that allows for the control of a physical, biological, or chemical hazard at a critical control point to prevent, eliminate, or reduce the identified food safety hazard to an acceptable level (FSIS, 2002).

Food safety hazard: Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption (FSIS, 2002).

Preventive measure: Physical, chemical, or other means that can be used to control an identified food safety hazard (FSIS, 2002).

Sanitation standard operating procedures (*SSOPs* or *sanitation SOPs*): Written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product (FSIS, 2015b).

Prerequisite programs: Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety. Prerequisite programs provide a foundation for an effective HACCP system. They are often facility-wide programs rather than process or product specific. They reduce the likelihood of certain hazards (FSIS, n.d.).

Management control: The organization, policies, and procedures used to ensure that business is conducted as expected; programs achieve their intended results; resources are used consistent with FSIS mission; programs and resources are protected from waste, fraud, and mismanagement; laws and regulations are followed; and reliable and timely information is obtained, maintained, reported, and used for decisionmaking (FSIS, 2008).

Assumptions

Assumptions Pertaining to the Variables

My assumptions regarding the variables were validated by the reviewed empirical literature. The first assumption was that because small and very small establishments were less capitalized, lacked food safety knowledge, experience, and resources needed to control *Lm* in their facilities, they were more likely to be noncompliant with the *Listeria* rule and would have a higher number of *Lm*-positive samples (see Fairman & Yapp, 2004; Yapp & Fairman, 2006; Henson & Heasman, 1998). The second assumption was that fully cooked products were more likely to be contaminated with *Lm* compared to

other RTE products. Therefore, establishments producing fully cooked products would be more likely to have a higher number of Lm-positive samples (see FSIS, 2010; New Zealand Food Safety Authority [NZFSA], 2009). My third assumption was that establishments using Alternative 3 would be more likely to receive a higher number of *Lm*-positive samples than establishment using Alternative 3, while establishments using Alternative 2 would be more likely to receive a higher number of Lm-positive samples than establishment using Alternative 1 (see Mamber et al., 2015). Finally, the fourth assumption was that establishments located in the western United States (District 05) would produce a higher number of *Lm*-positive samples than those located in other parts of the United States (see Bennion et al., 2008; Mamber et al., 2015).

Assumptions Pertaining to the Study Itself

The secondary data I used in this study was collected by the FSIS. I assumed that the data were complete, accurate, structured, and correctly coded because FSIS is a public health regulatory agency funded with taxpayers' money and reporting to the U. S. Congress. Moreover, it is FSIS policy to conduct management control audits to ensure that the organization, policies, and procedures are working as intended. In addition, since I thought it more appropriate to run a multiple logistic regression (statistical) test given the types of variables, I assumed normality, linearity, and homoscedasticity of residuals (see Burns & Burns, 2012; Field, 2013; Hill & Lewicki, 2006). The statistical tests will be covered in detail in Chapters 3 and 4.

Scope and Delimitations

Scope of the Study

My intention in this study was to determine whether, between 2012 and 2015, a statistical relationship existed between compliance with the *Listeria* rule (DV) and establishment size, RTE product type, alternative used, and FSIS district (IVs). The samples included large, small, and very small FIEs, the type of RTE products they produced, the *Listeria* alternatives they used, and the FSIS district where the FIEs were in the United States/U.S. territories. I focused on the association between compliance with the *Listeria* rule and establishment size, product type, alternative used, and FSIS district location.

Delimitations

This study was limited to include *Lm* samples that FSIS collected at FIEs producing RTE meat and poultry products in the 50 states and the U.S. territories only. I elected not include the *Lm* sample results of retail deli products that FSIS started in 2015. Furthermore, I also excluded the *Lm* sample results of imported RTE products. Therefore, the study's findings can only be generalized to the large, small, and very small FIEs located in the United States and the U.S territories.

Limitations

The primary limitation of this study involved the use of secondary data which, as the name implies, are data collected by someone other than the researcher. The FSIS collected the data to interpret the implementation of its regulations and validate its own version of compliance (Parker & Nielsen, 2011). The fact that I had the same

interpretation of regulatory compliance as that of the data collector (FSIS) strengthened the study's validity. In addition, the large sample size helped minimize mistakes in the data, which might have stemmed from incorrect data entry or just simple human error.

Another potential limitation of this study was my own professional status as an enforcement, investigation, and analysis officer (EIAO) working for FSIS and assessing the implementation of the *Listeria* rule by FIEs as part of my job description. Therefore, my knowledge and interpretation of the *Listeria* rule might have resulted in personal bias or conflict of interest. In Chapter 3, I describe the appropriate steps that I took to minimize personal bias.

Additional limitations of the study involved a threat to internal validity due to the methodology I used (regression test). Hill and Lewicki (2006) noted that "the major conceptual limitation of all regression techniques is that you can only ascertain relationships, but never be sure the underlying causal mechanisms" (p. 346). Said another way, factors other than the IVs could have affected the DVs (spuriousness). To prevent that, I used randomization and statistical control (see Engel, 2013).

Significance of the Study and Social Change Implications

My hope is that this study will help FSIS policymakers better understand the specifics of the establishments' compliance with the *Listeria* rule, which would allow them to identify and direct FSIS resources toward establishments that produce RTE meat and poultry products with a higher risk of *Lm* contamination. Furthermore, by knowing the product type, the establishments' size, the *Listeria* alternative they used, and the FSIS district(s) that were more noncompliant, the FSIS policy-makers might design focused

and evidence-informed strategies targeting those *problem* establishments and districts. In addition, this study also contributes empirically to the debate about the need, role, and usefulness of regulations and their impact on businesses, especially small and very small businesses. The findings also advanced theoretical knowledge by empirically demonstrating that DT could be used to determine compliance with food safety regulations.

More importantly, in this study I have generated evidence-informed knowledge that FSIS policymakers might use to train/educate their frontline inspection workforce (consumer safety inspectors, public health veterinarians, frontline supervisors, etc.) who are daily assigned to the large, small, and very small FIEs producing RTE meat and poultry products. Moreover, thanks to the study's findings, FSIS officials have empirical support for directing their outreach and education efforts towards the FIEs that produced the riskiest RTE products.

An important social change implication of this study is that it enables FSIS to know the specific district(s) and geographical distribution of the noncompliant FIEs, and move its education/outreach initiatives towards the vulnerable populations (pregnant women, the elderly, and the immunocompromised) living in those locations. The net benefit of the study's findings will be fewer deaths and hospitalizations due to listeriosis, increased economic productivity, better health promotion programs and, overall, the alleviation of a public health burden (human listeriosis). Additionally, in a global economy, the research findings might allow other industrialized countries (Canada, Europe, New Zealand, Australia) to align their *Listeria* control policy to that of FSIS and

possibly shift from a risk-based approach to a zero-tolerance approach regarding the presence of *Lm* in RTE foods (Warriner & Namvar, 2009). Finally, researchers may use my recommendations for further research as empirical research topics to advance and enhance science-based knowledge of *Lm* and human listeriosis, and to explore other food safety issues both in the developed world and in developing countries.

Summary

Human listeriosis, a foodborne illness, constitutes a significant and continuing national and international public health burden. While human listeriosis is a rare disease, it has a high fatality rate, especially among pregnant women, the elderly, and individuals with weakened immune systems. The purpose of this quantitative, nonexperimental, and cross-sectional study was to investigate whether a statistically significant relationship existed between compliance with the *Listeria* rule and the size of the FIEs, the type of RTE product they produced, the *Listeria* alternative they used, and the FSIS district(s), between 2012 and 2015. The theoretical foundation of the study was deterrence theory. To secure the *Lm* sampling data, I submitted a Freedom of Information Act (FOIA) request to the FSIS's FOIA office for the *Lm* samples it collected between 2012 and 2015, along with the type of RTE products, the size of the FIEs, the *Listeria* alternatives that the FIEs used, and the FSIS districts where the RTE products were produced. I then statistically analyzed the data using chi-square tests and multiple logistic regression, which were the most appropriate statistical tests in this context (categorical/dichotomous variables).

Chapter 2 includes a comprehensive review of the empirical literature along with a discussion of deterrence theory. The chapter also includes an overview of the FSIS and a background of the *Listeria* rule and other regulatory foundations that underpin the rule. My discussion of methodology, including the research design, data collection and analysis procedures, and ethical considerations, appears in Chapter 3. In Chapter 4, I summarize the results of the statistical test and finally, in Chapter 5, I draw the conclusions, make some recommendations for future research, and state the implications for positive social change.

Chapter 2: Literature Review

Introduction

In this chapter, I review the literature on compliance with the FSIS *Listeria* rule (DV) based on establishment size, product type, alternatives used, and FSIS district (IVs) from 2012 through 2015. After reviewing the studies that were pertinent to this cross-sectional research project, I summarized them and isolated what is known about the relationship between the IVs and the DV. The theoretical framework of the study centered on deterrence theory, which underpinned the methods and analysis that I used in this inquiry to investigate the relationships between the variables. In addition to the description of the literature search methods, this literature review includes four major sections, each with subsections. The four sections include discussions of: (a) the theoretical base of the study, (b) the *Lm* pathogen, (c) human listeriosis, and (d) the FSIS's regulatory initiative, including the *Listeria* rule, to control and prevent *Lm* in RTE products it regulates.

Search Strategies

To search the literature, I started by reviewing the FSIS website as well as the websites of other national and international public health organizations such as the CDC, the U.S. Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the World Health Organization (WHO), the Food and Agricultural Organization (FAO), the European Food Safety Authority (EFSA), and Health Canada (HC). I also purchased several peer-reviewed articles that were not available at the Walden University library. I also visited the websites of academic

institutions such as Texas A&M University, Kansas State University, the University of Wisconsin, and Iowa State University. Furthermore, I searched several databases, which I accessed via the Walden University library including Google Scholar, Thoreau Multi-Database Search, EbscoHost, ScienceDirect, SAGE Premier, SAGE Knowledge, ScholarWorks, ProQuest Central, ProQuest Dissertation & These Global, Academic Search Complete, MEDLINE with Full Text, ProQuest Criminal Justice Database, PubMed, PsycINFO, CINAHL Plus with Full Text, and Business Source Complete.

In this literature review, I included no date limiters since the Listeria rule came into effect 13 years ago, and I needed to include the history of the *Lm* pathogen and that of human listeriosis. To retrieve the most comprehensive list of peer-reviewed articles, I used the following search terms: *Listeria monocytogenes in the United States, Listeria monocytogenes contamination, Listeria monocytogenes detection, history of Listeria monocytogenes, characteristics of Listeria monocytogenes, Listeria monocytogenes subtyping, Listeria monocytogenes serovars, taxonomy of Listeria monocytogenes, prevalence of Listeria monocytogenes, incidence of Listeria monocytogenes, subtyping of Listeria monocytogenes, Listeria rule, Rules of Practice, HACCP, HACCP rule, Pathogen testing AND Meat, deterrence theory, listeria regulation, geographic distribution of listeria, listeria alternatives, listeriosis outbreak, foodborne surveillance, Listeria monocytogenes in food settings, Listeria monocytogenes in foods, treatment of listeriosis, virulence of Listeria monocytogenes, pathogenicity of Listeria monocytogenes, epidemiology of listeriosis, regulatory compliance theory*, and *food safety regulations.* Then I used the following Boolean search phrases: *Listeria monocytogenes AND meat*

OR poultry, Listeria monocytogenes AND ready-to-eat meat OR poultry, Listeria monocytogenes AND processing environment, risk assessment AND food safety, deterrence theory AND food safety, food infection control AND regulatory compliance, food safety AND fraud, regulation AND businesses, compliance AND food safety, risk assessment AND food safety, compliance AND food safety, FSIS District AND Listeria, Listeria monocytogenes AND food handling, deterrence AND multiple logistic regression OR odd ratio, food safety AND multiple logistic regression OR odd ratio, and *business size AND noncompliance.* After retrieving more than 170 articles, I used the following inclusion criteria: peer-reviewed, full text, and, based on the situational need, articles published in the last 5 years (2011 through 2016).

Theoretical Framework

In quantitative research, it is common for investigators to test a theory to find answers to their formulated research questions. Kerlinger (1979) defined theory as "a set of interrelated constructs (variables), definitions, and propositions that presents a systematic view of phenomena by specifying relations among variables, with the purpose of explaining natural phenomena" (as cited in Creswell, 2009, p. 51). In other words, by describing and explaining the relationship between and among the variables, a theory advances knowledge in a particular field. Grant and Osanloo (2014) echoed this view and postulated that a theory serves as a linchpin for the literature review, the methods, and analysis conducted for a study. Therefore, it can be argued that, in quantitative inquiry, theories are like beacons that guide readers throughout the research journey, allowing them to reach their destination without getting lost (Creswell, 2009).

The theoretical foundation of this research was deterrence theory, as described by Paternoster (2010). The author defined deterrence as "the omission of a criminal act because of the fear of sanctions or punishment" (p. 766). Simply put, the cornerstone of the theory is that the anticipated knowledge and expectation of some form of punishment would deter crime, violation, or by extension, noncompliance. May (2005) and Paternoster (2010) identified two types of deterrence: (a) general deterrence, which is like a sword of Damocles hanging over the heads of individuals or business owner/operators who have not yet committed a crime or engaged in regulatory noncompliance, and warning them of potential adverse consequences of a crime; and (b) specific deterrence which, presumably, should prevent criminals/violators from committing additional crimes/violations. It is worth mentioning that deterrence targets members of the general population who, by witnessing the horrors and shame of official punishment, would refrain from committing crimes or violations (May, 2005). In the context of this research, FIEs owners or operators who know about or have heard of their other colleagues who have been punished either through FSIS's enforcement actions, such as suspension or withdrawal of the grant of inspection (deterrence strategies) for violating the *Listeria* rule, would shy away from violating it (Paternoster, 2010). As confirmed by Straub (2011), "when the risk of punishment is high (deterrent certainty) and penalties for violations are severe (deterrent severity), the theory predicts that potential offenders will be inhibited from committing antisocial action" (p. 258). Straub grouped the severity and certainty of punishment under the umbrella term of disincentives.

The main constructs of DT are utility, certainty of punishment, severity of punishment, and to a lesser extent, celerity (swiftness) of punishment; utility being the satisfaction that individuals or businesses gain from a course of action (Kuperan & Sutinen, 1998; Paternoster, 2010). Therefore, deterrence theorists believe that individuals and FIEs would try to maximize utility by complying with regulations if the disincentives (*e.g.*, the certainty, celerity, and severity of the regulator's punishment) outweigh the benefits of noncompliance (Parker & Nielsen, 2011). Said another way, regular human beings, as well as the owners/operators of FIEs, weigh the benefits and costs of their actions before undertaking them, and only self-interest would motivate the commitment of a noncompliance (Kuperan & Sutinen, 1998). Deterrence theory is the cornerstone of criminal justice systems around the world.

According to Paternoster (2010), the two major precursors of deterrence in criminology were the works of Enlightenment philosopher C. Beccaria, who wrote a seminal treatise *On Crimes and Punishment* (*On Crimes*) in 1764, and J. Bentham, who published *An Introduction to the Principles of Morals and Legislation* (*Introduction to the Principles*) in 1789. While Beccaria was at odds with the cruel legal codes of the time in Europe, he suggested a more humane and rational legal system that would rule out torture and secret accusations, and make crime and punishment proportionate. Beccaria also believed that self-interest was the main motive for committing a crime (Paternoster, 2010).

Paternoster (2010) stated that *On Crimes* did not include the constructs of deterrence theory as it is known today, although it laid the foundation for the theory by

claiming that self-interest was the main motive for criminal/noncompliant behavior. Paternoster also postulated in the *Introduction to the Principles*, that Bentham offered a more holistic theory of deterrence that included constructs like "attainment of pleasure" (p. 770) and "avoidance of pain" (p. 770); hence the concept of self-interest. In that regard, J. Bentham is perceived as the actual precursor of deterrence theory.

Kuperan and Sutinen (1998) tested the deterrence theory using multiple logistic regression with a sample of 318 fishermen (202 Malay fisherman and 116 Chinese fishermen) to determine whether (a) high probability of detection and sanction, (b) great penalty if applied, (c) higher moral development of the individual, (d) high perception of the legitimacy of the regulation by the individual, and (e) high perception of the legitimacy of the regulation by the community at-large (IVs) would result in compliance with the fishery regulations (DV). The authors concluded that gains and losses as specified in the deterrence model alone *did not* prevent noncompliance, and they proposed the expansion of deterrence theory to include moral development, the behaviors of others, and perceived legitimacy of the regulator as additional determinants of compliance. By adding new constructs (legitimacy of the regulator, moral development, and social influence), Kuperan and Sutinen (1999) advanced knowledge, expanded classical deterrence theory, and created a new socio-economic theory of regulatory noncompliance. In support of Sutinen and Kuperan's findings, Parker and Nielsen (2011) disaggregated the motives for compliance into three types: (a) economic or material motives involve maximization of the firm's own utility; also referred to as "calculative thinking" (p. 10) or "rational choice" (p. 10); (b) social motives which consist of earning

the approval and respect of partners, employees, the public, regulators, and so on; and (c) normative motives which involve a moral duty to comply.

Straub (2011) also tested deterrence theory to investigate whether investing in information technology (IT) security by management would result in a decrease in computer abuse. Using data from 1,211 random organizations, the author hypothesized that (a) information system (IS) security deterrents were effective in reducing computer abuse, and (b) rival explanations such as using preventive security software were also effective in reducing computer abuse. The IVs in Straub's study included deterrents such as IS security efforts, disseminating information, acceptable system use guidelines, system use policies, and rival explanations such as preventive security software, motivational factors affecting abuse, and environmental factors affecting abuse. Computer abuse (e.g., number of incidents, actual dollar loss, opportunity dollar loss) was used as the DV. Straub ran multivariate and univariate correlation tests, nonstructural tests of covariance equality (canonical correlation), Kruskal-Wallis tests, and chi-square tests to test the hypotheses. He found that, as predicted by deterrence theory, all tests results showed that IS security deterrent lead to a significant decrease of computer abuse. Straub's finding provided empirical evidence that the *Listeria* rule might constitute an effective deterrent against noncompliant FIE owners and operators in addition to other deterrents such as the Rules of Practice (see Appendix A).

Finally, Maxwell (2000) also tested the DT to determine whether the perceived certainty of punishment among offenders, mandated as intensive probation and other levels of perceived certainty of punishment, could deter offenders from violating

probation requirements. The unit of analysis consisted of 546 individuals (offenders), of whom 516 were interviewed, enrolled in the New Jersey's Intensive Drug Probation Program between January 1989 and April 30, 1990. The DV was the offender's status at the end of the program, while the IV was the perceived certainty of sanction (Maxwell, 2000). Using logistic regression to explore the characteristics of offenders likely to succeed or complete the program, Maxwell found that the offenders' perception and knowledge of the certainty of sanction had a bearing on the offenders' status and duration in the program. As Burns and Burns (2012) stated, multiple regression is "a technique for estimating the value on the criterion variable from values on two or more other variables" (p. 385). In this study, multiple logistic regression will help determine if there is a correlation between establishment size, product type, alternative used, and FSIS district(s), and compliance with the *Listeria* rule.

The Variables in the Literature

Lm Contamination by Establishment Size

Like in most industries, size matters when it comes to complying with food safety regulatory requirements. For example, Fairman and Yapp (2004) and Yapp and Fairman (2006) claimed that small, medium-sized, and micro-enterprises (SMEs) in the UK lack the food safety knowledge, time, experience, information access, support, interest, and skills needed comply with regulations because they failed to internalize the hazards that their products might pose to the consumers, and the necessary external motivators such as trade associations or regulatory agencies. In their view, an external force must intervene

to make small businesses comply with regulatory requirements; hence the need for enforcement.

Henson and Heasman (1998) examined how large and small firms deal internally with regulatory compliance, and noted significant differences between small and large firms at the discovery stage. The discovery stage is when firm management becomes aware of the regulation and of their involvement level in the regulatory process. For example, large firms' owners/operators become aware of a regulation as it is being proposed, and may try to lobby the regulator to shape the regulations to their competitive advantage. Small firms, on the other hand, become aware of a regulation at a later stage or even after its implementation, and may decide to only partially comply or not comply at all (Henson & Heasman, 1998). Buckley (2015) echoed that argument, and posited that small firms' compliance methods tend to be reactive, while large firms are more proactive. Buckley (2015) also pointed out that trust, fairness, and legitimacy of the inspector also play a role in small FIEs' compliance. For my study, I hypothesize that small firms will be more likely due to their size, and limited personnel and finances, to have positive *Lm* samples (be less compliant with the Listeria rule) than large FIEs. By extension, small and very small FIEs, would also be inclined to use the least costly of the Listeria rule alternatives (Alternative 3).

Lm Contamination by RTE Product Type

Risks assessment findings indicated that ready-to-eat (RTE) products, especially deli meat and poultry products, whether prepackaged or sliced at retail, bore the highest risks of *Lm* contamination in the United States (FSIS, 2010). Similarly, the NZFSA also

reported that, in New Zealand, ready-to-eat hams, a deli product, were more likely to be contaminated with *Lm* (NZFSA, 2009).

In contrast, in Germany, Meyer et al. (2012) sampled 300 raw RTE and heat treated RTE poultry products and found that *Lm* was more prevalent ($p < 0.05$) in raw RTE poultry products than in heat-treated RTE poultry products. In Algiers, Bouayad and Hamdi (2012) also tested 227 samples of RTE foods (dairy products, fermented products from raw milk, unpacked sliced meat products, and cooked meat dishes) and concluded that 51.5% of the RTE fermented meat products tested positive for *Listeria.* While a large body of the literature examined the general prevalence of *Lm* in RTE meat and poultry products, it is noteworthy that a paucity of knowledge exists about compliance with the Listeria rule by product type. For this study, I hypothesize that deli meat and poultry products will be more likely to test positive for *Lm.*

Lm Contamination by Alternative Used

Based on the structure of the Listeria alternatives, it is safe to argue that Alternatives 1 and 2 have more control mechanisms (post-lethality treatment or antimicrobial agent or process) in them; therefore, it is understandable that FSIS officials target more of the FIEs using Alternative 3 for verification sampling than FIEs using Alternatives 1 and 2 (FSIS, 2014a). While the reviewed literature showed that hardly any study had examined compliance to the Listeria rule based on the alternatives FIEs use, I hypothesize that establishments using Alternative 3 would be more likely to have a higher number of product samples that test positive for *Lm* than those using Alternatives 1 and 2. Furthermore, I also hypothesize that FIEs using Alternative 2 are more likely to

have a higher number of positives than the ones using Alternative 1. Mamber et al.'s (2015) research provided support for my hypotheses with their analysis of FSIS' sampling data (product, FCSs, environmental) collected from 2005 through 2012 on RTE products based on alternative used. Mamber et al. (2015) found that FIEs using Alternative 1 had fewer positive samples that FIEs using Alternatives 2a, 2b, and 3. However, the small number of samples from Alternatives 1 and 2a limited the possibility for comparative analysis with these data (Mamber et al., 2015).

Lm Contamination by FSIS District

The *Lm* clone is a global pathogen that has been isolated on all five continents, thanks to "human travel, animal or food trade, wild animal migration, or wind and dust" (Chenal-Francisque et al., 2011, p. 1111). In addition, the *Listeria* species (spp.) ubiquity has been exemplified by its presence in urban and natural environment in the United States (Sauders et al., 2012). In their study of the nonperinatal *Listeria*-related mortality in the United States from 1990 through 2005, Bennion et al. (2008) analyzed the 1178 deaths due to listeriosis on record and found that the Midwest had the lowest mortality with 0.23 deaths per 1 million persons annually, followed by the Northeast with 0.29 deaths per million. The West, with 0.33 annual deaths per million, had the highest rate annually. Bennion et al.'s (2008) study showed that the Alameda, CA district (District 05) would have the highest mortality rate due to listeriosis. Supporting that finding, Mamber et al.'s (2015) study of the geographical distribution of the RTE product samples that tested positive for *Lm* in 2008, found that four out of the five products came from the western region while the fifth came from the North Central region. Interestingly, in one

of the largest listeriosis outbreaks implicating FSIS-regulated products (turkey deli meat) in 2002, most reported cases were from the northeast region (4 from Pennsylvania, 11 from New York City, 5 from New Jersey, 4 from Delaware, 2 from Maryland, 1 from Massachusetts) while one case was reported from the Midwest (CDC, 2002). Due to the apparent conflict in the data from 2012 through 2015, a new study was needed on the geographic distribution of *Lm* prevalence in RTE meat and poultry products in the United States/U.S. territories. My intent was to fill this knowledge gap through this study

The Food Safety and Inspection Services (FSIS)

FSIS (hereafter referred to as the Agency) is "the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged" (FSIS, 2016a, para.1). The Agency derives its authority from the 1906 Federal Meat Inspection Act (FMIA), the 1946 Agricultural Marketing Act (AMA, some sections only), the 1957 Poultry Products Inspection Act (PPIA) and the 1970 Egg Products Inspection Acts (EPIA).

FSIS has a workforce of more than 9,600 employees (policy writers, public health veterinarians, food inspectors, consumer safety inspectors, data analysts, risk managers, equal employment specialists, food safety educators, human resource specialists, purchasing and contract specialists, and so on). Its inspection force conducts inspections and performs enforcement duties in more than 6,000 large, small, and very small establishments nationwide. Every year, the Agency's personnel inspect 3 billion pounds of imported meat, poultry, and egg products, while its scientists perform nearly 190,000

scientific analyses (FSIS, 2016a). In 2014, FSIS's inspection force inspected 147 million heads of livestock, and 8.9 billion poultry carcasses. Every year, FSIS's inspection force condemns more than 425 million pounds of poultry, and over 257,000 heads of livestock (FSIS, 2014a).

Federally inspected establishments (FIEs) wanting to sell products in interstate commerce apply for a grant of inspection from FSIS, and must meet sanitation, facility, and operational standards requirements. Then, products that meet those requirements are stamped (bear the mark of inspection), demonstrating that they have been inspected and passed by the USDA and are safe to enter commerce (Kvenberg, Stolfa, Stringfellow, & Garret, 2000).

With respect to enforcement, after FIEs are apprised of their due process rights, FSIS has at its disposal an arsenal of enforcement tools codified in the Rules of Practices (ROP) under 9 C. F. R. 500 (FSIS, 2007). As described in Appendix A, the ROP may range from regulatory control action (retaining product, rejecting equipment, slowing or stopping production lines, etc.), withholding action (refusal to apply the marks of inspection to products), or suspension with or without prior notification (FSIS, 2007).

The *Lm* Pathogen

Historical Background

To say the least, the discovery of the *Lm* bacterium has caused controversy among researchers. Rocourt and Buhrieser (2007) claimed that scientists such as Hulphers had isolated some *Lm* strains in the 1900s, but failed to integrate their findings into a formal collection, making any comparison difficult. Citing early reports, Saha et al. (2015)

echoed that sentiment, and posited that *Lm* might have been isolated from patients in Germany in 1891, and from spinal fluid of meningitis patients in 1917 and 1920. Furthermore, Saha et al. (2015) claimed that the first case of diagnosed human listeriosis occurred in 1929, while the first report of a perinatal case of listeriosis dated back to 1936. The same view was held by Hoff (2003) who claimed that, in the early years of the *Lm* discovery, no general awareness existed among microbiologists, infectious diseases specialists, and food microbiologists about the new *Lm* strain.

In any case, most researchers concurred that the work of Murray, Webb, and Swan (Murray et al., 1926) constituted a breakthrough in the isolation of the *Lm* strain (Amenu, 2013; Gibbons, 1972; Hof, 2003; Lecuit, 2007; Rocourt & Buhrieser, 2007; Saha et al., 2015; Warriner & Namvar, 2009). In 1926, Murray et al. (1926) first described *Lm* in a formal publication when, two years earlier, they observed the sudden death of six rabbits in the animal laboratory of the Department of Pathology at Cambridge, England, and many more later. In their description of the disease, the scientists argued that, "the causative organism either has not been described previously, or has been inadequately described and so cannot be traced in the in the literature" (Murray et al., 1926, p. 408) and that "its salient character was the production of mononuclear leukocytosis" (Murray et al., 1926, p. 408). Therefore, they named it *Bacterium monocytogenes* but remained open to a name change through the collaboration of experts (Murray et al., 1926). A year later, Pirie discovered the same microorganism in gerbils in South Africa and named it *Listerella hepatolyca* in honor of British surgeon,

Sir Joseph Lister (1827-1912), an early advocate of antiseptic surgery (Saha et al, 2015; Warriner & Namvar, 2009).

When both Murray and Pirie separately sent their newly discovered strains to Dr John Leningham, the director of the National Type Collection at the Lister Institute in London, the latter noticed their similarity and decided to put Murray and Pirie in touch (Rocourt & Buhrieser, 2007). The two scientists then agreed to call the new bacterium *Listerella monocytogenes*. After rejection of the name *Listerella*--which was previously used for a mycetozoan and for a species of foraminifer--Pirie suggested using the name *Listeria* in 1940 (Gibbons, 1972; Hof, 2003; Rocourt & Buhrieser, 2007). Other names used to designate *Lm* include *Bacterium monocytogenes hominis, Listerella hominis, Cornyebacterium parvulum, Listerella ovis, Listerella bovina, L. gallinaria, L. cunniculi, L. gerbil, Erysipelothrix monocytogenes, and Corynebacterium infantispticum, granulomatosis infantiseptica,* and *Tiger River disease* (Hof, 2003; Rocourt & Buhrieser, 2007). In essence, early researchers concurred on the novelty of the *Lm* bacterium whose characteristics had hitherto been unknown.

Characteristics of *Lm*

The genus *Listeria* was first mentioned in the fourth edition of the *Bergey's Manual of Determinative Bacteriology* in 1934 and was classified in the *Kurthia* tribe of the Corynebacteriaceae family (Rocourt & Buhrieser, 2007). Then, on the ninth edition of the same manual, it was categorized in the *Lactobacillaeceae* family (Pagotto, Corneau, & Farber, 2006). Afterwards, the *Listeria* genus was classified with *Lactobacillus*, *Erysipelothrix, Brochothrix, Kurthia, Renibacterium,* and *Caryophanon* in Group 19,

under the "regular, nonsporing, Gram-positive rods" (as cited in Rocourt & Buhrieser, 2007, p. 3 and in Pagotto et al., 2006, p. 314). However, Rocourt and Buhrieser claimed that it was in 1988 that the *Listeria* genus was grouped with *Gemella*, *Brochothrix*, *Streptococcus*, and *Lactobacillus* in the Lactobacillaeceae family.

Listeria species are non-sporulating, unencapsulated, catalase-positive, oxidase-negative, Esculin hydrolysis positive, with individual cells measuring 0.5 μm in diameter and 1-5 μm in length (Amenu, 2013; Pagotto et al., 2006; Saha et al., 2015). As a Gram-positive rod-shaped bacillus, *Listeria* has rounded ends. In addition, the cells may be single units or short chains, and may be distributed in V and Y shapes or in palisades (Amenu, 2013; Nwaiwu, 2015; Rocourt & Buhrieser, 2007).

The pathogen can grow in a pH range of 4.3 to 9.6, a water activity of approximately 0.83, and salt concentration of 10 to 25.5% (Amenu, 2013; Donnelly, 2001). *Lm* is an aerobic, microaerophilic and facultatively anaerobic pathogen that can grow between 1^0C and 45^0C, which makes it a psychrotroph and a mesophile at the same time (Amenu, 2013; Food and Agricultural Organization [FAO], 2004; Montville & Matthews, 2008; Pagotto et al., 2006; Saha et al., 2015). It is worth noting that temperature plays a key role in the pathogen's growth and survival. At a temperature range of 20^0 to 25^0C, the bacillus is motile by means of a few peritrichous flagella. Nevertheless, at 37^0C, the organism is weakened or non-motile (Lucy et al., 2014; Pagotto et al., 2006; Rocourt & Buhrieser, 2007; Saha et al., 2015). Furthermore, the *Lm's* psychrotrophic nature allows it to grow at a temperature of 4^0C. That attribute

makes it distinct from other common foodborne pathogens, which are generally inhibited from growth at refrigerated temperatures (Amenu, 2013; Adzitey & Huda, 2010).

Taxonomy of *Lm*

The genus *Listeria* includes six recognized species: *Lm, L. ivanovii, L. innocua, L. welshimeri, L. seeligeri*, and *L. grayi*. (Amenu, 2013; Lucy et al., 2014; Montville & Matthews, 2008). Nevertheless, Jadhav et al. (2012) claimed that, in 2009, a seventh species, *L. marthii* was discovered at the finger Lakes National Forest in the United States. It is worth mentioning that only *Lm* is pathogenic to humans, while both *L. ivanovii* and *L. monocytogenes* are pathogenic to animals, especially sheep and cattle (Montville & Matthews, 2008; Saha et al., 2015). *Lm* differs from the other nonpathogenic *Listeria* species by its "ability to lyse red blood cells. . ." (Montville & Matthews, 2008, p. 175). While most experts agree on the existence of six *Listeria* species (Amenu, 2013; Adzitey & Huda, 2010; Lucy et al., 2014; Montville & Matthews, 2008; Pagotto et al., 2006). Furthermore, Saha et al. (2015) noted the previous discovery of a seventh species (*Listeria murrayi)* even though "DNA-DNA hybridization analysis, multilocus enzyme electrophoresis, and rRNA restriction fragment length polymorphism analysis proved that *L. murrayi* appeared to be subspecies within *L. grayii"* (p. 56). Additionally, the authors also recognized the isolation of two recent species: *L. marthii* and *L. rocourtiae.* Therefore, it can be argued with confidence that, to date, the total number of *Listeria* species remains unknown. As an illustration, Orsi and Wiedmann (2016) described 11 new species that were discovered as recently as 2009 and consisting

of *L. marthii, L. rocourtiae, L. weihenstephanensis, L. grandensis, L. riparia, L. booriae, L. fleischmannii, L. floridensis, L. aquatica, L. newyorkensis*, and *L. cornellensis*.

According to Adzitey and Huda (2010); Lomonaco et al. (2015), and Quendera et al., (2016), scientists have identified 13 serotypes of *Lm,* and grouped them into three lineages based on their pathogenicity and ability to transfer their pathogen potential:

(a) Lineage I includes serotypes 1/2b, 3b, 4b, 4d, and 4e. While serotypes 4d and 4e are similar to serotype 4e, they are rarely found in food clinical samples. Therefore, serovars 4b, 4d and 4e have been grouped under the designation of "serotype 4b complex" (Lomonaco et al., 2015, p. 173),

(b) Lineage II consists of serovars 1/2a, 1/2c, 3a and 3c, while

(c) Lineage III comprises serotypes 4a and 4c and some strains of the 4b serotype and includes three different subgroups, IIIA, IIIB, IIIC. A fourth phylogenic lineage, lineage IV differs phylogenically with other lineages was a reclassification of lineage IIIB.

Lineages I and II have been primarily isolated in sporadic (serotypes 1/2a, 1/2b. and 4b) and outbreak cases (mostly serotpyes1/2a and 4b) of humans listeriosis (Amenu, 2013; Chen, 2012; Lomonaco et al., 2015; Montville & Matthews, 2008; Saha et al., 2015). Lineage II (serovars 1/2a, 1/2c, 3a and 3c) and some lineage I strains such as serotypes 1/2b and 4b have been found in natural and farm environments.

Lineages III and IV (are significantly biodiverse and detected less frequently) have been isolated in ruminants and non-primate mammals. As Lomonaco et al. (2015) state, bacteria may achieve recombination (acquisition of new genes) through direct

contact between cells (conjugation), bacteriophage-mediated (transduction), and uptake of free environmental DNA (transformation). They observed that about 50% of core *Lm*/*L. innocua* could fulfill recombination. Furthermore, lineage II strains, through recombination, might adjust to different environmental conditions, while lineage I strain did adapt to the host (mostly humans) but were less inclined to recombination (Lomonaco et al., 2015). In recent years, robust and sensitive detection methods have been developed to better control and prevent listeriosis outbreaks.

Detection Methods for *Lm*

Since the isolation of the *Lm* pathogen in the early 20th century and its association with foodborne diseases in the 1980s (Schlech et al., 1983), scientists made considerable progress in detecting and differentiating the *Listeria s*pecies in general, and the species and sub-species of the *Lm* strains, in particular (Graves et al., 2007; Liu, 2006). Through various subtyping approaches, scientists (epidemiologists, chemists, and microbiologists) have been able to detect and track cases of human listeriosis as well as the source(s) of *Lm* contamination throughout the farm-to-fork food system continuum.

To better contain human listeriosis outbreaks, scientists developed novel (a) culture-based detection methods; (b) phenotypic or conventional subtyping methods such as serotyping, phage typing, multilocus enzyme electrophoresis (MLEE) as well as esterase typing; (c) genetic detection methods (also referred to as molecular or DNA-based) such as, ribotyping, pulsed-field gel electrophoresis (PFGE), Polymerase Chain Reaction/PCR-based subtyping; and (d) DNA sequencing-based subtyping such as multilocus sequence typing or MLST and MLVST or multi-virulence-locus-sequence

typing (Gasanov, Hughes, & Hansboro, 2005; Graves et al., 2007; Jeyaletchumi, Tunung, Margaret, Farinazleen, & Cheah, 2010; Liu, 2006). Each approach has its benefits and limitations.

Culture-based detection methods. This conventional approach requires the sample to be immersed in the selective enrichment for 48 hours, and identification through biochemical analysis may take up to 10 days to confirm a positive sample (Jadhav et al., 2012). Currently the FSIS uses the MLG8 A.05 and MLG8.09 culture-based detection methods, which take approximately five days to generate a presumptive positive, and another two days to confirm the presumptive positive through a CAMP test. In any case, the regulatory agencies (FSIS and FDA) require that the culture methods be able to detect one *Listeria* organism in 25g of food at a level of about 10^4 10^5 CFU ml^{-1} (Gasanov et al., 2005). Since *Listeria* cells do not compete well with other organisms, bacteriostatic agents (acriflavin and nalidixid acid) are introduced in the enrichment media or selective agar to suppress competition from other microflora (Gasanov et al., 2005; Liu, 2006; Zunabovic, Domig, & Kneifel, 2011). The scientists examine the esculinase reaction through the β-D-glucosidase activity, and the *Listeria* colonies would appear black. Suspect bacteria are considered *Listeria* if they are gram positive, aerobic and facultatively anaerobic, nonsporulating, oxidase negative, and catalase positive (Gasanov et al., 2005; see Figure 1). Critics of the culture-based method claimed that it is painstaking because it requires selecting and testing a preselected number of colonies from a single sample, which may lead to a false presumptive positive result. It also relies

heavily on phenotype, which changes with the environment and uses different chemicals (Jadhav et al., 2012).

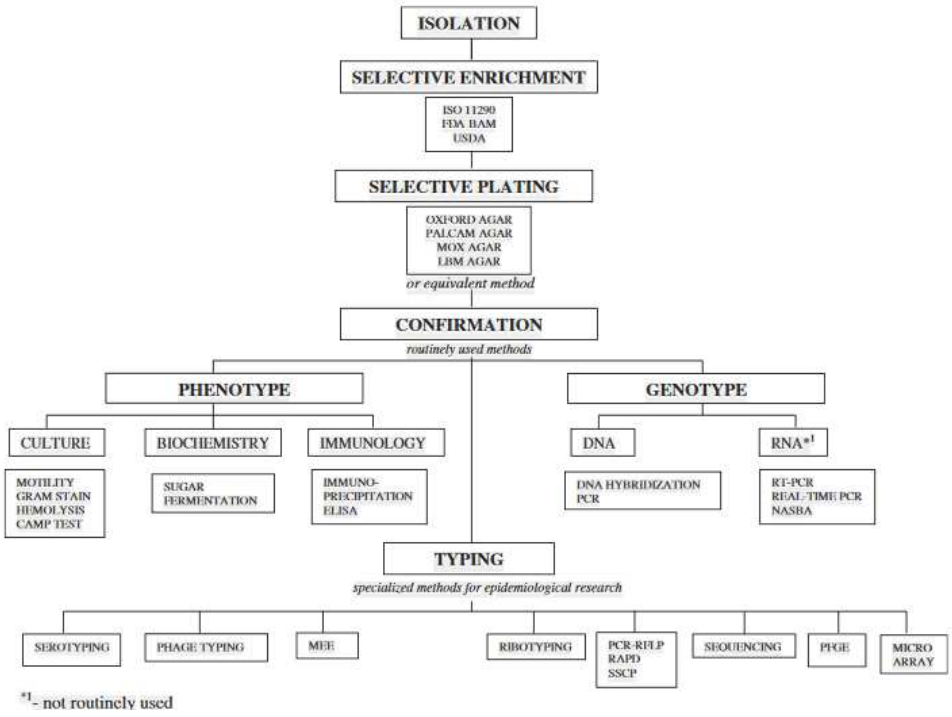

Figure 1. Overview of isolation, identification, and typing methods for *Listeria* and *L. monocytogenes* in foods and environmental samples. From "Methods for the isolation and identification of *Listeria* spp. and *Listeria monocytogenes*: A review," by Gasanov et al., 2005, *FEMS Microbiology Review*, *29*, p. 853. Copyright 2005 by Gasanov et al. Reprinted with permission.

Conventional subtyping methods.

***Serotyping*.** Considered the gold standard for typing *Lm*, serotyping consists of identifying the 13 serotypes (1/2a, 1/2b, 1/2c, 3a, 3b, 3c, 4a, 4ab, 4b, 4c, 4d, 4e and 7) using the serological reactions between somatic (O) and flagellar (H) antigens and their corresponding antisera (Graves et al., 2007; Wiedmann, 2002). This approach had been used in epidemiologic investigations as well as in the food industry through commercial tests kits such as Denka Seiken (Tokyo, Japan), and Difco (Difco Laboratories/Becton

Dickinson and Co., Sparks, MD, USA; Gasanov et al., 2005). Nevertheless, since serotypes 1/2a, 1/2b and 4b account for 98% of documented human listeriosis, serotyping is of limited usefulness in epidemiologic studies because of its poor discriminatory power (Graves et al., 2007). For example, Liu (2006) noted that serotyping has led to discrepant results because it can neither differentiate between serotypes 4a, 4b and 4c, nor correlate serotypes with species identities. Therefore, molecular subtyping methods have superseded serotyping.

Phage typing. Bacteriophages are viruses that can lyse bacterial cells. Phase typing relies on an analysis of bacteriophages, and the lysis of host-specific *Listeria* bacteria on agar plates, to group the *Listeria* strains into phagovars or phage groups, which epidemiologists may examine to track the source and course of an outbreak (Gasanov et al., 2005; Liu, 2006). In addition, according to Wiedmann (2002), phage typing has helped detect a human listeriosis outbreak in France, and established food consumption as the transmission route for *Lm.* Furthermore, phage typing had also been used in epidemiologic studies until the advent of genetic subtyping; however, because 10% of *Listeria* species (particularly serotypes 3 and ½ as well as *L. grayi* strains) were untypable, phage typing had a limited value in epidemiologic studies (Jeyaletchumi et al., 2010; Liu, 2006).

Multilocus enzyme electrophoresis (MLEE). As a widely-used detection method in the 1990s, MLEE is a protein-based method that distinguishes bacterial strains by isolating proteins from the strain of interest and separating them after gel electrophoresis, and then using a probe to detect a specific protein (Liu, 2006). Scientists then

differentiate the *Listeria* strains based on the variations in the electrophoretic mobility of the different enzymes (called electrophoretic types or ETs) under non-denaturing conditions (Jadhav et al., 2012; Liu, 2006; Wiedmann, 2002). This detection method requires careful optimization and standardization of the test procedure to minimize run-to-run variations (Jeyaletchumi et al., 2010).

Esterase typing. As a variant of MLEE, esterase typing measures the esterases (enzymes that hydrolyze esters into acids and alcohols or phenols) activity from cells of individual *Lm* strains on starch gels after electrophoresis (Liu, 2006). Scientists may examine the esterase typing and detect the electrophoretic types (ETs). The main disadvantages of esterase typing include low reproducibility, and the need for careful documentation and standardization due to the high number of ETs (Liu, 2006). Notably, esterase typing is currently used infrequently, especially with the advent of DNA-based subtyping approaches.

Genetic detection methods. According to Wiedmann (2002), genetic subtyping has improved researchers' ability to differentiate strains and subtypes of bacterial, parasitic, and viral pathogens, thanks to its superiority in terms of sensitivity, specificity, discriminatory power, and level of standardization. With the advent of new technologies that make subtyping results available in less than 24 h in some cases, Law et al. et al. (2015) and Wiedmann (2002) argued that molecular subtyping, such as ribotyping, is revolutionizing the characterization, identification, and enumeration of *Lm* strains.

Ribotyping. Ribotyping examines the relationship of organisms by how closely DNA sequences for a given ribosomal gene (rRNA) or protein match (Wiedmann, 2002;

Gasanov et al., 2005). Using rRNA gene probe, ribotyping consists of restricting enzyme digestion of chromosomal DNA, and then hybridizing the DNA. From there, the banding patterns are used to sort *Listeria* isolates into ribotypes and establish the relatedness of isolates (Gasanov et al., 2005; Liu, 2006; Wiedmann, 2002). This detection approach is reproducible but not widely used in epidemiological studies because it has low discriminatory power, especially for serotype 4b (Graves et al., 2007).

Pulsed-field gel electrophoresis (PFGE). As the platinum standard of molecular subtyping, PFGE compares genetic components from different isolates of the same bacteria (Graves et al., 2007). Scientists use restriction enzymes to cut chromosomal DNA into numerous pieces, separated in different sizes or banding patterns by agarose gel electrophoresis; then PFGE groups the *Lm* into subtypes or pulsotypes based on the DNA band patterns (Jeyaletchumi et al., 2010). In the United States, the CDC established PulseNet, a network of public health and food regulatory laboratories that subtype foodborne pathogens using PFGS to detect and track foodborne clusters and sources of contamination, especially during outbreaks (Graves et al., 2007; Wiedmann, 2002). Along with ribotyping, PFGE has the greatest discriminatory power and can subtype serotype 4b, which other subtyping methods cannot (Graves et al., 2007). Nevertheless, it may take up to 30 h or longer to complete the test, and requires special equipment and a highly-qualified workforce (Liu, 2006).

Polymerase Chain Reaction/PCR-based subtyping. As one of the most rapid detection methods, PCR-based subtyping includes arbitrary primed polymerase chain reactions (AP-PCR) and random amplified polymorphic DNA (RAPD). Graves et al.

(2010) and Liu (2006) posited that these subtyping approaches consist of enabling a single arbitrary selected primer to anneal at very low temperature (37^0C) to form nearly-complementary sequences on the target DNA. The annealed primer spreads on various areas and amplifies a plethora of DNA fragments of various sizes, resulting in DNA patterns that may be typed. Other less-used PCR-based subtyping methods include repetitive element-based subtyping (REBS), and amplified fragment length polymorphism (AFLP). Riemann and Cliver (2006) stated that, thanks to a combination of multilocus enzyme electrophoresis (MEE), PFGE, RAPD, and RFLP (restriction fragment length polymorphism), researchers have been able to groups serotypes 1/2a, 1/2c, 3a and 3c into lineage I; serotypes 1/2b, 3b, 4b, 4d and 4e into lineage II; and serotype 4a into a separate lineage. Nevertheless, PCR-based subtyping lacks epidemiologic relevance because it requires complex protocols and an automated DNA sequencer, and has inconsistent reproducibility (Graves et al., 2010).

DNA sequencing-based subtyping.

Multilocus sequence typing (MLST). MLST uses the DNA sequencing of internal fragments of multiple housekeeping genes to determine the genetic relatedness of *Lm* strains (Graves et al., 2007; Jadhav et al., 2012). MLST is being widely used because it is easy to interpret and helps researchers study the genetics, evolution, and population biology of living organisms, including *Listeria* pathogens. Jeyaletchumi et al. (2010) claimed that MLST will play a more central role in the DNA sequencing of *Lm* in the near future considering the gradual decrease in its cost, but noted that a major limitation of MLST is its a poor discriminatory power.

Multi-virulence-Locus-Sequence typing (MLVST). MLVST uses the sequence differences in three virulence genes and three virulence associated genes to differentiate *Lm* strains (Jadhav et al., 2012; Jeyaletchumi et al., 2010). Due to its high discriminatory power, MLVST analysis might help producers of ready-to-eat foods establish better control measures against *Lm* contamination (Zhang, Jayaroa & Knabel, 2004). Additional DNA-sequencing subtyping approaches include the multilocus variable number tandem repeats (MVLA), which scientists use to generate a DNA fingerprint or a bacterial isolate. MVLA requires a highly skilled and trained workforce and a specific protocol for each pathogen (Zhang et al., 2004).

Lm in the Food-Processing Environment

Listeria strains have been isolated in milk and dairy products, chopping boards, mincing machines, and cleaning cloths (Adzitey & Huda, 2010), raw buffalo meat samples, quail meat, partridge meat, and chicken meat (Rahimi, Yazdi, & Farzinezhadizadeh, 2012). Other sources of *Lm* contamination include poultry meat and meat products, cooked meats, cured meats, smoked salmon, vegetables and soft cheese, RTE foods, and raw, pasteurized and liquid eggs and egg-breaking plants (Adzitey & Huda, 2010; Mahmood, Ahmed, & Hussein, 2003; Rivoal et al., 2010; Rivoal et al., 2013). A lack of biocidal treatment in the end-use container, along with the microbial ecology of food-manufacturing plants (moisture, organic nutrients, pH, oxidation-reduction potential, temperature, presence or absence of inhibitors, time, interaction between microorganisms, maintenance and repair practices, factory and equipment design, and cross-contact between raw and cooked products) have led to *Listeria*

contamination of food, especially at the postprocessing stage (Kornacki & Gurtler, 2007; Tompkin, 2002). Furthermore, Pagotto et al. (2006) posited that improper cleaning and sanitizing, poor employee hygiene (contaminated hands and gloves), unsanitary equipment such as dicing machines also constituted contamination routes for *L. monocytogene*s at food factories. Recontamination after heat treatment was the primary contamination source for *Lm* in commercially processed foods, and to date, no recall of Listeria-contaminated food products has been associated with an inadequate heat treatment, even though the pathogen was more heat resistant than many other foodborne pathogens (Kornacki & Gurtler, 2007). Cox, Bailey, and Berrang (1997) also concluded that the postprocessing environment was the prime contamination route for *Lm* after studying the incidence of *Salmonella*, *Campylobacter jejuni*, *Campylobacter coli*, and *Lm* in poultry carcasses and poultry parts for sale on the Belgian retail market, and finding that one-fourth (27 out of 105) of the carcasses were contaminated after processing and at retail level. To prevent recontamination, Den Aantrekker et al. (2003) recommended that recontamination via air, processing equipment, and hand contact be included in quantitative risk assessments to better protect consumers, especially neonates, pregnant women, the elderly, and the immunocompromised.

Furthermore, Chasseignaux et al. (2001) analyzed 502 *Lm* isolates from a poultry processing plant and a pork processing plant and found the pathogen on floors, walls, drains, working tables, boxes, machines, knives, cutters, poultry raw materials, and poultry products. One of the reason for *Lm* omnipresence in the food processing environment is its ability to form biofilms. Kumar and Anand (1998) and Gandhi and

Chikindas (2007) state that biofilms attach and grow on food contact surfaces (FCSs) using extracellular polymeric substances (EPS) that allow them to change their membrane's fatty acid composition, achieve optimal fluidity, and grow at low temperatures. After that, biofilms develop quorum-sensing ability and antimicrobial resistance. Xavier and Bassler (2003) defined quorum sensing as "a process of bacterial cell-to-cell communication involving the production and detection of extracellular signaling molecules called autoinducers" (as cited in Gandhi & Chikindas, 2007, p. 7). Cell-to-cell signaling plays a key role in virulence, bioluminescence, sporulation, and biofilm formation. Significantly, biofilms can resist acid stress, antimicrobial agents, antibiotics, and bacteriocins (Gandhi & Chikindas, 2007). Therefore, to control and prevent biofilm formation, researchers suggested altering plants design and layout, and modifying their cleaning and sanitizing procedures, and their personnel's routine practices (Tompkin, 2002). Gandhi and Chikindas (2007) proposed inactivating the stress sigma factor (which allows the pathogen to respond to stress), using multiple hurdle technology that targets the bacterial cell, and using active packaging technology, e.g. including bacteriocins that either control the atmosphere within the package or inhibit the growth of spoilage and pathogenic organisms on the food item (Gandhi & Chikindas, 2007).

Microbial Pathogen Testing of Food

Currently, microbial pathogen testing of meat, poultry, and other food products, is part and parcel of food quality assurance and food safety. Along with heightened consumer awareness and demand for food safety, fear of a bad reputation, contractual

arrangements between buyers and suppliers, fear of lawsuits from the sale of tainted foods, local, state, federal, and even international regulations have increased the level and amount of food producers' investment in the safety of their product through the control of microbial pathogens, carcinogenic chemicals and other harmful food safety hazards (Economic Research Service, 2016). It is therefore not surprising that the worldwide demand for microbial pathogen testing, which is currently worth $4.8 billion, be projected to reach a staggering $8.04 billion by 2021 (Zion Market Research, 2017). In the same vein, the compound annual growth rate (CAGR) is expected to increase at a rate of 7.8% between 2016 and 2021 (Zion Market Research, 2017). Therefore, it cannot be business as usual for food producers and regulatory agencies alike considering the current demands.

Economically, the new norm materialized through consumer health consciousness and growing demand for better food safety, coupled with the emergence of novel testing technologies, resulting in a drastic change in the supply and demand for food safety information (Unnevehr, Roberts, & Custer, 2011). The advent of new and sensitive biotechnological testing equipment derived from modern medical diagnostics has enhanced the food producers' ability to detect microbial pathogens in foods, and prevent the contamination of their product. Unnevehr et al. (2011) had noted recent significant biotechnological advancements including: automated sequencing equipment which has simplified and shortened the time required to sequence proteins and microbial genomes; the ability to sequence the DNA nucleic acid of pathogens, allowing scientists to "construct *PCR primers* to detect that pathogen" (p. 2); and scientists' ability to separate

pathogens from food products thanks to membrane filters and filtering techniques. The U.S. food safety regulatory agencies have also followed suit.

FSIS switched to the more sensitive RT-PCR BAX test to improve its ability to detect *Salmonella* and *Listeria* in meat and poultry products (Unnevehr et al., 2011). Notably, as a regulatory public health agency, FSIS has a vested interest in knowing the prevalence of *Salmonella*, *Lm*, *Escherichia coli O157:H7,* and staphylococcus enterotoxins in RTE meat and poultry products because of the of health risks they pose to vulnerable persons. Between 1980s and 1990s, FSIS began sampling nine types of RTE meat and poultry products from producing establishments to obtain data on the most prevalent microbial hazards in RTE products, and direct its regulatory focus on the primary hazards of public health concern (Levine, Rose, Green, Ransom, & Hill, 2011). Levine et al. (2011) examined the FSIS's prevalence data of *Salmonella*, *Lm*, *Escherichia coli O157:H7,* and staphylococcus enterotoxins in those nine different categories of RTE products between 1980 and 1990 (sliced ham and luncheon meat-pork only; cooked beef, roast beef, and cooked corned beef; jerky-meat or poultry; cooked poultry products-uncured; meat or poultry salads, spreads, and pâtés; small-diameter cooked comminuted products-meat or poultry; dry and semidry fermented sausages; large-diameter cooked comminuted products-meat or poultry; and fully cooked meat patties). They found that none of the nine types of RTE meat and poultry products tested positive for *E. coli O157:H7* and staphylococcus enterotoxins. However, cumulative 10-year *Salmonella* testing showed that jerky had the highest prevalence rate with 0.31%, followed by sliced ham and luncheon meat, and cooked beef, roast beef, and cooked corned beef with

0.22%. Meat or poultry salads, spreads, and pâtés had the lowest rate with 0.05%. For *Lm*, sliced ham and luncheon meat had the highest prevalence rate with 5.16%, followed by small-diameter cooked comminuted products with 3.56%, cooked beef, roast beef, and cooked corned beef with 3.09%, and meat or poultry salads, spreads, and pâtés with 3.03%, while jerky had the lowest prevalence rate at 0.52%.

Naugle, Barlow, Eblen, Teter, and Umholtz (2006) investigated how FIEs (small, very small, and large) producing raw meat and poultry products were meeting the *Salmonella* performance standards associated with the HACCP rule (see PR/HACCP section) by reviewing sample sets, set failures, and establishment characteristics between 1998 and 2003. They analyzed sample set data from seven product categories: broiler chicken carcasses, cow and bull carcasses, market hog carcasses, steer and heifer carcasses, ground beef, ground chicken, and ground turkey; and found that, out of the 4607 sample sets, 93% (4255) passed. Naugle et al. (2006) also pointed out that establishment size, product class, and year were significant determinants of compliance with the performance standards. In addition, Naugle et al. (2006) found that while large establishments were less likely to fail than small and very small establishments, other categories were more likely to lead to set failure than ground beef, and set failures were more likely to occur early in the testing program (compared to 2003). However, they found no correlation between geographic location of an establishment and set failure (Naugle et al., 2006).

Eblen, Barlow, and Naugle (2006) also conducted an establishment-level analysis of compliance with the FSIS *Salmonella* performance standards for the following product

categories: turkey and chicken meat, broiler chicken, market goods, cows and bulls, steer and heifer carcasses, broiler chicken, and ground beef. Eblen et al. (2006) reviewed the *Salmonella* sample set data collected by FSIS from 1,584 federally inspected establishments (FIEs) between 1998 and 2003 in order to identify the determinants of set failures. The authors found that 80.9% (1,282) of the FIEs passed their sample set, while the remaining 302 (19.1%) FIEs failed. According to Eblen et al. (2006), the factors associated with sample set failures were: (a) the early stage of the testing (except for broiler), (b) establishment size (very small and large establishments were more likely to pass the set sampling than small establishments), and (c) product class (steer-heifer, market hogs, and ground beef producers were more likely to pass the set sampling than broiler producers). Eblen et al.'s (2006) findings concurred with Naugle et al.'s (2006) finding on *Salmonella* prevalence in raw meat and poultry in the United States: product class, establishment size, and early stages of the sampling set constituted the primary factors of failure. These studies support findings that size and raw product category, and period of the sampling, matter in food safety and food quality control.

Similarly, Ollinger, Muth, Karns, and Choice's (2011) examined the scope and use of food safety audits in the U.S. meat and poultry producing establishments as well as the correlation between use of audits and establishment size/structure and their use of food safety technology. They also found that larger establishments and multiple-firm establishments relied more on food safety technology than small and very small establishments (Ollinger et al., 2011). While FSIS only considered the RTE regulatory testing results as an indicator of the trend of pathogen presence in RTE products, it did

not regard the results as an indicator of national prevalence (FSIS, 2016d). Empirical research showed that small and very small establishments found it more difficult to meet the regulatory pathogen performance standards and lack the resources to invest in technology or other food quality assurance venues (food audits).

Human Listeriosis

In 1981, epidemiologists positively associated an outbreak of human listeriosis in Canada with consumption of contaminated coleslaw (Schlech et al., 1983; Schlech, 2000). In addition, contaminated mineral oil (Schuchat et al., 1991) and tainted hospital foods, especially diced celery (Gaul et al., 2013) have also caused human listeriosis outbreaks. Once an animal or a human being ingests listeria-contaminated food, the harmful bacteria might attack the central nervous system (neurolisteriosis) through (a) a retrograde neural route that allows the pathogen to cross the oral epithelium and cause rhombencephalitis in ruminants, and (b) a hematogenous route that allows the pathogen alone, or in conjunction with leukocytes, to breach the blood-brain barrier in humans (Disson & Lecuit, 2012).

It is noteworthy that public health officials have grappled with the epidemiology, and with what constitutes an infectious dose of listeriosis, because scientists disagree on the duration of the incubation period. For example, Linnan et al. (1988) estimated the incubation period to be between 31 and 35 days; Goulet et al. (2013) set the incubation period at 14 days for central nervous system and bacteraemia and 6 weeks for pregnancy-associated cases, while Mead et al. (2006) found that “one elderly man developed invasive listeriosis within 48h of a single exposure to contaminated meat” (p. 749).

The host population at risk of listeriosis includes pregnant women, the elderly, immunocompromised individuals, patients undergoing chemotherapy, patients with renal disease or organ transplants; and HIV-positive individuals. That vulnerable population is 500 times more likely to contract listeriosis than the general population (Schlech, 2000). Infants may contract listeriosis (a) through their pregnant mothers who may develop sepsis from a contaminated gastrointestinal tract and give birth to septic fetus or infant, or (b) during birth via the contamination of their skin and respiratory track by mothers who carry the pathogen in their GI tract and perianal region. Two to three weeks after exposure at birth, infants may develop bacterial meningitis (Schlech, 2000).

In infants, neonatal listeriosis encompasses (a) early-onset listeriosis, and (b) late-onset listeriosis. Early-onset listeriosis stems from maternal sepsis and chorioamnionitis and may lead to stillbirth, abortion or premature birth, and affects twin babies more than singletons. Signs of the disease include pustular skin lesions, also referred to as "granulomatosis infantiseptica" (Schlech, 2000, p. 772) due to granulomatous hepatitis. Infants born alive with this condition have a fatality rate of 20%, and that rate may rise to 50% when including abortion and stillbirths. The pathogen is generally present in infant's blood, skin and cerebrospinal fluid as well as the placenta, and severe sepsis is common. Late-onset listeriosis, on the other hand, generally manifests itself between 7 and 20 days after birth. Signs of neonatal meningitis include irritability, poor feeding, and meningeal irritation. The fatality rate is approximately 10% (Lecuit, 2007).

Listeriosis is associated with three clinical syndromes, including: (a) maternofetal listeriosis, also referred to as neonatal listeriosis; (b) bloodstream infection; and (c)

meningoencephalitis (Schlech, 2000). In addition, hematogenous spread may also result in a focal infection that may involve the joints, peritoneum, the eyes, and the endocardium. Furthermore, immunocompromised adults may develop acute or subacute bacterial meningitis. Schlech (2000, p. 772) argued that the clinical syndromes of *Lm* infection include:

- Neonatal sepsis and meningitis, both early-onset and late-onset types
- Bacterial meningitis in adults
- Rhombencephalitis in adults
- Sepsis syndrome in adults
- Native or prosthetic valve endocarditis
- Arterial infections
- Pneumonia
- Hepatitis
- Liver abscess
- Febrile gastroenteritis
- Spontaneous bacterial peritonitis
- Continuous ambulatory peritoneal dialysis peritonitis
- Osteomyelitis
- Septic arthritis

In a study of a cohort of 299 cases of invasive listeriosis in Denmark, Gerner-Smidt et al. (2005) examined whether risk factors predisposing people to invasive listeriosis might increase their risk of dying from it. The authors found that age was not a statistically significant risk factor for dying from the disease, because the predisposing

factors of patients' diseases were strongly associated with death among those aged below 70 years. However, risks were not strongly associated with death among patients aged above 70 years. In addition, non-hematological malignancies were the only underlying condition that was statistically related to mortality in younger patients (Gerner-Smidt et al., 2005). However, the authors found that hematological malignancies were not a high-risk factor of death from invasive listeriosis among those patients because that patient group was promptly treated with antibiotics when they felt sick. They also noted a difference in serotype virulence. For example, strains belonging to serotype 4 (compared to serotype ½) were more likely to cause death than strains belonging to serotype ½ (Gerner-Smidt et al., 2005). Left untreated, invasive listeriosis may lead to death. To treat the diseases, physicians may combine ampicillin and aminoglycoside, third-generation cephalosporin antibiotics, or vancomycin; the therapy may last 10 to 14 days for bloodstream infections, but for meningitis, experts recommend 14 to 21 days (Donovan, 2015).

Human Listeriosis Outbreaks

From an epidemiological standpoint, the CDC (2014) estimated that the average annual incidence of listeriosis in the United States is 0.26 cases per 100,000 population, indicating a 42% reduction compared to 1996-1998. even though the incidence rate remained the same between 2006-2008 and in 2012. Nevertheless, outbreaks continue to occur, and involve a variety of products such as pasteurized milk, ready-to-eat meat and poultry, dairy products, and seafood products. In this literature review, I will focus primarily on the outbreaks that involved FSIS-regulated products.

The first documented listeriosis outbreak in the United States took place between September and October 1979 in Boston, MA and involved 23 patients who had consumed raw vegetables and pasteurized milk (Ho, Shands, Friedland, Eckind, & Fraser, 1986). Between 1983 and 2000, 15 recognized outbreaks occurred in the United States, and six of them implicated FSIS-regulated products such as frankfurters and other delicatessen meat and poultry products (Olsen et al., 2005). Between May and December 2000, for example, a multistate (California, Connecticut, Georgia, Massachusetts, Michigan, New York, Ohio, Pennsylvania, Tennessee, Utah and Wisconsin) listeriosis outbreak occurred and resulted in 30 cases, 4 deaths and 3 miscarriages. Olsen et al. (2005) conducted a case-control study to identify the risk factors for infection and concluded that some cases might not have been reported. In addition, the processing plant, examined in their study, which produced contaminated turkey, recalled 16 million pounds of processed meats. The outbreak was attributed to serotype ½. It is important to note that investigating a listeriosis outbreaks is challenging because of its long incubation period, high mortality rate, the patients not being representative of the general population, and the poor recordkeeping of processing plants (Olsen et al., 2005).

The largest outbreak implicating FSIS-regulated products occurred from July through November 2002. Gottlieb et al. (2006) performed a case-control study, traceback, and microbiological investigation to track the source of that outbreak and suggested preventive measures. The outbreak resulted in 188 cases, eight deaths, and three fetal deaths due to the ingestion of turkey deli meats in nine states (Pennsylvania, New York, New Jersey, Delaware, Maryland, Connecticut, Massachusetts, Michigan, and Illinois).

Two processing plants (one in New York City and another in Massachusetts) recalled over 30 million pounds of precooked, RTE turkey deli meat products. Epidemiologists concluded that serotype 4b caused the outbreak. Their findings were consistent with Painter et al.'s (2013) that between 1998 and 2008, poultry products contaminated with *Listeria* and *Salmonella* spp. caused more deaths than any other food items in the United States.

Cartwright et al. (2013) examined listeriosis outbreaks occurring in the United States in a 10-year period from 1998 to 2008, and included factors such as the establishment in 1998 of PulseNet (a U.S. molecular subtyping network for outbreak detection) and the *Listeria* Initiative of 2005 (increased surveillance for outbreak investigation). During that period, 24 conformed outbreaks of listeriosis occurred and resulted in 359 illnesses, 215 hospitalizations, and 38 deaths (Cartwright et al., 2013). Cartwright et al. (2013) discovered that serotype 4b was responsible for the highest number of outbreaks and outbreak-associated cases. Furthermore, they found that from 1998 to 2004, RTE meats were the primary contamination vehicles, while between 2005 and 2008 newer contamination vehicles (sprouts, taco/nacho salads) appeared (Cartwright, et al., 2013). After the 2002 outbreak, FSIS issued the *Listeria* rule to contain the incidence and prevalence of *Listeria* contamination in RTE meat and poultry. The FSIS's regulatory initiative (*Listeria* rule) will be described in detail under the *Listeria* rule section below. Despite the regulatory efforts to contain listeriosis, outbreaks have continued to occur nationally and internationally since 1980 (Swaminathan & Gerner-Smidt, 2007)

As far as listeriosis surveillance is concerned, in 1996 the CDC established PulseNet, a national laboratory network that uses DNA fingerprinting and "allows investigators to find the source, alert the public sooner, and identify gaps in our food safety systems that would not otherwise be recognized." (CDC, 2016, para. 1). Once epidemiologists identify *Lm* strains in patients, they send them to state public health laboratories for standardized pulse-field gel electrophoresis and after isolation, the PFGE patterns are fed into the central database (PulseNet) for comparison. Then *Lm* isolates that are equal to or greater than two are assessed as a cluster within 120-day period; cluster detection allows PulseNet to identify potential outbreaks (CDC, 2016).

FSIS's Regulatory Initiatives to Control and Prevent *Lm*

The Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) Rule

Background. In the early 90s, foodborne pathogens were responsible for 6 to 33 million cases of infection and about 9,000 deaths each year in the United States, while meat and poultry products (regulated by FSIS) alone caused 5 million foodborne illnesses and 4,000 deaths each year (FSIS, 1998). The four major foodborne pathogens of concern at the time were *Campylobacter jejuni*/*coli*, *E. coli O157:H7*, *Salmonella*, and *Lm* (FSIS, 1998). Furthermore, a multistate outbreak of *E. coli O157:H7,* implicating undercooked hamburgers and occurring between November 1992 and February 1993, resulted in 500 laboratory-confirmed infections and four fatalities in Washington, Idaho, California, and Nevada (CDC, 1993). At that point, FSIS officials realized the limitations of the

traditional regulatory inspection system, which was primarily based on sensory methods such as sight, smell, and touch (FSIS, 1998).

As the Texas A&M University (TAMU, n.d.) put it, FSIS officials became aware that command-and-control inspection procedures alone could not prevent the presence of hazards in foods, and end-product testing was not sufficient to guarantee product safety. Therefore, they decided to shift the paradigm from a command-and-control system to a risk-based, science-driven inspection system and, in July 1996, phased in the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) rule, also referred to as the Mega-Reg (FSIS, 1998). Hontz and Scott (1999) stated that the new rule "would replace the old USDA/FSIS inspection model in which establishments often looked to inspectors to dictate day-to-day food safety and sanitation requirements and the agency imposed 'command and control' regulations on industry" (p. 118). Simply put, the science-based inspection system shifted the burden of foodborne illness prevention from FSIS inspectors to the regulated industry through the hazard analysis and critical control Points (HACCP) system. FSIS's personnel would be confined to a role of evaluation, verification, documentation, and enforcement (FSIS, 1998). Similarly, when in November 1996, 21 people died after an *Escherichia coli O157:H7* outbreak in Wishaw, Scotland, the Environmental Health Officers (EHO; the equivalent of FSIS's Consumer Safety Inspectors or CSIs) were subject to severe criticism for failing to identify the hazards at the butcher shop (Green & Kane, 2014). After that, the United Kingdom (UK) passed the Food Safety (General Food Hygiene) Regulations which introduced HACCP in accordance with European Union Directive 43/93. Like the U.S. food industry, the UK

also switched from a “do’s and don’ts, snap-shot inspection” (Green & Kane, 2014, p. 261) to an inspection system that was underpinned by an assessment of risk. The increased use of HACCP worldwide has led the Codex Alimentarius to develop guidelines for HACCP in 1993, then to include it into food hygiene code in 1995 (Unnevehr & Jensen, 1999).

According to Hontz and Scott (1999), the PR/HACCP rule required that federally inspected establishments (a) develop and implement HACCP plans, (b) slaughter establishments and establishments producing ground products meet the *Salmonella* performance standards, (c) develop Sanitation Standard Operating Procedures or SSOPs (see Appendix C2), and (d) test for generic *E. coli* (slaughter establishments only). In addition, as described in Appendix B.1, the HACCP rule classified FSIS-regulated products into nine HACCP processing categories, including: (a) slaughter (all species); (b) raw product-non-intact (ground); (c) raw product-intact (not ground); (d) thermally processed-commercially sterile; (e) Not heat-treated-shelf stable; (f) heat treated-shelf stable; (g) fully cooked-not shelf stable; (h) heat treated but not fully cooked-not shelf stable; and (i) products with secondary inhibitors-not shelf stable (FSIS, 2015).

Hazard analysis and critical control points (HACCP). HACCP is a systematic approach that proactively identifies the points in the production process that may pose a food safety risk, and establishes control for that risk (Hontz & Scott, 1999). Monitoring and verification of the whole process help provide feedback on problem areas and corrective actions that need to be taken to prevent the emergence of a food safety risk. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF)

defined HACCP as "a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution, and consumption of the finished product" (NACMCF, 1998, p. 1248). It is worth noting that the HACCP system is all-inclusive and takes into account the farm-to-fork continuum; in order words, it addresses all the physical, chemical, and biological food safety hazard that are reasonably likely to occur from the production to the consumption of foods. The NACMCF (1998) identified seven HACCP principles:

1. Conduct a hazard analysis
2. Determine the critical control points
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record-keeping and documentation procedures

To assist the regulated industry transition through HACCP, between December 1997 and January 1998, FSIS held four meetings nationwide about HACCP implementation. These meeting dealt with the challenges related to the role of prerequisite programs (see Appendix B) and due process, and provided the industry with HACCP information that allowed them to implement HACCP on January 26, 1998 (Hontz & Scott, 1999).

Risk assessments. Whiting (2011) argued that the notion of microbial risk assessment (MRA) is predicated upon the premise that the number of pathogens at the time of the food consumption determines the safety of the food. This rationale underlies the concept of food safety objective (FSO). This concept "establishes that the initial contamination, reductions through inactivation steps, potential recontamination, and possible growth during storage should be such that at the time of consumption, the pathogen will be below a specific level in every serving, termed FSO" (Whiting, 2011, p. 1525). The goal is to assess the risk of illness per serving, the number of cases in a year, or the acceptable level of protection. The dose-response relationship formulated for a pathogen and concerned consumers entail an association between the FSO and an acceptable level of protection or ALOP (Whiting, 2003).

Internationally, the Food and Agriculture Organization (FAO) of the United Nations (UN) and the World Health Organization (WHO) sponsored a quantitative microbiological risk assessment in 2003 in an effort to (a) estimate the risk of vulnerable populations (infants, elderly, pregnant women and immunocompromised patients) compared to the general population, (b) estimate the health risk of *Lm* from foods that allow growth and foods that do not allow growth under determined storage and shelf life conditions, and (c) estimate the health risk from *Lm* when the pathogen count was absent in 25g, present in 1000 colony-forming-units per gram or milliliter, or when the number of pathogen count was within a specified limit at the time of consumption (Rocourt, BenEmbarek, Toyofuku, & Schlundt, 2003). To meet those objectives, Rocourt et al.

(2003) suggested the development of new dose-response relationships and exposure assessments for RTE foods.

In the same vein, FSIS (2004) and Todd (2007) reported that the Food Safety and Inspection Service (FSIS) collaborated with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) in 2003, and developed a quantitative risk assessment using available scientific data to estimate the relative risks (through dose-response models) of serious illness and death associated with consumption of 23 types of *Lm* -contaminated RTE foods among perinatals (fetuses and newborns), the elderly (60 years or older) and intermediate-age (general population, less than 60 years of age). They concluded that deli meats constituted a very high-risk food category. After the release of the 2003 risk assessment, FSIS issued the *Listeria* rule requiring that federally-inspected establishments producing RTE meat and poultry products establish mechanisms to control for *Lm.*

The *Listeria* rule. FSIS established a zero-tolerance policy for *Lm* in ready-to-eat meat and poultry products as early as 1987 and issued the FSIS Directive 10,240.1, *Listeria monocytogenes*: *Testing Procedures and Sanitation Information* in 1998 (Engeljohn, 2015). The 2003 joint risk assessment with the FDA, coupled with the 2000 and 2002 listeriosis outbreaks that cumulatively resulted in 75 cases, 11 deaths, and 6 stillbirths and miscarriages have led to a change in FSIS's regulatory policy regarding *Lm* on RTE meat and poultry products (FSIS, 2004).

The *Listeria* rule, as described in Appendix D, requires that FIEs producing RTE meat and poultry products take measures to control *Lm* in their products through their

HACCP plans, Sanitation Standard Operating Procedures (SSOPs), or prerequisite programs (FSIS, 2014b). Furthermore, FSIS ruled that post-lethality exposed RTE meat and poultry products would be considered adulterated (unfit for human consumption), if they are either contaminated with *Lm* or come in contact with a food contact surface that is contaminated with *Lm* (USDA-FSIS Listeria Rule, 2003). The Listeria rule (9 Code of Federal Regulation [CFR] 430) identified three alternatives that FIEs might choose from:

Alternative 1 (Alt.1; 9 CFR 430.4(b)(1)). Under this alternative, FIEs use both a post-lethality treatment (PLT), and an antimicrobial agent or process (AMAP), to reduce, eliminate, limit or suppress *Lm* in the product. However, they do not have to test food contact surfaces (FCSs) for *Lm*, but are required to:

- Include the PLT in their HACCP plans;
- Validate the effectiveness of the PLT as required by 9 CFR 417.4
- Use an AMAP to control *Lm* and incorporate the agent or process in their HACCP plans, SSOPs, or other prerequisite programs;
- Document in their HACCP plans, SSOPs, or other prerequisite programs that the AMAP is effective in suppressing or limiting *Lm* growth. Furthermore, the AMAP should demonstrate that no more than 2-logs growth of *Lm* occur throughout the shelf life of the product (see Appendices B.1 and B.2).
- Maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416
- Evaluate the effectiveness of the *Lm* control measures if the PLT is included in the SSOPs

- Include the prerequisite program and its results in the documentation that FIEs must maintain under 9 CFR 417.5 if the *Lm* control measures are included in a prerequisite program other than the SSOPs (FSIS, 2014; USDA-FSIS Listeria rule, 2003).

Alternative 2 (Alt. 2; 9 CFR 430.4(b)(2)).

Alternative 2, Choice 1 (Alt. 2a). Under this alternative, FIEs use a PLT to reduce or eliminate *Lm* in the product. While they are not required to test FCSs for *Lm* and the PLT should demonstrate at least a 1-log decrease before the product is shipped, FIEs using this alternative must:

- Apply a PLT and include it in their HACCP plans
- Validate the effectiveness of the PLT as required by 9 CFR 417.4
- Maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416 (FSIS, 2014b; USDA-FSIS Listeria rule, 2003).

Alternative 2, Choice 2 (Alt. 2b). Under this alternative, FIEs use an AMAP to limit or suppress the growth of *L. monocytogenes* in the product. FIEs using this alternative are required to:

- Use either an agent or process and include it in their HACCP plans, SSOPs, or prerequisite programs
- Document in their HACCP plans, SSOPs, or prerequisite programs the effectiveness of the AMAP in suppressing or limiting *Lm* growth. FSIS recommends that the AMAP demonstrate no more than 2-logs of *Lm* growth throughout the shelf life of the product

- Evaluate the effectiveness of the *Lm* control measures if the AMAP is included in the SSOPs
- Include the prerequisite program and its results in the documentation that FIEs must maintain under 9 CFR 417.5 if the *Lm* control measures are included in a prerequisite program other than the SSOPs
- Test the FCSs in the post-lethality environment to demonstrate that proper sanitation is maintained on those FCSs and no indicator organisms (*Listeria* spp.) is present
- Indicate the FSCs' testing frequency, identify the size and location of the sizes to be tested, describe why the testing frequency is sufficient to control *Lm*, and identify conditions for hold and test procedures when an FCS tests positive for *Lm* or *Listeria* spp.
- Maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416 (FSIS, 2014; USDA-FSIS Listeria rule, 2003)

Alternative 3 for non-deli or non-hotdog products (Alt. 3; 9 CFR 430.4(b)(3)(i)). Under this alternative, FIEs use sanitation only to control *Lm* in the environment and on the product. They must:

- Provide sanitation control measures in their post-lethality processing environment either in their HACCP plans, SSOPs, or prerequisite programs
- Evaluate the effectiveness of the *Lm* control measures if they are included in the SSOPs

- Include the prerequisite program and its results in the documentation that FIEs must maintain under 9 CFR 417.5 if the *Lm* control measures are included in a prerequisite program other than the SSOPs
- Test the FCSs in the post-lethality environment to demonstrate that proper sanitation is maintained on those FCSs are no indicator organisms (*Listeria* spp.) is present
- Indicate the FSCs' testing frequency, identify the size and location of the sizes to be tested, describe why the testing frequency is sufficient to control *Lm*, and identify conditions for hold and test procedures when an FCS tests positive for *Lm* or *Listeria* spp.
- Maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416 (FSIS, 2014; USDA-FSIS Listeria rule, 2003)

Alternative 3 for deli or hotdog products (9 CFR 430.4(b)(30(ii). FIEs producing deli meat and hotdogs must meet separate requirements as well. In that regard, FIEs using this alternative are required to:

- Verify the effectiveness of corrective actions taken after an initial positive test for *Lm* or its indicator organism on an FCS located in the post-lethality environment. That verification may be conducted through follow-up (targeted) testing of *Lm* or an indicator organism on the FCS that is the most likely source of contamination as well as additional testing of the surrounding FCS area

- Hold and test products that may be contaminated using a sampling method and frequency with a level of statistical confidence that ensure that the lots are not adulterated if follow-up testing yields a second positive result (USDA-FSIS Listeria rule, 2003, FSIS, 2014). Figure 2 shows a breakdown of the three listeria alternatives and their requirements.

Figure 2. Control Requirements for *Listeria monocytogenes*

Requirements	→ Increasing Risk Levels and Frequency of FSIS Verification Testing →				
	ALTERNATIVE 1	ALTERNATIVE 2		ALTERNATIVE 3	
	Post-lethality Treatment AND Antimicrobial Agent or Process	Post-lethality Treatment OR Antimicrobial Agent or Process		Sanitation and Testing Program	
		Choice 1: Post-lethality Treatment	Choice 2: Antimicrobial Agent or Process	Non-deli, Non-hotdog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment's HACCP Plan and should show at least a 1-log reduction in *Lm* prior to distribution of the product into commerce	X	X			
Document effectiveness of antimicrobial agent or process: Must be included as part of the establishment's HACCP, Sanitation SOP, or Prerequisite Program and should demonstrate no more than 2-logs growth of *Lm* over the estimated shelf life.	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS) in the post-lethality processing environment for *Lm* or an indicator organism.			X	X	X
State testing frequency.			X	X	X
Identify size and location of sites to be sampled.			X	X	X
Explain why testing frequency is sufficient to control *Lm* or an indicator organism.			X	X	X
Identify conditions for Hold-and-Test, when FCS (+) for *Lm* or an indicator organism.			X	X	X
Additional Sanitation Program Requirements					
Follow-up testing to verify corrective actions are effective after 1st FCS (+) for *Lm* or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area.					X
If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots using a sampling plan that provides statistical confidence that the lots are not contaminated with *Lm* or an indicator organism. Release, rework, or condemn products based on results. Document results and product disposition.					X
Establishments in all three alternatives must maintain sanitation in accordance with 9 CFR 416.	X	X	X	X	X

Figure 2. Adopted from "FSIS compliance guideline: Controlling *Listeria monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products," by FSIS, 2014, p. 21.

Regardless of the alternative used, FIEs must meet the sanitation and HACCP system requirements of 9 CFR 416 and 417. Furthermore, FIEs using a PLT or AMAP may declare the PLT or AMAP on the product's label only if they have validated such claim by processing the product in a way that renders it RTE by achieving at least a 6.5 log reduction for *Salmonella* for cooked beef, roast beef, and cooked corned beef, a 5-log

reduction for uncured meat patties, and a 7-log reduction for cooked poultry products (FSIS, 2014b).

It is worth noting that the industry responded positively to the rule, and a 2004 FSIS survey found that 87% of more than 2,900 FIEs reported having made at least a change in their process to better control *Lm* (FSIS, 2004). Lastly, as part of its verification testing, FSIS tests about 10,000 product samples annually for *Lm,* and FIEs that have a positive sample receive a letter describing a list of all isolates within the last five years, the PFGE pattern name, and whether the positive sample was a result of harborage or cross-contamination along with suggested corrective actions (Engeljohn, 2015).

Impact of the *Listeria* Rule

In 1999, Mead et al. (1999) reported that *Lm* was causing more than 2,500 illnesses and 500 deaths each year in the United States. Between 2005 and 2007, the *Listeria* rule was not as effective as planned because FSIS-regulated products were responsible for 48% of *Lm* outbreaks in the United States (Engeljohn, 2015). Nevertheless, since 2008, only one *Lm* outbreak associated with pork products (an FSIS-regulated type of product) and causing nine illnesses was reported in 2011 (Engeljohn, 2015). Figure 3 shows the consistent decline of *Lm*-positive samples among the FSIS's routine regulatory testing of finished RTE meat and poultry products. In fact, the percentage of positive samples declined from 4.61% in 1990 to 0.32% in 2014. To achieve success in bending the curve of human listeriosis, FSIS improved its testing of RTE foods for *Lm* (Engeljohn, 2015) while the CDC, in 2005, launched the *Listeria*

Initiative, which in 2014, included 47 participating states. The *Listeria* Initiative is a surveillance system that "collects reports of laboratory-confirmed cases of human listeriosis in the United States" (CDC, 2016b, p. 1) and whose main objective is "aid in the investigation of listeriosis clusters and outbreaks by decreasing the time from outbreak detection to public health intervention." (CDC, 2016b, p. 1). In that regard, a combination of preventive and regulatory controls has led to 44% decrease in the prevalence of perinatal listeriosis in the United States (Lamont et al., 2011).

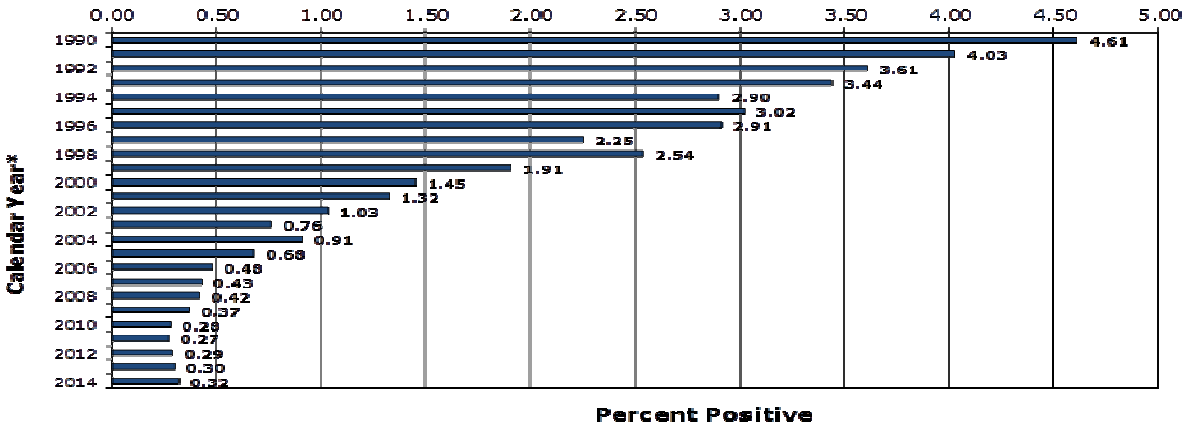

Figure 3. FSIS results of routine regulatory testing of finished RTE meat and poultry products analyzed for Lm (1990-2014). Approximately 4,000-10,000 samples taken annually. Adopted from Engeljohn, 2015, The FSIS approach to *Listeria,* slide 11.

Considering the consistent decline of *Lm* prevalence in FSIS-regulated products (as shown if Figure 3), it is safe to argue that FSIS is slowly but surely edging closer to the U.S. Department of Health and Human Services (USDHHS) target of 0.2 case per 100,000 population by 2020 (USDHHS, 2016).

Summary

This literature review examined the current knowledge of compliance with the FSIS's *Listeria* rule, based upon pathogen testing, establishment size, RTE product type, alternative used, and FSIS district(s) from 2012 through 2015. The review identified a gap in the literature regarding the compliance mechanisms, and motives of FSIS-regulated establishments producing RTE meat and poultry products. The main sections of the chapter were: a) the theoretical base of the study, (b) the *Lm* pathogen, (c) human listeriosis, and (d) the FSIS's regulatory initiative to control and prevent *Lm*. Multiple logistic regression was used to test the deterrence theory and determine whether establishment size, product type, the *Listeria* alternative FIEs use, and the FSIS district(s) of the FIEs can predict regulatory compliance or noncompliance with the *Listeria* rule. The research method will be covered in detail in the next chapter.

Chapter 3: Research Method

Introduction

Human listeriosis (a foodborne illness) and its causative agent, *Lm*, constitute a national public health concern in the United States. In an effort to bend the curve of this foodborne illness, the FSIS implemented the *Listeria* rule in 2003, mandating that all FIEs producing RTE meat and poultry products choose among one of the three *Listeria* alternatives in order to prevent the contamination of their products with *Lm.* Since FSIS has a zero-tolerance policy regarding the detection of *Lm* in RTE foods, it considers an *Lm*-contaminated product to be adulterated and therefore subject to recall if it has already entered commerce.

Several researchers have examined the history, characteristics, taxonomy, and detection of *Lm* in RTE foods (Adzitey, & Huda, 2010; Amenu, 2013; Gandhi & Chikindas, 2007; Gibbons, 1972; Graves et al., 2007; Jadhav et al., 2012; Lomonaco et al., 2015; Lucy et al., 2014) as well as the epidemiology, pathogenicity, treatment, and outbreaks of human listeriosis (Cartwright et al., 2013; Disson & Lecuit, 2012; Donovan, 2015; Gaul et al., 2013; Gottlieb et al., 2006). Nevertheless, no empirical research has been conducted exploring whether predictor variables such as the establishment size, the RTE product type, the *Listeria* alternative used by the FIEs, and the FSIS district where the RTE products were produced, had any association with the FIEs' compliance with the *Listeria* rule. Therefore, the purpose of this quantitative, nonexperimental, cross-sectional study was to examine the significance, if any, of the statistical relationship between establishment size, RTE product type, *Listeria* alternative used, FSIS district (IVs) and

compliance with the *Listeria* rule (DV) for FSIS's FIEs in the 50 U.S. states as well as the U.S. territories between 2012 and 2015. In the remainder of the chapter, I describe the study's design and rationale including the variables, the data collection and analysis procedures, the ethical protections. I conclude with a summary of the key points.

Research Design and Rationale

To identify a causal association or correlation between two or more phenomena (variables), social scientists observe the phenomena and interpret their observation. Said in a more specific way, the primary goals of social research and social policy are threefold: (a) to explore social phenomena, (b) to describe social phenomena, and (c) to explain social phenomena (Babbie, 2011). To explore, describe, or explain social phenomena, Creswell (2009) and Engel and Schutt (2013) postulated that researchers use numbers (quantitative research), actual text/words (qualitative research) but not numbers, counts or other quantities, or both numbers and text (mixed-method research). In any case, social scientists need a research design or a plan to describe what, why, and how they are going to collect, analyze, and interpret the data (Babbie, 2011).

When the purposes of their empirical studies are explanation, description, or evaluation, researchers use a quantitative study design, which might be experimental, quasi-experimental, or cross-sectional (Babbie, 2011; Engel & Schutt, 2013; Frankfort-Nachmias & Nachmias, 2008; Trochim & Donnelly, 2008). However, when they intend to explore and explain the lived experiences of the participants, a qualitative design is more suitable (Creswell, 2009). In this chapter, I focus on quantitative design and the rationale behind my choice of that design.

Cross-sectional studies (including correlation studies) are among the most widely used quantitative studies which and "allow researchers to carry out studies in natural, real-life settings using probability samples, thus increasing the external validity of their studies" (Frankfort-Nachmias & Nachmias, 2008, p. 133). Cross-sectional studies enable them to describe "the pattern of relations between variables" (Frankfort-Nachmias & Nachmias, 2008, p. 116). Social scientists use correlation to determine whether a causal relationship exists between two variables; hence the concept of nomothetic causal explanation (Babbie, 2011; Engel & Schutt, 2013; Frankfort-Nachmias & Nachmias, 2008). Engel and Schutt (2013) posited that nomothetic causality implies that changes in the predictor variable (IV) would be followed by changes in the outcome variable (DV), *ceteris paribus* (other things being equal). However, it is important to note that a variation of the IV with the DV does not necessarily mean that a cause-and-effect relationship exists between the two variables; in other word, the change in the IV is not necessarily caused by the change in the DV (Babbie, 2011; Frankfort-Nachmias & Nachmias, 2008). Therefore, for researchers to show nomothetic causality and establish a logical model of proof, Babbie (2011) argued that they must (a) demonstrate an empirical association between the variables (covariation), (b) eliminate spurious relations between the variables (in other words, ensure that a third variable does not account for the effect on both the IV and the DV under analysis, and (c) establish a time order of occurrence, which is tantamount to showing that "the assumed cause occurs first or changes prior to the assumed effect" (Frankfort-Nachmias & Nachmias, 2008, p. 93). Once those three conditions are met, then researchers might draw causal inferences about the variables of

interest. The major disadvantages of cross-sectional studies are (a) the researchers' inability to prevent nonspuriousness, which makes it difficult for them to make unequivocal inferences; and (b) the need for researchers to logically or theoretically infer the relations between the variables due to their inability to manipulate the IV (Frankfort-Nachmias & Nachmias, 2008).

For this study, I used a quantitative cross-sectional research design with four IVs (establishment size, RTE product type, *Listeria* alternative used, and FSIS district where the RTE product was produced), and one DV (compliance with the *Listeria* rule). The main purpose of the study was to investigate how the IVs, both singly or in combination, were statistically related to the FIEs' compliance with the *Listeria* rule. Figure 4 shows the hypothesized relationship between the four IVs and the dependent variable.

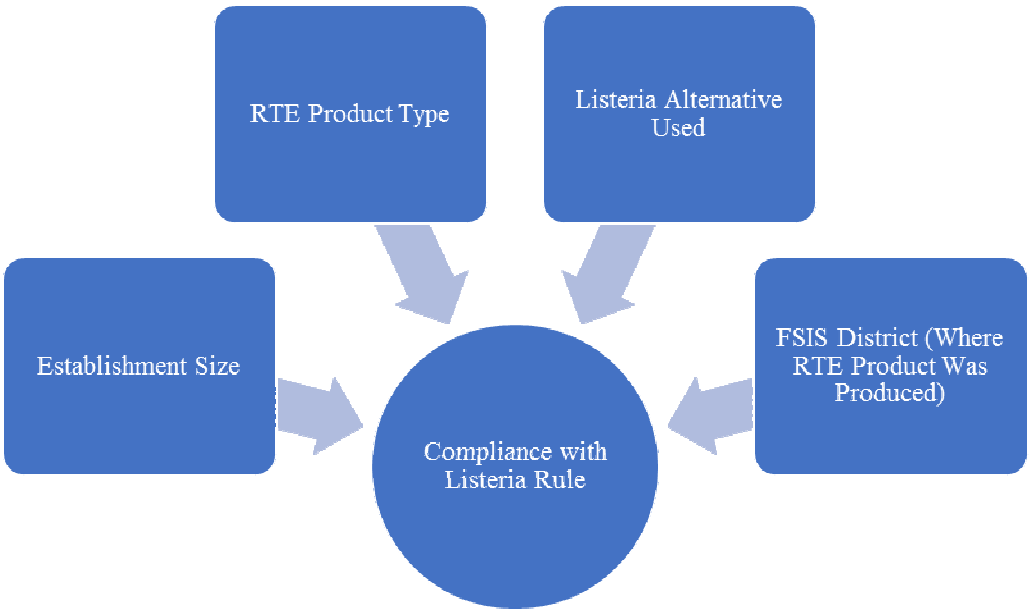

Figure 4. Model of hypothesized association between the four predictor variables and the outcome variable.

- The dependent variable, (regulatory) *compliance* was be operationally defined as obedience/conformance by a target FIE with regulatory rules (the *Listeria* rule) through an Lm-negative RTE product sample. The independent variables were operationally defined as follows: *Establishment size* refers to the three categories of establishment (plant) below:
- *Large establishments* are plants with 500 or more employees;
- S*mall establishments* have 10 or more employees, but fewer than 500
- *Very small establishments* have fewer than 10 employees or annual sales of less than $2.5 million.
- *Alternative*: A method of control for *Lm* adopted by an establishment to meet the requirements of the *Listeria* rule.
- *Alternative 1 (Alt. 1)*: Requires the use of a post-lethality treatment (PLT) that reduces or eliminates microorganisms on the product and an antimicrobial agent that suppresses or limits *Lm* growth.
- *Alternative 2*; *Choice 1 (Alt. 2a)*: Requires the use of a post-lethality treatment (PLT) that reduces or eliminates microorganisms on the product.
- *Alternative 2*; *Choice 2 (Alt. 2b)*: Requires the use of an antimicrobial agent or process that suppresses or limits *Lm* growth.
- *Alternative 3 (Atl. 3)*: Requires the use of sanitation measures only.
- *Ready-to-eat (RTE) Product Types:* An RTE product is a meat or poultry product that is edible and needing no additional preparation to achieve food safety. RTE

products are products that may be contaminated with *Lm* after the lethality treatment due to their exposure to the environments (post-lethality exposed products or PLEs). The different RTE product types are:

- *RTE fully-cooked meat and poultry-PLE*: Other fully cooked sliced products; hot dog products; salad/spread/pate products; RTE products with meat + nonmeat components; sausage products; patties/nuggets products; and other fully cooked not sliced RTE products.
- *RTE acidified/fermented meat and poultry without cooking-PLE*: RTE fermented meat and poultry (sliced or not sliced); acidified/fermented meat/poultry products.
- *RTE dried meat and poultry*-PLE: RTE dried meat and poultry (sliced or not sliced).
- *RTE salt-cured meat and poultry-PLE*: RTE salt cured meat and poultry (sliced or not sliced) (FSIS, 2016).
- *FSIS District*: One of the 10 districts that fulfill FSIS's mission in the 50 U.S. states and territories. The FSIS districts are:
- *District 05* (Alameda, CA District) which covers the states of Arizona, California, and Nevada
- *District 85* (Atlanta, GA District) which covers the states of Florida, Georgia, Puerto Rico, South Carolina, and Virgin Islands
- *District 50* (Chicago, IL District) which covers the states of Illinois, Indiana, Michigan, and Ohio

- *District 40* (Dallas, TX District) which covers the states of Louisiana, New Mexico, Oklahoma, and Texas
- *District 15* (Denver, CO District) which covers the states of Alaska, American Samoa, Colorado, Guam, Hawaii, Idaho, Northern Mariana Islands, Montana, Nebraska, Oregon, Utah, Washington, Wyoming
- *District 25* (Des Moines, IA District) which covers the states of Iowa, Minnesota, North Dakota, South Dakota, and Wisconsin
- *District 90* (Jackson, MS District) which covers the states of Alabama, Kentucky, Mississippi, and Tennessee
- *District 60* (Philadelphia, PA District) which covers the states of Connecticut, Massachusetts, Maine, New Hampshire, New York, Pennsylvania, Rhode Island, and Vermont
- *District 80* (Raleigh, NC District) which covers the states of Delaware, District of Columbia, Maryland, North Carolina, New Jersey, Virginia, and West Virginia
- *District 35* (Springdale, AR District) which covers the states of Arkansas, Kansas, ad Missouri (FSIS, 2016c).

Methodology

Population and Sample

The target population for the study was all large, small, and very small FIEs located in the 50 U.S. states and territories, and producing RTE PLE meat and poultry products under the regulatory oversight of the FSIS between 2012 and 2015. Only FIEs that produced RTE PLE meat and poultry products that were commercialized in the

United States were included in the study. Excluded from the study were establishments that import RTE PLE products and retail institutions that packaged RTE PLE meat and poultry products.

I set the level of significance or alpha at 0.05, and the statistical power at 95%. The statistical power was calculated using the G*Power 3.1 software, with a medium effect size of 0.15. G*Power 3.1 is a stand-alone power analysis software that is widely used by social, behavioral, and bio-medical scientists; it enables them to calculate the statistical power of correlation studies, linear regression studies, logistic regression studies, etc. (Faul, Erdfelder, Buchner, & Lang, 2009).

According to VanVoorhis and Morgan (2007), quantitative studies are often underpowered, meaning that the 0.05 significance level is not met. Simply said, researchers cannot be confident that their results are not due to chance. Therefore, having a well-powered study prevents researchers from committing a Type I error (when the data lead to the rejection of a true null hypothesis) and a Type II error (when the data lead to a failure to reject a false null hypothesis). To increase the power of their studies, Bakker, Hartgerink, Wicherts, and van der Mass (2016) advised scientists against using their intuition because "poor intuitions about power may lead to incorrect inferences concerning nonsignificant results" (p. 1075). As noted earlier, control of statistical power helps ensure the nonspuriousness of the variables, while having a representative sample size increases the generalizability level of a study's findings.

Using Maxwell's (2000) calculations, I determined that the sample size I needed with four predictors and a significance level of .05, was 311. However, as VanVoorhis

and Morgan (2007) noted, to enhance the power of their studies, researchers may increase the sample size because larger samples are more representative of the attributes of the population from which they are drawn. Therefore, I decide to use the entire data set population with a sample size 4,732 RTE meat and poultry products in order to raise the generalizability level of my study.

Data Collection

To secure the archival (secondary) *Lm* sampling data that included the FIEs, size, the RTE product type, the *Listeria* alternative that FIEs used, and the FSIS districts where the RTE products were produced between 2012 and 2015, I submitted a Freedom of Information Act (FOIA) request, via email, to the FSIS's FOIA office (see Appendix E) and waited for an employee from the FSIS's FOIA office to respond stating that the data were available and could be released to the public. After confirming that the data I needed were available and accessible, I felt confident that I could proceed with the study. However, before collecting the data, I sought and obtained Walden University's Internal Review Board (IRB) approval on February 22, 2017 (IRB approval # 02-22-17-0248641). I received the data from FSIS, which included the information related to the DV and IVs.

Data Analysis Plan

IBM's Statistical Package for the Social Science (SPSS) software was used to analyze the data and address the following research questions:

Research Question 1: Is there a statistically significant relationship between establishment size and compliance with the *Listeria* Rule?

$H_0$1: There is no statistically significant relationship between establishment size and compliance with the *Listeria* Rule.

H_a1: There is a statistically significant relationship between establishment size and compliance with the *Listeria* Rule.

Research Question 2: Is there a statistically significant relationship between RTE product type and compliance with the *Listeria* Rule?

$H_0$2: There is no statistically significant relationship between RTE product type and compliance with the *Listeria* Rule.

H_a2: There is a statistically significant relationship between RTE product type and compliance with the *Listeria* Rule.

Research Question 3: Is there a statistically significant relationship between the *Listeria* alternative used and compliance with the *Listeria* Rule?

$H_0$3: There is no statistically significant relationship between the *Listeria* alternative used and compliance with the *Listeria* Rule.

H_a3: There is a statistically significant relationship between the *Listeria* alternative used and compliance with the *Listeria* Rule.

Research Question 4: Is there a statistically significant relationship between the FSIS district and compliance with the *Listeria* Rule?

$H_0$4: There is no statistically significant relationship between the FSIS district and compliance with the *Listeria* Rule.

H_a4: There is a statistically significant relationship between FSIS district and compliance with the *Listeria* Rule.

To investigate the statistical relationship between the categorical DV (compliance) and individual predictor IVs (establishment size, RTE product type, alternative used, and FSIS district), I used a chi-square statistic test. According to Burns and Burns (2012), a chi-square test serves two purposes: (a) as a goodness-of-fitness test which describes how well an observed distribution fits a hypothesize or theoretical distribution, and (b) as a cross-tabulation between two categories, where each category can be divided into two or more sub-categories. In any case, the general principle of chi-square, regardless of the use of its use, remains unchanged (Burns & Burns, 2012, p. 325):

> One compares the observed frequencies in a sample with the expected (chance) frequencies and applies the chi square test to determine whether a difference between observed and expected frequencies is likely to be a function of sampling error (non-significant–retaining the null hypothesis H0) or unlikely to be a function of sampling error (significant association – reject the null hypothesis and support alternative hypothesis – H1).

In this study, I used cross-tabulation to investigate whether the predictor variables will be significantly related to the dependent variable at the .05 level of significance. To interpret the calculate chi square, Burns and Burns (2012) stated that SPSS uses degrees of freedom (df) which, in a goodness-of-fit test is equal to one less than the number of categories. A Pearson Chi Square (χ^2) with a value of less than -05 indicated a significant relationship between the IV and the DV (Field, 2013).

A multiple logistic regression test was run to determine whether a correlation existed between the RTE product type and the outcome variable (compliance with the *Listeria* rule) after controlling for the effects of the other three variables (establishment size, *Listeria* alternative used, and FSIS district where the RTE product was produced) with non-significant chi square results. According to Green and Salkind (2011) and Laureate Education (2009), a multiple logistic regression test is to be used when both the DV and the IVs are quantitative, especially when the DV is a dichotomous continuous variable. The DV in this study (compliance with the *Listeria* rule) was a dichotomous (binary) variable that was either a positive sample test (noncompliance) or a negative sample test (compliance). The reference categories for the regression will be (a) small FIEs for the establishment size predictor variable; (b) RTE fully-cooked meat and poultry for the RTE product type predictor variable; (c) alternative 1 for the alternative used predictor variable, and (d) District 05 for the FSIS district predictor variable.

As a robust, flexible, easy-to-use, and widely utilized statistical test (Trochim & Donnelly, 2008), logistic regression allows for a meaningful interpretation and tries to "find the best fitting and most parsimonious model to describe the relationship between the outcome (dependent or response variable) and a set of independent (predictor or explanatory) variables" (Pohar, Blas, & Turk, 2004, p. 144). In summary, a chi-square test was to investigate the statistical relationship between the individual predictor variables and the DV, while a multiple logistic regression test was run to determine the statistical relationship between all four predictor variables and the DV.

Threats to Validity

Role of the Researcher

As the only researcher for this study, it was my responsibility to collect and analyze the data and interpret the results. My professional role as an enforcement, investigation, and analysis officer (EIAO) working for FSIS, might involve potential bias and conflict of interest. Part of my professional duties is to collect R*Lm* samples and conduct food safety assessments in FIEs on a regular basis. To minimize bias, I bracketed my personal views before conducting the study. Furthermore, as an FSIS employee working with FSIS data, I might be inclined to *overdo* it for professional advancement purposes or to settle some scores that I might have regarding the implementation of the rule. I was not compensated or promised professional advancement to conduct this study. Therefore, I did not conduct this inquiry for any personal gain whatsoever. To prevent that type of conflict of interest, I only focused on the facts and what the data showed. I also refrained from injecting any of my personal preferences by solely providing an objective, impartial, and unbiased assessment of the data without any ulterior motive whatsoever. To address the potential conflict of interest associated with this research study, I consulted with a USDA/FSIS senior ethics program advisor to ensure that my dissertation involved no conflict of interest or other ethical issues (see Appendix F).

Ethical Protection

FSIS provided me with the data in an Excel spreadsheet that included the establishment IDs, the establishment numbers, the establishment names, the district numbers, the states where the establishments were located, the physical address of the

establishments, the size of the establishments, the FSIS circuit of the establishment, the formal IDs of the establishments, the sample collection dates, the year the samples were collected, the samples sources, the project codes, the project names, the RTE product names, the test codes, the test names, the test results, and the *Listeria* alternatives used. Only the establishments' size, the RTE product types, the alternative used, and the FSIS district where the products were produced were included in the statistical tests. All other data (including identifiers) were removed and destroyed. I also requested and obtained permission and approval from Walden University's Internal Review Board (approval number 02-22-17-0248641) to collect and analyze the data before I began any data collection. I stored the received data securely and kept an electronic copy in a password-protected computer. I will destroy all the data five years after completion of the study. Regarding the data itself, I assumed that they were valid and reliable because FSIS is a federal agency that reports to Congress, every year, and all its laboratories are certified. Therefore, I also conjectured that the data were accurate and properly coded.

Summary

In this chapter, I described the research methods for a quantitative, nonexperimental, cross-sectional study whose intent was to investigate how the IVs (establishment size, RTE product type, *Listeria* alternative used, FSIS district of production), singly or in combination, were statistically related to the DV (compliance with the FSIS's *Listeria* rule) between 2012 and 2015. Archival data from FSIS's sampling data were obtained and analyzed using a chi-square test and multiple logistic regression. Moreover, the chapter also presented a description of the research design and

rationale, including a statement of the independent and dependent variables. Lastly, the chapter described the study population, sampling procedure and sample size, data collection procedure, statistical tests and data analysis plan, threats to validity, and ethical procedures. In chapter 4, I will present the result of the study.

Chapter 4: Results

Introduction

The purpose of this study was to investigate how the IVs, both singly or in combination, were statistically related to the FIEs' compliance with the *Listeria* rule. The IVs were: (a) HACCP Processing Size = Establishment size (IV1), (b) Product Name = RTE Product Type (IV2), (c) Alternative = *Listeria* alternative (IV3), and (d) District Number = FSIS District (IV4). The DV was Test Result, which could be positive (indicating noncompliance with the rule) or negative (indicating compliance with the rule). This chapter includes a summary of the statistical analysis I used to test the following four null hypotheses:

$H_0$1: There is no statistically significant relationship between establishment size and compliance with the *Listeria* rule.

$H_0$2: There is no statistically significant relationship between RTE product type and compliance with the *Listeria* rule.

$H_0$3: There is no statistically significant relationship between the *Listeria* alternative used and compliance with the Listeria rule.

$H_0$4: There is no statistically significant relationship between the FSIS district and compliance with the *Listeria* rule.

I have used tables to present the results of each research question and hypothesis in the study. In addition, I also ran both statistical tests (chi-square and logistic regression) and performed all data computations using IBM's SPSS version 21. Moreover, all statistical tests were based upon a 0.05 level of significance ($p < .05$) and a

statistical power of 95%. This chapter includes discussions of the data collection method that I used, along with descriptions of the study sample and data analysis for each research question/hypothesis, bivariate analysis, and logistic regression. The chapter ends with a summary of findings and hypotheses.

Data Collection

I received IRB approval to collect secondary data on February 22, 2017. (Walden University IRB approval number 02-22-17-0248641). To collect the archival data, I submitted a FOIA request to the FSIS's FOIA office for *Lm* sampling data collected between 2012 and 2015, and I specifically requested the inclusion of the establishment size, the type of RTE product sampled, the *Listeria* alternative used by the FIEs, and the FSIS districts where the product was produced during that specific point in time. The FSIS's FOIA office sent me the data in an Excel spreadsheet that included the requested information along with FIE identifiers such as establishment ID, establishment numbers, establishment names, physical addresses, the FSIS circuits (subdivisions of districts), establishment formal IDs, and the FSIS project code and project name. All identifiers were removed during data processing.

I then reviewed and crosschecked the final Excel spreadsheet against the original spreadsheet to ensure data integrity. After that, I checked the final spreadsheet for mistakes, coding errors, missing data, and duplication. After consolidating and making the necessary changes to the raw data, I imported the final Excel spreadsheet into SPSS version 21 and then ran the chi-square tests and multiple logistic regression test.

Results of the Study

Descriptive Statistics

I calculated descriptive statistics for all variables using frequencies and percentages. To investigate the statistical relationship between the DV (compliance) and the individual predictor or IVs (establishment size, RTE product type, alternative used, and FSIS district), I used chi-square tests of association. In addition, a multiple logistic regression model was tested to assess the predictors of compliance with the *Listeria* rule.

The findings in Table 4 show that only .8% of the sample (n = 38) was positive for *Listeria*. More than half of the samples were from small establishments (51.4%, n = 2434). A majority of the products consisted of fully-cooked meat and poultry (85.9%, n = 4066). More than half of the sample used *Listeria* treatment Alternative 3 (55.9%, n = 2647). The products were from several districts (see Table 4).

Table 1

Frequencies and Percentages for the Study Variables (N = 4732)

Variables	*n*	%
Test results		
Negative	4694	99.2
Positive	38	.8
Establishment size		
Very small	1865	39.4
Small	2434	51.4
Large	433	9.2
RTE product type		
Fully-cooked meat and poultry	4066	85.9
Acidified/fermented meat and poultry without cooking	227	4.8
Dried meat and poultry	393	8.3
Salt-cured meat and poultry	46	1.0
Listeria alternatives		
Alternative 1	189	4.0
Alternative 2a	131	2.8
Alternative 2b	1765	37.3
Alternative 3	2647	55.9
FSIS district		
Alameda, CA	438	9.3
Denver, CO	530	11.2
Des Moines, IA	672	14.2

Variables	*n*	%
Springdale, AR	289	6.1
Dallas, TX	514	10.9
Chicago, IL	536	11.3
Philadelphia, PA	712	15.0
Raleigh, NC	551	11.6
Atlanta, GA	233	4.9
Jackson, MS	257	5.4

First Hypothesis

Research Question 1 was: Is there a statistically significant relationship between establishment size and compliance with the *Listeria* rule? I hypothesized that there would be a statistically significant relationship between establishment size and compliance with the *Listeria* rule. The findings in Table 5 show that establishment size was not significantly related to compliance with the *Listeria* rule, $\chi^2(2, N = 4732) = 2.46, p = .293$. As such, I accepted the first null hypothesis.

Table 2

Cross-Tabulation Results for Establishment Size and Listeria Rule Compliance

	Negative	Positive
Size	*n* (%)	*n* (%)
Very small	1851 (99.2)	14 (0.8)
Small	2411 (99.1)	23 (0.9)
Large	432 (99.8)	1 (0.2)

Note. Percentages reported above are within establishment size. *Listeria* rule compliance did not differ across establishment size, $\chi^2(2, N = 4732) = 2.46$, $p = .293$.

Second Hypothesis

Research Question 2 was: Is there a statistically significant relationship between RTE product type and compliance with the *Listeria* rule? I hypothesized that there would be a statistically significant relationship between RTE product type and compliance with the *Listeria* rule. The findings in Table 6 show that RTE product type was significantly related to compliance with the *Listeria* rule, $\chi^2(3, N = 4732) = 22.85$, $p < .001$. To determine which comparisons were contributing to the significant difference, I conducted six post-hoc procedures; alpha was accordingly adjusted to .008 (i.e., .05/6). Post-hoc cross-tabulations showed that the percentage of having a positive result was higher for salt-cured foods (91.4%, $n = 32$) than for fully-cooked foods (98.9%, $n = 4034$), $\chi^2(1, N = 4732) = 17.73$, $p < .001$. These findings indicate that my second hypothesis was supported.

Table 3

Cross-Tabulation Results for RTE Product Type and Listeria Rule Compliance

RTE Product Type	Negative *n* (%)	Positive *n* (%)
Fully-cooked meat and poultry	4034 (99.2)	32 (0.8)
Acidified/fermented meat and poultry without cooking	224 (98.7)	3 (1.3)
Dried meat and poultry	393 (100.0)	0 (0.0)
Salt-cured meat and poultry	43 (93.5)	3 (6.5)

Note. Percentages reported above are within product type. *Listeria* rule compliance differed significantly across product types, $\chi^2(3, N = 4732) = 22.85, p < .001$.

Third Hypothesis

Research Question 3 was: Is there a statistically significant relationship between the *Listeria* alternative used and compliance with the *Listeria* rule? I hypothesized that there would be a statistically significant relationship between *Listeria* alternative used and compliance with the *Listeria* rule. The findings in Table 7 indicate that *Listeria* alternative used was not significantly related to compliance with the *Listeria* rule, $\chi^2(3, N = 4732) = 4.68, p = .197$. Therefore, I accepted the third null hypothesis.

Table 4

Cross-Tabulation Results for Listeria Alternative Used and Listeria Rule Compliance

	Negative	Positive
Alternative	*n* (%)	*n* (%)
Alternative 1	187 (98.9)	2 (1.1)
Alternative 2a	131 (100.0)	0 (0.0)
Alternative 2b	1756 (99.5)	9 (0.5)
Alternative 3	2620 (99.0)	27 (1.0)

Note. Percentages reported above are within establishment size. *Listeria* rule compliance did not differ across *Listeria* alternative used, $\chi^2(3, N = 4732) = 4.68, p = .197$.

Fourth Hypothesis

Research Question 4 was: Is there a statistically significant relationship between the FSIS district and compliance with the *Listeria* rule? I hypothesized that there would be a statistically significant relationship between FSIS district and compliance with the *Listeria* rule. The findings in Table 8 show that FSIS district was not significantly related to compliance with the *Listeria* rule, $\chi^2(9, N = 4732) = 7.84, p = .550$. Thus, the fourth null hypothesis was not supported.

Table 5

Cross-Tabulation Results for FSIS District and Listeria Rule Compliance

District	Negative *n* (%)	Positive *n* (%)
Alameda, CA (District 05)	436 (99.5)	2 (0.5)
Denver, CO (District 15)	526 (99.2)	4 (0.8)
Des Moines, IA (District 25)	666 (99.1)	6 (0.9)
Springdale, AR (District 35)	289 (100.0)	0 (0.0)
Dallas, TX (District 40)	510 (99.2)	4 (0.8)
Chicago, IL (District 50)	534 (99.6)	2 (0.4)
Philadelphia, PA (District 60)	704 (98.9)	8 (1.1)
Raleigh, NC (District 80)	546 (99.1)	5 (0.9)
Atlanta, GA (District 85)	230 (98.7)	3 (1.3)
Jackson, MS (District 90)	253 (98.4)	4 (1.6)

Note. Percentages reported above are within establishment size. *Listeria* rule compliance did not differ across FSIS districts, $\chi^2(9, N = 4732) = 7.84$, $p = .550$.

Predictors of Compliance with the *Listeria* Rule

I conducted a logistic regression procedure to determine which among the four IVs would significantly predict compliance with the *Listeria* rule, after controlling for the effects of the other three variables. The first regression procedure did not yield a final solution. The results were examined to determine which variables were problematic. As expected, comparisons between the reference categories and categories with zero positive

results yielded very high unstandardized coefficients and standard errors. Therefore, I combined categories with zero positive results with categories that most closely resembled their *Listeria* compliance pattern. Specifically, I collapsed the following categories into a single category:

1. Fully-cooked food (99.2% negative) and dried food (100% negative);
2. Alternative 2a (100% negative) and 2b (99.5% negative);
3. Springdale, AZ (100% negative) and Chicago, IL (99.6% negative).

The findings in Table 9 show that only product type significantly predicted the likelihood of compliance with the *Listeria* rule, *Wald* (2, $N = 4732$) = 11.23, $p = .004$. In comparison to fully-cooked and dried food products, the odds that the results would be *Listeria*-positive for salt-cured products increased by 9.86, 95% CI [2.48, 39.25].

Table 6

Logistic Regression Results for the Listeria Compliance Model (N = 4732)

Predictors	*B*	*SE*	*Wald*	*df*	*OR*	95% CI for *OR* Lower	Upper
Establishment size			3.69	2			
Small vs. very small	-.63	.38	2.74	1	.54	.26	1.12
Small vs. large	-1.18	1.04	1.29	1	.31	.04	2.35
Type of product			11.23	2			
Fully-cooked and dried vs. acidified	.71	.69	1.04	1	2.03	.52	7.91
Fully-cooked and dried vs. salt-cured*	2.29	.71	10.53	1	9.86	2.48	39.25
Listeria alternative			3.59	2			
Alternative 1 vs. alternative 2	-.39	.87	.20	1	.68	.12	3.75
Alternative 1 vs. alternative 3	.39	.85	.21	1	1.48	.28	7.81
FSIS district			7.28	8			
Alameda, CA vs. Denver, CO	.64	.88	.53	1	1.89	.34	10.55
Alameda, CA vs. Des Moines, IA	.60	.84	.52	1	1.83	.35	9.47
Alameda, CA vs. Springdale, AR and Chicago, IL	-.51	1.01	.26	1	.60	.08	4.32
Alameda, CA vs. Dallas, TX	.67	.87	.59	1	1.96	.35	10.85
Alameda, CA vs. Philadelphia, PA	.92	.80	1.31	1	2.50	.52	12.01
Alameda, CA vs. Raleigh, NC	.75	.84	.80	1	2.12	.41	11.07
Alameda, CA vs. Atlanta, GA	.96	.95	1.02	1	2.61	.41	16.84
Alameda, CA vs. Jackson, MS	1.57	.88	3.20	1	4.85	.86	27.05

Note. *OR* = odds ratio. CI = confidence interval. Overall model $\chi^2(14, N = 4732) = 23.98$, $p = .46$.
* $p < .05$. ** $p < .01$.

Summary

I tested the hypotheses using chi-square and a logistic regression model. The results showed that my first null hypothesis, that there is no statistically significant relationship between establishment size and compliance with the *Listeria* rule, could be accepted.

My second null hypothesis, that there is no statistically significant relationship between RTE product type and compliance with the *Listeria* rule, was rejected based on the chi-square analysis. The percentage of having a negative result was higher for fully-

cooked food (98.9%, $n = 4034$) than it was for salt-cured food (91.4%, $n = 32$). In addition, product type emerged as a statistically significant predictor of compliance with the *Listeria* rule in the logistic regression model. In comparison to fully-cooked and dried food products, the odds that the results would be *Listeria*-positive for salt-cured products increased by 9.86, 95% CI [2.48, 39.25].

I accepted my third null hypothesis, that there is no statistically significant relationship between the *Listeria* alternative used and compliance with the *Listeria* rule. I also accepted the fourth null hypothesis, that there is no statistically significant relationship between the FSIS district and compliance with the *Listeria* rule. In Chapter 5, I cover the interpretation of the findings, the limitations of the study, the recommendations for future research, and the implications for positive social change.

Chapter 5: Discussion, Recommendations, and Conclusion

Introduction

The main purpose of this quantitative, nonexperimental, cross-sectional study was to investigate whether the four IVs of establishment size, RTE product type, *Listeria* alternative used, and FSIS district, individually or in combination, were statistically associated with compliance with the *Listeria* rule (dependent variable), in FIEs producing RTE PLE meat and poultry products under the regulatory oversight of FSIS in the 50 states as well as in the U.S. territories, between 2012 and 2015. I formulated four central research questions for this inquiry:

Research Question 1: Is there a statistically significant relationship between establishment size and compliance with the *Listeria* Rule?

Research Question 2: Is there a statistically significant relationship between RTE product type and compliance with the *Listeria* Rule?

Research Question 3: Is there a statistically significant relationship between the *Listeria* alternative used by FIEs and compliance with the *Listeria* Rule?

Research Question 4: Is there a statistically significant relationship between the FSIS district where the RTE products were produced and compliance with the *Listeria* Rule?

To answer the research questions, I used archival RTE meat and poultry sampling data ($n = 4732$) collected by FSIS between 2012 and 2015 from very small, small, and large FIEs ($n = 4732$) that used the three *Listeria* alternatives to produce RTE meat and poultry products in the 10 FSIS districts. Chi-square and multiple logistic regression

analyses were conducted to investigate the statistical relationship between establishment size, RTE product type, *Listeria* alternative used, FSIS district and compliance with the *Listeria* rule. Establishment size*, Listeria* alternative used by FIEs, and FSIS district had no statistically significant relationship with compliance. Only RTE product type was found to be associated with compliance, based on the chi-square tests. In addition, RTE product type was the only significant predictor of compliance with the *Listeria* rule, as shown in the logistic regression model. Moreover, after combining RTE product categories with zero positive results with categories having similar compliance pattern, I found that salt-cured products had a higher percentage of positive results than fully cooked and dried products.

Interpretation of the Findings

Research Question 1

I designed this question to assess for association between establishment size (small, very small, and large) and compliance with the *Listeria* rule. Using a chi-square test, I found no association between the two variables (χ^2 (2, N = 4732) = 2.24, p = .293). Said another way, when it comes to compliance with the *Listeria* rule, plant size does not matter. Previous researchers found that large FIEs had a higher compliance rate compared to small and very small FIEs (Eblen et al., 2006; Naugle et al., 2006; Ollinger et al., 2011). Buckley (2015) and Henson and Heasman (1998), for example, postulated that small plants tended to be reactive to regulation while large plants proactively anticipated all the implications of new regulations and took measures to minimize compliance cost. The equality of compliance rate between small, very small, and large

FIEs may also be due to the effectiveness of (a) the FSIS's regulatory enforcement style (Bardach & Kagan, 2010; Buckley, 2015; May & Winter, 2011); (b) its special attention to small and very small plants through a helpdesk/hotline that answers their questions and concerns; and (c) its outreach activities using the enforcement, investigation, and analysis officers to provide them with food safety materials associated with the type of product they produce, in compliance with the Small Business Regulatory Enforcement Act (FSIS, 2017). My findings, therefore, refute the empirical agreement in the literature that small and very small plants tend to be less compliant with government regulation.

Research Question 2

I designed this question to investigate the statistical relationship between RTE meat and poultry type and compliance with the *Listeria* rule. The null hypothesis was that no statistically significant relationship existed between RTE product type and compliance, while the alternative hypothesis was that there was a statistically significant relationship existed between RTE product type and compliance. The alternative hypothesis was supported because the chi-square test results showed a statistically significant relationship between RTE product type and compliance (χ^2 (3, N = 4732) = 22.85, p = .001). The multiple logistic regression test also showed that, among the four IVs, only product type could predict compliance with the *Listeria* rule (Wald ((2, N = 4732) = 11.23, p = .004). While the overall compliance rate between RTE products was high (98% or above), salt-cured product was more likely to be noncompliant than fully cooked products, and the odds of having an *Lm*-positive salt cured product increased by 9.86, 95% CI [2.48, 39.25]. It is worth noting that salt cured products represented only

1% (46) of the sample while fully cooked products represented 85.9% (4066) of the sample.

Based on the risk assessments conducted on RTE products, I empirically established that fully cooked deli meat and poultry products were more likely to be contaminated with *Lm,* and dose-response models were developed for prevention purposes (FSIS, 2004; NZFSA, 2009; Rocourt et al., 2003; Todd, 2007). Even FSIS developed the *Listeria* rule using the findings of the 2003 quantitative risk assessment it conducted in collaboration with the FDA and the CDC (FSIS, 2004; Todd, 2007). Furthermore, Levine et al. (2011) also found that RTE sliced ham and luncheon meat (fully cooked products) had a higher *Lm* prevalence rate among the nine RTE products they studied. My research findings ran counter to the empirical findings in the literature that fully cooked deli products were more prone to *Lm* contamination. In the same vein, Bouayad and Hamdi (2012) also found that RTE fermented meat products had a higher rate of *Lm* contamination than dairy products, unpacked sliced meat products, and cooked meat dishes. These new contamination rates might call for a review and revision of the FSIS's policy of *Lm* contamination in RTE products since fully cooked deli products no longer seem to be the riskiest products.

Research Question 3

With this question, I focused on the correlation between the *Listeria* alternative used (there are three alternatives) and compliance with the *Listeria* rule. I hypothesized that a statistically significant relationship would exist between *Listeria* alternative and compliance with the *Listeria* rule. Based on the chi-square test results, no correlation

existed between compliance and *Listeria* alternative (χ^2 (3, N = 4732) = 4.68, p = .197). These findings contradicted the FSIS's policy that RTE products produced under Alternative 3 were more likely to be contaminated with *Lm* than those produced under Alternative 1 or 2, resulting in a more frequent verification sampling of Alternative 3 products by FSIS (FSIS, 2014a). Even though Alternatives 1 and 2 appeared to include more preventive and control measures (PLT, AMAP), this study's findings failed to support the belief that they were more effective in preventing *Lm* contamination in RTE products. Therefore, I determined that a new approach is needed regarding the effectiveness and efficacy of the *Listeria* alternatives with respect to the prevention of *Lm* contamination in FSIS-regulated products.

Research Question 4

I designed this research question to investigate whether a statistically significant relationship existed between the FSIS district where the RTE product was produced and compliance with the *Listeria* rule. While I hypothesized that a correlation would exist between FSIS district and compliance, the chi-square analyses revealed no correlation between those two variables (χ^2 (9, N = 4732) = 7.84, p = .550). These results were not consistent with those of Mamber et al. (2015) and Bennion et al. (2008) who found that the western region (Alameda, CA, District 05) had the highest fatality rate due to human listeriosis as well as the highest *Lm*-contaminated RTE products. The current findings show a similar compliance rate among the 10 FSIS districts that may be due to a uniform enforcement of the *Listeria* rule across districts.

With an average compliance rate of 98% across FIEs and RTE product types, the findings confirmed the deterrence theory (Gray, 2010; Paternoster, 2010). Said differently, when punishment is certain, severe, and swift, FIEs complied with the *Listeria* rule by producing *Lm*-free RTE products. The results were consonant with Straub's (2011) findings showing that investment by management in information technology security deterred computer abuse by employees and resulted in its decline. In the same vein, Maxwell (2000) also tested the deterrence theory and found that certainty, severity, and celerity of punishment among offenders on probation led to a decrease in probation violation. Nevertheless, it would be presumptuous to believe that FSIS's effective deterrence strategy is the only justification of the low noncompliance rate.

As Parker and Nielsen (2011) and Sutinen and Kuperan (1999) argued, it might be necessary to factor in the motives behind the high compliance rates such as (a) economic motives or the tendency to maximize utility, (b) social motives or the efforts by FIE owners and/or operators to be perceived as upstanding members of society, and (c) normative motives or the moral obligation to comply with the *Listeria* rule (Parker & Nielsen, 2011). FIEs' owners and operators would do their utmost to comply because they found their self-interest (utility) in it through the avoidance of recalls, the prevention of lawsuits by consumers of *Lm*-contaminated products, and exponential legal fees, the preservation of their firms' reputation and competitive edge, and so on.

Limitations of the Study

The limitations of this study abound. While the sample size (n = 4732) was large enough and allowed for generalization to all small, very small and large FIEs located in

the United States and U.S. territories, I used secondary data collected by FSIS to validate its own conception of compliance. Furthermore, the methodology used (cross-sectional/correlation study) does not necessarily establish a nomothetic causality between the IVs and the DV (Babbie, 2011; Engel & Schutt, 2013; Frankfort-Nachmias & Nachmias, 2008; Hill & Lewicki, 2006). Therefore, only an association (or lack thereof) between variables could be inferred.

Another limitation of the study was the use of Risk-based *Listeria monocytogenes* (R*Lm*) sampling data. Before conducting R*Lm* sampling, the FSIS's enforcement, investigation, and analysis officers (EIAOs) are required to notify the inspector at the FIE, within six weeks before the month scheduled for sampling (FSIS, 2013c) and the inspector, in turn, notify the plant management of the date of sampling, providing them ample time to take sanitation and precautionary measures before sampling occurs. Therefore, the sanitary conditions during R*Lm* sampling may not reflect the routine and customary day-to-day conditions at the FIE.

Recommendations

To date, very few empirical studies have been conducted about FIE compliance with the *Listeria* rule. FSIS collects sampling data to interpret for its own needs. Based on the data collection and results of the study, a few recommendations can be made:

- FSIS's regulatory enforcement style should be examined in order to assess its impact of compliance with the *Listeria* rule. Bardach and Kagan (2010) stated that a "good inspector" (p. 123) should have three important traits: (a) responsiveness or being fair and providing reasons for enforcement actions taken, (b) forbearance

or overlooking non-serious violations, and (c) provider of information that helps FIEs comply. Since the same regulatory enforcement approach is used for both raw and RTE products, a comparison of the compliance rates between RTE products and raw products in relation to their respective pathogen of concern, could shed some light of the effectiveness and efficacy of the FSIS's regulatory enforcement style.

- Because salt-cured products have a higher *Lm* contamination percentage than fully cooked and dried products, future microbial risk assessments should examine FIE practices in producing salt-cured products to determine whether the food safety metrics such as salt amount/concentration, water activity, and pH level, were being followed. Future research may also assess how homemakers prepare salt-cured products, along with their food safety knowledge and practices.
- Future studies should investigate the prevalence of *Lm* in imported RTE meat and poultry and compare it to the *Lm* prevalence in domestically-produced RTE meat products.
- FSIS should refrain from targeting FIEs using Alternative 3 for routine *Lm* sampling and change its policy accordingly, because the findings do not support that practice.
- Future studies should also examine compliance with the rule through the perspective of FIE's owners and operators to fully grasp their conception of and motives for compliance as well as their opinion of the FSIS's regulatory enforcement style.

- While FSIS only regulates 10 to 20% of the U.S. food supply (Johnson, 2016), it goes without saying that the bulk of RTE products (80 to 90%) is regulated by the FDA. Therefore, future studies should look at the *Lm* contamination level of the FDA-regulated products and compare them with the *Lm* contamination level of the FSIS-regulated products for possible replication of FSIS's best practices and for uniformity of regulatory oversight.

Social Change Implications

This research study was designed to gather statistical information related to determinants of compliance with the FSIS's *Listeria* rule. The intent of this inquiry was to determine the relationship between establishment size, RTE product type, *Listeria* alternative used, and FSIS district and compliance with the rule. The importance of this research study was to bring an understanding of this matter to FSIS policymakers and the community at-large.

The findings indicate that salt-cured products were more likely to be contaminated with *Lm* than fully cooked and dried products. Therefore, FSIS policymakers should reach out to FIEs producing salt-cured products in order to educate them about the food safety parameters associated with this type of RTE products. Furthermore, since many salt-cured products are prepared and consumed at home, uninspected (Frame, 2012), FSIS policymakers should also develop an outreach and awareness campaign designed to sensitize the public at large, especially the elderly, pregnant women, and immunocompromised individuals. For example, Pillai and Chakraborty (2017) found that in Asian rural

communities, a significant portion of homemakers knew very little about food adulteration. Education and occupation were also significantly associated with food safety knowledge (Pillai & Chakraborty, 2017). While FSIS only regulates FIEs, it may also collaborate with state health departments and media outlets to heighten awareness among homemakers who use salt-cured products.

This study contributes to the debate about the usefulness of regulations and their impact on businesses in general, and small businesses in particular. The U.S. SBA estimated that, in 2010 alone, complying to regulations cost U.S. businesses a staggering $1.75 trillion, and small businesses were more adversely affected than large businesses (SBA, 2010). While compliance with the *Listeria* rule comes with a cost for small and very small FIEs, more importantly, it has significantly reduced the *Lm* contamination in RTE meat and poultry products. Since 2008, no RTE meat and poultry products have been implicated in an outbreak (CDC, 2017). Therefore, the *Listeria* rule is serving the greater good by protecting public health and reducing morbidity and mortality associated with human listeriosis in the United States. Thanks to the effectiveness of the rule, as demonstrated by this study's findings, FSIS is edging closer to the *Healthy People 2020*'s target of 0.2 case per 100,000.

This study has also public policy implications because it refutes the belief that (a) small and very small FIEs, (b) RTE deli meat and poultry products, and (c) FIEs using Alternative3 were more likely to be noncompliant with the *Listeria* rule. The findings indicate need for a review and revision of policies directing

more resources (sampling) towards FIEs producing RTE deli meat/poultry products or FIEs using Alt.3. If fewer *Lm* samples are collected from deli meat and poultry products and FIEs using Alt. 3, then FSIS could direct more resources to other areas of enforcement.

Finally, according to the USDA's Economic Research Service (ERS), with a cost of $1.7 million per case, *Listeria* is the third most costly foodborne pathogen in the United States (ERS, 2014). By providing data on the prevalence of *Lm* in FSIS-regulated RTE products, the overall social change implication of this study is the reduction of morbidity and mortality associated with Lm-contamination in FSIS-regulated products. Moreover, while the R*Lm* sampling data analyzed in this study showed a noncompliance rate of approximately 2%, in 2014, the noncompliance rate of routine regulatory testing of finished RTE products was 0.32% (Engeljohn, 2015). Therefore, this study provides the data that allows for a comparison of compliance associated with R*Lm* sampling and routine *Lm* sampling.

Conclusion

The purpose of this quantitative, nonexperimental, cross-sectional study was to investigate the association between establishment size, product type, *Listeria* alternative used, FSIS district (IVs) and compliance with the *Listeria* rule (DV) for FIEs producing RTE PLE meat and poultry products, under the regulatory oversight of FSIS, in the 50 states as well as in the U.S. territories, between 2012 and 2015. Using secondary *Lm* sampling data collected by FSIS,

chi square and multiple logistic regression tests were run to determine the association between the IVs and the DV. While no correlation was found between compliance and establishment size, alternative used and FSIS district, a significant statistical relationship was observed between RTE product type and compliance. Furthermore salt-cured products have a higher *Lm* contamination rate than fully cooked and dried products. The results were not consistent with the findings in the reviewed literature. In addition, this study confirmed deterrence theory and showed that FIE operators and owners complied with regulations when the punishment was certain, severe, and swift and they maximized utility. This study provided FSIS policy-makers with empirical evidence on the implementation of the *Listeria* rule that can be used to modify some aspects of the FSIS policies such as targeting FIEs using Alt.3 for more regulatory sampling than FIEs using Alt. 1 and Alt.2. Designing an education and outreach program that targets vulnerable populations (pregnant women, the elderly and the immunocompromised) may help reduce the morbidity and mortality associated with human listeriosis, especially among the individuals who prepare RTE salt-cured products at home without inspection, and will constitute positive social change.

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Appendix A: 9 CFR 500, FSIS's Rules of Practice

Contents

Authority: 21 U.S.C. 451-470, 601-695; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53.
Source: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

§500.1 Definitions.

(a) A "regulatory control action" is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.
(b) A "withholding action" is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.
(c) A "suspension" is an interruption in the assignment of program employees to all or part of an establishment.

§500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:
(1) Insanitary conditions or practices;
(2) Product adulteration or misbranding;
(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or
(4) Inhumane handling or slaughtering of livestock.
(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.
(c) An establishment may appeal a regulatory control action, as provided in §§306.5 and 381.35 of this chapter.

§500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:
(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;
(2) The establishment does not have a HACCP plan as specified in §417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§416.11-416.12 of this chapter;
(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;
(5) The establishment violated the terms of a regulatory control action;
(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or
(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.
(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§500.4 Withholding action or suspension with prior notification.
FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:
(a) The HACCP system is inadequate, as specified in §417.6 of this chapter, due to multiple or recurring noncompliances;
(b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§416.13 through 416.16 of this chapter;
(c) The establishment has not maintained sanitary conditions as prescribed in §§416.2-416.8 of this chapter due to multiple or recurring noncompliances;
(d) The establishment did not collect and analyze samples for Escherichia coli Biotype I and record results in accordance with §310.25(a) or §381.94(a) of this chapter;
(e) The establishment did not meet the Salmonella performance standard requirements prescribed in §310.25(b) or §381.94(b) of this chapter.

§500.5 Notification, appeals, and actions held in abeyance.
(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:
(1) State the effective date of the action(s),
(2) Describe the reasons for the action(s),
(3) Identify the products or processes affected by the action(s),
(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and
(5) Advise the establishment that it may appeal the action as provided in §§306.5 and 381.35 of this chapter.
(b) The prior notification provided for in §500.4 of this part will:
(1) State the type of action that FSIS may take;
(2) Describe the reason for the proposed action;
(3) Identify the products or processes affected by the proposed action;

(4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and
(5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.
(c) An establishment may appeal the withholding action or suspension, as provided in §§306.5 and 381.35 of this chapter.
(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.
(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§500.6 Withdrawal of inspection.
The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H because:
(a) An establishment produced and shipped adulterated product;
(b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;
(c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;
(d) An establishment did not maintain sanitary conditions;
(e) An establishment did not collect and analyze samples for Escherichia coli Biotype I and record results as prescribed in §310.25(a) or §381.94(a) of this chapter;
(f) [Reserved]
(g) An establishment did not slaughter or handle livestock humanely;
(h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or
(i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.
[64 FR 66546, Nov. 29, 1999, as amended at 79 FR 49637, Aug. 21, 2014]

§500.7 Refusal to grant inspection.
(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:
(1) Does not have a HACCP plan as required by part 417 of this chapter;
(2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;
(3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;
(4) Has not demonstrated that livestock will be handled and slaughtered humanely; or

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.
(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

§500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.
(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.
(b) FSIS will provide written notification that:
(1) Explains the reason for rescinding or refusing the approval;
(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and
(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.
(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H.

Appendix B: 9 CFR 417, HACCP Regulations

§417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species.

(ii) Raw product—ground.

(iii) Raw product—not ground.

(iv) Thermally processed—commercially sterile.

(v) Not heat treated—shelf stable.

(vi) Heat treated—shelf stable.

(vii) Fully cooked—not shelf stable.

(viii) Heat treated but not fully cooked—not shelf stable.

(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under §417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

[61 FR 38868, July 25, 1996, as amended at 62 FR 61009, Nov. 14, 1997]

§417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with §417.4(a)(2)(iii) and the recordkeeping requirements of §417.5 of this part.

§417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with §417.5(a)(3) of this part.

(3)(i) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

[61 FR 38868, July 25, 1996, as amended at 77 FR 26936, May 8, 2012]

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention.

(1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by §417.3 of this part;

(d) HACCP records are not being maintained as required in §417.5 of this part; or

(e) Adulterated product is produced or shipped.

§417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with §417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with §417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

Appendix C: 9 CFR 416, Sanitation Regulations

Contents

§**416.1 General rules**.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

§416.2 **Establishment grounds and facilities**.

(a) Grounds and pest control. The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

(b) Construction. (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

(c) Light. Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

(d) Ventilation. Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

(e) Plumbing. Plumbing systems must be installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

(f) Sewage disposal. Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) Water supply and water, ice, and solution reuse. (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and

packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) Dressing rooms, lavatories, and toilets. (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

§416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

§416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

§416.5 Employee hygiene.

(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

§416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a “U.S. Rejected” tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a “U.S. Rejected” tag.

§416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's. §416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

§416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

Appendix D: 9 CFR 430, The *Listeria* Rule's Regulations

Contents

§430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes,* or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes,* in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order

to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes,* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes.* Establishments must not release into commerce product that contains *L. monocytogenes* or that has been in contact with a food contact surface contaminated with *L. monocytogenes* without first reworking the product using a process that is destructive of *L. monocytogenes.*

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) *Alternative 1.* Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *and* an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with §417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(2) *Alternative 2.* Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *or* an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with §417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes,* its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*

will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) *Alternative 3.* Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) In order to release into commerce product held under this section, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes.* The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with §417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with §416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) [Reserved]

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the

growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

Appendix E: FSIS FOIA Letter

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United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW. Washington, D.C. 20250

JUN 0 6 2016

Amadou Samb
Amadou.Samb@fsis.usda.gov

RE: FOIA-2016-00214

Dear Mr. Samb:

This is the final response to your Freedom of Information Act (FOIA) request, dated May 24, 2016, to the Department of Agriculture's Food Safety and Inspection Service (FSIS), in which you requested a of Listeria sampling data by plant size and ID, product type, alternative used, and geographical location from 2012 to 2015.

In responding to a FOIA request, FSIS' search will include responsive records in its control on the date the search began. We have located two Excel spreadsheets that are responsive to your request. After a thorough review, we have determined that the spreadsheets may be released in their entirety.

You may appeal this determination within 45 days from the date of this letter. Your appeal should include copies of your original request and this response, as well as a discussion of the reasons supporting your appeal. The envelope should be plainly marked to indicate that it contains a FOIA appeal. If you decide to appeal this determination, please send your appeal to:

Alfred V. Almanza, Acting Administrator
Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW.
Room 2168, South Building
Washington, D.C. 20250-3700

Your FOIA request, including your identity and the information made available, is releasable to the public under subsequent FOIA requests. In responding to these requests, FSIS does not release personal privacy information, such as home addresses, telephone numbers, or Social Security Numbers, all of which are protected from disclosure under FOIA Exemption 6.

Sincerely,

for Mark R. Brok

Arianne M. Perkins
Director, Freedom of Information Act Office
Food Safety and Inspection Service

Enclosure

Appendix F: Internal Ethical Considerations

From: Lobeda, Donald - OE
Sent: Tuesday, October 25, 2016 11:31 AM
To: Samb, Amadou - FSIS
Cc: Lobeda, Donald - OE
Subject: RE: Dr. Samb- discussion on his proposed dissertation

To recap the basics of our conversation:

1. PH.D dissertation on Listeria:

a. Participating in a course of study as you described does not require permission or an OE 101.
b. I would also note you are not being compensated for this dissertation.
c. The subject matter of your dissertation appears to relate to your duties as you are involved in enforcing the FSIS Listeria rules that are the subject of your dissertation.
d. However, because you are not being compensated for this writing project the restriction of 5 CFR 2635.807 do not apply.
e. You are aware that you should not use non-public information for this dissertation or otherwise misuse government resources (time, equipment, official use only information). It appears you are using FOIA requests to obtain the information you need for your dissertation which is good.
f. I do not see any sort of conflict or other ethics objective to your dissertation. However, I recommend you informally discuss this with your supervisor to ensure he or she is comfortable with this and does not have any concerns.
g. I would be happy to discuss the issues and concerns with your supervisor.

Hopefully our discussion was useful.

Have an ethical day.

Donald G. Lobeda, Jr.
Senior Ethics Program Advisor
USDA Office of Ethics (Mail Stop 0122)Appendix G: Permission to Use Figure

Fwd: REQUESTING PERMISSION TO USE FIGURES IN YOUR ARTICLE

Inbox x

AMADOU SAMB <amadou.samb@waldenu.edu> May 31

to me

---------- Forwarded message ----------
From: **Phil Hansbro** <philip.hansbro@newcastle.edu.au>
Date: Sun, Jul 17, 2016 at 5:10 PM
Subject: Re: REQUESTING PERMISSION TO USE FIGURES IN YOUR ARTICLE
To: AMADOU SAMB <amadou.samb@waldenu.edu>

Hi Amadou

Yes that's fine.

Phil.

On 18 Jul 2016, at 6:55 am, AMADOU SAMB <amadou.samb@waldenu.edu> wrote:

Hello Dr. Hansboro,

My name is Amadou Samb; I am a doctoral student in public health at Walden University, USA. I am currently writing my dissertation on Listeria monocytogenes and would like your permission to use figures 1 and 2 in your article entitled:
Methods for the isolation and identification of *Listeria* spp. and *Listeria monocytogenes*: a review published in 2005 in the FEMS Microbiology Reviews, 29(2005), pp. 851-875.

May I?