Risk Analysis Based on Performance Criteria: A Food Safety Control System and Decision-making Tool to Control *Salmonella* from Whole Broilers

Mohammad A. Alshuniaber

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Joseph D. Eifert (chair) Christopher W. Zobel Robert C. Williams Amir H. Mokhtari

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Keywords: risk analysis, food safety control system, decision-making Copyright ©. 2014. Mohammad A. Alshuniaber Risk Analysis Based on Performance Criteria: a Food Safety Control System and Decision-making Tool to Control Salmonella from Whole Broilers

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ABSTRACT

Risk analysis is a powerful science-based tool that can be used to control and mitigate microbial food safety hazards. Codex recommends conducting preliminary risk management activities (PRMAs) to initiate risk analysis and to plan the risk assessment process. The information learned from these PRMAs should be utilized to construct a quantitative microbial risk assessment (QMRA) model. Then, risk management activities can utilize the QMRA model to identify and select microbial risk management (MRM) options. In this project, Codex recommendations for conducting risk analysis were followed to analyze the risk of acquiring salmonellosis from whole broiler (meat chickens) consumption within the United States.

At the first stage, the risk of *Salmonella* on whole broilers was quantitatively estimated by attributing reported annual salmonellosis to whole broilers. A quantitative microbial risk assessment (QMRA) model was constructed to build an informative risk analysis model based on performance criteria, while minimizing associated modeling complications.

The QMRA model was constructed in Excel® (Microsoft Corporation, Redmond, WA, USA) with the @RISK[®] "Add-ins" software (Palisade Corp., Ithaca, NY, USA). @RISK[®] software was used to perform Monte Carlo simulations that account for

attendant uncertainties. After the model was tested and calibrated, it estimated the annual salmonellosis cases from whole broilers as 216,408 case/year that corresponds to the number of salmonellosis reported by Center for Disease and Control Prevention (CDC). Furthermore, sensitivity analysis was performed where 16 sensitive inputs (potential places for food safety interventions) and 10 data gaps (inputs that significantly affect the overall uncertainty) were reported.

Some QMRA model results were transformed to MRM metrics. These MRM metrics, including ALOPs (Appropriate Level of Protection), FSOs (Food Safety Objectives), POs (Performance Objectives), and PC (Performance Criteria), were calculated along with a sampling plan for a food safety control system. The MRM metrics were utilized to identify and plan food control interventions such as risk communication, auditing, inspection, and monitoring. Furthermore, the QMRA model was utilized to identify and to quantitatively evaluate food safety interventions that affect *Salmonella* prevalence and/or concentration.

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LIST OF ABBREVIATIONS

AI	Annual Illnesses
ALOP	Appropriate Level of Protection
ARE	Annual Risk Estimate
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCPs	Critical Control Points
CDC	Center for Disease Control and Prevention
CLs	Critical Limits
COI	Cost of Illness
DALYs	Disability-Adjusted Life Years
EA	Exposure Assessment
FAO	Food and Agriculture Organization of the United Nations
FAO/WHO	Joint FAO/WHO Consultation
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service (of USDA)
FSMA	Food Safety Modernization Act
FSO	Food Safety Objective
G/R	Microbial Growth or Reduction (log)
GAP	Good Agricultural Practice
GHP	Good Hygienic Practice
GMP	Good Manufacturing Practice
НАССР	Hazard Analysis and Critical Control Point

JECFA	Joint FAO/WHO Expert Committee on Food Additives	
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- **JEMRA** Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
- MC Microbiological Criteria
- MRA Microbial Risk Assessment
- MRM Microbial Risk Management
- NCC National Chicken Council
- PC Performance Criteria
- PcC Process Criteria
- PdC Product Criteria
- PO Performance Objective
- **PRMAs** Preliminary Risk Management Activities
- **QMRA** Quantitative Microbial Risk Assessment
- RAn Risk Analysis
- RAs Risk Assessment
- RE Risk Estimate
- **RMAs** Risk Management Activities
- **SPS** Sanitary and Phytosanitary Agreement (a WTO Agreement)
- **TBT** Technical Barriers to Trade Agreement (a WTO Agreement)
- **USDA** United States Department of Agriculture
- WHO World Health Organization
- WTO World Trade Organization
- **XC** Cross-contamination

INTRODUCTION

Food safety is an important issue that involves public, governments, and food chain organizations. In the food safety arena, making the right food safety decision would promote public health and reduce the burden of foodborne illnesses. Such decisions are not readily available without knowledge, investigation, and support data. Despite the large quantity of food safety knowledge and data available, they may not be sufficiently employed to make the best food safety decisions. Therefore, available food safety knowledge and data should be utilized to identify the best food safety interventions that can minimize potential public health risks. However, food safety data and knowledge should be utilized in systematic structured ways to inform food safety decision-making.

Many techniques have been used by decision makers to ensure transparent and justified decision(s). These techniques include, but are not limited to, decision tree analysis, statistical analysis, and risk analysis. Risk analysis is considered to be a science-based decision making process that is based on estimating risk magnitude and mitigation options efficacy. The main point of conducting a risk analysis is to protect public health by estimating risks to human health and to provide a tool that can evaluate and compare different risk mitigation options (FAO/WHO, 2002b; FAO/WHO, 2006a). A risk analysis can ensure that food safety resources will be directed to the most effective risk mitigation options.

Risk analysis consists of three interconnected activities: risk assessment, risk management (decision making stage), and risk communication (Codex, 2007b). Risk

assessment is the major step in risk analysis and is a complex, data-driven, and science-based process. Risk assessment has been used to identify appropriate interventions to promote public health by estimating a potential reduction in number of illnesses or other important goals (Codex, 1999). In risk management, decision makers (i.e. risk managers) use risk assessment results along with other information and data to evaluate possible food safety interventions; and then identify the optimal intervention(s) (Codex, 2007a). Risk communication is about exchanging information through risk analysis processes among all interested parties in a timely manner (Codex, 2007b).

Since the early 1990s when the World Health Organization (WHO) and Food and Agriculture Organization (FAO) of the United Nations, represented by the Codex Alimentarius Commission (CAC), adopted the idea of risk analysis, many governmental agencies and researchers around the world have followed the proposed risk analysis process. Therefore, governments started to form food safety regulations based on risk analysis to ensure that they are implementing appropriate interventions. In the United States, there are two agencies that are primarily responsible for food safety: the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). These agencies conduct risk analyses to aid food safety decisions.

This project aims to facilitate food safety decision-making based on risk analysis in relation to a specific commodity/hazard combination throughout the food chain from farm to fork. In this project, the risk of *Salmonella* spp. from whole broiler chicken will be analyzed. However, this project aims to quantitatively assess the risk of *Salmonella* from whole broilers from farm to fork as the total number of salmonellosis cases per year that result from consuming *Salmonella*-contaminated whole broilers.

Consequently, the effect of potential interventions can be quantified and compared, and their effect on the total annual number of salmonellosis illnesses can be estimated.

In the risk assessment phase, the performance of the U.S. broiler production system in controlling the prevalence of *Salmonella* will be estimated using the concept of Performance Criteria (PC). PCs express the required microbial outcomes to be achieved by the implementation of control measures at different steps within the food chain. However, information and data regarding *Salmonella* initial contamination, cross-contamination, and growth/reduction events for each step from farm to fork are collected from literature or estimated using microbial predictive models. This information will be used to assess the exposure of broilers to *Salmonella* from farm to consumer kitchen and the exposure of consumers to *Salmonella* from whole broiler chicken. Risk assessment outputs include risk estimation (i.e. probability of contamination and probability of illness) and risk description (i.e. Annual Illness (AI), Annual Risk Estimate (ARE), Disability Adjusted Life Years (DALYs), and Cost of Illness (COI)). These measures are used to assess the performance of the U.S. broiler production system in controlling the risk of salmonellosis from whole broilers.

In the risk management phase, the results of risk assessment (i.e. a decisionmaking tool) will be used to calculate microbial risk management (MRM) metrics (i.e. Appropriate Level of Protection (ALOP), Food Safety Objectives (FSO), Microbial Criteria (MC), Performance Criteria (PC)), and sampling plans to test compliance with required performance objectives (PO). However, to account for variability and uncertainty @RISK[®] software (Palisade Corp., Ithaca, NY) will be used to simulate risk assessment models and generate results in the form of distributions. As an add-in to

Microsoft Excel[®] (Microsoft Inc., Redmond, WA), the @RISK software performs Monte Carlo simulation to show the distribution of risk assessment outcomes. The final results are the estimation of the current MRM metrics and represent the current situation with no actions taken or interventions applied (i.e. baseline model). Therefore, potential risk mitigation options may be assessed in comparison with the baseline model results. Finally, when optimal mitigation options are identified, all relevant MRM metrics and a sampling plan to enforce the new change will be estimated by the model.

CHAPTER I: REVIEW OF LITERATURE

1. WHOLE BROILER PRODUCTION AND FOOD SAFETY

Chicken is considered a preferred animal protein option for U.S. consumers because of its acceptable price compared to other meats, and the large variety of chicken products available in the market. In 2011, the U.S. annual consumption of broiler chicken averaged 86 pounds per person, more than triple of the 1960 average which was 28 pounds per person (MacDonald, 2008). In 2011, the total broiler chicken production in the U.S. was estimated to be 8.6 billion birds with total weight produced approximately 49.2 billion pounds. The total value of 2011 broiler production was estimated as \$23.2 billion (USDA, 2012).

According to USDA ERS, approximately 18% of broiler production was exported while 82% was sold locally. However, chilled and frozen whole broilers, at retail, represent only 12% of the U.S. broiler market, or about 845 million broilers in 2011. Chicken parts (i.e. cut-up) represent 42% of the U.S. broiler market, while the further processed chicken represents 46% (National Chicken Council, 2011).

Broilers, young chickens bred for meat, account for 99% of all ready-to-cook chicken meat and 86% of poultry meat produced in the United States in 2006 (MacDonald, 2008). Broiler production starts in primary breeder farms which produce grandparent flocks. Grandparent flocks then produce the final generation of broiler breeders (i.e. multiplier/parent flock). Subsequently, multiplier/parent flocks produce eggs that then are hatched to become broilers for human consumption. Almost all

broiler farms receive chicks produced by company-owned multiplier flocks (sometime from primary breeder). Market weight broilers are transported onto and off farm by company-owned vehicles; and then slaughtered by company-owned slaughter facilities (APHIS, 2011).

The broiler industry in the United States has a unique organization, mainly coordinated by production contracts. In such cases, firms (integrators) own hatcheries, feed mills, and processing plants. Integrators then contract with independent breeders (growers) to raise their broilers to required weights. In this system, growers are compensated based on the grower's performance. In most cases, integrators provide growers with feed and vaccinations (MacDonald, 2008).

The USDA Agricultural Resource Management Survey (ARMS), of 2007, classified broilers in four size classes. The smallest size class (4.25 lb. or less) accounted for 32% of all birds. This class spends an average of 39 days on farm. The most common size class (4.26–6.25 lb.) accounted for 40% of the total production, and spends an average of 49 days on farm. The third size class (6.26–7.75 lb.) accounts for 19% of the total production, and spends an average of 56 days on farm. The largest size class (more than 7.75 lb.) accounted for 9% of the total production, and spent an average of 63 days on farm (MacDonald, 2008).

The broiler production in the U.S. is geographically concentrated in 19 states that produce about 97% of the U.S. broilers (USDA, 2012). Geographic concentration encourages growth of large facilities by reducing the transportation costs (e.g. chicks, feed) by locating hatcheries, processing plants, feed mills, and rearing farms near one another. This geographic concentration results in poultry litter concentration which

increase the risks of water and air pollution, and the risk of contagious poultry diseases spread within a network (MacDonald, 2008).

Integrators may require breeders to conduct certain rearing practices such as flocks must be all-in, all-out, houses must be cleaned out after each flock, operations must have a HACCP plan, operations must specify animal welfare practices, and/or no antibiotics can be added to feed or water (unless birds are ill). Moreover, production contracts may require breeders to carry out some related testing of flocks for avian influenza, *Salmonella*, and/or other pathogens. In most cases, those tests are conducted by integrators (MacDonald, 2008).

Generally, a significant percentage of broilers can be contaminated by Salmonella during rearing on the farm, thus, broiler carcasses can be frequently contaminated by Salmonella during processing, retailing, and/or preparation. Salmonella from live birds can be transferred through production and processing by contaminated feces, intestinal tract contents, equipment, and workers. Also, Salmonella which is not eliminated during processing may cross-contaminate other foods during preparation.

Salmonella is widely spread in nature; it colonizes the intestinal tracts of humans and most animals including poultry. Salmonella is a member of the Enterobacteriaceae family; it is a gram-negative rod-shaped bacilli. There are more than 2500 serotypes of Salmonella that cause human illness. According to CDC, serotypes Enteritidis, Typhimurium, and Newport account for about half of culture-confirmed Salmonella isolates in the United States. When Salmonella is ingested, it may cause a gastrointestinal illness called salmonellosis (Typhoidal or nontyphoidal). The clinical

symptoms of salmonellosis include diarrhea (sometimes bloody), fever, and abdominal cramps. Occasionally they can establish a localized infection or enter the bloodstream. *Salmonella* affects all age groups with greater risk for infants, elderly, and immuno-compromised persons. This pathogen is typically transmitted through the fecal-oral route and through contact with contaminated materials (FDA, 2012).

According to the Centers for Disease Control and Prevention (CDC), the annual incidence of salmonellosis is 14.4/100,000 persons (about 1.23 million cases/year) 94% of which is carried by food (about 1.03 million case/year). Additionally, foodborne salmonellosis causes about 19,000 hospitalization and about 378 death annually (CDC, 2011). In 2008, the CDC study of attribution of foodborne illnesses to food commodities based on outbreaks data shows that between 10–30% of salmonellosis cases were attributed to poultry products (Painter et al., 2009). However, Risk Assessment Division, FSIS, USDA estimated a factor to attribute salmonellosis to young chicken (i.e. broiler) equal to "0.163" (APHIS, 2011). Accordingly, salmonellosis attributed to broilers consumption was estimated to be 223,000 cases/year. Importantly, the annual number of salmonellosis cases can fluctuate depending on the number and size of outbreaks, number of people who report their illnesses, and the number of illnesses that can be traced to a contaminated food.

In the U.S., the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) has responsibilities to inspect raw and processed poultry and eggs products against adulteration and/or production under insanitary conditions. The primary legislation that empowers FSIS includes the Poultry Products Inspection Act and the Egg Products Inspection Act. In 1996, the FSIS published the

Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems: Final Rule. This document established performance standards and testing criteria to control *Salmonella* at the slaughterhouse. Performance standards are based on the percent of *Salmonella*-positive samples tolerated out of a total of 51 samples. In 2011, the performance standard was adjusted to no more than 5 positive samples (~10%). The PR/HACCP verification program demonstrates fluctuating reductions in the proportion of positive samples from 11.2% in 1998-2003 to 7.2% in 2009 (Finstad et al., 2012).

Moreover, as a part of its responsibility, FSIS may conduct baseline studies to qualitatively and quantitatively estimate pathogens and/or indicator bacteria (i.e. coliform) presence in raw products. Such studies are statistically designed to assess a specific industry's sanitation measures and food safety practices. In 2007-08, the Microbiology Division of the USDA conducted a nationwide microbiological baseline data collection program for young chicken. The program found that 40.7% of broilers at the Re-Hang step were *Salmonella* positive with a mean concentration of 2.99 MPN/ml. At the Post-Chill step, 5.2% of broilers were *Salmonella* positive with a mean concentration of 0.7 MPN/ml (FSIS Microbiology Division, 2008).

2. CONTROL OF FOOD HAZARDS

Epidemiological data collected from around the world repeatedly highlights five major risk factors that significantly contribute to foodborne illness. These major food safety risk factors are: improper holding temperatures, inadequate cooking,

contaminated equipment, food from unsafe sources, and poor personal hygiene (FDA, 2009). In 2003, Codex published a food hygiene guideline called "The General Principles of Food Hygiene", which was first published in 1969. This guideline addresses the major food hygiene principles that help control food safety hazards (Codex, 2003). In the last decade, the food protection activities of the U.S. Public Health Service (PHS) led to the conclusion that effective disease prevention requires implementation of comprehensive food sanitation measures (i.e. preventive measures) from farm to fork (FDA, 2009).

The public confidence in the efficacy of a national food safety system is important, and foodborne disease outbreaks affect such confidence. However, effective food safety systems should implement preventive food safety measures at all stages from farm to fork, rather than only conducting inspection and testing of finished products for acceptance and rejection. Therefore, national governments should establish an efficient and science-based food control system with foremost responsibility to enforce applicable food laws and regulations to protect public health from unsafe, impure, and fraudulently presented food (FAO/WHO, 2001).

However, the production of safe food requires national governments along with industrial sectors to design, implement, monitor, and review effective food safety control systems (Codex, 2003). Such systems control food hazards at any stage of food production, processing and preparation (government level), or at any specific process within a food organization (organization level), by taking appropriate preventive measures. FAO/WHO defined food control as "a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure

that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law" (FAO/WHO, 2001).

Most food hazards can be controlled by implementing preventive food safety measures and practices throughout the food chain such as good agricultural practices (GAPs), good manufacturing practices (GMPs), and good hygienic practices (GHPs). These codes of practices are usually called "prerequisite programs". Although, in some cases, the application of prerequisite programs is sufficient, a structured and systematic preventive control program should be required. This led the Codex Committee on Food Hygiene (CCFH) to formalize the principles of Hazard Analysis and Critical Control Point (HACCP) programs (FAO/WHO, 2001). HACCP addresses the implementation of the prerequisite programs; and provides a systematic structure to identify and control food hazards.

The acceptable level of a risk related to a commodity/hazard combination and the required measures to control the risk could be communicated to industry and governmental agencies using Food Safety Objectives (FSOs) and Performance Objectives (POs). The International Commission on Microbiological Specifications for Foods (ICMSF) introduced the concept of FSOs which later was adopted by the Codex Committee on Food Hygiene (CCFH). After that, CCFH included the FSOs concept into the Microbiological Risk Management document. A FSO is defined as "the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides appropriate level of protection". A PO is defined as "the maximum frequency and/or concentration of a hazard in a food at a specific point in the food chain" (ICMSF,

2006). FSOs and POs refer to distinct levels of foodborne hazards that cannot be exceeded at different points in the food chain. These levels can be met by implementation of appropriate food safety preventive control measures such as GAPs, GHPs, GMPs, and HACCP.

Performance Objectives (POs) should be expressed by risk managers to provide operational risk-based limits to food organizations within a specific food chain. POs may be based on risk analysis and are specific for a hazard/commodity combination. However, since POs are conceptually linked and aim to achieve intended FSO, the impact of previous and subsequent steps of a PO should be considered when setting its value (Codex, 2007a). Compliance with POs can be achieved by implementing control measures such as a HACCP system. Additionally, competent authority may verify and validate established POs by conducting a monitoring program (Codex, 2007a).

Microbiological criteria (MCs) indicate the maximum permitted microbial load of raw materials, ingredients, and/or end products at a specific step in the food chain. According to Codex, a microbiological criterion for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms and/or quantity of their toxins per unit of mass, volume, area, or lot. However, a MC should be science-based, and where sufficient data is available, the MC will preferably be based on risk analysis. It should be transparent and not be trade restrictive (Codex, 1997). MCs would be used as basis for microbial inspection of a food or food product; it could also be used to verify the efficacy of food safety control programs (i.e. HACCP) when other means of verification are absent. Finally, MCs should be technically

achievable by applying preventive control measures (i.e. GMP, GAP, GHP, and HACCP).

Performance Criteria (PCs) express the required outcomes to be achieved (i.e. to achieve a PO at specific point in the food chain) by the implementation of control measures. PCs for microbiocidal control measures, e.g. thermal treatment, address the desired reduction of microbial prevalence/concentration by the application of such control measures (Codex, 2007a). For instance, a PC can be a 3-log reduction in Salmonella concentration during chilling through the use of chlorine. Moreover, PCs for microbiostatic control measures, e.g. reduction of a_w, address the maximum acceptable increase in microbial prevalence/concentration due to the various conditions during which the measure is applied (Codex, 2007a). For instance, a PC can be that no more than 3% of broilers will be newly contaminated during transportation to the slaughter house, thus, control measure(s) should be used to achieve this PC. PCs are generally set by individual food businesses. However, PCs may be set by governments as advice to food organizations to evaluate required achievement of control measures. Finally, PCs should be technically attainable by applying preventive control measures (i.e. GMP, GAP, GHP, and HACCP).

Consequently, competent authorities and/or the food industry translate performance criteria (PCs) into Process Criteria (PcC) and/or Product Criteria (PdC) (Codex, 2007a). PcC refers to a process's variables (e.g. time, temperature, chemical) which need to be controlled to achieve a required PC. For example, a PC is 3-log reduction of *Salmonella* concentration in broiler by washing, this PC could be translated to a PcC. The PcC will be water temperature, chlorine concentration, and water flow.

Furthermore, PdC include product characteristics (e.g. pH, a_w) which need to be controlled in some cases to achieve a required PC. Such characteristics would affect pathogen growth or reduction (e.g., adding sugar to decrease a_w). In whole broiler production and processing, no specific product characteristic is known to contribute in achieving PCs. Finally, if PcC and PdC are the Critical Control Points of a HACCP system; they could be estimated using appropriate predictive models.

3. RISK ANALYSIS

When a significant food safety issue arises, decision makers (i.e. risk managers) may require to conduct risk analysis to reduce or eliminate the effect of the food safety issue. Risk analysis is usually conducted by risk managers in four phases as follows:

a. Preliminary risk management activities: that aim to identify and describe food safety problem. Risk managers in charge should aggregate available science and information regarding the food safety problem in a risk profile. Risk profiles could be sufficient for making risk management actions or could be used as a guide for further work (i.e. risk attribution, risk ranking, and/or risk assessment) (FAO/WHO, 2006a). Risk ranking tools are used to rank risks and prioritize regulatory activities based on knowledge of risk factors. For example, if salmonellosis was identified as a public health concern, risk managers may need to rank sources of salmonellosis (e.g. broilers, chicken nuggets, tomatoes ...etc.) and start working on the most frequently identified source of Salmonella. Risk attribution is based on epidemiological

observational studies of human illness (FAO/WHO, 2006a). In this case, epidemiological data can be used to allocate and proportionate risks of salmonellosis from consumption of specific foods. Risk attribution and ranking are often used in combination.

If risk assessment is needed, risk managers should commission the risk assessment process to risk assessors and determine the scope of questions for the risk assessment and risk management (Codex, 2007a). At the end of these preliminary risk management activities, the result of risk assessment would be delivered to risk managers and further discussion about the results should be held with risk assessors. During the preliminary phase, sound risk communication should be maintained. Risk communication includes internal communication between risk managers and risk assessors and external communication with other interested parties (Codex, 1999; FAO/WHO, 2006a).

b. Identify and evaluate possible risk mitigation options: in this phase, risk assessment results will be evaluated taking into consideration any economic, legal, ethical, environmental, social, and political factors associated with risk mitigation measures (FAO/WHO, 1997; FAO/WHO, 2006a). The economic evaluation enables risk managers to examine the feasibility of a food safety intervention and its impact on public health. This phase is considered as a multi-criteria decision making process. In addition, effective risk communication is required in this phase to collect relevant information and

opinions from stakeholders, industry, and consumers that are valuable inputs in this decision-making process.

- c. Select and implement risk mitigation option: it should be implemented by the relevant parties (e.g. industry). In some cases, a non-regulatory risk management option (e.g. consumer education) may be selected as a mitigation option (Heggum, 2011). However, national food safety authorities should validate and verify implementation of selected risk management option(s).
- d. Monitoring and reviewing implemented risk management option(s): aims to evaluate its/their efficacy in achieving an intended public health goal, and if there are any other unintended effects (FAO/WHO, 2006a). Government and industry should be involved in monitoring implemented risk management option(s). If monitoring information shows a need for review, risk managers should review the implemented option(s) and begin a new cycle of risk management activities with participation of all interested parties, as appropriate (Codex, 1999; FAO/WHO, 1997; Heggum, 2011).

3.1 History

In 1948, the General Agreement on Tariffs and Trade (GATT) entered into force with several general requirements that still apply today. This agreement received several amendments prior to the establishment of the World Trade Organization (WTO) in January 1995 (Horton, 2001). In 1991, the Joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Conference on Food Standards,

Chemicals in Food, and Food Trade recommended that the Codex Alimentarius Commission (CAC) incorporate risk assessment principles into its decision-making process (FAO/WHO, 2006a). In 1995, the (WTO) Sanitary and Phytosanitary (SPS) Agreement entered into force. The SPS Agreement aims to protect human, animal, and plant health from risks arising from pests, toxins, microorganisms, and/or additives in foods, beverages, and feeds (FAO/WHO, 2006a). However, WTO members are allowed to set up any measure to protect public health, but those measures should be sciencebased to be justifiable and not to be considered as trade barriers. Therefore, risk analysis was required by the WTO agreement to help WTO members to justify their food safety requirements based on sound science to ensure unbiased and sciencebased policy and regulation. The SPS Agreement is an incentive for using a systematic and transparent Microbiological Risk Assessment (MRA) process (Hoffmann, 2010).

Another WTO agreement that supports international trade while maintaining national health is the Technical Barriers to Trade Agreement (TBT). The TBT agreement came into force in 1995 with the establishment of WTO. The TBT agreement covers a wider range of products than the SPS Agreement including non-food products. It aims to ensure that product standards and technical regulations are science-based and do not create unnecessary trade barriers. Similar to the SPS Agreement, the TBT Agreement reserves the right for each country member to establish and maintain standards and technical regulations to protect its human, animal, and plant life and health and the environment, and to prevent deceptive practices (Horton, 2001). The SPS and TBT Agreements were the major driver of risk analysis around the world.

In 1963, FAO and WHO established the Codex Alimentarius Commission (Codex) with defined goals to protect human health, ensure fair trade practices, and coordinate international organizations' work on food standards. The main work of Codex is to publish food standards, guidelines, and codes of practices to achieve its goal. The FAO's Food Quality and Standards Service and the WHO's Food Safety Department have worked together to develop the process of Microbial Risk Assessment for application at national and international levels to help countries to understand MRA and to provide risk-based scientific advice to Codex Alimentarius Commission (Codex) (FAO/WHO, 2002b). In 1991, the FAO and WHO recommended Codex to promote and implement risk analysis principles in its decision-making process and in its publications (Hoffmann, 2010). Since then, Codex has developed general principles of risk analysis and has played a central role in shaping the use of risk analysis in food safety policy. Currently, within Codex, extensive and on-going scientific risk assessment is presented by the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) and the Codex Committee on Food Hygiene (CCFH). As part of this effort, FAO and WHO publish the Microbiological Risk Assessment series which provides data and guidelines regarding MRA. This series of publications consists of risk assessment for particular microorganism/commodity combinations, interpretative summaries of the risk assessments, guidelines for conducting risk assessment, and reporting other pertinent aspects of MRA.

In the United Kingdom, in 2005, Philip Hampton published a report titled "Reducing administrative burdens: effective inspection and enforcement" which aims to promote risk-based regulatory inspection and enforcement. The principles are designed

to properly balance protection of public health and governmental spending. The review team considered the principles as innovative alternatives to the classic regulation that is based on evidence. These principles are based on using risk assessment in regulatory activities. According to Hampton's report, risk assessment is widely recognized as fundamental to effectiveness; thus, it should be comprehensive and be the basis for all regulators' enforcement programs. Moreover, risk analysis can direct efforts to most needed areas; however, it should reduce administrative burdens without compromising regulatory outcomes. Therefore, enforcement should be based on risk assessment and there should be no inspections without a reason (Hampton, 2005). Based on Hampton's report, the Food Standards Agency (FSA) has taken action to improve its risk assessment system.

In the United States, in 1983, risk evaluation was described by the National Academy of Science's National Research Council (NAS–NRC) in a report titled "Risk Assessment in the Federal Government: Managing the Process" (CAST, 2006). In 1999, the President's Council on Food Safety, and the General Accounting Office (GAO) published a testimony titled "U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System". The testimony noted that the U.S. food safety system is lacking the vision of a science-based approach (GAO, 1999). In 1999, the first quantitative microbial risk assessment in support of a regulatory initiative was completed by the USDA's Food Safety and Inspection Service (FSIS).

The Food Safety Modernization Act (FSMA) of 2011 broadens the Food and Drug Administration's (FDA) authority over food safety inspection; and gives it the authority to issue mandatory recalls. Additionally, the FSMA aims to shift FDA's food

safety intervention approach to hazard analysis and risk-based intervention (U.S. Congress, 2010). Therefore, FDA's food safety interventions are needed to be riskbased to comply with the FSMA requirements. As an example of the FDA effort to comply with the FSMA requirements, several risk assessment efforts have been conducted to identify optimal risk-based food safety interventions. For example, in 2012, FDA in cooperation with Health Canada published the "Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada".

3.2 Risk Assessment

In the 1990's risk analysis emerged as a tool for improving food safety by enabling or supporting food control systems to produce safer food and to reduce the number of foodborne illnesses. According to Codex, there are many working principles that should be considered by national governments when conducting risk analysis. Risk analysis should be relevant to national context and be established as an integral part of a national food safety system with an overall objective of ensuring public health protection (Codex, 2007b). Risk analysis is a structured process that consists of risk assessment, risk management, and risk communication (FAO/WHO, 2002b). Risk assessment is the science-based component of risk analysis which provides a framework for organizing collected data and knowledge to facilitate better understanding of the interaction between microorganism, food matrix, and human illness (FAO/WHO, 2006a). Although risk assessment was originally developed to assess chemical risk, the process then extended to cover microbial risk assessment (Heggum, 2011). Risk

assessment comprises four major steps; hazard identification, exposure assessment, hazard characterization, and risk characterization. Risk assessment should include a statement of purpose and be fully documented (Codex, 1999).

Risk assessments can be utilized to establish food safety standards, guidelines, and recommendations (i.e. risk management outcomes). This process can inform decision makers about public health risks, food safety hazards, process control options, and research needs. Risk assessments should be transparent and based on sound science to persuade stakeholders in management decision; and to promote compliance with the food safety control measures (Codex, 1999; FAO/WHO, 2002b). Transparency includes opening the process to interested parties, base it on sound science, and communicating limitations, assumptions, and rationale that lead to a decision (CAST, 2006; FAO/WHO, 2006a).

Risk assessment models should have the ability to estimate the risk of human illness from a specific microorganism/commodity combination. Risk assessment results should be compared with reported human illness data to examine the reliability of the predicted estimate. When new data become available, a risk assessment may need to be revisited for reevaluation (Codex, 1999). The National Research Council (NRC) of the National Academies defines a model as: "a simplification of reality that is constructed to gain insights into select attributes of a particular physical, biological, economic, or social system". Models may be based on scientific, economic, socioeconomic, and/or other types of data. Mostly, models are used to understand the correlation between control (intervention) and quality and/or safety to predict outcomes when observational studies are inapplicable.

In most cases, conducting a microbial risk assessment (MRA) is a multidisciplinary approach and resource-intensive task (FAO/WHO, 2002b). Quantitative models of food safety risk assessment can enhance the role of science in decision making by linking available data to public health outcomes. MRAs should be structured and include quantitative information to the greatest extent possible in the estimation of risk (Codex, 2007a). Recently, risk assessment authorities became more interested in quantitative microbial assessment. However, MRA poses many difficulties that negatively affect its precision. For example, microbes can multiply in food, limited data may be available, and hazard characterization may be incomplete (Heggum, 2011). In addition, the inherent variability and uncertainty of microbial data affect the quantitative microbial risk assessment process. Hence, food safety risk assessments should include different or multiple scenarios (i.e. thousands of iterations) to better describe the pathways from farm to fork (Heggum, 2011). Consequently, Monte Carlo simulation is often used to generate probabilistic distributions for outputs to minimize the effect of variability and uncertainty.

MRA could be quantitative or qualitative based on data and knowledge available, and the complexity of the food safety problem (CAST, 2006). The process starts with identifying a food safety problem then identifying the required sophistication to assess the specific problem. Not all food safety problems require extensive risk assessment. In some cases, for example, risk profile—the document required by Codex in conducting risk assessment—may be sufficient to conduct risk management activities. Risk assessment extent, type, and structure depend on the nature of risk management question, public health problem, the availability of data and knowledge, and the
available time (CAST, 2006; Codex, 1999; FAO/WHO, 2006a). In most cases, data required for risk assessment is limited, however, all other parties should be informed about these data gaps. Therefore, to deal with these data gaps, risk assessors should incorporate uncertainty when estimating risks. If uncertainty is broad, this may limit risk managers ability to address food safety decisions (CAST, 2006).

An early example of a microbial risk assessment was published as "Risk assessments of *Salmonella* in eggs and broiler chickens" (FAO/WHO, 2002). This work assessed the risk of *Salmonella* in eggs and broiler chickens from processing to consumer table. The risk assessment model is general in nature and does not represent any particular country or region. This publication provides an example of a risk assessment framework and evaluates the efficacy of some risk management interventions. However, this risk assessment predicted that approximately 2% of the broilers prepared for consumption in the home could potentially contain viable cells of *Salmonella* (FAO/WHO, 2002b).

Oscar (2004) constructed a Quantitative Microbial Risk Assessment (QMRA) model in an Excel spreadsheet which was simulated using @RISK. The QMRA model simulated the concentration of *Salmonella* in whole chickens from retail to table based on a series of inputs including initial concentration at retail, growth during consumer transportation, thermal inactivation during cooking, cross-contamination during serving, and a dose response model. The author used published data and predictive models (i.e. growth and inactivation models) for *Salmonella* to establish the input settings. The change in incidence of *Salmonella* contamination was predicted by simulating noncontaminated chickens. Predicted *Salmonella* prevalence changed from 30% at retail to

0.16% after cooking to 4% at consumption. Out of the five input settings, only growth during transportation was found to have no impact on the risk of salmonellosis. The model predicted 0.44 cases of salmonellosis per 100,000 which was less than reported epidemiological data (0.66–0.88 case/100,000 chicken consumer) (Oscar, 2004).

Bucher et al. (2012) in their systematic review-meta-analyses (SR-MAs), quantitatively compared the effectiveness of various interventions for *Salmonella* in broiler production in Ontario, Canada. The results were used to inform a quantitative exposure assessment to compare multiple intervention scenarios. Three packages of interventions were compared; package of on-farm interventions, package of processing interventions, and package of combination interventions. The packages' effect on the prevalence and concentration of *Salmonella* were estimated at the end of chilling. Reductions of 89.94 – 99.87% in *Salmonella* prevalence and 43.88 – 87.78% in *Salmonella* concentration was reported. A package of on-farm and processing interventions was found to be the most effective for *Salmonella* reduction.

Smadi and Sargeant (2013) established a model that simulated the contamination level of *Salmonella* on chicken breasts from retail to consumer table. The risk of salmonellosis due to the consumption of chicken breasts in Canada was estimated. Growth and inactivation predictive models were used to model the change in concentration of *Salmonella*. The model predicted an average of 318 cases of salmonellosis per 100,000 consumers annually in Canada due to the consumption of chicken breasts. The sensitivity analysis showed that the concentration of *Salmonella* at retail, inadequate cooking, and cross-contamination due to not washing cutting boards,

utensils, and hands after handling raw meat are the most significant factors that affect the risk of salmonellosis.

The above risk assessment (RAs) works highlight the FAO/WHO and North American RAs related to *Salmonella*/chickens. To the best of the author knowledge, for *Salmonella*/chicken combination, no comprehensive risk analysis—that include risk ranking, MRM metrics, and multi-criteria decision analysis—has been published. Also, no RAs was done from farm to fork and no RAs was based on performance criteria.

3.3 Risk Management

Major considerations and principles of Microbial Risk Management (MRM) are presented "Principles and Guidelines for the Conduct of Microbiological Risk Management" (Codex, 2007a). This guidance document discusses the four steps of risk management and microbiological risk management metrics. Specifically, MRM should follow a structured approach that includes preliminary MRM activities, identification and selection of MRM options, implementation of MRM activities, and monitoring and review implemented option(s) (Codex, 2007a). Risk management is an ongoing process, thus, all new data and information resulting from evaluation and review of risk management decisions should be taken into account (Codex, 2007b). Risk management is the managerial and political part of risk analysis. In this process, risk managers transform risk assessment results into food safety actions in accordance with political priorities (Heggum, 2011).

According to Codex, risk management is defined as "the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting

and implementing appropriate control options, including regulatory measures". Codex Alimentarius Committees (CAC) use risk management to develop food safety standards, guidelines, and other recommendations (FAO/WHO, 1997). A primary goal of risk management is to protect public health by controlling identified risks effectively by selecting and implementing appropriate risk mitigation measures. In some risk management efforts, however, other factors may be taken into consideration such as economic costs, benefits, technical feasibility, and societal preferences. These considerations should not be arbitrary and should be made explicit (FAO/WHO, 1997).

Risk management goals are usually set as Appropriate Level of Protection (ALOP). According to the SPS Agreement of the WTO, country members may set up sanitary and/or phytosanitary measures to achieve the planned ALOP. However, those measures should be technically practicable and economically feasible; and must not be more trade restrictive than required (Heggum, 2011). ALOP is defined by the SPS Agreement as "the level of protection deemed appropriate by the member state to protect human life within its territory and could, for instance, be expressed as the acceptable number of cases of a particular foodborne disease per million inhabitants". When no urgent food safety issue exists, the ALOP could be estimated from the sanitary and phytosanitary measures that are already in practice (Codex, 2007a; FAO/WHO, 1997; FAO/WHO, 2006a; Heggum, 2011).

3.3.1 Risk Management Activities:

When a food safety hazard arises—which may be associated with one or more food commodities—risk managers should consider taking action(s) to protect public

health from that hazard. In some cases, food issues are urgent and require immediate action (e.g. recall) without further scientific analysis (i.e. risk assessment). however, risk managers should ensure that optimal food safety option(s) are selected that protect consumer health; are scientifically justifiable, practicable, and transparent; and are not trade restrictive (Codex, 2007a). In many cases, risk managers may base their decisions either on a risk profile (if it gives sufficient information about a food safety issue) or on Codex standards, recommendations, and guidance where available. In some cases, however, a risk manager may decide to conduct a risk assessment for an in-depth evaluation and to facilitate the decision making process (FAO/WHO, 1997).

At the national level, competent authorities play a key role in risk management activities by identifying the required level of food safety control to be achieved by food organizations within a particular food chain. Typically, the required control will be in the form of food safety metrics such as product criteria (PdC) (e.g. aw, pH ...etc.), process criteria (PcC) (e.g. temperature, packaging ...etc.), and microbial criteria (MC). Internationally, Codex had been working to find a way to link the traditional food safety metrics (i.e. MC, PdC, and PcC) to the Appropriate Level of Protection (ALOP). As a result, risk management metrics were developed, including the Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC). FSOs translate food risks into food-related targets (i.e. maximum exposure, prevalence and concentration, to a food safety hazard) to achieve the intended ALOP. However, a FSO indicates the overall performance of a specific food system in achieving intended public health goals. Moreover, POs describe the required performance of a specific segment of the food system to achieve a FSO. The PCs express the targeted change required in

prevalence and concentration of a food safety hazard by the application of control measures (Codex, 1997; Codex, 2007a; FAO/WHO, 2006a; Heggum, 2011).

3.3.2 Decision-Making within Risk Management:

When conducting risk management activities, risk managers will face two events where they need to rank or prioritize options. In preliminary risk management activities, risk managers may need to rank different hazard/commodity combinations based on their risk to public health. Hazard/commodity combinations are typically ranked based on multiple criteria (e.g. exposure likelihood, risk severity, affected population) to direct efforts and resources to the riskiest hazard/commodity combination. Additionally, risk ranking may involve risk attribution which is usually based on available epidemiological data by identifying pathogens (i.e. hazards) and vehicles (i.e. food commodities). Risk attribution aims to estimate the proportion of illnesses associated with each hazard/commodity combination (Batz et al., 2004b; FAO/WHO, 2006a).

There are some examples for risk ranking models such as the Foodborne Illness Risk Ranking Model (FIRRM) developed by the Food Safety Research Consortium (FSRC). FIRRM is a computerized risk ranking model aims to prioritize food safety hazards (i.e. foodborne pathogens) based on their distribution across different food product using several measures of public health impact (FSRC, 2005). It ranks hazard/commodity combinations based on five measures of public health impact: estimated number of illnesses, hospitalizations, deaths, estimated economic impact, and loss of Quality Adjusted Life Years (QALYs) (Batz et al., 2004a). The FIRRM combines estimates of the incidence of foodborne illness by the Centers for Disease

Control and Prevention (CDC), cost-of-illness studies by the USDA's Economic Research Service (ERS), and a dataset created by the Center for Science in the Public Interest (CSPI) in which outbreaks are linked to causal food vehicles. FIRRM is a topdown ranking tool (i.e. starts with total illnesses) constructed in Analytica—a Monte Carlo simulation environment with a visual interface—to produces confidence intervals and statistics (Batz et al., 2004a).

Another risk ranking tool is the Produce Risk Ranking Tool (RRT) which was established by the Food and Drug Administration (FDA) and the Research Triangle Institute (RTI). The RRT utilizes risk ranking algorithms for hazard/commodity pairs based on illness outbreaks from fresh produce. It is based on the relative ranking of hazard severity and likelihood of adverse health events. The RRT ranks produce risks based on information such as probability of consumption, contamination, infectious dose, commodity shelf life, growth potential, hospitalizations, deaths, and susceptible populations (RTI, 2009). Another risk ranking tool is the "iRISK" which was established by the Institute of Food Technologists (IFT), Risk Sciences international (RSI), and FDA. It is a web-based system that aims to quantitatively analyze data to compare risks of hazard/commodity pairs and estimate the resulting health burden at the population level. Microbial and chemical hazards can be compared with iRISK, and exposure assessment, hazard characterization, process information, and public health metrics such as Disability Adjusted Life Years (DALY) can be considered (National Research Council, 2010).

On the other hand, during risk management activities, risk managers need to identify best possible mitigation options. However, risk managers may conduct risk

prioritization which is inherently a multi-factorial risk management tool to prioritize risk mitigation options. It is important to determine how to compare interventions' feasibility, cost, and effectiveness taking into consideration the context of the multiple factors that contribute to the occurrence of foodborne illness (Fazil et al., 2008). Therefore, to select the optimal mitigation option, risk managers should evaluate risk assessment results taking into account any economic, legal, ethical, environmental, social, and/or political factors associated with risk mitigation measures (Codex, 1997; FAO/WHO, 2006a).

Henson et al. (2007) developed a Multi-Factorial Risk Prioritization Framework to capture all relevant factors that might influence food safety decisions. Four prioritization factors are used: public health impact (as a central criterion), consumer risk perception, market-level impacts on risk management (e.g., the size of an industry domestically), and social sensitivity (e.g., risks that affect pregnant women). This decision-making framework is implemented in three stages. The first stage is to create systematic information cards. The second stage is to map the information cards into cobweb diagrams to create a graphical profile for hazard/commodity pairs with respect to the four risk prioritization factors. And, the third stage is a formal multi-criteria decision analysis to develop risk priorities (Henson et al., 2007).

Another risk prioritization framework is the Conceptual Framework for Food Safety Priority-Setting Decisions developed by the Food Safety Research Consortium (FSRC). The goal was to improve risk-based allocation of food safety resources, and to reduce the public health burden of foodborne illnesses. This tool was organized around four analytical elements. First, risk ranking of relative public health impact based on known human health outcomes (e.g., risk assessment results). Second, intervention

assessment to identify mitigation options and understand their feasibility, effectiveness, and cost. Third, health impact estimation of public health effectiveness (e.g., annual illnesses, hospitalizations, or fatalities) and benefits (e.g., economic valuation or qualityof-life metrics) of specific mitigation options. Finally, a combined evaluation integrates data from the risk ranking, intervention assessment, and health impact estimation to inform resource allocation and decision-making. Additionally, cost-effectiveness analysis and cost-benefit analysis may be combined, when appropriate (FSRC, 2005).

3.4 Risk Communication

Risk communication is the third component of risk analysis. According to FAO/WHO, risk communication is "an interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions". Risk communication is considered a two-way process, it should include "outgoing" and "incoming" processes. For instance, it should provide the public and affected parties with clear and up-to-date information about food safety risk and measures; and should collect information, data, opinion, and feedback from affected parties. By doing so, the risk analysis process will be trustworthy and transparent; and risk management decisions will be adequate and effective to address affected parties' concerns (FAO/WHO, 2006a).

Risk communication is crucial for open, transparent, and effective risk analysis. It enhances public trust and confidence in the food safety system by promoting public

understanding of risk analysis processes by strengthening working relationships and promoting involvement of all interested parties (Codex, 2007b). Effective risk communication ensures that all relevant information and opinions required for effective risk management are incorporated into the decision making process to generate informed decisions (Codex, 2007b; FAO/WHO, 2006a). However, all risk management activities should rely on risk communication either internally with risk assessors or externally with interested parties. Communicated information should be correct and upto-date, and should be delivered in a timely manner to avoid conflict and distrust of risk management decisions (Heggum, 2011).

Risk communication can be difficult to carry out since extensive planning and resources are required. Furthermore, specialized communication skills, awareness, and training may be needed (FAO/WHO, 2006a). In the United States, the Food Safety Modernization Act requires authoritative bodies (i.e. USDA and FDA) to prepare risk communication tools and to enhance public awareness through outreach. And, the Act requires that the Federal Government, state and local governments, and the private sector work together to ensure organized and consistent risk communication to the public (U.S. Congress, 2010).

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CHAPTER II: RISK MANAGEMENT (PRELIMINARY ACTIVITIES)

ABSTRACT

Control of food safety hazards is a complex and significant public health issue; however, a powerful science-based approach such as risk analysis can mitigate these hazards while properly allocating available food safety resources. Codex recommends conducting preliminary risk management activities (PRMAs) when initiating a food safety risk analysis to appropriately plan and scope the risk analysis process.

In this chapter, the risk of *Salmonella* on whole broilers (commercially raised meat chickens) was quantitatively estimated as 223,000 cases of salmonellosis, 398 hospitalizations, and 12 premature deaths occurred annually due to the consumption of contaminated whole broilers prepared either at consumer homes or at food service facilities. It also was semi-qualitatively described in the Risk Profile by answering ten questions recommended by Codex as a part of a risk profile. This information—with prior intention to conduct quantitative risk assessment—was utilized to establish the risk management goals and risk assessment policy. The RM goals and RAs policy were further used to formulate the project's overall goal of establishing an informative risk analysis model based on performance criteria, while minimizing associated modeling complications. However, to achieve the established goal, the RAs framework was developed and a data collection process was conducted to identify available RAs inputs.

The RAs inputs were collected from literature and/or predicted by microbial predictive models; and then optimized to address the attendant uncertainties related to

the RAs inputs. Finally, after conducting PRMAs, most of the information required to start constructing the QMRA were attained. Additionally, the risk profile was developed to replace the hazard identification part of the risk assessment process.

1. INTRODUCTION

Food safety improvements mainly rely on preventive interventions that aim to minimize and/or mitigate risks (i.e. resulted from physical, chemical, and/or microbial hazards). Generally, food safety efforts aim to reduce foodborne illnesses and other public health burdens, and to facilitate domestic and international trade. However, governments around the world employ many resources to control and improve food safety. As recommended by Codex, food safety should be managed by implementing appropriate food control systems. For any food chain (e.g. broiler production system), the food control system is demonstrated by in-place food safety policies and regulations that are implemented to control relevant hazards. However, establishing such policies is always controversial, and consumers and other interested parties may demand that they be science-based. Therefore, public health decision-making based on risk analysis is considered a modern approach to creating new policies and weighing policy alternatives.

In a food control system, governments may set food safety measures such as the maximum acceptable level of food hazards that may not be exceeded. The level of protection deemed appropriate is usually established by decision-makers (e.g. politicians) to quantify the tolerable level of risk the community is willing to accept (e.g. Appropriate Level of Protection). Afterwards, a competent authority translates those numbers to a code of practices (e.g. GAP and GMP) and to food policies (e.g. HACCP and MCs) to communicate ALOPs to industrial sectors. However, food producers and manufacturers should observe their processes performance (e.g. PdC and PcC) to

ensure compliance with issued standards and policies. More recently, the concept of risk management metrics (e.g. FSO, PC, and PO) was introduced to facilitate the communication of ALOPs to food industry in measurable parameters. Furthermore, a food control system should comprise all the above mentioned parameters and metrics. Thus, establishing a food control system is a complex process that requires extensive science, data, and communication.

Ensuring food safety remains a challenge for governments around the world as foodborne illnesses still occur and new hazards continue to emerge. However, food safety risk analysis has become a widely accepted approach which can be implemented to assess hazards and potential mitigation options to inform food safety decision-making process. Risk analysis was originally applied to control chemical hazards in food and/or environment, however, recently risk analysis has been expanded to assess microbial risks to public health. It is a systematic science-based approach that aims to establish a decision-making tool, food standards, and food control measures. Risk analysis is a structured model that includes risk assessment, risk management, and risk communication (FAO/WHO, 2002b). As recommended by Codex, the risk analysis process should be initiated, planned, and scoped by conducting preliminary risk management activities (PRMAs). However, these activities require extensive communication between risk assessors and risk managers; and in some cases with stakeholders, interested parties, and public.

It is widely accepted that, risk analysis model can be highly informative that can yield more than a decision-making tool. If properly constructed, risk analysis models can be used to establish food standards (e.g. PdC, PcC, and MCs) and control measures

(e.g. FSO, PC, and PO). However, risk managers can use risk analysis results to identify the appropriate food safety standards and measures and to plan the food control system. In such cases, the food safety control system is considered to be a science- and risk-based system.

Risk analysis models may be refined and updated by seeking public and stakeholder comments (e.g. on RAs framework, data used, underlying assumptions, and modeling approach). Moreover, a RAn model should be revisited and recalibrated if required—when new data become available, changes occur to the modeled system, and/or changes occur to regulatory and/or societal risk perception (CAST, 2006; FAO/WHO, 2006a).

In this project, a complete risk analysis process, including a quantitative microbial risk assessment (QMRA) model, was performed to highlight how we can get the most out of risk analysis. In this chapter, the preliminary risk management activities are described that were conducted to plan and focus the risk analysis process.

2. PRELIMINARY RISK MANAGEMENT ACTIVITIES

The preliminary risk management activities are important in focusing and scoping risk analysis. The PRMAs aim to describe the food safety problem and risk, address risk management goals and questions, establish risk assessment policy, demonstrate a risk assessment framework, and highlight available information. A professional and successful set of preliminary management activities would result in a powerful, transparent, and focused risk analysis framework. It requires extensive interaction and

communication among risk assessors, risk managers, other interested parties, and consumers to identify available data and technical limitations. It is strongly recommended to maintain functional separation between risk management and risk assessment tasks (i.e. by clearly identify roles and responsibilities) when performed to ensure process transparency (CAST, 2006; FAO/WHO, 2006a).

At this stage, the scope and direction of risk analysis process will be derived from the articulated food safety problem. Problem identification process aims to describe food safety problem. Then "Risk Profile" should be established and documented to describe the risk before commencing risk assessment. It usually used by risk managers to set up risk management questions and goals. If risk assessment is needed to achieve risk managers goals and to answer risk management questions, then risk managers should issue the risk assessment policy and then commission risk assessment tasks to the appropriate party. After commissioning the risk assessment, risk assessors—with extensive communication with all interested parties should issue the preliminary result of risk assessment which include the results of planning and scoping (i.e. risk assessment framework) and results of data collection (i.e. available risk assessment inputs).

2.1 Problem Identification

Generally, risk analysis is a tool used to resolve complex problem and facilitate decision-making. However, it starts with problem identification which may or may not require risk assessment to resolve the problem (CAST, 2006). A food safety problem

might be simple (e.g. has only one practical or available solution), urgent (i.e. requires immediate intervention), and/or lack sufficient data and/or knowledge to conduct risk assessment. However, risk analysis may be characterized by a single expert elicitation, or may require a sophisticated and comprehensive quantitative risk assessment process (Bassett et al., 2012).

Problem identification is the first step in any risk analysis process. In some cases, risk managers need to initiate risk analysis to control a new, severe, or urgent food safety problem. Usually, in those cases risk magnitude is considered high (i.e. based on risk manager's standard) and intervention is required. In other cases, there is no specific food safety problem that needs to be resolved but risk managers still need to work to improve public health. In such cases, risk managers need to rank existing risks based on their effect on public health. Therefore, the problem identification step will be a risk attribution process (or risk ranking). For example, risk managers may want to reduce the risk of salmonellosis in a community, however, they need to attribute salmonellosis to relevant commodities and then perform risk analysis to the commodity with highest risk (i.e. commodity that caused more salmonellosis).

Risk ranking can be conducted either top-down or bottom-up to better identify and quantify the food safety problem. In the top-down approach, public health data (e.g. annual salmonellosis) will be attributed to vehicles food commodity (e.g. broilers). For example, the CDC estimated that about 30% of salmonellosis was attributed to poultry. Moreover, the USDA further estimated that 16.3% of salmonellosis was attributed to broilers. Attribution is usually based on epidemiological case-control studies, outbreak investigation, microbial subtyping, and/or expert elicitation (Havelaar et al., 2008). On

the other hand, the bottom-up approach may involve multiple comparative risk assessments to compare the effect of one or more hazards (e.g. *Salmonella* and/or *Campylobacter*) in one or more food commodities (e.g. broilers and/or leafy greens) on public health. For instance, different hazard/commodity combinations can be compared based on their effect on population (e.g. illnesses, DALYs, and cost of illness). Comparative risk assessment can also be done for different routes of transmission such as "hazard/water" or "hazard/animal contact" combinations. As a result, the relative risk for each hazard and/or the importance of each transmission route can be identified (Havelaar et al., 2008). Finally, both approaches give insight in the magnitude of risk related to different hazard/commodity combinations to inform the decision-making process.

In the U.S., *Salmonella* is the leading cause of confirmed bacterial foodborne illness. And, chicken (including whole broilers, cut-up parts, ground chicken, and other products) is consumed more per capita than any other food animal product. Many cases and outbreaks of salmonellosis have been linked to chicken consumption. This is one reason that the USDA conducts regular sampling and testing of some processed chicken for *Salmonella*. Additionally, this testing program is also used to evaluate the effectiveness of a poultry processor's Hazard Analysis and Critical Control Point (HACCP) plan. The control of *Salmonella* in chicken products is an important public health issue.

Both risk ranking approach (i.e. top-down and bottom-up) are performed to facilitate further comparison with any other hazard/commodity combinations. A topdown attribution was performed using 2010 CDC reported numbers. After attributing

reported annual salmonellosis to whole broilers, it was estimated that whole broilers caused 223,000 cases of salmonellosis, 398 hospitalizations, and 12 premature deaths. Additionally, it was estimated that 142 salmonellosis outbreaks out of 877 reported salmonellosis outbreaks, which occurred between 1998 and 2008, were attributed to broilers. The following information was used to conduct the attribution;

- 1) Annual salmonellosis
- 2) Attributing salmonellosis to poultry (attribution factor = 30%)
- 3) Attributing salmonellosis to broilers (attribution factor = 16.3%)
- Attributing salmonellosis to whole broilers (12% of total annual broiler production)
- Salmonellosis under-reporting multiplier (7 under-reported cases per reported case)
- 6) Salmonellosis hospitalization and death rates, 1.5% and 0.04% respectively.

Furthermore, the bottom-up attribution was performed using socio-economic information to calculate DALYs and COI. For 2010 estimation, it was estimated that the U.S. population lost 921 (289 – 1850 CI) years of healthy life (DALYs) due to salmonellosis from whole broilers. It was also estimated that the community lost 67 (27 – 126 CI) million dollars due to salmonellosis. However, the above information can be considered as the basis for identifying the problem of salmonellosis resulting from consuming whole broilers. Moreover, this information can be used to compare the risk of *Salmonella* from whole broilers with other risks from different hazard/commodity

combinations. (CDC, 2011; Economic Research Service, 2012; FSIS, 2011; Hall et al., 2008; National Chicken Council, 2011; USDA, 2013).

2.2 Risk Profile

The risk profile concept was adopted by Codex as a part of the preliminary risk management activities; and might be considered as a preliminary qualitative risk assessment (Bassett et al., 2012). According to Codex (2007a), risk profile is "a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential MRM options that have been identified to date, when any, and the food safety policy context that will influence further possible actions." A risk profile should be up-to-date, appropriately detailed, and thoroughly documented, and can be employed during the risk analysis process as follows (Codex, 2007a; FAO/WHO, 2006a; FSIS and EPA, 2012):

- 1- Risk managers may use risk profile to generate initial decisions related to risk analysis process such as articulating risk management questions, collecting more information, ranking risks (comparing different risk profiles), re-reviewing food safety problem to develop risk managers' knowledge, commissioning risk assessment, and/or implement an immediate and/or temporary intervention(s) (FSIS and EPA, 2012).
- 2- Risk profile may be used to generate food safety decisions without conducting risk assessment. This can take place in the following situations:

- a) Insufficient resources and scientific information to conduct risk assessment;
- b) When the food safety problem is simple and the information given in risk profile is sufficient for risk managers to make food safety decision; and
- c) A significant and immediate risk was identified which require urgent response from risk manager to reduce the effect of risk. In such case, interim control measure(s) may be undertaken (based on risk profile) while risk assessment is complete (FAO/WHO, 2006a).
- 3- Risk managers may find that risk assessment is necessary to support decisionmaking. In this case, if risk profile is appropriately detailed, it may replace the hazard identification step within risk assessment process.

For the quantitative risk assessment of this project, the scope and the amount of information related to *Salmonella* in literature (i.e. epidemiological studies) will limit the details given in the risk profile. Additionally, the risk profile will be written in a way to replace the hazard identification step within risk assessment process. As recommended by Codex the following information may be included in a risk profile (FAO/WHO, 2006a):

Initial statement of the food safety issue: Salmonella is a major source of foodborne enteric infection disease worldwide. According to CDC, around 40,000 of culture-confirmed Salmonella infections are reported to CDC each year in the U.S. (FAO/WHO, 2002b). Moreover, it is known that Salmonella can naturally colonize the animal (especially poultry) intestinal track. Although proper processing and cooking of broilers should eliminate Salmonella, illness outbreaks still occur.

Description of the hazard and food(s) involved: The tribe Salmonellae is classified under the Enterobacteriaceae family. *Salmonella* is a non-spore forming, motile (with few exceptions), facultative anaerobic, rod-shaped, Gram negative bacteria. It grows in pH between 4 – 8, and temperature between 6 and 46 °C. There are two species of infectious *Salmonella*: *S. enterica* and *S. bongori. Salmonella enterica*— which pose the greatest foodborne health concern—is divided into six subspecies (known as *Salmonella* spp.) which are further subdivided into serotypes based on surface and flagellar antigens. As of 2007, more than 2,500 serotypes of *Salmonella* were discovered (FAO/WHO, 2002b; FDA, 2012).

Chicken meat is a preferred source of protein in the U.S. because of its competitive price and the large variety of chicken products available in the market. In 2011, the total broiler chicken production in the U.S. was estimated to be around 8.6 billion birds with total weight produced around 49.2 billion pounds. The total value of 2011 broiler production was estimated as \$23.2 billion (USDA, 2012). Furthermore, according to USDA ERS, approximately 18% of broiler production was exported while 82% was sold locally. However, chilled and frozen whole broilers, at retail, represents only 12% of the U.S. broiler market. The chicken parts (i.e. cut-up) represents 42% of the U.S. broiler market, while the further processed chicken represents 46% (National Chicken Council, 2011). The whole broilers that are sold chilled or frozen in the U.S. market was about 845 million broilers.

Which foods expose consumers to the hazard and how those foods are consumed by various populations: There are many sources of *Salmonella* that contribute to illnesses such as water, food, handling animals and pets, and human (i.e. person-to-person contact). However, a wide range of food commodities has been associated with salmonellosis such as fruit, vegetables, meats, poultry, eggs, and dry foods (e.g. spices and nuts). Poultry is a known source of *Salmonella*, as *Salmonella* can naturally colonize and proliferate in poultry intestinal tract (FAO/WHO, 2002b; FDA, 2012).

The National Chicken Council (2012) estimated that 90% of the U.S. population eats chicken from retail and foodservice during any two week period. In 2006, the U.S. annual consumption of broiler chicken averaged 86 pounds per person (MacDonald, 2008). However, this number was attributed to whole broilers and converted to broilers servings rather than pounds, hence, it was estimated that the average consumption of whole broilers for U.S. consumer is between 10 - 20 servings/year (for more detail see 2.6.2.3; subsection D).

How and where the hazard enters the food supply: Salmonella may naturally colonize live broilers and survive commercial processing and cooking (i.e. in case of undercooking) to cause illnesses in exposed consumers. Therefore, the major source of *Salmonella* in broiler production system is considered to be the live birds. Furthermore, because broilers are processed in large numbers, cross-contamination may occur in the production system. However, due to cross-contamination, *Salmonella* can enter the

food chain at the farm (i.e. colonization), processing (i.e. cross-contamination), and retail (i.e. cross-contamination).

Frequency, distribution and levels of occurrence of the hazard in foods: Volkova et al. (2011), in an observational study in the U.S., demonstrated that 12.5 - 50% (mean = 38.5%) of flocks (76 flocks were sampled) were *Salmonella* positive (gastrointestinal tracts samples). The within flock prevalence was reported as 15 - 65% (caeca) and 9 - 50% (external); with overall contamination (i.e. internally, externally, and both) reported as 0 - 86.7% (FAO/WHO, 2002b). According to Cason et al. (2007) the external concentration of *Salmonella* in broilers feather, picked carcasses (skin), and head-feet were 3.8 ± 0.8 , 3.6 ± 0.7 , and 3.1 ± 0.7 log MPN/sample, respectively.

From the FSIS Microbiology Division (2008) baseline data collection program, the percent of *Salmonella* positive samples at Post-Chill was 5.19% with a mean concentration of 0.7 ± 0.14 MPN/ml. The prevalence of *Salmonella* was estimated to be 7.5% at the end of processing. However, an earlier literature review reported that the prevalence of *Salmonella* in the U.S. retail was 7.3 – 50%, with concentration ranged 0.34 – 0.5 MPN/ml (FAO/WHO, 2002b).

Furthermore, in consumer kitchens, the prevalence and concentration of *Salmonella* is affected by the percent of cross-contamination and the probability of undercooking. The CDC reported that about 37% of foodborne diseases caused by bacteria from 1993-1997 were associated with cross-contamination (18% from contaminated equipment, and 19% from poor hygienic practices) (Pérez-Rodríguez et

al., 2008). However, the probability of inadequate cooking was estimated from 0.05 – 0.15, with 0.1 as the most likely value (FAO/WHO, 2002b; Smadi and Sargeant, 2013)

Identification of possible risks from the available scientific literature:

Salmonella is a leading cause of foodborne illness (i.e. salmonellosis) around the world. Its symptoms range from mild to severe gastroenteritis, while some cases may develop septicemia, bacteremia, and/or other associated chronic conditions. This pathogen is usually transmitted through the fecal-oral route (i.e. ingestion of contaminated food or water).

Salmonella can cause two different types of illness: typhoidal illness (i.e. by serotypes S. Typhi and S. Paratyphi) and gastrointestinal illness (i.e. mainly by other serovars of *Salmonella* spp.). Typhoidal illness is caused by exclusively host-adapted serovars and resulted in a typhoid-like enteric fever. Typhoidal *Salmonella* serovars are genetically differ from the majority of *Salmonella* serovars and have different virulence characteristics. Symptoms related to typhoidal illness include high fever, malaise, aches, anorexia, constipation, and diarrhea (in later stage). In immune-compromised patient, *Salmonella* may spread to other organs causing much serious illness. If not treated, the mortality rate is estimated as high as 10%. The illness onset is about 1 - 3 weeks, with a duration of 2 - 4 weeks (FAO/WHO, 2002b; FDA, 2012). Generally, typhoidal illness is associated with sewage contaminated food and/or water, however, these serovars are usually not related to broilers and will be out of project scope.

Gastrointestinal illness caused by non-typhoidal *Salmonella enterica* is typically a self-limiting (i.e. cured without medications usually within a week) episode of

gastroenteritis. Illness can be caused by ingesting as low as one cell; with symptoms onset from 6 – 72 hours after exposure that generally last 4 – 7 days. Infective dose, disease onset, duration, and severity are generally dependent on *Salmonella* strain, ingested dose, and host factors. Symptoms usually include diarrhea, vomiting, abdominal cramps, fever, and dehydration. Normally, symptoms are mild and not reported to public health agencies. However, health complications may occur especially in susceptible populations (i.e. elderly, very young, and immuno-compromised) more than in healthy populations (i.e. immuno-competent). *Salmonella* (typhoidal and non-typhoidal) may penetrate the small intestine epithelium into bloodstream (i.e. septicemia) which may deliver the organism to other organs where inflammation may occur (i.e. bacteremia) causing sequelae (e.g. reactive arthritis). Generally, non-typhoidal *Salmonella* has an approximate 1.5% hospitalization rate and 0.04% death rate, while S. Enteritidis may have a higher death rate (~ 3.6%) (FAO/WHO, 2002b; FDA, 2012).

Nature of values at risk (human health, economic, cultural, etc.): According to the Centers for Disease Control and Prevention (CDC), the annual incidence of salmonellosis in the U.S. is 14.4/100,000 persons (about 1.23 million cases/year) 94% of which is linked to food consumption (about 1.03 million cases/year). Additionally, foodborne salmonellosis causes about 19,000 hospitalizations and about 378 deaths annually (CDC, 2011). It is important to note that, the reported annual salmonellosis cases can fluctuate depending on the number and size of outbreaks, number of people

who report their illnesses, and the number of illnesses that can be traced to a contaminated food.

In 2008, the CDC study of attribution of foodborne illnesses to food commodities based on outbreaks data showed that 10–30% of salmonellosis was attributed to poultry products (Painter et al., 2009). Furthermore, Risk Assessment Division, FSIS, USDA further attributed salmonellosis to young chicken (i.e. broiler) and mean was estimated as 16.3% (FSIS, 2011). Accordingly, salmonellosis attributed to broilers consumption was estimated to be 223,000 cases/year with 921 (289 – 1850 CI) DALYs, and 67 (27 – 126 CI) million dollars total cost of salmonellosis.

Distribution of the risk (who produces, benefits from, and/or bears the risk): Mostly, *Salmonella* can cause systematic gastrointestinal illness, and the majority of serovars can cause manifestation (i.e. affect other organs in addition to intestinal track) mainly in elderly, infant or young, and immuno-compromised. After infection, humans and animals (e.g. pets, reptiles, and poultry) may shed *Salmonella* in feces for five weeks making them capable to spread the organism to other humans and/or animals by contact. Moreover, the emergence of multiple antibiotic resistant strains is consider a risk factor related to salmonellosis. Patients who acquire an antibiotic resistant strains are more likely to be hospitalized, and for a longer time (FAO/WHO, 2002b; FDA, 2012).

Characteristics of the commodity/hazard that might affect the availability and feasibility of risk management options: Typically, washing or rinsing does not

eliminate *Salmonella*, however, preventive food safety measures should be in-place (i.e. safe storage, preparation, and through cooking). Additionally, other *Salmonella* characteristics are summarized above.

The broiler production in the U.S. is geographically concentrated in 19 states that produce about 97% of the U.S. broilers (USDA, 2012). Geographic concentration encourages growth of large facilities by reducing the transportation costs (e.g. chicks, feed) by locating hatcheries, processing plants, feed mills, and rearing farms near one another. This geographic concentration results in poultry litter concentrations which increase the risks of water and air pollution, and the risk of contagious poultry diseases spread within a network. The broiler industry in the United States is mainly coordinated by production contracts. In such cases, firms (integrators) own hatcheries, feed mills, and processing plants. Integrators then contract with independent breeders (growers) to raise their broilers to required weights. In this system, growers are compensated based on the grower's performance. In most cases, integrators provide growers with feed and vaccinations. Furthermore, integrators may require breeders to conduct certain rearing practices such as flocks must be all-in, all-out, houses must be cleaned out after each flock, operations must have a HAACP plan, operations must specify animal welfare practices, and/or no antibiotics can be added to feed or water (unless all birds are ill). Moreover, production contracts may require breeders to carry out some related testing of flocks for avian influenza, Salmonella, and/or other pathogens. In most cases, those tests are conducted by integrators (MacDonald, 2008). The construction of the U.S. broiler production system may empower the government to have more control over the

broiler production system, however, any information on controlling the risk of *Salmonella in* broilers may be communicated between the USDA and integrators.

Current risk management practices relevant to the issue, including any regulatory standards in place: In the U.S., the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) has responsibilities to inspect raw and processed poultry and eggs products against adulteration and/or production under insanitary conditions. The primary legislation that empowers FSIS includes the Poultry Products Inspection Act and the Egg Products Inspection Act. In 1996, the FSIS published the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems: Final Rule. This document established performance standards and testing criteria to control *Salmonella* at the slaughterhouse.

Public perceptions of the possible risks: The government, food industry, and public have a high awareness and concern about *Salmonella*. Government and industry perception may be inferred from in-place regulations. The USDA publishes performance standards and conducts a nationwide microbiological baseline data collection program to evaluate microbial quality for a variety of foods and microorganisms including *Salmonella* in broilers. However, the industrial sector checks its compliance with regulatory standards by conducting HACCP plans and microbial tests to monitor *Salmonella*—among other microorganisms—levels in broilers.

Public awareness about *Salmonella* may have been formed based on the fact that *Salmonella* is the leading cause of bacterial foodborne illness in the U.S. with the

highest number of hospitalizations and deaths. The large number of *Salmonella* outbreaks and their implications on public health may have also affected public perception. For each outbreak, the CDC publishes the perception of affected people to the specific risk as a part of the outbreak report. However, such information may also be used to estimate the public perception of *Salmonella*.

2.3 Risk Management Goals

Salmonella is a leading cause of foodborne illness in many developed and developing countries. In the United States, raw chicken is considered an important vehicle of salmonellosis transmission. The risk of salmonellosis from whole broilers can be understood and evaluated from the problem identification (see section 2.1) and the risk profile (see section 2.2). In this section, the project's goals will be set in an effort to provide a decision-making tool that is capable of evaluating potential options to mitigate the risk of salmonellosis from whole broilers within the United States.

A) Scope of Work:

"To perform a comprehensive risk analysis framework in accordance with international guidelines and standards in conducting risk analysis, to construct an informative risk analysis model that delivers more than a decision-making tool while minimizing modeling complexity to quantitatively assess the risk of Salmonella from whole broilers from farm to fork in the U.S. population to improve public health and to optimize food safety resources deployment"

B) Risk Analysis Framework:

As stated in the scope of work, this project aims to perform a comprehensive risk analysis process based on performance criteria in accordance with published international standards and guidelines. At this stage, a risk analysis framework (Figure 2.1) was established to ensure the project transparency and to avoid deviation from the established goals. It demonstrates the project organization, and the linkage points between risk analysis stages (i.e. dissertation chapters).

C) Goals and Objectives:

To Inform:

- Risk analysis should facilitate better understanding of the relationship and interaction between *Salmonella* and whole broilers to deliver sound risk assessment. This can be done by categorizing risk analysis inputs (i.e. organizing available knowledge and data).
- 2- The model should give a wide range of outputs such as risk ranking information, microbial load at each step, performance criteria for each stage and step, risk magnitude, and risk management metrics. This can be done by modeling exposure assessment based on performance criteria to estimate the effect of each step—from farm to fork—on *Salmonella* prevalence and concentration on whole broilers. Additionally, estimating *Salmonella* contamination for a flock rather than individual broilers (i.e. each iteration
represent a flock not a broiler) will enable the model to estimate the distribution of performance criteria.

3- The model should demonstrate data gaps by highlighting and describing attendant uncertainties after performing sensitivity analysis.

To Evaluate:

- Risk analysis should allow the evaluation of the current practices of the U.S. whole broilers production system by estimating the Microbial Risk Management Metrics (i.e. PC, and PO) for each step from farm to fork.
- 2- The model should be flexible in scope so it can evaluate the risk of salmonellosis for individuals, the U.S. population, or a sub-population (e.g. estimating ARE for elderly by changing the affected population and doseresponse inputs to represent elderly sub-population). Additionally, it should be able to estimate the effect of an increase or reduction in whole broilers production and/or consumption on public health (e.g. estimating AI after 10% increase in whole broiler production).
- 3- The model should be able to evaluate the effect of important variables such as season raised or harvested, broiler type (i.e. frozen or chilled), and broiler distribution (i.e. retail/grocery for home preparation or food service facility).

To Mitigate:

1- Risk assessment model should facilitate coherent, transparent, justifiable, practical, and science- and risk-based food safety decisions that are capable to promote public health (i.e. reduce salmonellosis from whole broilers) and to optimize food safety resources allocation.

- 2- It should quantitatively estimate the risk magnitude (i.e. likelihood and severity) of Salmonella exposure from whole broilers with an iterative approach to enable the evaluation and comparison of different salmonellosis mitigation options.
- 3- It should be able to estimate the impact of a wide range of food safety interventions on reducing salmonellosis burden from whole broilers. And, it should be able to answer a wide range of risk management questions.

To Control:

- 1- Risk analysis should facilitate the evaluation and establishment of food safety goals, policies, and regulations (e.g. food standards and control measures). However, it should facilitate the establishment of a solid food safety control system—including sampling plans for system observation and verification— for whole broilers to control *Salmonella*. This can be done by calculating food safety measures and risk management metrics.
- 2- It should be useful for both policy makers and food chain sectors. Policy makers may use the model to evaluate the current performance and to identify potential intervention(s) to improve it. Furthermore, it should be useable by food chain organizations to promote their reputation and to protect consumer's health. It should help food chain organizations to evaluate and improve whole broilers safety and quality; and to solve some food safety and

quality issues by estimating the results of potential solutions. This can be done by enabling organizations to recognize required performance criteria (e.g. MCs), estimate microbial quality from a previous stage, and to evaluate risk mitigation options.

3- It should enable risk managers to confirm the suitability and adequacy of current practices, regulations, policies, and standards; and should enable them to weigh policy alternatives (for both domestic and imported broilers). It should facilitate establishing justified-science-based policies to fulfill SPS and TBT agreements requirements and to avoid unnecessary trade barriers.

2.4 Risk Assessment Policy

Risk assessment policy often defines risk assessment elements including, but not limited to, hazard (may include risk ranking), food commodity, food chain, geographic area, and population of interest to formulate risk assessment framework. It also aims to clarify the scientific boundaries in risk assessment framework to ensure its appropriateness for decision-making. It should be documented; and should facilitate understanding of risk assessment scope and framework. Although establishing risk assessment policy is the risk managers responsibility, risk assessors and stakeholders should collaborate to ensure appropriateness, consistency, and transparency of the process (FAO/WHO, 2006a; FSIS and EPA, 2012). Generally, risk assessment policy is characterized by available data and the need for making assumptions when there is a lack of data.

This project aims to estimate the risk of Salmonella from whole broilers throughout the food continuum (i.e. from farm to fork) in the United States population (including normal and susceptible population). It considers all Salmonella serotypes associated with poultry (i.e. S. enterica serotypes). Antibiotic resistant, Typhoidal (e.g. S. Typhi and S. Paratyphi), and highly invasive Salmonella not commonly associated with poultry (e.g. S. Dublin and S. Cholerasuis) are not considered. However, to include a range of Salmonella strains in risk assessment, the (α) parameter in a dose-response model should be a distribution to represent Salmonella serotypes of interest. The project considers frozen and chilled whole broilers produced and sold in the U.S. that are either going to consumer kitchens (homes) or to food service facilities (restaurants). However, chicken parts and further processed chicken products are not covered in the project scope. The public health outcomes (i.e. end point) include salmonellosis (i.e. acute gastroenteritis and invasive Salmonella), hospitalization, premature death, and socioeconomic outcomes (i.e. DALYs and COI). However, public health and socio-economic outcomes can be estimated using Salmonella hospitalization and death rates, and Salmonella socio-economic data; and can be used to estimate the severity of salmonellosis from whole broilers and to compare it with other risks (i.e. used for risk ranking). Furthermore, in case of insufficient data, underlying assumptions may be made to improve the overall result. However, the effect of assumed inputs (which consider additional source of uncertainty) on the overall uncertainty should be examined and reported, when applicable.

2.5 Commissioning of Risk Assessment

At this stage, risk managers would have decided whether or not a risk assessment is required to answer risk management questions. If risk assessment is required, risk managers should assemble a multidisciplinary risk assessment team to carry out risk assessment task. Afterward, risk managers should commission the risk assessment task to the assembled team. Generally, this step requires extensive risk communication between risk managers and assigned risk assessment team, while maintaining functional separation (FAO/WHO, 2006a). However, at this stage, sufficient information (i.e. problem identification, risk profile, risk management goals, and risk assessment policy) to initiate risk assessment will be available. Risk managers may include all of the above information in a documented charge to the assigned risk assessment team to launch risk assessment process. In this project, risk analysis was conducted as a part of the author's dissertation, therefore, the author will conduct both risk management and risk assessment activities.

2.6 Developing the QMRA Model: Initial Risk Assessment Results

PRMAs should provide most, if not all, necessary information to conduct a quantitative risk assessment including problem identification (including risk profile), RAs policy, RAs framework, and RAs available data. At this step, and before modeling commencement, risk assessors—with extensive risk communication with risk managers—should employ all information given in PRMAs to clearly define the scope,

purpose, and goals of risk assessment. In this project, however, the PRMAs are used to establish the risk assessment framework and to guide the RAs data collection process.

2.6.1 Risk Assessment Framework

Establishing a RAs framework requires rigorous communication and interaction between risk managers, risk assessors, and other interested parties. The RAs framework should be followed throughout the risk assessment process to answer the risk management questions while preventing deviation of the process from the overall goal. However, a clear risk assessment framework will provide a sound foundation to conduct and evaluate (i.e. audit) the risk assessment process (CAST, 2006; FAO/WHO, 2006a; FSIS and EPA, 2012).

In this project, risk profile (see section 2.2), risk management goals and questions (see section 2.3), and risk assessment policy (see section 2.4) are used to formulate the risk assessment framework. The risk assessment framework (Figure 2.2) was established to clearly state the scope, purpose, goals, and transparency of the risk assessment. Moreover, (Figure 2.2) illustrates the systematic implementation of risk assessment; it demonstrates RAs steps, inputs, and outputs.

Scope: the scope of RAs is assessing the risk imposed by *Salmonella* spp. (i.e. all serotypes) on whole broiler (i.e. produced and sold locally in the U.S. of all weights). It covers ready-to-cook chilled and frozen whole broilers sold in retail (i.e. going to consumer home) and broilers prepared and served in food service facilities (i.e. restaurants and/or catering). Although it aims to assess the risk in the entire whole broiler consumer within the U.S. including susceptible population, it can be used to

assess the risk for a specific sub-population after modifying dose-response inputs to represent the sub-population.

Purpose: it aims to estimate the magnitude of salmonellosis resulted from consuming whole broiler within the United States. However, it quantitatively evaluates the current performance of the U.S. broiler production system in controlling *Salmonella* prevalence and concentration on whole broilers from farm to fork based on performance criteria (PCs).

Goals: the main goal of the RAs is to deliver a decision-making tool to aid risk managers to identify best mitigation option(s). It aims to give a complete risk estimate (i.e. measures of probability and measures of impacts) to facilitate decision-making based on multiple factors such as risk likelihood, severity, and its socio-economic impact. Furthermore, because the RAs was established on the idea of performance criteria, it can be used to establish a food safety control system (see chapter IV) for the broiler production system.

Transparency: risk assessment aims to identify the optimal intervention(s) to mitigate risks. Such decision should be transparent to all interested parties to ensure their perception and compliance with the decision (e.g. a new food safety control action). However, risk assessment is a complex process, thus, the level of required transparency may differ based on targeted audiences (i.e. risk assessment expert, risk manager, interested industrial parties, and/or a consumer advocate). In some cases, risk assessment may comprise confidential data or information. However, if such data and information leads to better decision-making, it may be excluded from transparency requirement. Additionally, transparency can be promoted by using science-based

inputs, evidences, and assumptions in model development and construction. Also, calculation should be disclosed and understandable; and the model should be accessible (Bassett et al., 2012). However, complying with all transparency requirements may not communicate risk assessment limitation and the degree of confidence of its results (FAO/WHO, 2009b).

In this project, risk assessment transparency is ensured by documenting—and communicating when applicable—all risk assessment processes (see RAn and RAs frameworks (Figure 2.1 and Figure 2.2), rationales and assumptions (see QMRA data collection (section 2.6.2), limitations (see results and discussion (Chapter IV, section 3), calculations and modeling approach (see material and method (Chapter III, section 2), associated variability and uncertainty (see QMRA data collection (section 2.6.2), and sensitivity analysis result (Chapter III, section 3.1 and 3.2). Moreover, transparency was promoted by using science-based inputs—which were derived from peer-reviewed scientific publications and/or governmental reports—that are related to the U.S. whole broiler production system. A probabilistic modeling approach to account for randomness, and incorporating variability and uncertainty will further promote transparency.

2.6.2 QMRA Data Collection

Risk assessment is considered a data consuming process, thus, QMRA models are usually constructed based on available knowledge. Basically, each risk assessment input is a piece of information that describe a specific point of the system under study. However, risk assessors need to collect a large amount of information to be used as

inputs in the QMRA model. Generally, there are four sources of data that are mostly used in identifying QMRA models inputs. These sources are: 1) scientific literature such as technical reports and observational studies, 2) using microbial predictive models to inform exposure assessment, 3) experts elicitation, and 4) underlying assumption. All information and data collected should be pertinent to a specific situation (e.g. all collected data should be related to the U.S. food production system), unless it is generic information (e.g. transfer rate). Furthermore, collected data need to be optimized (i.e. reported as distribution) to incorporate uncertainty and/or variability, if applicable.

In this section, literature was reviewed to collect data to quantify QMRA and predictive models' inputs. Some assumptions were made for some inputs; and no data was elicited from expert opinions. Moreover, assumption may be made to incorporate uncertainty if an input was reported as a single data value (e.g. only the mean is reported). All data was optimized and reported as a probability distribution of all possible values (i.e. QMRA inputs format) to account for inputs' uncertainty and variability, if applicable. This QMRA model is characterized by 68 inputs classified as follows:

 Exposure assessment (36 inputs): these include prevalence between flocks (PBF), prevalence within flock (PWF), initial contamination, probability of growth during transport to plant, transfer rate, percent of cross-contamination (for 12 steps), growth/reduction log (for 12 steps), temperature abuse (for 4 steps), percent of undercooked chicken, and percent of protected cells (Figure 2.3).
 These inputs will be collected from literature and/or predicted using predictive models, and modeled later in chapter III section (2.2.4).

- Hazard characterization (2 inputs): these include (α) and (β) parameters of the dose-response model (Figure 2.4). These inputs will be only collected from literature, and modeled later chapter III section (2.3).
- 3) Risk characterization (30 inputs): these include production characteristics inputs (6), affected population inputs (5), epidemiological data inputs (5), and socio-economic analysis inputs (14) (Figure 2.4). These inputs will be only collected from literature, and modeled later in chapter III section (2.4). It is important to note that, there are 2 inputs related to production characteristics that cause variability within exposure assessment. These inputs are broilers type (i.e. frozen or chilled) and broilers destination (i.e. home or food service facility).

2.6.2.1 Exposure Assessment Data (36 Inputs)

In this section, 35 exposure assessment's inputs are discussed below; and one input, which is transfer rate, is discussed in the cross-contamination section (see chapter III, section 2.2.2). Additionally, there are other inputs used in the predictive models that inform exposure assessment (see chapter III, section 2.2.3). Data required to run predictive models' (i.e. PM's inputs) and generate QMRA inputs will be collected, analyzed, and optimized, if applicable.

Based on literature, each step of broiler production can potentially decrease or increase the prevalence and/or concentration of *Salmonella* on broilers. The effect of each step on microbial load can differ depends on the facilities, implemented technologies, and employed hygienic practices (FAO/WHO, 2002b). However, this exposure assessment aims to observe the prevalence and concentration of *Salmonella*-

positive broilers throughout the sequential steps from farm to fork which comprise four stages with total 13 steps.

A) Farm Stage (2 steps; 6 inputs)

This stage illustrates the performance of rearing and transporting live birds to the slaughter house in controlling *Salmonella* on live broilers. This would be achieved by estimating the prevalence and concentration of *Salmonella* at processing commence (i.e. slaughter house, specifically at scalding). However, five inputs settings are required to estimate the performance of the farm stage in controlling *Salmonella*. These inputs are; prevalence between flocks, prevalence within flock, initial contamination, percentage of potential cross-contamination event during birds transportation, and growth/reduction event that may occur during transportation.

A.1 Rearing: According to National Chicken Council, broilers are usually raised in a large open grow-out houses (broilers house) which equipped with mechanical feed and water system. These houses are also equipped with environmental system to provide protective and comfortable environment including heating and ventilation. Houses floors are covered with bedding materials consists of wood chips, rice hulls, or peanut shells. It is recommended to have a minimum one-half sq. ft. /bird, however, in the U.S. the average space was estimated at 0.8 sq. ft. /bird. There are several safety measures implemented during broilers rearing in broilers houses include, but not limited to, access to clean water, carefully formulated feed, careful parent flock management, adequate room to grow, veterinary attention, and proper handling (NCC, 2014a).

However, microorganisms, including *Salmonella*, can transmit by two major routes among live birds. First, vertical transmission which is transfer of microorganisms from breeding flock (i.e. parent flock) to production flock. Second, horizontal transmission which is transfer or microorganisms among birds in the same flock either by contact or through the environment (Thakur et al., 2013).

Ranta and Maijala (2002) used the Finnish National *Salmonella* Control Program data to build up a probabilistic transmission model to estimate true *Salmonella* prevalence in primary broiler production chain. Three models were used; vertical transmission, horizontal transmissions, and the dynamical model of infections. They found that, the prevalence of *Salmonella*-positive flocks was (17.4% \pm 1.3), and (43.1% \pm 2.8) in the case of one infected grandparent flock. Volkova et al. (2011), in an observational study in the U.S., demonstrated that 12.5 – 50% (mean = 38.5%) of flocks (76 flocks were sampled) were *Salmonella* positive (gastrointestinal tracts samples). The within flock prevalence was reported as 0 – 86.7% (both internally and externally), it was reported as 15 – 65% (caeca) and 9 – 50% (external) (FAO/WHO, 2002b). However, based on an extensive review by Oscar (2004), *Salmonella* prevalence in whole broilers varied from 0 – 100%, with 30% as a median value.

Cason et al. (2007) conducted research to partition external and internal bacteria carried by broiler chickens before processing. They found that, 71% of chickens at loading dock (at processing facility) were *Salmonella*-positive externally, internally, or both. External contamination was quantified by taking samples from feathers, picked carcasses (skin), and heads or feet. The concentration of *Salmonella* was 3.8 ± 0.8 , 3.6 ± 0.7 , and 3.1 ± 0.7 log MPN/sample, respectively.

Predictive model inputs: Volkova et al. (2011) conducted a field observational study by sampling gastrointestinal (GI) tracts from 65 broiler flocks at time of delivery to farm (i.e. broiler house). They reported that 25 flocks were Salmonella-positive and the mean PWF was 6.5% (0 – 86.7%). The final PWF (i.e. at de-population day) is characterized by the initial PWF (i.e. at day one in broiler house) and Salmonella transmission rate among birds. Transmission rate within a flock could be estimated by observing the change in the prevalence of colonized broilers over time. Transmission rate is defined as "the number of secondary infections caused by one colonized bird per day" (van Gerwe et al., 2009). Thomas et al. (2009) estimated the transmission rate of Salmonella enterica to be 0.47 per day (95% CI, 0.3 to 0.72). The authors reported that the average number of broilers infected by one colonized broiler in a susceptible population was estimated to be 2.8 (95% CI, 1.9 to 4.2). The generation time "the average time between colonization of first broiler and colonization of susceptible broilers" was estimated to be 7 days (95% CI, 5 to 11.6) (Thomas et al., 2009). Therefore, if a chick is colonized at day t, Salmonella transmission will begin at day t+7. Finally, based on literature, Conlan et al. (2007) estimated the number of contacts which lead to Salmonella transmission—a broiler makes per day as 1.04 – 2.13. Finally, the above data was used in the transmission model (see chapter III, section 2.2.3, model A) to predict PBF and PWF. The inputs of the transmission models are as follows:

Number of sampled flocks (r) = 65;

Number of positive flock (s) = 25;

Transmission Rate (*TR*) = Triang (0.003, 0.0047, 0.0072);

Flock size (N) = Triang (15000, 20000, 25000); Initial colonization (I_c) = Triang (0, N*0.01, N*0.03); Probability of contacting a contaminated bird (P_c) = I_c / N ; Number of contact (y) = Uniform (1.04, 2.13); Probability of transmission (b) = Uniform (0.4, 0.5); Generation time (t_o) = Triang (5, 7, 11.6); De-population day (t_d) = Triang (39, 49, 56). (MacDonald, 2008)

Inputs Optimization: the prevalence of *Salmonella*-contaminated flocks (PBF) in the U.S. was reported as 12.5 - 50%; the reported means were 17.4, 38.5, and 41%. Moreover, a transmission model (model A, section 2.2.3, chapter III) using the above PM inputs was used to predict PBF. The predicted result (90% confidence of 1000 iterations) corresponds to the reported literature values (Figure 2.5) with a slightly wider range as follows:

> **PBF** = mean (0.386); SD (0.0594); min (0.125); max (0.5) =RiskNormal (0.386, 0.06, RiskTruncate (0.125, 0.5))

The prevalence within flock (PWF) at end of rearing was reported between 0 – 100%, minimum reported (other than 0) is 9%, while maximum reported (other than 100%) is 86.7%. The reported means were 6.5 and 30%. Moreover, a probabilistic transmission model with two transmission phases (model A, section 2.2.3, chapter III) using the above PM inputs was used to predict the PWF. The predicted result (90%

confidence of 1000 iterations) matches the reported literature values (Figure 2.6), but with a higher predicted mean.

PWF = mean (0.573); SD (0.312); min (0.09); max (0.867) =RiskNormal (mean, SD, RiskTruncate (0.09, 0.86))

The maximum contamination was estimated as a broiler with all three sampled sites (i.e. feather, skin, and head-feet) contaminated. In this case the total concentration is around 4.9 log MPN/broiler. The minimum concentration is estimated as a broiler with only one site contaminated (the minimum reported number is 3.1 ± 0.7) with concentration around 2.4 log MPN/broiler (Cason et al., 2007). However, the initial contamination is uniformly distributed as follows:

IC = Uniform (2.4, 4.9)

While uncertainty is noticeable from the brief literature above, the following are examples of variability in the rearing step that affect the exposure of broilers to *Salmonella*;

- PBF: rearing facilities, methods, and practices; chicken breeds; climate condition; vertical transmission.
- PWF: first colonization time; transmission rate of the *Salmonella* strain; levels of stress among birds; other diseases that affect broilers immunity; flock size.
- IC: methods of lab analysis in or on a bird; site of contamination; climate conditions.

A.2 Transport to plant: Transport to plant refers to moving live broilers from broiler houses to slaughter houses. Broilers transportation from farm to slaughter house usually include feed and drink removal, broiler catching, hauling crates on truck or trailers, transport to processing plant, unloading crates, broilers picking and shackling, washing and disinfecting empty crates (Fries, 2002). Transporting is usually carried out in open crates that are placed on top of each other. Thus, stress during bird transporting would increase fecal excretion and therefore the possibility of cross-contamination (FAO/WHO, 2002b). However, more *Salmonella* contaminated broilers during transport could increase the chance of broilers eating contaminated litter during transport and/or waiting time at the processing plant (Mainali et al., 2009).

During transportation, birds may got contaminated from other contaminated birds in the same crate, feces dripping from colonized birds on upper crates, and contaminated crates (i.e. previously used to transport a contaminated flock). There are several safety measures in place to reduce cross-contamination during broilers transportation to slaughter house including feed and water withdrawal, logistic transport, shorter transport and wait time, and crates and truck wash and disinfection (Berghaus et al., 2013; Fries, 2002; Mainali et al., 2009; Rasschaert et al., 2007).

During transportation from farm to abattoir the prevalence of *Salmonella* increased by 0.1 - 1.8% (~ 2 – 30.5% relative differences) (van der Fels-Klerx et al., 2008). This information is used to ensure that predicted percent of cross-contamination is matching experimental data.

Predictive model inputs: Transporting time can vary from 20 minutes to up to 8 hours (mean = 2.5 ± 2 h). The birds then will wait at the processing plant from 0 - 8.3

hours (mean = 3.4 ± 2.1 h). Longer transport and wait times were associated with increases in *Salmonella* prevalence in crops, ceca, and neck skin (Mainali et al., 2009). Transportation temperature is characterized by season. The mean temperature (°C) of each season for the largest broiler producing states (i.e. Georgia, Alabama, and Arkansas) was obtained from Bing® Weather history. However, the inputs of growth models are as follows:

Time (t) = Triang (0.33, 5.9, 12)

Temperature (T) = Winter: Triang (1, 1, 13); Spring: Triang (5, 5, 26);

Summer: Triang (19, 19, 31), Fall: Triang (6, 6, 23)

Inputs Optimization: in this step, a contamination predictive model and a growth model are used to predict cross-contamination (XC) percent and growth event (log), respectively. Inputs for contamination model are discussed in chapter III (section 2.2.2). Predicted cross-contamination percent is similar to the reported percent with a higher maximum around 73% (Figure 2.7). However, the contamination model is used to predict cross-contamination percent of each flock with maximum percent equal to 30.5% (i.e. reported maximum). Furthermore, a growth model (model C, section 2.2.3, chapter III) was used to estimate growth based on season (Figure 2.8). Moreover, according to FAO/WHO (2002b) the maximum *Salmonella* concentration at the stun step is 7.54 log cfu/broiler, however, this number is used as a maximum contamination to avoid overestimation by growth model.

$$G / R = \begin{cases} Winter = min (0), mode (0), max (0.01); P. Growth (0.185) \\ Spring = min (0), mode (0), max (0.504); P. Growth (0.717) \\ Summer = min (0), mode (0), max (2.23); P. Growth (1) \\ Fall = min (0), mode (0), max (0.195); P. Growth (0.756) \end{cases}$$

The following are examples of variability in transport to plant step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: feeding withdrawal; pickers' hygiene; vehicle conditions; crates contamination; transporting time, conditions, and temperature.
- Growth/reduction: microbial load; transporting time; climate conditions; site of contamination; transport method.

B) Processing Stage (6 steps; 12 inputs)

This stage illustrates the performance of processing in controlling *Salmonella* on broiler carcasses. However, changes in *Salmonella* prevalence and concentration due to these process steps will be achieved by estimating potential cross-contamination events (%) and growth/reduction events (log) at each step within the processing stage.

Poultry processing within a slaughter house usually improves the microbial quality and safety of final product (i.e. chilled or frozen broiler). Normally, the prevalence and concentration of *Salmonella* in carcasses are lowered. The processing stage starts with broilers are stunned, usually by immersing birds' heads into water with electrical current or by exposure to one or more gases. They are then killed using electrical saw

to remove heads. Generally, the stun and kill steps are unlikely to cause a significant cross-contamination (FAO/WHO, 2002b).

B.1 Scalding: Scalding involves immersing of broilers in hot water to facilitate feather removal. Scalding water temperature can depend on whether the broilers are to be sold chilled (i.e. soft-scald at 50 – 52°C) or frozen (i.e. hard-scald at 56 – 58°C) taking into consideration that too hot water may cause skin discoloration. Although scalding temperatures impact microbial load, some *Salmonella* species may remain viable in the scald tanks for long periods. Chemicals may be added to scalding water to assist microbial reduction and to limit cross-contamination (FAO/WHO, 2002b; Finstad et al., 2012).

Scalding also aims to reduce microbial load, dirt, feces, and litter from broiler carcasses. The presence of organic materials (e.g. urine and feces) become a source of contamination and increase the potential for cross-contamination; these materials also reduce antimicrobial activity of some chemicals such as chlorine (Buncic and Sofos, 2012; Finstad et al., 2012). Finally, the scalding tank can spread *Salmonella* when feces build up in the tank, inadequate temperature is used, and the water is not agitated (Finstad et al., 2012).

Data collected at the stun and kill step indicated that percent of *Salmonella*positive feather samples was 53 - 75% with population around $5.3 - 7.4 \log cfu/g$; while the per cent of positive skin samples was 27 - 55% with population around $5.6 - 6.5 \log cfu/g$. Data collected at scalding step demonstrated that *Salmonella* population at scalding was $3 - 3.5 \log MPN/carcass$. Based on literature review, scalding reduces the

Salmonella prevalence by 36.9% (calculated from experimental results) (FAO/WHO, 2002b). Scalding at 60 °C was found to reduce *Salmonella* by 2 log more than scalding at 50 °C. Exposure to chemical antimicrobial agents (e.g., chlorine, lactic acid) may reduce *Salmonella* contamination by 0.8 – 2.5 log (Buncic and Sofos, 2012).

Predictive model input: According to Finstad et al. (2012), in the U.S., scalding water temperature is 56 - 63 °C. Scalding time is controlled by conveyor speed. Generally, scalding time is 2 - 3 minutes. Although using water (i.e. washing effect) in scalding is the major means of *Salmonella* reduction, scalding water temperature also will cause reduction. The effect of water temperature can be predicted using the above data in an inactivation model (model B, section 2.2.3, chapter III). However, the inputs of the inactivation model are as follows:

T = Uniform (56, 63);

t = Uniform (2, 3).

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). However, predicted cross-contamination should not affect prevalence reduction percent (i.e. around 37% reduction in prevalence should be achieved).

Reduction could not be estimated by inactivation model, the model predicts only a small reduction (~ 0.02 log) which is expected because insufficient scalding water temperature. Additionally, the major reduction is expected to be as a function of washing rather than thermal inactivation. Reduction during scalding was reported between 0.8 and 2.5 log; only one mean was reported as 2 log reduction.

XC = prediction only **G/R** = Triang (-0.8,-2,-2.5)

The following are examples of variability in scalding step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; contamination level (carcass and environment); number of contact with contaminated materials; processing conditions (e.g. scalding water age and temperature).
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. water temperature, time, chemical addition ...etc.).

B.2 De-feathering: De-feathering involves mechanical removal of feathers from carcasses after scalding, usually by machinery with counter-rotating domes or discs with rubber fingers (FAO/WHO, 2002b). Chemicals such as chlorine and acetic acid may be used for rinsing carcasses during de-feathering (Buncic and Sofos, 2012). As feathers are removed, contaminated aerosol and/or soil spread to the environment and equipment which is difficult to clean and sanitize. Therefore, de-feathering is regarded as a major source of contamination (Buncic and Sofos, 2012; FAO/WHO, 2002b).

De-feathering increases the *Salmonella* prevalence by 23% on chicken (calculated from experimental results) (FAO/WHO, 2002b). Other research found that 55% of neck skin samples were *Salmonella*-positive after de-feathering (Finstad et al., 2012). A study conducted by Berghaus et al. (2013) observed 55 broiler flocks and reported that the prevalence of *Salmonella* outside slaughter plant was 45.9% with a

concentration 3.44 \pm 0.71 log₁₀ MPN. The prevalence and concentration of *Salmonella* decreased as a result of processing to 43% and 2.77 \pm 0.59 log₁₀ MPN at rehang, respectively. In 2008, the Microbiology Division of FSIS of USDA conducted the nationwide microbiological baseline data collection program in young chicken to estimate the national level of *Salmonella* in broiler during processing. The percentage of *Salmonella*–positive samples at Re-Hang was 40.7% with a concentration of 2.99 \pm 0.85 MPN/ml (FSIS Microbiology Division, 2008).

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). From the above data, de-feathering may reduce or increase prevalence. The maximum reported increase in prevalence was 23%, however, this number will be as the maximum cross-contamination percent.

Salmonella concentration after de-feathering of broilers is reported as 2.18 - 3.36 log cfu/broiler (this range includes baseline data collection results). De-feathering is expected to reduce Salmonella concentration by 0.5 - 0.8 (log) (calculated from population before and after de-feathering).

XC = max 0.23 **G/R** = Triang (-0.5,-0.65,-0.8)

The following are examples of variability in de-feathering step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; contamination level (carcass and environment); number of contact with contaminated materials; processing conditions (e.g. washing and disinfecting de-feathering machine).
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. time, chemical addition ...etc.).

B.3 Evisceration: Evisceration involves the removal of intestinal tract and other organs from carcasses cavity after de-feathering using a series of interconnected machines. Usually, the intestinal tracts remain attached to be inspected, however, damage can occur due to inflexibility of evisceration machinery toward broiler size (FAO/WHO, 2002b). Leakage of contaminated intestines contents would contaminate other carcasses, equipment, workers, and inspectors. However, continuous water spraying during evisceration helps in removing organic material, minimizing microbial attachment, and reducing microbial contamination (Buncic and Sofos, 2012). Furthermore, based on literature review, evisceration affects the *Salmonella* prevalence from 25.7% reduction to 30.3% increase (calculated from experimental results) (FAO/WHO, 2002b).

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). From above data, evisceration can decrease or increase *Salmonella* prevalence. The maximum reported increase in prevalence due to evisceration is 30.3%, which can be used as the maximum cross-contamination percent. Furthermore, it was assumed

that evisceration would affect the prevalence of *Salmonella*-contaminated broilers, and it would not affect the concentration of *Salmonella* on the surface of contaminated broilers.

XC = max 0.303 **G/R** = Triang (0, 0, 0.1)

While uncertainty is noticeable from the brief literature above, the following are examples of variability in the evisceration step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; contamination level (carcass and environment); number of contact with contaminated materials; processing conditions (e.g. number of GI tract damaged).
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. time, chemical addition ...etc.).

B.4 Washing: Washing with/without added chemicals can reduce or remove soil, dirt, and microbial contamination acquired during de-feathering and evisceration (Buncic and Sofos, 2012; FAO/WHO, 2002b). Carcass inside-outside washing (i.e. spraying, rinsing, or immersing) usually involves sufficient pressure to remove visible contamination (Buncic and Sofos, 2012). Depending on washing methods, water volume, spray pressure, and chemicals used, the prevalence of *Salmonella* may increase or decrease (FAO/WHO, 2002b). However, *Salmonella* concentration is expected to be decreased due to carcasses washing.

Multiple and sequential washing steps were reported to reduce Salmonella prevalence on broiler carcasses by 40 - 90%, depending on the nature and number of washing steps. The inside-outside spray washing with 20 – 50 ppm chlorine may reduce Salmonella prevalence by 20% (FAO/WHO, 2009c). Research found that 55% of neck skin samples were Salmonella-positive after de-feathering, while 27% of samples were positive after evisceration. This reduction is related to the inside-outside high pressure washing followed by evisceration. Another study reported that the inside-outside bird washer was able to reduce Salmonella concentration on broilers carcass by 2.1 log without increasing water temperature or using chlorine (Finstad et al., 2012). Several studies summarized that, washing may reduce the prevalence of Salmonella on broiler carcasses by 50 - 90%, and the population by $0.6 - 1.3 \log$ (Buncic and Sofos, 2012). Berghaus et al. (2013) reported that the prevalence of Salmonella was decreased due to processing from rehang to chilling (i.e. evisceration and washing) from 43% to 18.2%; the Salmonella concentration was also decreased from 2.77 ± 0.59 log₁₀ MPN at rehang to $2.57 \pm 0.44 \log_{10} MPN$ at pre-chill.

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). From above data, washing may decrease *Salmonella* prevalence by 20 - 90% (estimated mean 50%), while it may reduce *Salmonella* concentration by $0.6 - 2.1 \log$ (estimated mode 1.3 log).

XC = prediction only (no max XC reported)

G/R = Triang (-0.6,-1.3,-2.1)

The following are examples of variability in washing step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; contamination level (carcass and environment); number of contacts with contaminated materials; processing conditions (e.g. water pressure).
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. time, chemical addition, water pressure ...etc.).

B.5 Chilling (Tank): Chilling aims to reduce carcasses temperature (to 4 °C or lower) after evisceration as fast as possible to control microbial growth, taking into consideration any aspect associated with rigor mortis rates (Buncic and Sofos, 2012). Generally, broiler carcasses are chilled by immersion in chilling tank, air chiller, or their combination. In the U.S. the immersion chilling is generally used with a counter flow current and the addition of chlorine (FAO/WHO, 2002b). Yang et al. (2009) reported that chilling water temperature is 2 - 4 °C, and broiler takes 23 - 50 minutes in chilling tank. At chilling tank, the available chlorine should be maintained at 50 - 70 ppm with 0.4 - 5 ppm available free chlorine, and 6.0 - 6.5 pH (FAO/WHO, 2009c). However, organic materials released from broiler carcasses would bind with chlorine and reduce the free chlorine level, hence, reduce it effect in reducing microbial load. Furthermore, although chlorinated chilling water reduces contamination, it may also be a source of contamination. The cross-contamination level during chilling (tank) depends on

prevalence of contaminated carcasses, chilling water overflow and replacement, and load of carcasses in the tank (Buncic and Sofos, 2012).

In the chilling tank, many broilers may get contaminated directly by contacting with a contaminated broiler or indirectly by the water. In 1987, a FSIS project—aimed to determine microbial prevalence and concentration at different processing stepsdemonstrated that chilling tanks significantly reduce Salmonella spp. concentration, while significantly increase prevalence from 10 – 12.5% to 27.5 – 37.5%. Yang et al. (2009) simulated the chilling tank process and reported that the contamination probability was affected by chlorination and water age (h). Moreover, bactericidal effects of chlorine were diminished due to deposited organic materials in the water. The probability of contamination was estimated at 0.12 when using water only; and 0.02 when using < 4 hour old chlorinated water (50ppm); and 0.12 when using 5 – 16 hours old 50ppm chlorinated water. Furthermore, data collected at chilling demonstrated that the prevalence of Salmonella before chilling was 6 – 13%, and 12 – 38% after chilling; with population estimated to be 1 - 30 MPN. When chlorine was added, the prevalence was estimated from 2 - 29%, with a population <0.4 MPN/g. Based on a literature review, chilling increases the Salmonella prevalence by 7 – 164% (calculated from experimental results) (FAO/WHO, 2002b).

Chilling tank using water with antimicrobial agent (usually chlorine in the U.S.) may decrease *Salmonella* prevalence by 50%. The population of *Salmonella* on broiler carcasses may be reduced by 2 – 2.6 log₁₀ cfu after immersion chilling using antimicrobial agents (FAO/WHO, 2009c). Finstad et al. (2012) reported that when 30 ppm chlorine was added, 57% reduction in *Salmonella* was observed. According to

Berrang et al. (2009) Salmonella prevalence was reduced from 72% (35% - 97%) at rehang to 20% (from 2.5% to 60%) at post-chill. Berghaus et al. (2013) also reported that the prevalence and concentration of Salmonella was decreased due to chilling. The prevalence was decreased from 18.2% at pre-chill to 2.4% at post-chill, while the concentration was decreased from 2.57 ± 0.44 log₁₀ MPN at pre-chill to 2.32 ± 0.19 log₁₀ MPN at post-chill. In FSIS Microbiology Division (2008) baseline data collection program, the percent of positive sample at Post-Chill was 5.19% with concentration 0.7 ± 0.14 MPN/ml.

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). From above data, chilling process using chlorine may reduce *Salmonella* concentration by $2 - 2.6 \log$ (estimated mode = 2.3 log which calculated from reported concentration before and after chilling).

XC = prediction only **G/R** = Triang (-2, -2.3, -2.6)

NOTE: The chilling (tank) step may increase or decrease the prevalence of *Salmonella*-contaminated broilers. An increase in prevalence may be related to the reduction of free chlorine in chilling water due to the presence of organic materials. This affects the ability of the chilling process to significantly reduce *Salmonella* populations. Thus, a smaller decrease in prevalence will result and cross-contamination events (estimated mean = 8.7%) would increase the

prevalence. However, it was assumed that chilling (tank) process will be efficiently controlled and the level of free chlorine will always be maintained at appropriate level (i.e. 0.5 – 5 ppm), thus, between 0.81 and 2.6 log reduction is always achieved. Therefore, the model will always estimate reductions in prevalence at the chilling (tank) step.

While uncertainty is noticeable from the brief literature above, the following are examples of variability in chilling step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; contamination level (carcass and environment); number of contact with contaminated materials; processing conditions (e.g. water age, current speed).
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. water temperature, time, chemical addition ...etc.).

B.6 Grading and packaging: After chilling, whole broilers will be graded based on weight and then shrink wrapped or tray wrapped (using appropriate plastic films) and placed in boxes. The final product (i.e. chilled or frozen whole broilers) may then be placed in refrigerators or freezers prior to distribution. When portioning is not considered, the packaging step is not regarded as a significant source of contamination (FAO/WHO, 2002b).

Prevalence of *Salmonella* on finished carcasses and portions in the U.S. was estimated between 3% and 21.4% with population ranged from <12 to 1200 MPN/carcass (FAO/WHO, 2002b). According to Oscar (2004) the population of

Salmonella at processing plant ranged from 1 - >300 MPN/chicken. The prevalence of Salmonella was estimated to be 7.5% at the end of processing (FSIS Microbiology Division, 2008).

Predictive model inputs: a growth model can be used at this step to estimate process time and plant temperature on *Salmonella* concentration. Whole broilers may take 1 - 2 hours from stun to initial storage at plant, however, broiler carcasses will spend 23 - 50 minutes in chilling tank where growth is not expected due to presence of chlorine and the use of cold water $(2 - 4^{\circ}C)$ (Yang et al., 2009). Moreover, ambient temperature was reported as $12.8 - 40.5 \ ^{\circ}C$ (mode = 27.8) (Audits International/FDA, 1999). However, it was assumed that the maximum ambient temperature in slaughter house is $30 \ ^{\circ}C$ to avoid overestimating growth. This information—as well as initial contamination—can be used in a growth model (model C, section 2.2.3, chapter III) to estimate the total growth *Salmonella* may achieve during processing. The model inputs are as follows:

T = Triang (12.8, 27.8, 30);

t = Uniform (1, 2) – Uniform (0.38, 0.84)

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). The reported post-chill prevalence and end of process prevalence can be used to estimate the effect of grading and packaging step on *Salmonella* prevalence. However, it was estimated that this step would increase the prevalence by 44.5%, and the concentration by around 1 log. However, the predictive growth model predicted no growth (90% CI; 2000 iterations).

XC = max 0.445 **G/R** = Triang (0, 0, 0.01)

The following are examples of variability in grading and packaging step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; contamination level (carcass and environment); number of contact with contaminated materials; processing conditions (e.g. quality of packaging).
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC.

C) Retail Stage (2 steps; 6 inputs)

The retail stage demonstrates the performance of retail in controlling *Salmonella* on chilled or frozen whole broilers. The prevalence and concentration of *Salmonella* are predicted by modeling potential cross-contamination events (%) and growth/reduction events (log) at retail steps (i.e. distribution and storage at retail).

C.1 Distribution:

After processing, end products (i.e. chilled or frozen whole broilers) will be distributed to retails or directly to food service facilities. At this stage, end products are packaged and boxed, however, cross-contamination is expected to be minimum. The distribution is usually carried out using refrigerated trucks to reduce microbial growth, however, microbial growth is expected when temperature abuse present. There was no data reporting possible growth during broiler distribution, therefore, it will be predicted using a growth model.

Temperature abuse may occur during distribution due to long loading and unloading times, product held outside of refrigerators of freezers, and distribution truck with damaged cooling systems. There was no data to quantify such scenarios, however, these processes are usually controlled. Therefore, it was assumed that 4 - 6% of broilers flocks (randomly assigned) will experience temperature abuse during distribution. The effect of temperature abuse is estimated using a growth model.

Predictive model inputs: The water activity on broiler surfaces might vary depending on air moisture, packaging method, and/or chilling conditions. Generally, the reported a_w of broiler is 0.98 - 0.99. Additionally, the pH of broiler varies among muscle types and reported to be 5.7 - 5.9 for breast meat, and 6.4 - 6.7 for leg meat and skin. Data collected from chilling and freezing chain, the surface temperature of chilled broilers during transportation was 1 - 3 °C; and was -32 °C for frozen broiler. Moreover, the muscle temperature was reported to be 0.7 - 2.4 °C during transportation for chilled broilers; and (-31.6) - (-32.3) °C for frozen broilers. The transport time was 1 - 6 hours (FAO/WHO, 2002b). Mostly, broilers distribution is conducted by refrigerated truck, however, temperature abuse may occur. Audits International/FDA (1999) reported that change in product temperature due to transportation ranged from 3.3 - 8 °C. However, to account for potential temperature abuse, product temperature change will be considered. Finally, the above data can be used in a growth model (model C, section

2.2.3, chapter III) to predict potential *Salmonella* growth due to temperature abuse during distribution. The growth model inputs are as follows:

pH = Uniform (5.7, 6.7);

 $a_w = \text{Uniform } (0.98, 0.99);$

t = Uniform (1, 6);

T = chilled broiler: Uniform (1, 3) + Uniform (3.3, 8);

frozen broiler: Uniform (-32.3, -31.6) + Uniform (3.3, 8)

Inputs Optimization: Cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). It was assumed that the maximum cross-contamination percent is 2% for chilled broilers and 1% for frozen broilers (i.e. to avoid overestimation) because at this stage broilers are packaged and boxed. Furthermore, the predictive growth model predict no growth for both chilled and frozen broilers (90% CI; 2000 iterations).

XC = max 0.02 (chilled); max 0.01 (frozen)

G/R = Chilled: Triang (0, 0, 0.1); Frozen: Triang (0, 0, 0.01)

Temperature abuse (%) = Triang (0.04, 0.05, 0.06)

While uncertainty is noticeable from the brief literature above, the following are examples of variability in the distribution step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; level of contamination (environmental and product); distribution conditions; package quality; number of contact with contaminated broiler.
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. distribution time and temperature).

C.2 Storage at retail: When chilled or frozen whole broilers arrive to retail, they will be stored in refrigerators or freezers until they are picked by consumers. Mostly, the temperature of retail refrigerators and freezers are controlled and monitored, however, abusive storage at retail may occur. There was no data to quantify such scenarios, however, it was assumed that 4 - 6% of broilers flocks (randomly assigned) will experience temperature abuse during storage at retail. The effect of temperature abuse is estimated using a growth model.

According to extensive literature review, the prevalence of *Salmonella* in the U.S. retail market was estimated as 7.3 – 50%, with a concentration range of 0.34 – 0.5 MPN/ml (FAO/WHO, 2002b). Oscar (2004) reported that the *Salmonella* concentration at retail ranged from 10 – 1100 MPN/chicken. Oscar et al. (2010) conducted a study to map the distribution of *Salmonella* on young chicken carcasses by isolating *Salmonella* from 70 Cornish game hens obtained from retail over a 3-year period; further each hen was aseptically portioned into 12 parts. The authors reported that *Salmonella* prevalence was 21.5% for parts and 57.1% for carcasses. According to the 2010 executive report from the National Antimicrobial Resistance Monitoring System

(NARMS) of the FDA, the prevalence of *Salmonella* in retail chicken breast was 13.0% (Thakur et al., 2013).

Predictive model inputs: based on data collected by Audits International/FDA (1999), the temperature of meat products at retail ranged from -7.2 - 14.5 °C (mean = 4 ± 2.8 °C) for chilled meat; and ranged from -33 - 0 °C (mean = -14 ± 7 °C) for frozen products. Retail storage temperature ranged from -11 - 15.6 °C (mean = 3.3 ± 2.9 °C) for backroom refrigerators; and -35.5 - 7.2 °C (mean = -13 ± 6.3 °C) for backroom freezers. The storage time at retail was estimated as 2 - 7 days (assumed to be uniformly distributed) (FAO/WHO, 2002b). Finally, the above data can be used in a growth model (model C, section 2.2.3, chapter III) to predict potential *Salmonella* growth model inputs are as follows:

pH and a_w = same values as in distribution step;

t = Uniform (48, 168);

T = chilled broilers: Normal (4, 2.8) (max = 14.5, min = -7.2);

frozen broilers: Normal (-14, 7) (max = 0, min = -33).

Inputs Optimization: cross-contamination is predicted within the exposure assessment framework using a contamination model (model B.1, section 2.2.2, chapter III). It was assumed that the maximum cross-contamination percent is 2% for chilled broiler and 1% for frozen broilers (i.e. to avoid overestimation) because at this stage broilers are packaged and boxed. Furthermore, growth during storage at retail was estimated using the predictive growth model. There was no growth reported for frozen broilers; while for chilled broilers predicted growth was between 0 and 0.056 log (90% CI; 2000 iterations) (Figure 2.9).

XC = max 0.02 (chilled); max 0.01 (frozen)
G/R = Chilled: Triang (0, 0, 0.06); Frozen: Triang (0, 0, 0.01)
Temperature abuse (%) = Triang (0.04, 0.05, 0.06)

The following are examples of variability in storage at retail step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; level of contamination (environmental and product); storing conditions; package quality; number of contact with contaminated broiler.
- Growth/reduction: microbial load; product criteria PdC and process criteria PcC (e.g. storing time and temperature).

D) Consumer Kitchen Stage (3 steps; 11 inputs)

The consumer kitchen stage illustrates the performance of domestic kitchens, including food service facilities, in controlling *Salmonella* on ready-to-cook broilers. The prevalence and concentration of *Salmonella* are predicted by modeling potential cross-contamination events (%) and growth/reduction events (log) at consumer kitchen's steps (i.e. transport to home, storage at home, and preparation (cooking)).

D.1 Transport to home: This step models the potential growth and crosscontamination that may occur as a result of consumer shopping and transporting
groceries to home. This step starts after consumer pick whole broiler(s) from retail refrigerators or freezers. In this step, cross-contamination may occur with hands, shopping carts, and/or other items in shopping cart. Cross-contamination is expected to be minor in frozen broilers because of packaging, while it could be higher for chilled broilers because of presence of liquid that might leak and contaminate other items. The growth of microorganisms, including *Salmonella*, may occur depending on shopping and transporting time, product temperature, and climate condition.

Handling raw broilers during shopping and transporting to home may cause cross-contamination if the package is leaking. A study found that 12% of shopping bags were contaminated by *E. coli* (Carrasco et al., 2012b). Moreover, it was assumed that 4 – 6% of product transported to home will involve temperature abuse.

Predictive model inputs: Based on data collected by Audits International/FDA (1999), the transportation time of fresh meat to home was 13 - 380 min, with 90% of cases at 45 - 105 minutes (mean = 64 ± 26 minutes). Frozen and chilled meat product temperatures at retail were reported within the storage at retail step. The reported change in product temperature due to consumer transportation ranged from 3.3 - 8 °C. Oscar (2004) used the above data in a growth model; and predicted the potential *Salmonella* growth event from 0.0005 to 0.15 log (median = 0.04 log). Furthermore, temperature abuse was estimated using a growth model (see chapter III, section 2.2.3, model C). There was no growth reported for frozen broilers; while for chilled broilers predicted growth (90% CI; 1000 iterations) was as follows:

pH and a_w = same as previous values;

t =Normal (1.07, 0.433), (min = 0.22, max = 6.33)

T = chilled broilers: Normal (4, 2.8) + Uniform (3.3, 8);

frozen broilers: Normal (-14, 7) + Uniform (3.3, 8).

Inputs Optimization: in this step cross-contamination will not result in a prevalence change because it will be occurred with other items (e.g. hand, shopping cart, bags, and/or other items in the bag). There was insufficient data to quantify cross-contamination. If a flock was assigned to go for food service facilities the cross-contamination is considered as 0% regardless if broilers are frozen or chilled. However, if a flock was assigned to be sold at retail, the maximum cross-contamination percent for frozen broilers was assumed as 1% (because of packaging and physical state). Moreover, for chilled broilers, it was reported that 12% of shopping bags were contaminated (Carrasco et al., 2012b). This number will be generalized for cross-contamination and uncertainty will be added as follows:

XC = chilled: Uniform (0.01, 0.12); frozen: 0.01

Furthermore, *Salmonella* growth resulted from transporting broilers from retail to home was estimated using a growth model. If a flock is assigned for food service, the growth will be (0) log. For flocks assigned for retail, growth will be zero because transport to home step is not applicable. For flocks assigned for home, both chilled and frozen broilers are predicted to achieve no growth using the growth model (90% CI; 2000 iterations) (Figure 2.13).

G/R = chilled: Triang (0, 0, 0.1); frozen: Triang (0, 0, 0.01)

Temperature abuse (%) = Triang (0.04, 0.05, 0.06)

The following are examples of variability in transport to home step that affect the exposure of broilers to *Salmonella*:

- Cross-contamination: shopping behavior; handling and hygienic practices; package quality.
- Growth/reduction: microbial load; shopping time and conditions; product criteria PdC and process criteria PcC (e.g. shopping time and temperature).

D.2 Storage at home: In many cases, consumer further store broilers at their home before preparation. Typically, consumers' refrigerators and freezers are monitored less and less efficient than retail refrigerators and freezers. However, temperature abuse is a possibility at this step and microbial growth will depends on storage time and temperature. Cross-contamination can occur with other items in refrigerator/freezer especially if it is highly loaded. Because broilers are packaged at this stage, a minor number of cross-contamination events is expected especially for frozen broilers. However, in the case of chilled broilers, liquid may leak and contaminate other items in refrigerators. The FSIS—in its recommendations to safely handle and prepare chicken at home—recommends to immediately place chicken in a refrigerator (at 4.4 °C) for 1 - 2 day; or in a freezer (at -17.8 °C) for 1 year (FSIS, 2012). However, it was assumed that 4 - 6% of these packages will be involved in temperature abuse due to either not complying with recommendations or because of deficient home refrigerators.

Predictive model inputs: the temperature of product stored (after 24 hours) in domestic refrigerators in the U.S. was reported to be -6.1 - 21.1 °C (mean = 4 ± 2.65

°C); and ranged from -28.8 – 8.9 °C (mean = -15.5 \pm 3.2) in domestic freezers (Audits International/FDA, 1999). The storage time at home refrigerators was estimated between 0 – 5 days, with 2 days as most likely value (FAO/WHO, 2002b). This data is used to estimate *Salmonella* growth during home storage using a growth model (model C, section 2.2.3, chapter III).

pH and *a*^{*w*} = same as previous values;

t = Triang (0, 2, 5);

T = chilled broiler: Normal (4, 2.65), (min = -6.1, max = 21.1);

frozen broiler: Normal (-15.5, 3.2), (min = -28.8, max = 8.9).

Inputs Optimization: In this step, cross-contamination will not result in a prevalence change because it would occur with other items in refrigerators. There was insufficient data to quantify cross-contamination. However, cross-contamination is expected to be minimal regardless of whether a flock is stored at home or at a foodservice facility. It was assumed that cross-contamination is uniformly distributed as follows:

Generally, if broilers are stored for FSIS's recommended storage time, no growth is expected; however, abusive storage conditions may still occur. Potential *Salmonella* growth during home or food service storage was predicted using a growth model. There was no growth predicted for both chilled and frozen broilers (90% CI; 2000 iterations).

G/R = chilled: Triang (0, 0, 0.1); frozen: Triang (0, 0, 0.01)

Temperature abuse (%) = Triang (0.04, 0.05, 0.06)

The following are examples of variability in storage at home step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; storage conditions; package quality.
- Growth/reduction: microbial load; shopping time and conditions; product criteria PdC and process criteria PcC (e.g. storing time and temperature).

D.3 Preparation (cooking): These steps include broiler preparation (e.g. package removal, thawing, portioning, washing, and marinating), cooking, and serving. This step is expected to reduce microbial load because of washing and cooking. In contrast, depending on thawing method and time, thawing may increase the microbial load. According to FSIS recommendations for handling and preparing safe chickens, three methods of thawing are recommended: in the refrigerator, immersion in cold water, and in a microwave oven. Thawing may take 1 - 2 days in a refrigerator, 2 - 3 hours in cold water, or several minutes in a microwave oven. Washing raw poultry before cooking is not recommended because bacteria in raw poultry juices may be spread and cause cross-contamination (FSIS, 2012).

In the preparation step, cross-contamination is expected in a high percentage because of the high number of contacts a broiler makes before cooking (e.g. contact with hands, cutting board, knives, surface, washing facilities, and utensils). Consumer mishandling is considered as a main source of cross-contamination. Inadequate

storage, handling, and cooking are considered a main cause of foodborne infection. It was demonstrated that 25% of reported outbreaks are caused by consumer mishandling and food preparation at home (Carrasco et al., 2012b). The CDC reported that about 37% of foodborne diseases caused by bacteria from 1993 – 1997 were associated with cross-contamination (18% from contaminated equipment, and 19% from poor hygienic practices). Additionally, a United Kingdom surveillance report stated that cross-contamination was a main factor (32%) in outbreaks reported from 1999 – 2000 (Pérez-Rodríguez et al., 2008). However, in a study conducted by Oscar (2013), only a single cross-contamination event occurred out of the 57 meals (1.8%) prepared under the simulated conditions. The author simulated the worst-case food preparation scenario by using the same knife, cutting board, and latex gloves for preparing raw chicken and cutting cooked chicken without first rinsing or washing the cutting board, knife, or hands.

Based on a review conducted by Oscar (2004), the cross-contamination event rate in consumer kitchens averaged 28%. Redmond et al. (2004) studied nine crosscontamination behaviors in consumer kitchens in the United Kingdom. The study examined three consumer groups: adults aged 60 – 75 years, mothers with one or more children, and single males aged 18 – 28 years. The potential contamination rates were 33%, 11%, and 44%, respectively. Another study which evaluated the crosscontamination events in domestic kitchens found that the frequency of crosscontamination for *Salmonella* spp. was 16.6% (Pérez-Rodríguez et al., 2008). A study conducted by Cogan et al. (2002) demonstrated that after meal preparation with *Salmonella*-contaminated chicken, but before cleaning, 40% of hand- and food-contact

surfaces (i.e. hand, board, cloth, tap, knife, and door handle) were contaminated with a concentration between <1 to >3 log cfu/m². The proportion of *Salmonella*-contaminated surfaces was not significantly decreased where surfaces were cleaned using a bowl-wash routine with a detergent but without rinsing. When surfaces were cleaned using a bowl-bowl-wash procedure followed by thorough rinsing under running water, the proportion of contaminated surfaces was significantly reduced from 40% to 16.7%.

Poultry is recommended to be cooked (i.e. roasted, simmered, or grilled) for 60 - 90 minutes to achieve an internal temperature of 73.9 °C (FSIS, 2012). Thorough cooking is expected to eliminate all pathogenic bacteria on broilers. According to FAO/WHO (2009c) cooking to a minimum internal temperature of 74 °C may reduce *Salmonella* by 7 log₁₀ cfu. Oscar (2004) simulated the cooking process using inactivation model to estimate the effect of cooking on *Salmonella* concentration and reported that cooking reduced *Salmonella* by 0.83 – 9.6 log (mode = 8.1 log).

Generally, shorter cooking time and/or lower cooking temperature would result in undercooked broilers with potential surviving bacteria. The probability of inadequate cooking was assumed to be from 0.05 - 0.15, with 0.1 as the most likely value (FAO/WHO, 2002b; Smadi and Sargeant, 2013). However, Audits International/FDA (1999) reported that 55% of cooked poultry was under recommended cooking specification (i.e. ≤ 73.9 °C). Furthermore, according to FAO/WHO (2002b) 10 - 20% (mode = 16%) of *Salmonella* on contaminated broilers is in protected areas that receive a milder cooking process. The protected areas are assumed to be exposed to a lower cooking temperature range 60 - 65 °C (mode = 64 °C) for a shorter time ranged 0.5 - 1.5 minutes (mode = 1 minute).

Predictive model inputs: the reported temperature of cooked poultry in domestic kitchens was reported as from 37.8 - 115.6 °C (mean = 70.3 ± 11.5) (Audits International/FDA, 1999). Smadi and Sargeant (2013) reported that the internal temperature resulted from chicken cooking were 55 - 70 °C; this range was covered by meta-analysis of inactivation studies. Based on Chicken Farmers of Canada recommendations for cooking chicken breasts, cooking time was assumed to be 45 - 90 minutes, with 60 minutes as the most likely value. Oscar (2004) assumed cooking time as 15 - 45 minutes (median = 30 min). Moreover, the FSIS recommendation for cooking whole broiler varies depending on the weight and cooking method.

From the above review, cooking time may range between 35 to 180 minutes (mode = 60 minutes) depending on cooking methods, broiler weight, and consumer preference. However, in the cooking process, broilers need some time to reach the desired internal temperature, thus, holding time is much less than cooking time. The reported cooking time is used to calculate process lethality based on D-values. Additionally, it might be appropriate to assume that holding time accounts for 1 - 10% of cooking time, thus, holding time nay be used in D-value calculation to avoid overestimation of D-value.

The above data is used to estimate *Salmonella* inactivation due to cooking using an inactivation model (model B, section 2.2.3, chapter III). The model has a range of temperature between $55 - 70^{\circ}$ C; however, both cooking and undercooking events can be modeled using this model. Cooking is modeled when the model uses temperature inputs between $66 - 70^{\circ}$ C; while undercooking is modeled when the model uses temperature inputs between $55 - 65^{\circ}$ C. The inactivation model inputs are as follows:

Salmonella constant (**a**) = 0.1316;

Salmonella constant (b) = 8.7344; Temperature (T) = cooking: Uniform (66, 70), undercooking: Uniform (55, 65); Time (t) = Triang (35, 60,180), in protected cells = Triang (0.5, 1, 1.5); z-value (z) = Uniform (5.34, 5.56); Reference Temperature (T_{ref}) = 70;

D-value at T_{ref} (**D**_{ref}) = Uniform (0.07, 0.09); (Murphy et al., 2004b)

Transient Time (dt) = 1 second = 0.017 minute. (Murphy et al., 2004a)

Inputs Optimization: it was reported that 1.8 - 37% (estimated mode = 25) of outbreaks are related to consumer mishandling (i.e. cross-contamination). This range is used to quantify cross-contamination from uncooked cells (i.e. cross-contamination caused by hands and/or surfaces). Moreover, cross-contamination percent at consumer kitchens was reported as 11 - 44% (estimated mean = 29%).

XC (raw) = Triang (0.02, 0.25, 0.37) **XC** = Uniform (0.11, 0.44)

The minimum percent of protected cells on broilers was changed to zero, to account for broilers with external contamination only. The inactivation model was used to estimate the effect of cooking (process lethality) for cooked broilers (Figure 2.10), undercooked broilers (Figure 2.11), cooked protected cells (Figure 2.12), and undercooked protected cells (Figure 2.13).

$$\mathbf{G/R} = \begin{cases} \text{Cooked} = \text{Triang} (-3.07, -8.25, -22) \\ \text{Protected cells} = \text{Triang} (-0.04, -0.07, -0.22) \\ \text{Undercooked} = \text{Triang} (-0.04, -0.08, -2.9) \\ \text{Undercooked protected cells} = \text{Triang} (-0.01, -0.01, -0.06) \\ \text{Undercook} (\%) = \text{Triang} (0.05, 0.1, 0.15) \\ \text{Protected cells} (\%) = \text{Triang} (0, 0.16, 0.2) \end{cases}$$

While uncertainty is noticeable from the brief literature above, the following are examples of variability in preparation (cooking) step that affect the exposure of broilers to *Salmonella*;

- Cross-contamination: handling and hygienic practices; surfaces and utensils contamination.
- Growth/reduction: microbial load; shopping time and conditions; product criteria
 PdC and process criteria PcC (e.g. cooking time temperature, thawing time and temperature).

2.6.2.2 Hazard Characterization Data (2 inputs)

Hazard characterization is an iterative process that aims to estimate the probability of illness for specific commodity if microbial load is known. A hazard characterization for *Salmonella* can be used in risk assessment for a variety of commodities. In QMRA, hazard characterization is performed using a dose-response model which provides a quantitative description of the relationship between ingested dose of *Salmonella* and the probability of adverse health effects (i.e. salmonellosis)

(FAO/WHO, 2002b; FSIS and EPA, 2012). The dose-response model calculates the probability of illness (P_{iil}) resulted from a specific dose taking into consideration host characteristics (i.e. normal or susceptible). The dose-response model developed by the FSIS of the USDA is used to perform the quantitative hazard characterization. This model is characterized by the dose (i.e. exposure assessment result), beta parameter (β) (i.e. represent host variability), and alpha parameter (α) (i.e. represents *Salmonella* infectivity, and variability if applicable). The uncertainty present in dose amount and the beta parameter, however, alpha parameter can also a probability distribution.

Inputs Optimization: Dose-response model's inputs (i.e. α and β parameters) were reported by FAO/WHO (2002b) as follows:

- (β) Normal population = Normal (21.159, 20), min = 0, max = 60
- (β) Susceptible population = Normal (2.116, 2), min = 0, max = 6
- (α) for Salmonella = 0.2767 (or can be Triang (0.0763, 0.1324, 0.2767))

2.6.2.3 Risk Characterization Data (30 Inputs)

A) Epidemiological Data (5 inputs):

The epidemiological data after attribution to whole broilers will not be used in (ARE) or (AI) calculation, it will only be used to validate the risk assessment baseline model. According to the Centers for Disease Control and Prevention (CDC), in 2011, the average annual incidence of foodborne salmonellosis was estimated as 1,027,561 (644,786 – 1,679,667) case/year (~ 14.4/100,000 persons). The average annual hospitalizations was estimated as 19,336 case/year, while average annual deaths was

estimated as 378 per year (CDC, 2011). Based on U.S. data, about 93% of patients with salmonellosis fully recovered without a physician visit, 5% visited a physician and recovered fully, 1.1 - 1.5% required hospitalization, and 0.04 - 0.1% die (FAO/WHO, 2002b). However, hospitalization and death rates can also be estimated from CDC's reported numbers. Furthermore, duration and severity of salmonellosis are varied, however, underreporting is expected. It was estimated that the salmonellosis underreporting multiplier is 4 - 16 (median = 7). This multiplier can be used to estimate salmonellosis incidents in the community (Hall et al., 2008).

In 2008, the CDC study of attribution of foodborne illnesses to food commodities based on outbreaks data shows that 10 – 30% of salmonellosis was attributed to poultry products (Painter et al., 2009). Approximately 4.4% of salmonellosis in the United States was attributed to chicken for a rate of 0.66 – 0.88 cases per 100,000 chicken consumer (Oscar, 2004). The Risk Assessment Division, FSIS, USDA in its report "Potential Public Health Impact of *Salmonella* and *Campylobacter* Performance Guidance for Young Chickens and Turkeys" estimated illnesses from *Salmonella* attributed to be 0.163 (FSIS, 2011). In 2007, an expert elicitation attributed 35% of foodborne salmonellosis in the U.S. to poultry. Additionally, 35% of hospitalizations and 18% of deaths associated with salmonellosis were attributed to poultry (Finstad et al., 2012).

Inputs Optimization: From the above information the epidemiological data inputs are as follows:

Annual salmonellosis (not attributed) = Triang (644786, 1027561, 1679667) cases/year

Hospitalization Rate = Triang (0.01, 0.015, 0.022) Death Rate = Triang (0, 0.0004, 0.001) *Salmonella* attribution factor to whole broiler = Triang (0.096, 0.163, 0.288) Under-reporting Multiplier = Triang (4, 7, 16)

NOTE: CDC attributed 10 – 30% of foodborne salmonellosis to poultry. The USDA estimated the mean of salmonellosis from poultry as 17%, and 96% of those cases will be from broilers. Therefore, it was estimated that 16.3% of salmonellosis is attributed to broilers. Similarly, the minimum (9.6%) and maximum (28.8%) attribution factors were estimated, although not reported by the USDA.

B) Production characteristics (6 inputs):

In 2011, the total broiler chicken production in the U.S. was estimated to be around 8.6 billion birds (about 107.8 million birds lost) with total weight produced ~49.2 billion pounds. The total value of 2011 broiler production was estimated around \$23.2 billion (USDA, 2012). According to Economic Research Service (2012), around 18.5% of broiler production was exported while 81.5% was sold locally. However, chilled and frozen whole broilers, at retail, represents only 12% of the U.S. broiler market. According to NCC (2014a), the mean flock size in the U.S. was estimated to be 20,000 bird/house. Furthermore, according to the National Agricultural Statistics Service (NASS) of the USDA, frozen young chicken contributes approximately 10% of the total production based on weight (USDA, 2013).

In 2010, based on National Chicken Council (2012) data, the U.S. consumers buy chicken from grocery stores 3.6 times every 2 weeks; and eat chickens at food service facilities 2.1 times every 2 weeks. However, it was estimated that 45.6% of flocks are going to food service facilities and the other 54.4% are going to retail then to consumers. Flocks going to food service facilities will skip Storage (retail) and Transport (home) steps.

Inputs Optimization: From the above information the production characteristics inputs are as follows:

Annual whole broiler production ≈ 8.49 billion bird/year Proportion of domestic broilers = 0.815 Proportion of whole broilers = 0.12 Flock size = 20,000 bird/house Proportion of broilers going to consumers' home = 0.544 Proportion of frozen broilers = 0.1

C) Affected population (5 inputs):

According to the United States Census Bureau, the population of the U.S. in 2010 was estimated around 308 million capita. The National Chicken Council (2012) estimated that 90% of consumers eat chicken from retail and foodservice during two weeks. Moreover, according to NCC, in 2010–11, the U.S. annual consumption of broiler chicken averaged 84 pounds per capita (NCC, 2014b). However, this number should be attributed to whole broiler and converted to serving rather than pound to be used in ARE calculation. The living weights of broilers in the U.S. ranges between 4.25

and 7.75 lb. (estimated mean = 5.25 lb.) (MacDonald, 2008). Furthermore, edible meat and other parts of a broiler after processing contributes 58.7% of the living weight (Rose, 1997). Due to the variation in broiler weight, it was assumed that one whole broiler will yield 3 - 6 servings with 4 the most likely number.

Susceptible people to foodborne illnesses include, but are not limited to, young children, elderly, pregnant women, alcoholics, diabetics, and people with diseases that affect the immune systems. The susceptible population in developed countries including the U.S. is estimated at 15 – 20% (Lund and O'Brien, 2011).

Inputs Optimization: From the above information the affected population inputs are as follows:

U.S. population = 308,000,000 capita Proportion of chicken consumers = 0.9 Proportion of susceptible population = Uniform (15, 20) Number of servings = Triang (3, 4, 6) Annual consumption = $84 \times 0.12 \approx 10.1$ (lb. from w. broiler/year) = $10.1 / (5.25 \times 0.587) \approx 3.3$ (w. broiler/year) = 3.3×1000 km ber of serving/broiler (w. broiler servings/year)

D) Socio-economic Analysis (14 inputs):

According to CDC, salmonellosis usually lasts 4 – 7 days, and patients recover within a week without antibiotic treatment. In some cases, however, symptoms (i.e. diarrhea, fever, and abdominal cramps) may be so severe that the patient needs to be hospitalized. Hospitalization is more likely for patients with antibiotic-resistant Salmonella (FAO/WHO, 2002b). The immune-compromised, elderly, and infants are more likely to have a severe illness.

The severity of salmonellosis is illustrated by "disability weight" which reflects the average degree of disability a person may suffer due to illness on a scale of 0 - 1, where 0 is equivalent to perfect health and 1 is equivalent to death (FAO/WHO, 2009b). The WHO in its report "Global burden of disease 2004 update: disability weights for diseases and conditions" demonstrated that diarrhea episodes mean disability weight is 0.137 (0.086 – 0.461 depends on severity, age, and treatment) (WHO, 2004). Gkogka et al. (2011) demonstrated that the disability weight of salmonellosis depends on the severity and potential sequelae. The disability weight for underreported cases was estimated at 0.067; 0.393 for cases with gastroenteritis, 0.26 for cases with inflammatory bowel disease; 0.042 for cases with irritable bowel syndrome; and 0.154 for cases with reactive arthritis.

According to CDC, in 2010, the life expectancy at birth in the U.S. was estimated as 81 years for females and 76.2 years for males (average = 78.7) (CDC, 2013). The average cost due to premature death will vary from \$1.4 million (at age 85) to \$8.5 million (at birth) depends on age at death and gender. However, two thirds of people died as a result of salmonellosis were aged 65 years or older, therefore, ERS estimated the average of premature death between \$3.5 million for females and \$4.1 million for males (average = \$3.8 million/death) (Frenzen et al., 1999). Adhikari et al. (2004), however, estimated the average cost of premature death as \$4.63 million/death.

Economic Research Service (ERS) estimated that 170,000 salmonellosis cases visited a physician (i.e. outpatient) (64% of hospitalized cases, 1.8% of non-hospitalized

cases, and 90% of death cases). The average days lost due to salmonellosis was estimated to be 0.5 day for cases not visiting a physician; and 1.6 days for cases visiting a physician, and 4.5 days for hospitalized cases (Frenzen et al., 1999).

Adhikari et al. (2004) estimated the average cost of productivity loss due to salmonellosis at \$53 with assumption that mild illness would only cause 0.5 day of work and household services. The average cost of outpatients was estimated at \$298, with average 1.6 days lost, and \$169 lost wages and household services. The average cost of inpatient was \$7,734 (\$ 5,981/ inpatient with gastrointestinal infection; and \$16,215/ inpatient with invasive infection), with 4.2 – 8.9 days in hospital.

In 1998, ERS estimated the annual cost of salmonellosis ranged from \$0.9 billion to \$3.7 billion under the human capital approach (Frenzen et al., 1999). The total burden of *Salmonella* in the U.S. was estimated at \$2.8 (CI: \$1.6 – \$5.3 billion) billion/year, with approximately \$2.472/case (Adhikari et al., 2004).

Inputs Optimization: From the above information, the socio-economic analysis inputs are as follows:

Lost life year = 78.7 (average life expectancy) – Triang (1, 65, 78) Disability weight: Illness = Uniform (0.042, 0.393); Hospitalization = 0.393 Disability duration (illness and hospitalization) = Uniform (1, 7) Proportion of outpatient: Illness = 0.018; Hospitalization = 0.64; Death = 0.9 Number of days lost: Illness = (0.5 - 1.6); Hospitalization = Uniform (4.2, 8.9) Cost of: Days lost = 53; Outpatient = (298+169) = 467; Inpatient = Uniform (5981, 16215); Premature death = Uniform (3.8, 4.63) million dollars

3. CONCLUSION

The main goal of the preliminary risk management activities (i.e. Chapter II) is to plan and scope the risk analysis process. Every management activity provides valuable information which facilitates the planning and scoping process. Information resulting from PRMAs would facilitate the compliance with the established frameworks to ensure the achievement of the determined risk management goals without deviation. Additionally, collected RAs data would facilitate modeling the QMRA model in a way that can achieve all the risk management goals, while maintain compliance with RAs policy.

At this stage, the food safety problem (i.e. *Salmonella*/whole broilers) was identified and semi-qualitatively described (in the risk profile). Such information is valuable to facilitate sound understanding of the characteristics of *Salmonella*/whole broilers combination and its associated risk. Furthermore, the risk management goals—which represent the project goals—are identified; and will be considered throughout the risk analysis process to ensure that the resulted risk analysis model is satisfactorily fulfill all determined risk management goals (the project goals). Moreover, the risk assessment policy demonstrates the scientific boundaries (i.e. relevant *Salmonella* strains, product, and population) that ensure sound and relevant risk assessment results. Additionally, the last activity in PRMAs (i.e. developing the QMRA model) illustrates the risk assessment framework as well as available risk assessment data (i.e. inputs). In some cases, data was collected to facilitate the prediction of certain RAs inputs using microbial predictive models. However, the collected and predicted data

were optimized (i.e. presented as distributions) to address RAs inputs' attendant uncertainties.

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5. FIGURES AND TABLES









Exposure Assessment (Performance Criteria)												
STAGE	STEP		Mean	Std Dev.	This Flock							
		I. C. (log)	2.4	4.9	PBF/PWF	Туре	Distination	Season				
Farm	Rearing	PBF (%)	0.3860	0.0594	0.2585	Chilled	FoodServ	Fall				
		PWF (%)	0.5730	0.312	0.3302	1	2	4				
	Transport to Plant	X.C. (%)	TR (Max)	TR (Min)	G/R (Min)	G/R (Mod)	G/R (Max)	P. Growth				
		0.213	0.55	0.04	0	0	0.195	0.834				
Processing	Scalding	0.226	0.55	0.04	-2.5	-2.00	-0.8					
	Defeathering	0.175	0.55	0.04	-0.8	-0.65	-0.5					
	Evisceration	0.191	0.55	0.04	0	0.00	0.1					
	Washing	0.250	0.55	0.04	-2.1	-1.30	-0.6					
	Chilling (Tank)	0.082	0.55	0.04	-2.6	-2.30	-2	Temp.				
	Grading & Packaging	0.017	0.54	0.04	0	0.00	0.01	Abuse (%)				
Retail (FS)	Distribution	0.00	0.54	0.04	0	0.00	0.1	0.047				
	Storage at Retail	0.003	0.56	0.04	0	0.00	0.06	0.050				
Consumer Kitchen	Transport to Home	0.00	0.55	0.04	0.00	0.00	0.01	0.048				
	Storage at Home	0.000	0.55	0.04	0	0.00	0.01	0.047				
	Preparation (Cooking)	X.C. (%)	X.C. (raw)		G/R (Min)	G/R (Mod)	G/R (Max)	UnderCeele				
		0.408	0.294	Cooking	-22	-8.26	-3.07	(%)				
				P.Cells Cook	-0.22	-0.07	-0.04	(70)				
		TR (Max)	TR (Min)	Undercook	-2.9	-0.08	-0.04	0.085				
		0.54	0.04	P.Cells UC	-0.06	-0.01	-0.01	0.005				
		% of prote	ected cells	0	0.16	0.2						

Figure 2.4: Hazard and Risk Characterization inputs as they appear in the QMRA model.

Hazard & Risk Characterization												
Dose-Respo	nse Model Characte	rization"	"Hazard	Production Characteristics								
Normal		Susceptible		Annual Broil	ler Production	8,499,807,000						
(α)	0.1432	(α)	0.1318	Locally Sold	Broiler (%)	0.815						
(β) Min	20	(β) Min	2	Whole Broil	er (%)	0.12						
(β) Mean	21.16	(β) Mean	2.116	Flock Size (Mean)		1,000						
(β) Max	60	(β) Max	6	Home (%)	FoodServ(%)	Frozen (%)	Chilled (%)					
SD	20	SD	2	0.54	0.46	0.1	0.9					
Epidemiological Data				Affected Population + Consumption Pattern								
Annual Salmonellosis		1,214,961		Population		308,000,000						
Hospitalization Rate		0.014		Susceptible Popu, (%)		0.167						
Death Rate		0.00070		Chicken Consumer (%)		0.9						
Broiler Attribution Factor		0.171		Annual Serving		16.5						
Under-Report Multiplier		6.3		Number of Servings		5						
			Socio-econc	omic Analysi	S							
Disab	oility-Adjuste	d Life Year (D	OALY)	Cost of Illness (COI)								
		Illness	Hospit.	Lost Day	Outpatient	Inpatient	Death					
Disability We	eight	0.260	0.393	53	467	10,484	3,913,923					
Disability Du	ration (day)	5.8	4.9		Illness	Hosp.	Death					
Lost Life Year (year)		54.1		Out Pnt. (%)	0.018	0.64	0.9					
				# Day Lost	1.6	4.7						

Figure 2.5: Estimated Salmonella PBF (%) at rearing step (using transmission PM)



Figure 2.6: Estimated Salmonella PWF (%) at rearing step (using transmission PM)



Figure 2.7: Estimated cross-contamination (%) at transport to plant step (using transportation contamination PM)



Figure 2.8: Estimated growth (log) during transport to plant step (using growth PM)



Figure 2.9: Estimated growth (log) during storage at retail step for chilled broilers (using growth PM)



Figure 2.10: Estimated reduction (log) during preparation step resulted from cooking (using inactivation PM)


Figure 2.11: Estimated reduction (log) during preparation step resulted from undercooking (using inactivation PM)



Figure 2.12: Estimated reduction (log) for protected cells during preparation step resulted from cooking (using inactivation PM)



Figure 2.13: Estimated reduction (log) for protected cells during preparation step resulted from under-cooking (using inactivation PM)



CHAPTER III: QUANTITATIVE MICROBIAL RISK ASSESSMENT

ABSTRACT

A risk assessment was conducted to estimate the likelihood and severity of salmonellosis attributed to whole broiler consumption in the United States. At this stage, the information resulted from PRMAs was utilized to construct a quantitative microbial risk assessment (QMRA) model in Excel® (Microsoft Corporation, Redmond, WA, USA). @RISK[®] "Add-ins" software (Palisade Corp., Ithaca, NY, USA) was installed to Excel to account for attendant uncertainties by performing Monte Carlo simulation. In the QMRA model, exposure assessment (EA) is characterized by performance criteria of each step from farm to fork. Generally, PCs for each step is characterized by the step effect on *Salmonella* prevalence and concentration (i.e. growth/reduction and cross-contamination events).

After constructing the QMRA model, the model was reviewed and tested to quantify the effect of RAs modeling approach on the overall results. This process demonstrated that modeling growth/reduction events first within EA using @RISK distribution (for 1000 broilers) gives better AI estimation. Additionally, some secondary results of the QMRA model such as prevalence and concentration of *Salmonella* at different steps were compared with reported data and found to correspond.

The model was then calibrated using the @RISK "Risk Optimizer" function while targeting uncertainties related to growth/reduction during scalding, de-feathering, washing, and chilling. With minor changes to targeted RAs inputs, calibration

successfully reduced the estimated annual salmonellosis from around 367,000 cases to around 222,000 cases which is similar to CDC reported salmonellosis attributed to whole broilers. Furthermore, sensitivity analysis for EA inputs—after eliminating variability—identified 10 inputs that significantly affect the annual illnesses uncertainty and their effect on AI mean; and one input with significant linear correlation with AI. At this stage, the QMRA model is ready to inform the food safety decision-making process and to establish a food safety control system for whole broilers.

1. INTRODUCTION

1.1 Risk Assessment:

Codex defines risk assessment as "a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization." These four steps facilitate the systematic implementation of risk assessment, however, their details will depend on risk assessment scope (FAO/WHO, 2002b). Risk assessment is considered a data consuming process. However, risk assessors need to collect a large amount of information to be used as inputs in the risk assessment model. All information and data collected should be pertinent to a specific situation (e.g. all collected data should be related to the U.S. food production system). In case of a generic input or no country specific data, risk assessors might make underlying assumption based on data published in somewhere else around the world (FAO/WHO, 2002b).

Risk assessment aims to estimate the likelihood and severity of risk (e.g. salmonellosis) attributed to a specific hazard/commodity combination (e.g. *Salmonella*/whole broiler) on public health. It facilitates the understanding of how the risk is influenced by various factors from farm to fork (CAST, 2006; FAO/WHO, 2002b). Additionally, risk assessment links hazard presence in food (due to exposure of food to the hazard) to public health (due to population exposure to the hazard resulting from consuming contaminated food). However, this can be done mathematically by establishing a risk assessment model. Additionally, a risk assessment model does not estimate risk precisely due to insufficient data (i.e. model's inputs) and modeling

assumptions that result in various sources of uncertainty throughout risk assessment model. However, uncertainty should be incorporated into risk assessment to deal with a lack of data. Although large uncertainty would result in very broad risk estimates, decision making must often proceed. Finally, sensitivity analysis can help in determining the importance of model parameters (i.e. magnitude of inputs effect) on risk assessment outputs, therefore, parameters with high impact should be identified and data collection efforts should be focused on these parameters to reduce their uncertainty (CAST, 2006; Havelaar et al., 2008).

Risk assessment models can be qualitative or quantitative depends on knowledge and data availability taking into account the complexity of the food safety problem and the available time and resources to conduct risk assessment. In qualitative model, risk will be classified as low to high, while in quantitative model risk will be described numerically. The choice between qualitative and quantitative model is greatly depends on data availability, underlying assumption, and type of outputs (i.e. what output required to inform decision-making). Furthermore, quantitative risk assessment can be either deterministic (i.e. a single value estimate, e.g., mean and/or best/worstcase scenario) which does not include randomness; or probabilistic (i.e. probability distribution) that include randomness component. Generally, probabilistic model better represent the real system by incorporating randomness inherent in nature. Additionally, probabilistic model incorporate variability (i.e. heterogeneity which is not reducible by more data) and/or uncertainty (i.e. incomplete knowledge that can be reduced by further study or data collection) in risk assessment inputs as distributions of values. Finally, the process of risk assessment involves subjective judgments including, but not limited to,

choosing model type, selecting data, and analyzing data (Bassett et al., 2012; CAST, 2006; FAO/WHO, 2009b).

After the required information and data were collected, they should be optimized to fit in risk assessment model as inputs taking into consideration the model construction. The optimization process is transforming literature review and/or predictive model results to values that incorporate uncertainty and/or variability to risk assessment inputs. During data collection and optimization, risk assessors can identify data gaps (i.e. inputs that have limited or no data reported in literature and cannot be calculated using predictive models). Data gap is usually compromised by making assumption, or eliminating the input from risk assessment model. The data gap along with associated uncertainty should be reported to risk manager.

After constructing the appropriate model and collect all the required data, the baseline model (i.e. no action scenario) will be constructed. Baseline model estimate the unrestricted risk (i.e. level of risk present if no deliberate action were taken) which has a key role in estimating the efficacy of current risk management approaches and in estimating the effect of possible intervention(s). Using "what-if" scenario, model's parameters can be changed to predict the potential effect of possible intervention(s) on the model results (i.e. public health). However, the baseline model is considered as the starting point of decision-making (i.e. risk management) (FAO/WHO, 2009b).

A. Hazard Identification:

The term "Hazard" may be defined as "the stressor or agent capable of causing an adverse effect on the exposed individual(s)." However, risk assessment process

should begin with hazard identification step to identify and describe the hazard of interest. In microbial risk assessment context, hazard term refers to the pathogen of interest (i.e. *Salmonella*); while risk term refers to the associated health adverse effects (i.e. salmonellosis) (FSIS and EPA, 2012). According to Codex (1999), hazard identification is defined as "the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods." It aims to qualitatively identify a hazard and its associated health adverse effect by providing important information about the hazard, food commodity, and host interface. Furthermore, hazards can be identified from relevant data sources such as epidemiological studies, governmental reports, foodborne outbreaks data, food industry, published scientific literature, and expert elicitation (Bassett et al., 2012; Codex, 1999).

Hazard identification demonstrates hazard/commodity and hazard/affected population relationships. It usually identifies the susceptible population, type of disease (i.e. chronic or acute), and the mechanism of causing effect on host (i.e. infection or intoxication) (Bassett et al., 2012). Generally, for new or emerging pathogens, hazard identification should be fully developed. In contrast, for well-known pathogens, hazard identification may be simple and straightforward process (FAO/WHO, 2008). In some cases, risk profile document which resulting from preliminary risk management activities may be sufficient and may replace hazard identification process (FAO/WHO, 2006a).

B. Exposure Assessment:

After the enactment of the SPS Agreement, ALOP became the scientific basis for food safety regulatory measures which aims to quantify the health impact of a food hazard. ALOP is a political question that addressed to risk managers. However, when a clear defined ALOP is unavailable, risk managers may consider predicting it statistically as a unique quantitative exposure assessment. This would be achieved by identifying a hazard and assessing the potential exposure (i.e. ingestion) to that hazard. Therefore, exposure assessment is considered a critical element of risk assessment to estimate the likelihood and the quantity of consumer exposure to a hazard. It could be applied to hazardous and beneficial substances related to food including naturally present substances, food additives, food supplements, contaminants, and pesticide residues (Verger and Fabiansson, 2008). There are a number of factors that define microbial exposure assessment including, but not limited to, source of microorganism and its characteristics, exposure route, cross-contamination, growth/reduction events, and consumer intake (i.e. consumption pattern).

According to Codex (1999), exposure assessment is defined as "the qualitative and/or quantitative evaluation of the likely intake of a microbial hazard via food with the potential to cause an adverse health effect." The main goal of exposure assessment is to determine the route, frequency, duration, and amount of exposure to a microbial hazard in a population (FSIS and EPA, 2012). When conducting exposure assessment, process-specific factors would affect the prevalence and concentration of a hazard, and hence the final exposure. Such factors are expected to be both inherently variable due to differences in process specifications, and uncertain due to lack of sufficient

knowledge. Because variability describes real and natural process or situation, it cannot be reduced. Moreover, uncertainty is related to availability of data and can only be reduced by more knowledge (i.e. after identifying data gaps). Generally, variability and/or uncertainty should be identified and their influence on the risk assessment outcome should be described (FAO/WHO, 2002b; FAO/WHO, 2008).

Quantitative risk assessment, including exposure assessment, requires constructing mathematical models with the use of logical tests and conditional statements (e.g. "what-if" scenarios) within the model (FAO/WHO, 2008). However, the use of a probabilistic model is more favorable than a deterministic (or point of estimate) model in conducting risk assessment. Probabilistic models represent variability and/or uncertainty using probability distributions. Probability distributions describe the relative weightings of each possible outcome and can provide more realistic results by accurately characterizing the impacts of sources of variability and uncertainty. Probabilistic models can be implemented using Monte Carlo simulation which involves a large number of iteration (i.e. events repetition) to produce a probability distribution to estimate exposure (FAO/WHO, 2002b; FSIS and EPA, 2012).

Exposure assessment can be facilitated by predictive microbiology. The dynamics of microbial population depends on environmental factors (e.g. nutrients, time, temperature, a_w, pH ...etc.) and other biological factors (e.g. transmission rate, adhesion, mobility, growth specification, thermal inactivation ...etc.). However, change in microbial prevalence and/or population due to microorganism behavior across different environmental conditions can be predicted using microbial predictive models (e.g. transmission, cross-contamination, growth, inactivation models). Therefore, data

regarding environmental factors, biological factors, and microbial load is required to be used in the microbial predictive models (FSIS and EPA, 2012).

In some cases, exposure assessment may be a stand-alone process without conducting a complete risk assessment (i.e. without hazard characterization and risk characterization). In such cases risk managers only seek to minimize exposure or when there is no data available to conduct a dose-response assessment (FAO/WHO, 2008). In other cases, however, quantitative exposure assessment provides data as input for dose-response model. This data will be in a form of exposure distribution that provides the likelihood and concentration of a hazard at the time of consumption. The frequency and concentration of an ingested hazard will also depend on the amount of food consumed (at a consumption event), however, the final stage of exposure assessment model is the determination of consumption patterns of a food commodity. In risk characterization stage, exposure assessment and dose-response assessment are combined to estimate the risk (e.g. salmonellosis) of a specific hazard (e.g. *Salmonella*/whole broilers) on a specific population (e.g. the U.S. population) (FAO/WHO, 2002b; FAO/WHO, 2008; FSIS and EPA, 2012).

Usually, exposure assessment can be calculated with and without the proposed mitigation option(s). If the current practices (i.e. with no action) are modeled in the exposure assessment, the result will represent the baseline exposure. Whereas, if proposed mitigation option(s) is/are modeled in the exposure assessment, the results will represent predicted exposure. However, the effect of mitigation option(s) can be estimated by comparing the baseline exposure with predicted exposure. According to

FAO/WHO (2008), exposure assessment may be undertaken for different purposes and in different contexts. For example, exposure assessment could be conducted to:

- Combine with hazard characterization to estimate risks related to a hazard/commodity combination.
- 2- Evaluate the effectiveness of the current control measures.
- 3- Identify best step to apply mitigation option(s) to be most effective.
- 4- Compare the efficiency of potential mitigation options in reducing hazards.
- 5- Compare the exposure resulting from different routes such as crosscontamination, initial contamination, in-place control measures, and different contamination sources.
- 6- Identify data gaps (e.g. information needs and research activities) that could improve exposure estimation.
- 7- Identify and validate potential Critical Control Points (CCPs).

C. Hazard Characterization:

According to Codex (1999), hazard characterization is "The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents a dose–response assessment should be performed. For biological or physical agents a dose–response assessment should be performed if the data are obtainable" (Bassett et al., 2012). Hazard characterization can be a stand-alone process to estimate the probability of illness for specific commodity if microbial load is known (e.g. estimating potential illness from a patch of chilled broilers with known *Salmonella* load). It can also be used as a component of risk assessment model. However, in both cases hazard characterization is an iterative process. Unlike exposure assessment, hazard characterization is not a country specific. A hazard characterization for a specific pathogen can be used in risk assessment for a variety of commodities (FAO/WHO, 2003). For instance, a hazard characterization for *Salmonella* can be adopted by any risk assessment model, regardless of the commodity under study. Furthermore, the dose-response assessment (i.e. quantitative hazard characterization) provides a quantitative description of the relationship between a hazard and its effect. It mathematically describe the relationship between ingested dose and the probability of adverse health effects (FAO/WHO, 2002b; FSIS and EPA, 2012).

Hazard characterization describes pathogen, host, and food characteristics that may affect the survival of the pathogen, hence, the public health outcome. However, these characteristics characterized the variability and uncertainty related to hazard characterization process. To illustrate, humans' stomach acidity is considered a vital defense line against pathogens, however, pathogen, host, and food factors define the ability of a pathogen to survive stomach acidity and colonize the GI tract causing illness. Therefore, *Salmonella*—or other pathogens—must survive host environments (e.g. temperature, osmolarity, oxidation-reduction potentials, pH, organic and inorganic nutrient, peristalsis, epithelial surface, and the host immune response) to cause infection. However, *Salmonella* has the ability (i.e. pathogen characteristics) to withstand human microenvironment. For example, it has a complex and inducible acid survival technique to tolerate the low pH during pathogenesis (FAO/WHO, 2002b). Furthermore, host characteristics are defined by host demographic and socioeconomic

factors (e.g. age, gender, race, nutritional status, social, and foreign travel); and health factors (e.g. pregnancy, immune status, previous exposure, concurrent diseases, and medications). These factors can influence the outcome of exposure of human to *Salmonella*. Moreover, from literature, it can be noticed that salmonellosis is associated with a variety of food. However, there are many food related factors (i.e. food characteristics) that can affect the *Salmonella* infectivity such as the amount of food ingested, nutrient composition, fat content, ability to buffer stomach pH, nature of contamination, and the meal composition (Bassett et al., 2012; FAO/WHO, 2002b; FSIS and EPA, 2012).

Exposure assessment results are the distribution of the likelihood of consuming a contaminated serving and the distribution of doses per contaminated serving (i.e. concentration of *Salmonella*/serving) at time of consumption. In hazard characterization process, exposure assessment results and dose-response assessment are combined to estimate the potential risk (i.e. probability of illness) due to human exposure to a specific commodity/hazard combination. The exposure of products to a hazed (i.e. exposure of broilers to *Salmonella*) will be combined with the exposure of consumer to the hazard due to consuming contaminated products. Consumer exposure to a hazed is characterized by the frequency and size of the product (i.e. annual consumption and serving size). However, the result of hazard characterization will be the distribution of the probability of illness due to human exposure to the hazard. Finally, hazard characterization results along with consumption data (i.e. annual consumption and serving size); and production data (i.e. attributed total annual production) will be used in

risk characterization process to estimate the Annual Risk Estimates (ARE) and the Annual Illness (AI).

Dose-response model: for several decades, mathematical dose-response models have been used to estimate the probability of illness from chemical toxins. Currently, such models are used in the field of food and water microbiology to provide valuable information of microbial infectivity while considering variability and uncertainty (FAO/WHO, 2003). Generally, dose-response models mathematically describe the complex relationship between the magnitude of human exposure to a hazard (i.e. ingested dose) and the associated adverse event (response) resulting from this exposure (CAST, 2006). Briefly, there are two major types of dose-response models, threshold and non-threshold models. Threshold models use a minimum infectious dose (MID) which expresses the lowest number of organisms required to cause illness in any individual under given circumstances. However, the non-threshold models assume that there is always a non-zero probability of infection, and a single viable cell may cause illness. Non-threshold models are believed to be more cautious and appropriate for addressing public health (Bassett et al., 2012).

Dose-response models are the translation of the available quantitative information of infectivity which describe the relationship between ingested dose and potential illness. Data relevant to dose-response assessment can be obtained from literature (e.g. published risk assessment), clinical studies, laboratory animal (e.g. *in-vivo* studies), and public health databases (e.g. epidemiological investigation) (Bassett et al., 2012). Epidemiological investigation, however, is considered as an important source of data for dose-response assessment. Usually, these investigation collect

significant amount of quantitative data that delivers valuable information about the hazard pathogenicity to the general population. However, outbreaks may be considered as a realistic feeding trial with a quantitative data regarding dose and affected population. Moreover, population and commodity characteristics can be investigated. Therefore, epidemiological information derived from real-world outbreaks is considered valuable information to evaluate dose-response relationships and to establish a dose-response model (FAO/WHO, 2002b).

Dose-response models address the primary transmission which resulted from contaminated food products (e.g. broiler). However, secondary transmission (i.e. transmission of pathogen via person-to-person contact within the incubation period of the pathogen and following exposure to a primary case) may cause infection and illness. The secondary transmission can be described by the reproduction rate or ratio (R_0) which represent pathogen ability to spread through a population. For example, $R_0>1$, indicates that infection can spread, thereby causing more than one case per primary transmission. Several factors affect the reproduction ratio such as infection duration, number of susceptible population, number of contact, length of infectious period, and microorganism's infectiousness (FSIS and EPA, 2012).

D. Risk Characterization:

Risk characterization is defined by Codex as "The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure

assessment" (Codex, 1999). Risk characterization integrates exposure assessment and hazard characterization results to describe and estimate the magnitude of risk. Risk characterization is the final step of risk assessment, hence, it is the starting point for risk management process that deliver a sound decision-making tool. Therefore, it should be transparent, complete, and informative. To achieve that, risk characterization should be scientifically accurate, sufficiently technical, and comprehensible taking into account the attendant uncertainty and underlying assumptions. Risk characterization involves two steps; risk estimation and risk description (FSIS and EPA, 2012). In risk estimation step the measures of probability will be calculated to estimate risk likelihood; while in risk description the measures of impact will be calculated to estimate risk severity. However, by estimating risk likelihood and severity, risk will be described and its magnitude will be assessed.

The risk characterization process presents the results of risk assessment in the form of risk estimates and risk descriptions to provide answers to risk managers' questions. However, risk assessment results are expected to provide the best available science-based evidence to provide sound and reliable answers to risk managers' questions to assist them in controlling food safety. Furthermore, there are many possible ways to express risk magnitude within risk assessment. There are three measures that can be used to express the magnitude of a risk: measure of probability, measure of impact, and measure of risk. The measure of probability is related to the level of exposure (e.g. illness due to consuming broilers for a year; or illness due to an individual exposure event) and may expressed as the average annual number of illnesses. The measure of impact addresses illnesses, hospitalization, death, economic

impact, and/or social impact. These measures are used by risk managers to facilitate decision-making in various levels. The measure of risk combines the two previous measures with attendant uncertainties to provide a description of the risk. However, to account for uncertainty, risk measures should be in a form of a probability distribution. Finally, two levels of measures of risk are presented by a risk characterization process: individual level (i.e. probability of a random individual become ill due to consuming a serving of the food; and annual individual probability of illness) and population level (i.e. annual number of illness) (FAO/WHO, 2009b).

Finally, there are many sources of variability in risk characterization processes which are considered as the major source of uncertainty associated with an estimated number of illnesses. These sources of variability include microorganism characteristics (e.g. environmental tolerance and virulence factors), host characteristics (e.g. demographic, socioeconomic, and health factors), and other factors (e.g. secondary transmission, seasonality, food matrix, and microbial load) (FAO/WHO, 2002b).

Socio-economic analysis: risk-benefit analysis comprises three stages: 1) riskbenefit assessment which is a science-based process which aims to estimate risks and benefits for human (qualitatively or quantitatively) due to exposure to a food using comparable units; 2) risk-benefit management which aims to weigh policy alternative based on risk-benefit assessment results and other relevant information; and 3) riskbenefit communication which aims to interactively exchange scientific opinion and other related information amongst risk assessors, managers, and other interested parties (Tijhuis et al., 2012a). Risk-benefit analysis may include weighing the benefit of risk reduction (e.g. reducing pathogenic bacteria in a specific food commodity) on public

health (e.g. morbidity). However, it aims to address whether the risks clearly outweigh the benefits or the benefits clearly outweigh the risks. Furthermore, risk-benefit assessment can be defined as "an approach that weighs the probability and severity of harm as a consequence of exposure against the probability and magnitude of benefit" (Magnusson et al., 2012). It estimates risks and benefits at relevant exposure using common metrics (i.e. metrics that expressed in the same unit, e.g. mortality). Therefore, using a composite metric that combine more than one element to reflect a number of dimensions of health (i.e. morbidity, mortality, and quality of life) such as Disability-Adjusted Life Year (DALYs) or Quality-Adjusted Life Years (QALYs) is more informative, common, and preferred (EFSA Scientific Committee, 2010).

Moreover, because of inherent uncertainties, the outcomes of risk benefits might be not fully clear. Uncertainty and recommendations on data needs to decrease uncertainty should be reported to risk managers. Furthermore, if risk-benefits analysis involves a probabilistic exposure assessment and/or dose-response mode (i.e. quantitative risk assessment), uncertainty can be statistically quantified (i.e. reporting confidence intervals). Additionally, it important to describe the underlying assumptions made to ensure transparency (EFSA Scientific Committee, 2010). Generally, Monte Carlo simulation—which can be performed using @RISK—can be used to evaluate uncertainties by representing them as a probability distribution which can be used for calculating the statistical parameter of interest (e.g. the mean). Moreover, sensitivity analysis can be performed to investigate which uncertainties and/or assumptions are significantly affecting the final results (Tijhuis et al., 2012b).

Risk-benefit assessment integrates two separate processes: risk assessment and benefit assessment (Magnusson et al., 2012). However, risk assessment can be achieved by constructing a quantitative microbial risk assessment model; while benefit assessment can be achieved by performing a socio-economic analysis. Socio-economic analysis is a tool to measure the impact of risk on society and economy. It will be used to express the risk with metrics that could be used to express the benefits. Both risks and benefits can be measured using a common social metric such as DALYs; they also can be measured using a common economic metric such as cost (i.e. comparing cost of illnesses with cost of intervention). In such case, both risk and benefit will be expressed with the same units, therefore, they can be compared. Furthermore, this analysis can be incorporated into risk characterization process—within the risk assessment model—to estimate risk impact (i.e. risk severity). By incorporating the socio-economic analysis in risk assessment model, risk-benefit analysis can be performed.

DALYS: DALYS is a common unit for measuring health outcomes. It demonstrates a population-aggregate measure of loss of health. It also demonstrate the gap between the ideal health (i.e. the entire population are free of disease and disability) of a population and the current health status (i.e. with disease and/or disability). One DALY denotes the loss of a year of full health (i.e. a year lived with disease and/or disability). However, lower numbers of DALYS represent better health status or lower health loss (FAO/WHO, 2009b; Tijhuis et al., 2012b). Typically, DALY is used to compare risks of different nature (e.g. chemical vs microbial) or risk from different hazard/commodity combinations. Additionally, the impact of an intervention on DALYS (i.e. averted DALYS) can be estimated by calculating DALYS with and without

the intervention, thus, it can be used for ranking and prioritizing risk to allow resources allocation (Fox-Rushby and Hanson, 2001; WHO, 2001). For instance, risk with higher DALYs may be funded before those with lower DALYs (risk ranking); also intervention with higher reduction in DALYs per monetary unit may be funded before those with lower DALYs per monetary unit (prioritizing interventions).

DALYs are the sum of the Years of Life Lost (YLL) due to premature death and the Years Lost due to Disability (YLD) due to a specific illness within a specific population. The YLL is characterized by the age at time of death and life expectancy for the object population. The YLD is characterized by the length of illness (year) and its severity (i.e. disability weight). The disability weight reflect the average degree of disability a person may suffer due to illness on a scale of 0 - 1, where 0 equivalent to perfect health and 1 equivalent to death. However, to calculate YLD, case duration will be multiplied by disability weight (FAO/WHO, 2009b; Tijhuis et al., 2012b; WHO, 2001). Finally, several social value weights can be used to adjust DALYs such as the 3% time discounting weight which can be used to estimate the net present value of years of life lost by adjusting weight of lived year at young and older ages. This can prevent giving excessive weight to death at younger age (WHO, 2001).

Cost of illness (COI): in the governmental level, the costs of implementation of a new proposed regulation is often compared with its net benefits to ensure feasibility. In food safety arena, the primary benefit of reducing food safety risks is improving public health, however, the socio-economic impacts can be important in some cases. Economic analysis aims to evaluate human impact in monetary unit, and to permit the evaluation of changes in public health (i.e. impact of intervention) in monetary unit. It

evaluates the current economic burden of a risk (i.e. annual cost of salmonellosis) and estimates the improvement in public health (i.e. saved money due to reducing annual salmonellosis). However, the economic benefit of interventions (i.e. money saved due to improving public health) can be compared with the costs of intervention (i.e. cost of industrial and/or governmental changes, in the short and long term). This will inform decision-makers about the potential amount of economic gain and loss for each mitigation option. Finally, economic analysis can be conducted using either (COI) or Willingness to Pay (WTP) techniques (FAO/WHO, 2009b).

According to CDC, COI is defined as "the value of the resources that are expended or foregone as a result of a health problem." This include the cost of pain and suffering (intangible costs), the value of lost productivity by the patient (indirect cost), and health sector costs (direct cost). It provides a monetary estimation for the burden of diseases to assess their economic impact. It can be used to compare the amount of money spent on illness with the amount of money spent on intervention to decrease or eliminate the illness (i.e. cost of intervention) to assess the feasibility of potential intervention(s) (CDC, 2010). For instance, risk with higher COI may be funded before those with lower COI (risk ranking); also intervention with reduction in COI may be funded before those with lower reduction in COI (prioritizing interventions).

1.2 Variability and Uncertainty:

According to FAO/WHO (2002b), "Variability is a property of the phenomenon and the variations that are described are a reflection of what could be expected in nature. Uncertainty is driven by the lack of knowledge about the nature and behavior of

a phenomenon". Thus, variability and uncertainty are separate concepts and resulted from different reasons. Variability is an inherent property and characterized by the modeled system, however, it can be reduced by minimizing the systematic errors of risk assessment model and maximizing the model precision. In contrast, uncertainty is characterized by the available knowledge regarding the modeled system. However, uncertainty can be reduced by improving knowledge base (IPCS, 2008). However, good data should represent the actual variability of a phenomenon with less uncertainty. It is recommended to explicitly separate variability and uncertainty within risk assessment, however, in some cases this is impractical and could lead to a complex risk assessment model (FAO/WHO, 2002b).

In some cases, uncertainty and variability can be combined in one-dimensional Monte Carlo simulation when inputs distributions represent both variability and uncertainty; this usually results in less complex models. In such case, an output will be presented as a single, and therefore wider, distribution which represents a mixture of variability and uncertainty. However, such distribution interprets the uncertainty distribution of a random individual being exposed. In contrast, two-dimensional Monte Carlo simulation (usually more complex model) disaggregates and quantifies variability and uncertainty to estimate their interactions. In this case, outputs can show variability and uncertainty separately as a chart with three curves of which the central curve represents the median estimate of the output distribution; and the other curves represent the confidence limits (IPCS, 2008).

Uncertainty represents the quality of inputs and it is a function of the amount and accuracy of data, information, and knowledge available for risk assessors. The

complexity of real-world processes and systems along with imperfect measurement methods are considered a major source of uncertainty. However, different amount of information and knowledge available for risk assessors may lead to produce different uncertainty (i.e. outputs with different probability distributions) (FAO/WHO, 2009b). To illustrate, inputs derived from sufficient data (i.e. a large representative data that are scientifically generated and analyzed) are less uncertain than inputs derived from insufficient data (i.e. data derived from small sample size and/or inaccurate scientific methods, or reported as a single value). If a single data value (i.e. only the mean) was reported, risk assessor may generate a distribution around that value which will cause some uncertainty (FAO/WHO, 2002b).

There are different sources of uncertainty associated with risk assessment process including, but not limited to, data uncertainty (e.g. lack of knowledge), assumptions uncertainty (e.g. input, modeling, and scenario assumptions), doseresponse relationship uncertainty (e.g. strains specific data and host immune status), and predictive models uncertainty (e.g. experimental and statistical errors). The Scientific Committee of the EFSA classified uncertainty into: measurement uncertainty, sampling uncertainty, extrapolation uncertainty, model uncertainty, dependencies, imprecise language, disagreement and ignorance (Verger and Fabiansson, 2008). It is obvious from the multiple sources of uncertainty, mentioned above, that eliminating uncertainty is impossible. However, uncertainty can be identified (i.e. during data collection), evaluated (i.e. performing uncertainty and/or sensitivity analysis), and reduced (i.e. identify data gaps and collect more information to reduce uncertainty).

Uncertainty can be reduced by acquiring new knowledge, however, it is important to understand and quantify uncertainty to be able to reduce it. Large range of uncertainty (i.e. outputs with wide distribution around the mean) may cause the result to be ambiguous and influence decision-making. In such case, uncertainty needs to be reduced to generate better results that can be used to weigh decision alternatives (FAO/WHO, 2009b). However, uncertainty can be reduced by performing uncertainty analysis and/or sensitivity analysis that can be performed in different methods (FSIS and EPA, 2012). Therefore, a probabilistic QMRA is needed to address uncertainty (i.e. demonstrate the probability distribution of outputs) and to conduct uncertainty and/or sensitivity analysis. However, superimposing uncertainty in a complex QMRA may result in infeasible and/or computationally extremely demanding models (Havelaar et al., 2008).

Uncertainty analysis can be performed to investigate the impact of attendant uncertainties (i.e. from various sources in risk assessment model) on the risk assessment outputs. It aims to evaluate the impact of inputs uncertainties on the total uncertainty to identify data gaps (i.e. which input(s) need further data collection or scientific research) that is important to reduce uncertainty (FSIS and EPA, 2012). This can be done by re-simulating the model using a fixed value for an uncertain input (i.e. best, worst, and/or mean scenario) while maintaining all other inputs uncertainties (i.e. addressed as probability distribution). This allows highlighting risk extremes (i.e. minimum and maximum) within risk distribution resulted from uncertainty. In other words, baselines model uncertainty (i.e. all inputs uncertainty is considered) will be compared with tested uncertainty (i.e. tested input will be a fixed value rather than a

distribution) to evaluate the impact of specific input's uncertainty. However, a complete uncertainty analysis for all models inputs is difficult, time consuming, and not necessarily to be more informative (FAO/WHO, 2002b).

Sensitivity analysis can be performed to estimate the effect of model inputs' uncertainty on model outputs. In QMRA, sensitivity analysis aims to determine the primary predictor(s) of risk likelihood (i.e. what input(s) significantly influence RE) and risk severity (i.e. what input(s) significantly number of illness). This can help in directing data collection activities to reduce the uncertainty of the significant inputs (i.e. inputs with greater impact on risk likelihood and severity) (FSIS and EPA, 2012; Havelaar et al., 2008). Furthermore, uncertainty analysis aims to investigate the effect of uncertainties (i.e. each input uncertainty) on the overall uncertainty (i.e. uncertainty around outputs); while sensitivity analysis aims to identify inputs with significant impact on outputs. However, both analyses can be used to reduce uncertainty by directing data collection activities; and both results are not independent from each other. For instance, if an input uncertainty significantly contributes in the overall uncertainty (through uncertainty analysis), then that input is expected to have high impact on outputs (through sensitivity analysis) (FSIS and EPA, 2012).

2. MATERIALS AND METHODS

In this chapter a QMRA model is constructed in compliance with the risk assessment guidelines published by FAO/WHO as a part of the "Microbiological Risk Assessment Series" and guidelines published by Codex. The QMRA model will utilize

the information gathered from the PRMAs (see chapter II) such as risk profile, risk assessment policy, risk assessment framework, and data collection. However, a probabilistic QMRA model was constructed including exposure assessment (i.e. prevalence and concentration), hazard characterization (i.e. dose-response model), and risk characterization (i.e. measures of probability and impact).

Modeling risk assessment was initiated using the information given in the data collection review, risk profile (i.e. hazard identification), RAs policy, and RAs framework. The QMRA model is constructed in Excel[®] (Microsoft Corporation, Redmond, WA, USA). However, to account for variability and uncertainty, @RISK[®] "Add-ins" software (Palisade Corp., Ithaca, NY, USA) was installed to Excel to perform Monte Carlo simulations that show the distribution of risk assessment outputs (i.e. the results with attendant uncertainty).

Assumptions: *Salmonella*-negative flocks will have no effect on public health (i.e. do not contribute in salmonellosis), thus, the model simulates *Salmonella*-positive flocks only. However, every run (i.e. iteration) will represent a *Salmonella*-positive flock.

Cross-contamination—including re-contamination—will be estimated for each step from scalding to storing at retail. It will be modeled in four different trends based on process/step characteristics (see 2.2.2 (C)). Cross-contamination is estimated using the contamination model (see 2.2.2 (B)) which incorporated in exposure assessment model to account for specific flock characteristics (i.e. PWF) and for process characteristics (i.e. number of contact resulting from the process). Cross-contamination events will be modeled after the growth/reduction events using the arithmetic values (i.e. number of

cells) to avoid incorrect transfer rate (i.e. transfer rate should not be presented by the logarithmic values).

Few assumptions are made for some of the model's inputs, however, most inputs were either collected from literature and/or predicted by the appropriate microbial predictive models. Collected and/or predicted inputs were optimized to account for uncertainty.

Construction: the model is built in three spreadsheets (within one file). Sheet(1) contains the User Interface (UI) where inputs are entered and results are displayed. The inputs are divided into two categories; exposure assessment inputs (performance criteria) and hazard/risk characterization inputs (see chapter II). The outputs also are divided into two categories; risk assessment outputs (see 3.2) and risk management outputs (see chapter IV). Sheet(2) contains the exposure assessment and doseresponse models. In this sheet exposure of broiler to Salmonella from farm to fork and exposure of consumer due to exposure to contaminated broiler are modeled. It identify the step source of contamination (i.e. in which step a broiler get contaminated and that contamination last to time of consumption). It also identifies the final source of contamination either from cooked broiler or from other cross-contaminated food items. Sheet (3) contains the microbial predictive models that are used to identify some exposure assessment model's inputs without incorporating them in the exposure assessment model. Additionally, a deterministic model was built for case-study, when required.

Inputs: To ensure that the model is fit-for-purpose, a data collection review (see chapter II) has been used to collect the risk assessment model's inputs based on data relevant to the U.S. whole broiler chickens production system. However, some data is generic (e.g. growth rate, broiler pH ...etc.) and not related to a specific country. Data was collected either from scientific research done within the U.S. or from governmental reports published by interested governmental agencies such as USDA, FDA, and CDC. After all required data (i.e. all RAs model's inputs) was collected, it was optimized to fit the model and to incorporate uncertainty. Finally, having these data, the RAs baseline model for the current performance of the U.S. whole broiler production system in controlling *Salmonella* will be established.

Variability and Uncertainty: because this is a probabilistic model, randomness was incorporated using "RiskUniform (0, 1)" distribution in @RISK. This function generates a random number which is uniformly distributed between 0 - 1. This number is used to randomly assign initial contamination, broiler involve in cross-contamination, transfer rate, growth/reduction (log), number of contaminated servings, and (β) and/or (α) in dose-response model. Furthermore, variability and uncertainty were incorporated within the risk assessment model by expressing models inputs as probability distributions. Then one-dimensional Monte Carlo simulation was performed using @RISK to propagate inputs' variability and uncertainties to outputs. Therefore, the results include the frequency distribution of outputs values which can be statistically analyzed.

Finalizing: the baseline model should be compared to the current CDC epidemiological data to calibrate and validate the model if required. The reported epidemiological data should be in central location of the baseline model's results, for instance, the reported data should be close to the mean, average, or mode of annual illnesses estimated by the model. If this is not the case, the baseline model should be calibrated and validated. However, the validated baseline model can be used as a reliable tool for decision-making at any step from farm to fork.

2.1 Hazard Identification

Hazard identification is the first step in risk assessment process. The hazard of interest (i.e. *Salmonella*) needs to be identified and described and this information should be kept in consideration throughout risk assessment process. Hazard identification provide qualitative and some quantitative information which demonstrates the relationship among *Salmonella*, whole broiler, and affected population. However, *Salmonella* is considered a well-known pathogen with lots of information in literature that describe its characteristics, a large number of analyzed outbreaks, and epidemiological studies. Therefore, in this project, the "risk profile" given in chapter II, section (2.2), which resulted from the preliminary risk management activities, is considered sufficient in identifying and describing *Salmonella* to carry-out risk assessment.

2.2 Exposure Assessment

The risk assessment model is defined by exposure assessment parameters that describe the efficiency of broilers rearing, processing, marketing, and preparation in controlling *Salmonella* prevalence and concentration. The exposure assessment demonstrates the exposure of whole broilers to *Salmonella* within the U.S. broilers production system by following the movement of *Salmonella*-contaminated broilers from farm to fork. PCs express the targeted change required in prevalence and concentration of a food safety hazard by the application of control measures (Codex, 1997; Codex, 2007a; FAO/WHO, 2006a). PCs can be achieved by the implementation of control measures such as sanitary measures (i.e. hygienic practices) and process measures (i.e. PcC, and PdC) at different steps. However, changes in *Salmonella* prevalence and concentration on broilers were modeled based on the performance criteria (PCs) of each step—from farm to fork—that are accomplished by the current practices of the U.S. broilers production system.

Salmonella prevalence was presumed to only increase due to crosscontamination and will be decreased due to a Salmonella reduction process (i.e. a step where physical, chemical, and/or thermal treatments occur). Moreover, it was also assumed that Salmonella concentration will be characterized by growth or reduction events. Although concentration will be changed in broilers that involved in crosscontamination (characterized by transfer rate), it is not considered a growth/reduction event (i.e. the grand population of Salmonella will not be changed due to crosscontamination). However, the potential cross-contamination event (%) and

growth/reduction event (log) at each step should be estimated and modeled to estimate the performance of each step in controlling *Salmonella* prevalence and concentration. The general exposure assessment model can be used for case-study as a deterministic model (see "Sheet3"). The general exposure assessment model is:

$$FC = \Sigma \left(P_n * 10^{TriangG/R(\log)} \right)$$

Where,

FC is the final contamination of a meal (containing 4 servings);

 P_n is the population at process n;

G/R is growth OR reduction log.

Finally, the last step of exposure assessment combines the whole broilers exposure to *Salmonella* from farm to fork—due to processing, biological, and environmental factors—and consumer exposure to *Salmonella* due to consuming contaminated broilers. In this step, the frequency and concentration of an ingested hazard will depend on the amount of food consumed (i.e. number of servings per year and serving size). However, the final results of exposure assessment are the distribution of prevalence of contaminated meals (i.e. likelihood of consuming contaminated serving) and the distribution of number of *Salmonella* cells per a contaminated meal (i.e. dose) at time of consumption. The concentration is used to estimate final dose which will be used within hazard characterization process (i.e. dose-response model) to estimate the probability of illness. The prevalence is used to estimate other measures of probability within risk characterization process such as the probability of contaminated serving.

2.2.1 Growth and Reduction Events

Microorganisms in food respond to the surrounding conditions either by growth or reduction. At any step, where microorganism population is expected to achieve a possible growth or reduction, it will be called a growth or reduction event. The term "event" was used because the potential growth or reduction is characterized by many factors including initial contamination, time, environmental conditions, and product and process criteria (PdC and PcC). However, based on these factors the growth or reduction event can be estimated as change (log) in population. Therefore, because of the variety of contributing factors, the growth or reduction events are subjected to variability and uncertainty.

Generally, the prevalence and concentration of a microorganism in food are characterized by the in-place sanitary (i.e. GAP, GMP, and GHP) and process measures (i.e. PdC and PcC). The prevalence of microorganism in food can be reduced by the by process measure; for example, cooking may eliminate *Salmonella* in broilers, hence, prevalence will decrease. However, the prevalence is characterized by the sanitary measures which defined by percent of cross-contamination. In other word, prevalence will only increase by cross-contamination after harvest or slaughter. For instance, in a processing step with high cross-contamination percent, the prevalence of contamination is expected to increase. However, this indicates that the sanitary measures need to be improved to reduce cross-contamination and the prevalence of

contaminated product. Therefore, increase in prevalence is related to sanitary measures; while decrease in prevalence is related to process measures (e.g. cooking) and sanitary measures (e.g. reduce product/workers contact). Furthermore, cross-contamination events would affect the concentration of microorganism due to cell transfer, however, such effect is defined by the transfer rate. The concentration is generally characterized by the process measures. Process measures are defined by product and process criteria (PdC and PcC) which characterize growth and/or reduction events. However, microbial concentration (i.e. microbial load) can be controlled by improving PdC and/or PcC. Therefore, if the best intervention was found to be reducing microbial load at any step, the intervention should be improving the process measures.

In this project, the risk assessment model is based on performance criteria, so it will evaluate the performance of the U.S. whole broilers production system (i.e. in-place sanitary and process measures) in controlling *Salmonella* in whole broilers. However, growth/reduction and cross-contamination inputs represent the performance of the U.S. whole broiler production system in controlling *Salmonella* prevalence and concentration from farm to fork. The growth/reduction events inputs—in the exposure assessment model—are derived from literature and will also be predicted using microbial predictive models (i.e. growth and inactivation models), if applicable. Both literature data and predicted results were optimized and modeled within the exposure assessment framework. After modeling the growth/reduction event, the effect of an intervention on *Salmonella* population—then on public health—can be estimated. The following are examples of decision-making based on the idea of the growth/reduction events.

EXAMPLE (1): the effect of increasing scalding temperature (i.e. process criteria) 10% on public health can be estimated. The microbial reduction will be estimated using the inactivation predictive model and the resulted reduction (log), then, will be used in the exposure assessment models to estimate the effect on public health (i.e. number of illnesses).

EXAMPLE (2): the effect of additional 25% reduction in *Salmonella* population in chilling tank was found to result in a satisfactory public health improvement. The next step is translating the required reduction to new PdC and/or PcC (e.g. temperature, pH, chlorine level ...etc.) using predictive models.

2.2.2 Cross-contamination

Generally, cross-contamination refers to the transfer of a hazard (e.g. bacteria) from contaminated materials (e.g. product, environment, worker, surface, equipment ...etc.) to susceptible non-contaminated materials (e.g. product, other ingredient ...etc.). In some cases, cross-contamination term includes re-contamination which refers to exchange hazard (i.e. bacteria) between two or more contaminated materials. Re-contamination will affect the concentration of a hazard rather than the prevalence of the hazard. Mostly, sanitary measures are implemented to control identified risk factors that contribute in spreading a hazard (e.g. *Salmonella*). However, to evaluate the best sanitary measures and their effect on public health, risk assessment should be conducted. The sanitary measures should be implemented in organized and auditable way such as GAP, GMP, and GHP. Furthermore, most of outbreaks related to steps
where extensive growth was permitted (i.e. abusive storage) or where insufficient reduction was achieved (i.e. undercooking). However, according to CDC, about 37% of bacterial foodborne diseases occurred in the U.S. in 1993 – 1997 was related to contaminated equipment and poor hygiene practices (Pérez-Rodríguez et al., 2008).

In this project, cross-contamination, in all steps from transport to plant to preparation, is characterized by; 1) potential percent of cross-contamination (and recontamination) events; and 2) the transfer rate. However, cross-contamination route differ among steps from farm to fork. In live birds, vertical (from parent flock) and horizontal (from other broilers and environment) transmission characterize the crosscontamination (Rasschaert et al., 2008). However, after slaughter the transmission will be ceased (because of the abortion of fecal-oral route) but cross-contamination will continue by another route which is contacting contaminated materials. Therefore, crosscontamination was modeled in different trends to address different process characteristics and different cross-contamination routes. In all cases, broilers were randomly assigned for a cross-contamination event, and a random transfer rate was assigned to each involved broiler. To preserve the microorganisms mass, transferred cells are added to newly contaminated broiler (or to re-contaminated broiler) and deducted from sources of contamination (note: exact number may not be achieved).

EXAMPLE: an intervention (i.e. a sanitary measure) in chilling tank process was found to reduce the percent of cross-contamination by 50%. The effect of this intervention on public health can be estimated by replacing baseline value of the percent of cross-contamination in chilling step with the new value (i.e. after

intervention). These new outputs will be compared with the baseline outputs to estimate the effect of the intervention.

A. Transfer rate:

Like most of pathogens, *Salmonella* are disseminated from many sources to broilers as they move within food chain. Such sources include, but are not limited to, skin, feather, litter, feeding, feces, water, ice, air, equipment, and workers. *Salmonella* is asymptomatically carried in the gastrointestinal tract and can be readily transferred through fecal-oral route (colonization) or by cross-contamination (external contamination). It can remain viable in the environment for a significant period of time which promotes cross-contamination events. Cross-contamination is characterized by the transfer rate; for instance, if cross-contamination was occurred the transfer rate will determine the number of cells to be transferred from source of contamination to crosscontaminated material. However, transfer rate is used in all steps to address crosscontamination events from transport to plant to preparation.

The ability of microorganism, including *Salmonella*, to transfer is linked to many factors including, but not limited to, bacterial attachment, the physical-chemical properties of surface, moisture, pressure, contact time, ability of bacterial to produce exo-polysaccharide, biofilm formation, and/or the presence of extra-cellular structures (e.g. fimbriae) (Carrasco et al., 2012b). Furthermore, the transfer rate should be distributed to capture the uncertainty and variability inherent to the TR data.

Carrasco et al. (2012b) reviewed the transfer rate of bacterial cells during crosscontamination. Based on their literature review, transfer rate of *Salmonella* ranging from

1.6 – 34.8% depending on many factors including initial contamination, contamination route, and the time of cells recovery. Oscar (2004) reported that Salmonella transfer rate between contaminated surfaces was found to be 2.1 - 24% (median = 5.7%). Moreover, Kusumaningrum et al. (2003) studied the transfer of Salmonella-and other pathogens—from kitchen sponges to stainless steel surfaces and from these surfaces to foods to provide cross-contamination data for quantitative microbial risk assessments. They found that the recovery of Salmonella from stainless steel surface using a single contact and five consecutive contacts was $(23\% \pm 6)$ and $(42\% \pm 12)$, respectively. The transfer rate of Salmonella from kitchen sponges to stainless steel surface immediately after contamination was estimated to be between $(21\% \pm 8)$ and $(29\% \pm 23)$ for moderate and highly contaminated sponges, respectively. Moreover, the transfer rate of Salmonella from stainless steel surface to roasted chicken fillet was estimated $(55\% \pm 21)$ and $(32\% \pm 9)$ with and without pressure, respectively. Furthermore, based on literature review for four major cross-contamination routes conducted by Smadi and Sargeant (2013) the transfer rate from raw chicken to hand was 0.45 - 41.69% (mean = 4.13 - 10%), the transfer rate from hand to food was 0.06 - 41.69%96.89% (mean = 0.76 - 17.09%), the transfer rate from raw chicken to surfaces was 3 - 100%32.36% (mean = 5 – 10%), and the transfer rate from surfaces to food was 2.04 - 86%(mean = 7.94 - 65%).

From the above data, the transfer rate—that is used in the exposure assessment model to characterize cross-contamination events for all steps from transport to plant to preparation—was optimized as an exposure assessment input. Smadi and Sargeant (2013) in their literature review reported TR means from 0.06 – 96.89% based on four

cross-contamination routes. Additionally, minimum reported mean was 0.76%, while the maximum reported mean was 65%. However, the minimum and maximum numbers were disregarded and the optimized TR was assumed to be uniformly distributed between reported means, as follows:

B. Predicting cross-contamination level:

Contamination models predict contamination percent from transport to plant to storage at retail. Contamination includes cross-contamination (i.e. in susceptible population) and re-contamination (i.e. in contaminated population). Contamination can result from contaminated products (i.e. broilers) due to processing activities and/or from the processing environment. In this case, broilers are considered the main source of *Salmonella*. However, contamination percent was characterized by contamination resulting from contaminated broilers. In this project, contamination was predicted using three models, as follows:

1) <u>Contamination during transporting live birds model</u>:

This model predicts cross-contamination during transportation of live broilers from farm to slaughter house. In this case, the cross-contamination percent is characterized by the probability of contacting contaminated materials and the probability of contamination carry-over from previously transported contaminated flocks.

$$P_{c(+ve)} = (P_{cm} + P_{co}) - (P_{cm} * P_{co})$$

$$P_{co} = (1 - (1 - PBF)^{N}) * R$$

 $P_{cm} = 1 - (1 - PWF)^{n}$

 $P_{c(+ve)}$ is the probability of contamination in a Salmonella-positive flock;

P_{cm} is the probability of contacting with contaminated materials;

 P_{co} is the probability of carry-over contamination from previously transported contaminated flocks;

PBF is the prevalence between flocks;

N is the number of previous flocks transported;

R is dampening factor for carry-over contamination.

PWF is the prevalence within a flock;

n is the number of contact an uncontaminated bird may have with *Salmonella* contaminated material on a transport truck.

$$P_{c(-ve)} = P_{co}$$

Where,

 $P_{c(-ve)}$ is the probability of contamination in a Salmonella-negative flock.

In transportation, the cross-contamination during transportation of live birds from farm to processing facility (i.e. slaughter house) is characterized by the probability of contacting contaminated materials (which depends on PWF and number of contacts) and the probability of contamination carry-over from previously transported positive flocks (which depends on PBF and number of flocks transported). Bucher et al. (2012) estimated the contacts a broiler makes with the environment is 1.5 - 4.5 (mode = 3), however, this input was triangularly distributed. The prevalence between flocks was estimated from exposure assessment; and the number of prior flocks transported was assumed as 0 - 5 flock. The probability of carry-over is multiplied by dampening factor (*R*) to correct the estimation. Bucher et al. (2012) reported that the dampening factor is uniformly distributed 0 - 0.5.

The inputs of the contamination models are as follows:

PWF = from EAPBF = from EAn = calcTriang (1.5, 3, 4.5)N = uniform (0, 5)R = uniform (0.01, 0.5)

2) <u>Contamination from broilers model</u>:

This model was developed from literature to estimate the percent of crosscontamination (in susceptible population) and re-contamination (in initially contaminated population) in broiler carcasses (i.e. from scalding to storage at retail). Contaminations is characterized by the prevalence of contaminated carcasses and the potential number of contacts among carcasses (Bucher et al., 2012; Carrasco et al., 2012b; FAO/WHO, 2002b; FAO/WHO, 2009c). It was assumed that cross-contamination will only occur when a susceptible carcass come in contact with a contaminated carcass; while recontamination will occur between two contaminated carcasses (it was assumed that cells will transfer to the carcass with the lower microbial population).

$$P_{c} = P_{i} * b$$

$$N_{xc} = 1 - (1 - P_{c})^{n}$$

$$TXC (\%) = \frac{N_{xc}}{n}$$

To quantify cross-contamination and re-contamination, the following equations apply;

$$C_c = XC * I$$

 $C_s = XC * S$
 $XC (\%) = Beta (C_s, S)$
 $RC (\%) = Beta (C_c, I)$

Where,

TXC is total percent of cross-contamination;

XC is cross-contamination only (within susceptible population);

RC is re-contamination only (within contaminated population);

I is the number of contaminated carcasses;

S is the number of susceptible carcasses;

 C_c is the number of contamination contacts occur by contaminated population;

 C_s is the number of contamination contacts occur by susceptible population;

n is the number of contact/carcass;

 P_c is the probability of cross-contamination;

N_{xc} is number of cross-contamination contacts;

 P_i is the probability of contacting a contaminated carcass (i.e., P_i equals to prevalence of contaminated carcasses);

b is the probability of transmission (i.e. the probability a single contact will cause contamination).

NOTE: N_{xc} is the number of cross-contamination contacts. It is used to calculate total cross-contamination (TXC) percent by dividing it by total number of contact. However, to calculate XC and RC, beta distribution is used to account for variability and uncertainties associated with (*n*) and (*b*).

This model is characterized by the numbers of contacts among carcasses and the prevalence of contamination (i.e. contaminated broilers). The prevalence of contamination is described by two inputs, flock size and the prevalence of contaminated carcasses which will be derived from the exposure assessment model. Furthermore, the number of contacts among carcasses is characterized by the probability of transmission (*b*). The probability of transmission is the probability of a single contact will cause cell transfer which depends on many factors including, but not limited to, site of contact, length of contact, availability of microbes, mobility, adhesion, detachment, and contamination cluster. The probability of transmission was assumed to be uniformly distributed between 0.4 - 0.5 (FAO/WHO, 2009a); and between 0.01 - 0.2 at the final product (assumption was made because the final product will be packaged and the transmission is assumed to be lesser) where broilers are packaged. The number of contact a carcass make with other carcasses is vary. For instance, in steps where

carcasses are hanged and ordered (i.e. from scalding to washing) the number of contacts was assumed as 1 - 4 contacts/carcass (FAO/WHO, 2009a). However, in steps where carcasses are processed randomly and without ordering (i.e. from chilling to storage at retail), the number of contacts was estimated as 2 - 10 contacts/carcass.

The inputs of these contamination models are as follows:

N =from EA

I =from EA

C = uniform (1, 4) ordered steps; uniform (2, 10) random steps

b = uniform (0.4, 0.5) carcass; uniform (0.01, 0.2) final product (packaged)

3) Contamination from processing environment model:

The above model estimates contamination among carcasses while disregarding environmental contamination. However, another contamination model was developed to estimate the percent of re- and cross-contaminations from environment (i.e. machinery, surfaces, aerosols, worker, processing aids (e.g. water, steam, air) ...etc.). If the environmental contamination is considered, the total contamination will be the sum of contamination percent among carcasses and from the environment.

Cross-contamination (%) =
$$C_t * (\frac{S}{N})$$

 $C_t = (P_{xc} + P_{co}) - (P_{xc} * P_{co})$
 $P_{co} = (1 - (1 - PBF)^{N_f}) * R$
 $P_{xc} = 1 - (1 - P_c)^n$
 $P_c = P_e * b$

Re-contamination (%) = $C_t * (\frac{I}{N})$

Where,

N is the population (i.e. flock size); I is the number of contaminated carcasses;

S is the number of susceptible carcasses;

 C_t is the total contamination from environment (%);

n is the number of contact/carcass;

 P_{xc} is the probability of cross-contamination contacts;

 P_{co} is the probability of contamination carry-out from prior contaminated flocks;

N_f is the number of previously processed flocks;

R is dampening factor for carry-over contamination;

 P_c is the probability of cross-contamination;

 P_e is the prevalence of contamination in environment;

b is the probability of transmission (i.e. the probability a single contact will cause contamination).

This model is characterized by the prevalence of contamination in the environment, the number of contacts between broilers and contaminated surface, and the probability of carry-over contamination from positive flocks. The prevalence of contamination varies between steps, however, data regarding environmental contamination for each step should be collected and addressed as a distribution. The number of contacts a carcass makes also varies between steps, and will be addressed as a distribution for each step. Bucher et al. (2012) estimated that the contacts a broiler makes with the environment is 1.5 - 4.5 (mode = 3), however, it was assumed that the

contacts with the environment are uniformly distributed (1 - 5). Additionally, at the final product (i.e. when broilers are packaged) the number of contacts with the environment was assumed as 0 - 2. As stated above, the cross-contamination contacts were characterized by the probability of transmission (*b*). Finally, the probability of carrying-over contamination from previously-processed contaminated flocks is characterized by the provention of prior flocks processed.

The inputs of these contamination models are as follows:

$$P_e = N/A$$

C = uniform (1, 5)

b = uniform (0.4, 0.5) carcass; uniform (0.01, 0.2) final product (packaged)

 N_f = uniform (1, 5)

R = uniform (0.01, 0.5)

PBF = from EA

C. Modeling cross-contamination:

Live broilers might be contaminated (i.e. externally contaminated with *Salmonella* in feather, head, feet, and/or skin), colonized (i.e. internally colonized by *Salmonella*), or both. External contamination may be quantified by sampling feather, head, feet, and picked carcasses; while the internal colonization might be quantified by sampling ceca and/or crop. The major route of colonization is the fecal-oral route, although other routes may be possible. However, if a broiler is *Salmonella*-colonized, it can contribute in cross-contamination in rearing, transporting, and/or evisceration. In contrast, if a broiler

is externally contaminated, it can contribute in cross-contamination at all steps from rearing to packaging (and may be after packaging in case of damaged package).

In the exposure assessment model, cross-contamination should be modeled using the arithmetic form rather than logarithmic form. In this project, crosscontamination is modeled within the exposure assessment framework, the results then will be compared to data reported in literature. Three trends are used to model crosscontamination as follows:

1) <u>Random trend</u>: this modeling trend addresses the cross-contamination percent in a random population. For instance, when a random broiler cross-contaminate (or re-contaminate) another random broiler (i.e., in transport to plant, chilling, grading & packaging, distribution, and storage at retail). In steps with random cross-contamination trend, the broiler source of contamination and the cross-contaminated broiler are randomly picked from population. The transferred cells will be deducted (<<u>+</u>10% difference) from source of contamination.

2) <u>Ordered trend</u>: this modeling trend addresses the cross-contamination percent in an ordered population. In some steps (e.g., scalding, de-feathering, evisceration, and washing) where broilers are hanged in order, a random broiler can cross-contaminated (or re-contaminate) the following or previous broiler within the processing line. When a broiler was randomly picked to be involved in crosscontamination event, the model will check the population in the randomly picked broiler and the broiler next to it. Then, contamination will transfer from the higher contaminated

broiler to the lower contaminated broiler. Exact number of cells are deducted from broiler source of contamination and added to contaminated broiler.

NOTE: It is important to note that in the ordered cross-contamination trend the broilers source of contamination—that are involved in cross-contamination event—are randomly picked (independent), while the susceptible broilers will be picked depending on their places on the processing line (independent). However, in random cross-contamination trend, both source of contamination and susceptible broilers are randomly picked by the model (i.e. both are independent).

3) <u>Other materials trend</u>: this modeling trend addresses the cross-contamination percent between final product (i.e. chilled or frozen broilers) and other materials that may come in contact with the final product due to consumer activities (i.e. transport to home, storage at home, and preparation). However, this trend is used to model cross-contamination when a random broiler contaminates another surface, food, and/or hands. Broilers involved in cross-contamination are randomly assigned and proposed to contaminate other objects during transport to home and storage at home (e.g., shopping cart, hands, other surface, other food items, etc.). In this case, transferred cells due to cross-contamination will be calculated and regarded as lost cells from broiler source of contamination. In the preparation step, however, transferred cells are assumed to face one of three fates: cooked with broiler (e.g. vegetables that usually cooked with food), washed away (e.g. resulted from washing and cutting some part of the broiler), or transferred to other items that will be eaten raw (e.g. salad).

2.2.3 Predictive Models

The dynamics of microbial population depends on environmental factors (e.g. nutrients, time, temperature, a_w, pH) and other biological factors (e.g. transmission rate, detachment, mobility, growth specification, thermal resistance). However, changes in microbial population due to microorganism behavior across different environmental conditions can be predicted using microbial predictive models. The response of microorganism population to environmental factors is believed to be reproducible. Dominant environmental factors that control the growth rate can be experimentally observed, identified, and mathematically described. However, the response of microorganism to other similar environment can be predicted. Moreover, the global interest is growing to apply such mathematical equations in the field of public health. To improve public health, predictive models can be used to inform risk assessment and/or HACCP system.

Predictive models reliability and appropriateness to the exposure assessment should be assessed prior application. Additionally, it is important to validate predictive models results with data in literature that states microbial prevalence and concentration (FAO/WHO, 2002b). Generally, extrapolation of models beyond the tested range of predictive models should not be made to ensure reliable predictions. Therefore, the results of predictive models should be interpolated within the predictive models' limits (i.e. experimental range) (Baranyi et al., 1996). Furthermore, to improve the effectiveness of predictive models as food safety tools, they could be integrated within risk assessment framework. Integrating predictive models within risk assessment model

would create complicated and difficult to use models. However, to establish a simple and applicable risk assessment model, predictive models can be used outside the risk assessment framework and inform it by predicting some inputs such as microbial growth and/or reduction (Oscar, 2002). In this project, only cross-contamination models are incorporated in exposure assessment models because they are characterized by the prevalence of contaminated broilers which is estimated by the exposure assessment model.

The predicted results and the data derived from literature will be optimized and used as exposure assessment inputs. Furthermore, @RISK is used to incorporate uncertainty around some predictive models' inputs (i.e. probability distribution). Three predictive models were used to inform the exposure assessment:

- <u>Transmission model</u> to predict PBF and PWF at the end of rearing.
- <u>Inactivation model</u> to predict pathogen reduction due to cooking (also will be used to evaluate the effect of scalding water temperature).
- <u>Growth model</u> to predict microbial growth as a function of time, initial contamination, and environmental factors in transport to plant, processing (at grading and packaging step), distribution, storage at retail, transport to home, and storage at home.

A. Transmission Model

The transmission model is a predictive model that predicts the prevalence between flocks (PBF) and prevalence within flock (PWF). It predicts the beta distribution of (PBF) from experimental data including number of flocks sampled and the number of

Salmonella-positive flocks. Moreover, it predicts the (PWF) in two stages: 1) Chain binomial; and 2) Epidemic spread (FAO/WHO, 2009a). The predicted (PWF) is characterized by the number of infected chicks at day one in broiler house. However, the predicted PWF is considered as the performance criteria of the hatchery step (i.e. PC = prevalence of contaminated chicks at day one). Consequently, the effect of an intervention in the hatchery step on PWF, and then on public health, can be predicted by the risk assessment model.

$$PBF = Beta(r + 1, s - r + 1)$$

Where,

PBF is prevalence between flocks;

r is number of positive flock;

s is number of flocks sampled.

PWF: stage 1 (Chain Binomial):

$$C_{s1} = P_{cont.} * (N - I_c)$$

Where,

 C_{s1} is the colonized broilers at stage 1;

*P*_{cont} is the probability of a susceptible broiler to get contaminated;

N is the flock size;

 I_c is the number of initially colonized birds;

 $(N - I_c)$ = the initial number of susceptible chicks at day one.

$$\boldsymbol{P_{cont.}} = \mathbf{1} - \left(\mathbf{1} - \boldsymbol{P_{c}} * \left(\frac{l}{N}\right) * \left(\frac{1 - EXP^{-yb}}{1 - EXP^{-y}}\right)\right)^{N}$$

 P_c is the probability of contact with a contaminated broiler (i.e. prevalence of contaminated birds);

y is the mean number of contacts with other broilers;

b is the probability of transmission due to contact with contaminated broiler.

PWF: stage 2 (Epidemic Spread):

$$PWF = \frac{(N-S)}{N}$$

Where,

S is number of susceptible broiler at de-population day;

(N - S) = number of infected broiler.

$$\mathbf{S} = \frac{S_{s1} * N}{S_{s1} + C_{s1} * EXP (TR * (t_d - t_o))}$$

Where,

 S_{s1} is the susceptible broiler at stage 1 (i.e., $S_{s1} = N - (C_{s1} + I_c)$);

TR is the transmission rate (%);

*t*_d is de-population day;

*t*_o is time required for stage 2 to begin (generation time).

The PWF can also be predicted by implementing transmission rate mathematically. In this case, the PWF is characterized by the number of contaminated birds and the transmission rate (i.e. not characterized by number of contacts a bird make). It can be used to predict the PWF at the end of rearing step (i.e. at the depopulation day (t_d)) from experimentally found PWF at any prior day (i.e. $t_s < t_d$).

PWF = Beta (NIB + 1, N + 1)

$$NIB = N - S$$

Where,

PWF is prevalence within flocks;

NIB is the final number of infected broiler;

N is the flock size (i.e. sampled population);

S is the final number of susceptible broilers.

$$\mathbf{S} = \frac{S_i * N}{S_i + (N - S_i) * EXP(TR * (t_d - t_s))}$$

Where,

 S_i is the initial number of susceptible broilers;

TR is transmission rate;

*t*_d is exit day (de-population day);

 $t_{\rm S}$ is sampling day.

B. Inactivation Model

This model estimates the effect of a thermal process (i.e. cooking) on *Salmonella* population on the broiler carcasses. The lethality of a thermal process can be characterized by the measured internal temperature of a processed product (i.e. broilers). This model can estimate the log reduction of a thermal process (i.e. process lethality) from an internal temperature ranged 55 – 70 °C (FAO/WHO, 2009a; Oscar, 2004). Although the reported internal temperature of cooked poultry has a wider range than the used model, the model will be run for its range of temperature to ensure reliable results.

To predict the thermal inactivation (e.g. the effect of cooking) of *Salmonella*, the effect of temperature and holding time (i.e. D-value and *z*-value) on the organisms should be experimentally determined. The D-value is the time required at a specific temperature to decrease the population by 1 log. The *z*-value is the temperature increase required to reduce the D-value by 90% (FAO/WHO, 2009a). In case of transient thermal process—where product temperature changes with time—the process lethality (*F*) can be estimated using the time required to cause 1 (log) reduction in bacterial population at a given reference temperature (T_{ref.}). The predicted log reduction can be estimated by dividing the process lethality on time required to achieve 1 log reduction at the reference temperature (i.e., *F* / *D_{ref.}*). The total process lethality is the sum of (*F*) at each transient time (Murphy et al., 2004a).

The reported D-values in literature will be used to validate the thermal inactivation model. In literature, reported D-values for *Salmonella* are vary due to a variety of experimental variable. Murphy et al. (2004b) determined the D-value and *z*-

value of *Salmonella* in chicken thigh/leg meat and skin for different temperatures. The resulted D-values were (43.5 ± 5.8) , (6.5 ± 0.4) , (0.65 ± 0.1) , and (0.08 ± 0.007) for temperature 55, 60, 65, and 70 °C, respectively. The *z*-value was obtained by linear regression of D-value vs. heating temperature, and was reported as 5.34° C for the meat and 5.56° C for the skin. Moreover, Juneja (2007) had conducted a study aimed to estimate the thermal inactivation of *Salmonella* in ground chicken breast and thigh meat. In this study the D-value and *z*-value for *Salmonella* spp. was estimated for both chicken breast and thigh. Four temperatures were tested 55, 57.5, 60, and 62.5 (°C); the reported D-values were (8.13 ± 0.25), (4.5 ± 0.4), (3.02 ± 0.07), and (0.715 ± 0.015), respectively. The reported z-values were 8.1, 8.4, 6.9, and 7.2, respectively. Finally, when running the model the resulted D-values were matching the reported D-values. Therefore, the cooking models (using constant by Oscar (2004)) was found to be suitable for estimating cooking effect on *Salmonella* population in temperature range of $55 - 70 ^{\circ}$ C.

D-value = 10^{(-aT)+b}

Where,

T is cooking temperature (°C);

a is constant;

b is constant.

$$Log.R = \frac{t}{D-value}$$

Log.R is the log reduction;

t is cooking time (min).

$$PR = \frac{F * dt}{D_{ref}}$$

$$F = 10^{(T - T_r)/z}$$

Where,

F is the process lethality;

PR is the final process reduction;

T process temperature;

 T_r is the reference temperature;

z is the z-value of Salmonella in chicken;

t is the transient time (time required to change temperature);

D_{ref} is the D-value at the reference temperature. (Murphy et al., 2004a)

C. Growth Model

Generally, growth rate is characterized by microbial growth specifications, product criteria, and/or process criteria. However, temperature abuse (i.e. process criteria, e.g., storage at home) may occur and the pH and a_w of a product (i.e. product criteria) may permit microorganism to grow (i.e. microbe's growth specification). In such case, predictive microbial growth model can be used to predict the growth of the microorganism based on the above information. There are two types of growth models; Growth/No Growth model (G/NG) and Growth rate model (μ). The G/NG model evaluate the environmental conditions (i.e. temperature, pH, and a_w) in accordance with microorganism's growth specifications. However, this model evaluate specific event and determine whether or not the microbe of interest will grow under the specified conditions. In this project, four environmental factors (i.e. temperature, pH, a_w, and concentration of inhibitory substances, if applicable) were evaluated using G/NG model to estimate the suitability of a specific condition (i.e. a process or step) for *Salmonella* growth. Results of G/NG model is characterized by *Salmonella* minimum, optimum, and maximum growth limits. For instance, if any observed factor is above the maximum limit or below the minimum limit the G/NG model will result in "No Growth". The result will demonstrate the probability of *Salmonella* growth as follows:

$$\mathsf{IF} \begin{cases} \mathbf{GNG} < 0, & No \ Growth \\ 0 < \mathbf{GNG} < 1, & probability \ of \ growth \\ \mathbf{GNG} > 1, & Growth \end{cases}$$

If G/NG is negative, that means no growth will occur because one or more environmental factor(s) is/are out of *Salmonella* growth limits. If G/NG is positive, *Salmonella* growth is expected and the probability of growth will be reported (i.e. if 0 <G/NG < 1). However, a G/NG model including the effect of an inhibitory substance on the growth rate (e.g. could be used to estimate the effect of chlorine in chilling tank) is used (Carrasco et al., 2012a; Polese et al., 2011).

$$G/NG = \eta * (T - T_{min}) * (pH - pH_{min}) * (a_w - a_{w min}) * \Pi (1 - \frac{Ci}{MIC})$$

This model characterizes the growth based on the minimum limits, however, if a factor was set above the maximum limit (e.g. 50°C for *Salmonella*) the model will result in growth. Therefore, maximum growth limits were incorporated in the G/NG model (developed for this project). The modified G/NG model is as follows:

$$G/NG = \eta * (T_{max} - T) * (pH_{max} - pH) * (a_{w max} - a_{w}) *$$
$$(T - T_{min}) * (pH - pH_{min}) * (a_{w} - a_{w min}) * \Pi (1 - \frac{Ci}{MIC})$$

Where,

 η is Salmonella related constant (n = 0.96) (Polese et al., 2011);

T, pH, a_w are actual value (tested conditions) for each growth factor;

T_{max}, *pH_{max}*, a_{w max} are Salmonella maximum growth limits;

T_{min}, *pH_{min}*, *a_{w min}* are Salmonella minimum growth limits;

Ci is concentration of inhibitory substance;

MIC is the minimal inhibitory concentration.

NOTE: G/NG model's variability is characterized by *Salmonella* species (within η factor), while uncertainty is characterized by the accuracy of identification of growth limits.

After determination growth probability, a growth rate (μ) model is used to predict the specific growth rate (log/hour) of *Salmonella* population under specific environmental conditions. This model will check the G/NG model result, if the result is "Grow" the growth rate (μ) will be calculated. However, if "No Growth" was reported, the model will report the initial contamination (log) without any growth. The benefit of using the G/NG model is to prevent false growth—by considering *Salmonella* growth specifications—to ensure sound growth estimation. The growth rate will be predicted using two different models, the first model will predict (μ) as a function of temperature only (Oscar, 2002). The second model will predict (μ) as a function of temperature, pH, and a_w (Carrasco et al., 2012a; Fakruddin et al., 2011; Koseki, 2009; Polese et al., 2011).

The first growth rate model predicts the growth rate as a function of temperature. This model predict μ in three stages; 1) primary modeling which aim to calculate growth (log) using λ , μ , and initial contamination; 2) secondary modeling which aim to calculate λ (hour) and μ ; and 3) tertiary modeling which aim to simulate lag time and growth rate to estimate the final population as a probability distribution (Oscar, 2002).

$$N_t = N_o + \mu (t - \lambda)$$
$$\lambda = \frac{1}{p * (T - T_{\min})^2}$$
$$\mu = (b(T - T_{\min}))^2 (1 - EXP (c(T - T_{\max})))$$

Where,

N_t is total growth (log);

 N_0 is initial contamination (log);

t is holding time;

 λ is lag time (hour);

p is the rate of change of lag time as a function of temperature; *b* is the rate of change of the specific growth rate between T_{min} and T_{opt}; *c* is the rate of change of the specific growth rate between T_{opt} and T_{max}.

It is important to note that the above model can be used to estimate growth at a specific temperature *T*. However, it can be used to calculate μ_{opt} for *Salmonella* by using the optimum growth temperature of *Salmonella* as (*T*). Calculating μ_{opt} will optimize growth around the optimum temperature. The μ_{opt} will further be used to calculate the specific growth rate (μ) as follows:

 $\mu = \mu_{opt} (D/E)$ $D = (T - T_{max}) (T - T_{min})^{2}$ $E = (T_{opt} - T_{min}) ((T_{opt} - T_{min})(T - T_{opt}) - (T_{opt} - T_{max})(T_{opt} + T_{min} - 2T))$ Where,

 μ is the specific growth rate;

 μ_{opt} is the growth rate at Salmonella optimum growth temperature.

The second growth rate model uses bacteria growth limits as a normalization constant. It assumes that the effect of each factor on growth probability is linear dependent upon its distance from the lower limit. This model is used to predict growth rate as a function of temperature, pH, and a_w (Koseki, 2009).

$$\sqrt{\mu} = c * (T - T_{\min}) * \sqrt{(a_w - a_{w\min})} * \sqrt{1 - 10^{(pH\min-pH)}}$$

c is a species-independent constant (Carrasco et al., 2012a):

$$c = \frac{1}{(T_{\max} - T_{\min}) * (pH_{\max} - pH_{\min}) * (a_{w\max} - a_{w\min})}$$

After calculating (μ), total log growth (N_t) can be predicted as a function of time and initial microbial concentration. However, final population equal to the total growth plus the initial contamination (i.e. $FP = N_t + N_0$, in arithmetic number). (Fakruddin et al., 2011; Koseki, 2009; Oscar, 2002)

$$N_t = N_o + \mu (t - \lambda)$$
$$N_t = EXP (\mu + LN(N_o))^t$$
$$N_t = LOG (N_o * EXP (\mu * t))$$

Where,

N_t is the final population after *t* hour;

 N_o is the initial contamination (log);

t is the holding time (hour).

Growth Model Inputs: in this project, *Salmonella* growth limits, product criteria (i.e. whole broiler pH, a_w, and initial contamination), and process criteria (i.e. temperature, time, and concentration of inhibitory substances) were identified to be used in the growth model to predict *Salmonella* growth under specific conditions. The growth model will be used several times to inform exposure assessment inputs,

however, only process criteria will vary among processes; and PcC inputs were discussed under relevant steps. Therefore, in this section, *Salmonella* growth limits and whole broiler criteria are discussed (these inputs will not be changed among process).

ICMSF summarized *Salmonella* growth limits as follows: temperature (°C) 5.2 – 46.2 (optimum 35 – 43); pH 3.8 – 9.5 (optimum 7 – 7.5); water activity (a_w) 0.94 – 0.99 (optimum \geq 0.99) (FAO/WHO, 2002b). Lianou and Koutsoumanis (2011) developed a stochastic model to predict the maximum specific growth rate (μ_{max}) of *Salmonella* enterica as a function of pH, water activity (a_w), and intra-species variability. The observed μ_{max} values corresponding to growth at pH = 7.0 and a_w = 0.992. The optimum growth temperature for *Salmonella* was reported to be 37 (°C). On the other hand, the product criteria (PdC) (i.e. whole broiler characteristics) are as follows: pH 5.7 – 6.7; a_w 0.98 – 0.99 (Audits International/FDA, 1999). However, based on the above data, the growth model inputs are as follows:

$$T_{min} = 5.2, T_{opt} = Triang (35, 37, 43), T_{max} = 46.2;$$

$$pH_{min} = 3.8, pH_{opt} = Triang (7, 7, 7.5), pH_{max} = 9.5;$$

$$a_{w min} = 0.94, a_{w opt} = 0.99, a_{w max} = 0.99;$$

$$pH (broiler) = 5.7 - 6.7;$$

$$a_{w} (broiler) = 0.98 - 0.99.$$

Validation of the Growth Model: literature was reviewed to collect information about *Salmonella* growth rate to be used in growth model validation. Oscar (2009b) in a study aimed to estimate the survival and growth of *Salmonella* Typhimurium on chicken skin demonstrated that *Salmonella* growth rate would be 0.469 – 1.118 log/h in

temperature between 25 and 45 (°C) (Oscar, 2009b). Dominguez and Schaffner (2008) reported the growth rates of *Salmonella* in different temperatures by both lab experiment and predictive model. For growth temperatures ranged from 10 - 35 (°C), the observed growth rate ranged $0.0147 - 1.495 \log$ cfu/hour, while the predicted growth rate ranged from $0.0252 - 0.6949 \log$ cfu/hour. Another study by Oscar (2009a) demonstrated that *Salmonella* (three serotypes) growth resulted from short-term temperature abuse (5 - 50 °C; for 0 - 8 hours) would be $0.03 - 4.8 \log$.

The growth models were validated and their suitability for predicting *Salmonella* growth were assessed by comparing predicted results with reported growth in literature. The experimental inputs reported in literature were used in the growth model, and predicted growth was compared with reported growth. The growth model predictions corresponded to the reported results with slight deviations.

2.2.4 Modeling Exposure Assessment

Exposure assessment inputs were collected, predicted, and optimized (see chapter II, section 2.6.2.1). Those inputs are modeled as follows:

A) Rearing:

Initial contamination is randomly assigned to broilers using generated random number. Broilers with a random number less than or equal to the prevalence of contaminated broilers (PWF) (PWF is randomly assigned to each flock within the specified distribution), will be assigned an initial contamination from the specified initial contamination distribution.

 $IC = IF \begin{cases} \rho \leq PWF, & 10^{uniform (IC_{min}, IC_{max})} \\ Other, & 0 \end{cases}$

Where,

 ρ is a random number;

IC is the initial contamination (minimum and maximum); *PWF* is the prevalence within the flock.

B) Transport to plant:

There was insufficient data in literature to quantify cross-contamination percent during transport of live birds to slaughter houses. However, cross-contamination is predicted using a contamination model. The contamination predictive model is incorporated into the exposure assessment model, thus, PWF is case specific (i.e. calculated by EA mode). The contamination model uses PWF, number of contact a bird may make during transportation, and probability of transmission to predict crosscontamination percent (see section 2.2.2, model B.1). Cross-contamination percent is then used in the exposure assessment model as an input (i.e. a performance criterion).

Furthermore, there was insufficient data in literature to describe the possible growth of external *Salmonella* population on broilers during transport to plant. However, a predictive growth model that is characterized by temperature only (see section 2.2.4, model C) was used to predict growth during transportation. The growth model used was not incorporated into the exposure assessment model.

During transportation of live birds, microbial growth is characterized by transportation time, temperature (i.e. season), and initial contamination (i.e. process

criteria). Transporting temperature is vary depends on the season, geographic location, and/or transportation methods (e.g. covered truck). However, growth models can be used to estimate the effect of these factors on the concentration of *Salmonella* on live broilers during transportation to slaughter houses.

Growth/reduction event is modeled before cross-contamination event (random trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* in rearing step (IC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2). However, the transport to plant step is modeled as follows:

$$Pop. = IF \begin{cases} \rho \leq PG \text{ and } IC \geq 1, & IC * 10^{Triang(G/R)} \\ \\ Other, & IC \end{cases}$$

$$CC = IF \begin{cases} \eta \leq XC, & uniform(IC) * uniform(TR) \\ 0 & 0 \end{cases}$$

$$TP = IF \begin{cases} IC \ge 1 \text{ and } \theta \le XC, & (IC + CC) - (IC * uniform(TR)) \\ 0 \text{ ther}, & (IC + CC) \end{cases}$$

Where,

 ρ , η , and θ are random numbers (represent a random broiler);

Pop. is the population after the reduction event;

IC is initial contamination (at rearing);

PG is the probability of growth;

G/R is growth or reduction amount (log);

CC is number of transferred cells due to cross-contamination;

XC is percent of cross-contamination;

TR is transfer rate;

TP is the contamination level at the end of transport to plant step.

C) Scalding:

Growth/reduction event is modeled before cross-contamination event (ordered trend). It was assumed that cells will transfer from higher contaminated broiler to lower contaminated broiler. Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after transport to plant step (TP)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

Pop. =
$$TP * 10^{Triang(G/R)}$$

$$CC = IF \begin{cases} Pop. \geq 1; and \rho \leq XC; and B_P > B_F, & (-B_P * uniform(TR)) \\ Pop. \geq 1; and \rho \leq XC; and B_P < B_F, & (B_F * uniform(TR)) \end{cases}$$

$$SCC = Pop. + CC + (-CC_p)$$

Pop. is the population after the reduction event;

TP is contamination level at transport to plant step;

G/R is growth/reduction amount (log);

CC is number of transferred cells due to cross-contamination;

 ρ is a random number (represent a random broiler);

XC is percent of cross-contamination;

TR is transfer rate;

 B_P is the contamination level at previous broiler in the line;

 B_F is the contamination level at following broiler in the line;

 CC_P is the CC at the previous broiler (number of transferred cell to previous broiler in the processing line);

SCC is the contamination level (cells per broiler) at the end of scalding;

D) De-feathering:

Growth/reduction event is modeled before cross-contamination event (ordered trend). It was assumed that cells will transfer from higher contaminated broiler to lower contaminated broiler. Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after scalding step (SCC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

Pop. = SCC
$$* 10^{Triang(G/R)}$$

$$\mathbf{CC} = \mathbf{IF} \begin{cases} Pop. \geq 1; \ and \ \rho \leq \mathbf{XC}; \ and \ B_P > B_F, \\ Pop. \geq 1; \ and \ \rho \leq \mathbf{XC}; \ and \ B_P < B_F, \\ \mathbf{B_F}, \\ \mathbf{B_F},$$

$$DC = Pop. + CC + (-CC_p)$$

DC is the contamination level at the end of de-feathering.

E) Evisceration:

Growth/reduction event is modeled before cross-contamination event (ordered trend). It was assumed that cells will transfer from higher contaminated broiler to lower contaminated broiler. Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after de-feathering step (DC)—after performing growth/reduction event in "Pop." column— and transfer rate (TR). The transferred cells are then deducted from broilers source of contamination (conducted in the "Final Pop." column in Sheet2).

Pop. =
$$DC * 10^{Triang(G/R)}$$

$$CC = IF \begin{cases} Pop. \ge 1; and \rho \le XC; and B_P > B_F, & (-B_P * uniform(TR)) \\ Pop. \ge 1; and \rho \le XC; and B_P < B_F, & (B_F * uniform(TR)) \end{cases}$$

$$EC = Pop. + CC + (-CC_p)$$

EC is the contamination level at the end of evisceration.

F) Washing:

Growth/reduction event is modeled before cross-contamination event (ordered trend). It was assumed that cells will transfer from higher contaminated broiler to lower contaminated broiler. Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after evisceration step (EC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

Pop. = EC $*10^{Triang(G/R)}$

$$CC = IF \begin{cases} Pop. \ge 1; and \rho \le XC; and B_P > B_F, & (-B_P * uniform(TR)) \\ Pop. \ge 1; and \rho \le XC; and B_P < B_F, & (B_F * uniform(TR)) \end{cases}$$

$$WC = Pop. + CC + (-CC_p)$$

Where,

WC is the contamination level at the end of washing.

G) Chilling (Tank):

Growth/reduction event is modeled before cross-contamination event (random trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after washing step (WC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

Pop. = WC
$$*10^{Triang(G/R)}$$

 $CC = IF \begin{cases} \rho \leq XC, & uniform(WC) * uniform(TR) \\ 0 & 0 \end{cases}$

$$CHC = IF \begin{cases} Pop. \geq 1; and \theta \leq XC, & Pop. -(Pop. * uniform(TR)) \\ Other, & (Pop. + CC) \end{cases}$$

Where,

 ρ and θ are random numbers (represent a random broiler);

CHC is the contamination level at the end of chilling.

H) Grading and packaging:

Growth/reduction event is modeled before cross-contamination event (random trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after chilling step

(CHC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

$$Pop. = IF \begin{cases} CHC \ge 1, & CHC * 10^{Triang(G/R)} \\ \\ Other, & 0 \end{cases}$$

$$CC = IF \begin{cases} \rho \leq XC, & uniform(CHC) * uniform(TR) \\ \\ Other, & 0 \end{cases}$$

$$GPC = IF \begin{cases} Pop. \geq 1; and \theta \leq XC, & Pop. -(Pop.*uniform(TR)) \\ Other, & (Pop. + CC) \end{cases}$$

Where,

GPC is the contamination level at the end of grading and packaging.

I) Distribution:

Growth/reduction event is modeled before cross-contamination event (random trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after grading and packaging step (GPC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).
$Pop. = IF \begin{cases} GPC \ge 1 \text{ and } \eta \le TA, & GPC * 10^{Triang(G/R)} \\ \\ Other, & GPC \end{cases}$

$$CC = IF \begin{cases} \rho \leq XC, & uniform(GPC) * uniform(TR) \\ \\ Other, & 0 \end{cases}$$

$$DSC = IF \begin{cases} Pop. \geq 1; and \theta \leq XC, & Pop. -(Pop.*uniform(TR)) \\ Other, & (Pop. + CC) \end{cases}$$

Where,

 ρ , η , and θ are random numbers (represent a random broiler);

TA is the probability of temperature abuse during distribution;

DSC is the contamination level at the end of distribution (i.e. at market).

J) Storage at retail:

Growth/reduction event is modeled before cross-contamination event (random trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after distribution step (DSC)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

$$Pop. = IF \begin{cases} DSC \ge 1 \text{ and } \eta \le TA, & DSC * 10^{Triang(G/R)} \\ \\ Other, & DSC \end{cases}$$

$$CC = IF \begin{cases} \rho \leq XC, & uniform(DSC) * uniform(TR) \\ \\ Other, & 0 \end{cases}$$

$$SR = IF \begin{cases} Pop. \geq 1; and \theta \leq XC, & Pop. -(Pop.*uniform(TR)) \\ Other, & (Pop. + CC) \end{cases}$$

SR is the contamination level at storage at retail (i.e. at time of purchase).

K) Transport to home:

Growth/reduction event is modeled before cross-contamination event (other materials trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after storage at retail step (SR)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

$$\textbf{Pop.} = \textbf{IF} \begin{cases} SR \geq 1 \text{ and } \eta \leq TA, & SR * 10^{Triang(G/R)} \\ \\ Other, & SR \end{cases}$$

$$CC = IF \begin{cases} \rho \leq XC, & Pop. * uniform(TR) \\ \\ Other, & 0 \end{cases}$$

$$TH = Pop. - CC$$

TH is contamination level at transport to home step (i.e. at consumer kitchen).

L) Storage at home:

Growth/reduction event is modeled before cross-contamination event (other materials trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after transport to home step (TH)—after performing growth/reduction event in "Pop." column—and the transfer rate (TR). The transferred cells then deducted from broilers source of contamination (this to be conducted in the "Final Pop." column in Sheet2).

$$Pop. = IF \begin{cases} TH \ge 1 \text{ and } \eta \le TA, & TH * 10^{Triang(G/R)} \\ \\ Other, & TH \end{cases}$$

$$CC = IF \begin{cases} \rho \leq XC, & Pop. * uniform(TR) \\ \\ Other, & 0 \end{cases}$$

Where,

SH is the contamination level at storage at home step (i.e. at time of cooking).

M) Preparation (cooking):

Growth/reduction event is modeled before cross-contamination event (other materials trend). Broilers involved in cross-contamination are randomly identified. The number of cells transferred is characterized by concentration of *Salmonella* after storage at home step (SH)—after performing growth/reduction event in "Pop." column— and the transfer rate (TR).

$$CC = IF \begin{cases} \rho \leq XC, & SH * uniform(TR) \\ \\ Other, & 0 \end{cases}$$

Where,

 ρ is random numbers (represent a random broiler);

XC is percent of cross-contamination;

TR is transfer rate;

SH is the contamination level at storage at home step (i.e. at time of cooking).

Cells transferred due to cross-contamination might be washed-out (i.e. washed cells), transfer to a food item which will be cooked with broiler (cooked cells), and/or transfer to a food item which will be digested raw (raw cells). The cross-contamination cells (CC) will be classified randomly as follows:

$$CC \begin{cases} washed cells = CC * \theta \\ raw cells = IF \rho \leq (XC * RXC), \quad (CC - washed cells) \\ cooked cells = CC - washed cells - raw cells \end{cases}$$

 θ is random numbers (represent a random broiler);

RXC is percent of cross-contamination with raw items (cells which is not cooked);

CC is number of transferred cells due to cross-contamination.

As mentioned above, some *Salmonella* cells will be in protected areas within broilers. It was reported that protected cells will have less cooking impact. In this step, different cells (i.e. protected cells and regular cells) will be modeled separately, however, they were identified as follows:

$$Total Cells \begin{cases} protected cells = (SH - CC) * Triang(0.1, 0.15, 0.2) \\ regultr cells = (SH - CC) + cooked cells \end{cases}$$

Furthermore, both protected cells and regular cells might be undercooked. Undercooking is characterized by undercooking percent (UC). However, the effect of cooking and undercooking were predicted and modeled as follows:

$$PC = IF \begin{cases} \rho > UC, & protected cells * 10^{Triang(C)} + other cells * 10^{Triang(C)} \\ \rho \le UC, & protected cells * 10^{Triang(U)} + other cells * 10^{Triang(U)} \end{cases}$$

Where,

UC is undercooking percent;

PC is the contamination level at preparation step (i.e. at time of consumption); (*c*) and (*u*) represent reductions due to cooking and undercooking, respectively; *FC* is the final contamination per meal containing several servings (chicken and other contaminated food items).

2.3 Hazard Characterization

The final result of the exposure assessment is the Final Contamination (FC) (see 2.2.4). This number describes the final concentration of *Salmonella* cells in a meal prepared with a contaminated broiler. It includes cells from broiler and from other cross-contaminated food items. However, the distribution of cells (i.e. cells cluster) in a contaminated meal is vary. For instance, all estimated cells might only be in one serving while other servings has no contamination. However, for each contaminated meal, the number of contaminated servings is randomly assigned. Therefore, the number of cells is then divided equally by the randomly assigned number of contaminated servings. It was assumed that a whole broiler will yield 2 - 8 servings (mode = 4) dependent on its weight. However, the number of contaminated servings is uniformly distributed between "1" (the minimum number of contaminated servings) and the "number of serving/broiler" that is randomly assigned for each flock.

$$Dose = \frac{FC}{N_c}$$

Where,

FC is the final contamination in a meal at time of consumption (EA result); N_c is number of contaminated servings (N_c = uniform (1, Triang (2, 4, 8))).

The mean dose for each contaminated meal was used in a dose-response model to estimate the probability of illness (P_{ill}) for each contaminated meal. The dose-response model developed by the FSIS of the USDA is used to calculate the probability of illnesses resulting from consuming contaminated cooked broiler and/or other cross-contaminated food items. It is a beta-Poisson model based on the use of a surrogate pathogen data fitted to human feeding trial data (FAO/WHO, 2002b). It is characterized by two parameters; beta (β) which represent host characteristic (i.e. β for normal and susceptible populations) and alpha (α) which represent hazard characteristics (i.e. *Salmonella*). Although the uncertainty is usually introduced into the beta parameters (i.e. normally distributed), the alpha parameter can also be distributed to address uncertainty related to the hazard infectivity. The dose-response model is as follows:

$$P_{ill} = 1 - (1 + \frac{Dose}{\beta})^{-\alpha}$$

Furthermore, the final P_{ill} (i.e. $\sum P_{ill}$ for a flock) is the mean of P_{ill} of all meals. Finally, the mean probability of illness is used in risk characterization process along with other information to estimate ARE and AI.

2.4 Risk Characterization

The risk characterization estimates the magnitude of salmonellosis resulting from consuming contaminated whole broilers in the United States. The exposure assessment and hazard characterization results (i.e. dose distribution and probability of illness, respectively) are combined along with other information (i.e. risk characterization inputs) to estimate the magnitude of salmonellosis (i.e. likelihood and severity) from whole broilers in public health. Risk likelihood is characterized by the measures of probability such as the probability of broiler exposure to Salmonella from farm to fork, the probability of consumer exposure to Salmonella due to consuming contaminated serving, and the probability of illness as a result of that exposure (see 2.4.1 (A)). Risk severity is characterized by the measures of impact, for instance, salmonellosis severity is addressed by calculating annual salmonellosis (i.e. ARE and AI), annual hospitalization, annual death, social impact (i.e. DALY), and the economic impact (i.e. COI) (see 2.4.1 (B)). Furthermore, the above measures (i.e. risk likelihood and severity) are combined with attendant uncertainty to describe risk magnitude. However, salmonellosis magnitude is presented as its likelihood probability distribution and its severity probability of distribution. Later in the risk management phase, salmonellosis magnitude will be used as ALOPs to estimate the impact of potential intervention(s) (i.e. decision-making tool), and to establish a food safety control system for controlling Salmonella from whole broilers.

In risk characterization process, the Annual Risk Estimate (ARE) is calculated using final dose distribution, probability of illness, and information regarding affected population. By calculating ARE, the model can be used to quantify the burden of salmonellosis for a specific sub-population; and to identifying intervention in favor of specific sub-population (e.g., school children). Additionally, in case of studying a sub-

population, dose-response model should be optimized for the specific sub-population (i.e., identify α and β for the sub-population).

However, there is always a great uncertainty associated with estimating consumption pattern within a population. For example, estimating the individual annual consumption of whole broilers in the U.S. population will impose uncertainty. Therefore, a new method for estimating public health risk (i.e. salmonellosis) is used. In addition to (ARE) calculation, Annual Illnesses (AI) is calculated based on final dose distribution, probability of illness, and information related to production volume. The reason behind this is the noticeable uncertainty associated with estimated consumption pattern, while data regarding food production volume is readily available and more accurate.

Lastly, the other measures of impact are calculated after estimating annual salmonellosis (i.e. ARE and AI). Number of annual hospitalization and death are estimated by calculating proportion of hospitalization and death from epidemiological data. Subsequently, socio-economic analysis is conducted to estimate DALY and COI.

Finally, risk characterization is the final step in risk assessment, however, risk characterization outputs (i.e. the magnitude of salmonellosis in the U.S.) are the final results of the risk assessment model. By completion of risk characterization, risk assessment baseline model will be established. The baseline model provides a decision-making tool to quantify the impact of potential intervention on public health (i.e. number of salmonellosis) by estimating its effect on *Salmonella* prevalence and concentration at a specific step. However, the effect of any change to any risk assessment input on public health can be estimated.

Modeling Risk Characterization: modeling RC requires information from exposure assessment (i.e. hazard prevalence and concentration), hazard characterization (i.e. probability of illness), and other data regarding production characteristics, affected population, and socio-economic analysis. Those inputs are used to describe risk magnitude (i.e. risk likelihood and severity) as follows:

1) Risk Likelihood:

Risk likelihood is addressed by exposure assessment and hazard characterization outputs. It demonstrates the probability of broiler exposure to *Salmonella* from farm to fork, the probability of consumer exposure to *Salmonella* due to consuming contaminated serving, and the probability of illness as a result of that exposure.

PB_i = Prev_i * PBF

Where,

 PB_i is the probability of contaminated broiler at stage (*i*); $Prev_i$ is the prevalence of contaminated broiler at stage (*i*); PBF is the prevalence between flock.

NOTE: *PBF* is used to characterize the probability of contaminated broiler to the total annual production, since the model only simulates *Salmonella*-positive flocks.

$$P_m = \left(\frac{n_m}{N_m}\right) * PBF$$

 P_m is the probability of contaminated meal;

*n*_m is the number on contaminated meals estimated by the model;

 $N_{\rm m}$ is the total number of meals (equivalent of flock size).

$$P_{s} = \left(\frac{n_{s}}{N_{s}}\right) * PBF$$

Where,

*P*_s is the probability of contaminated serving;

*n*s is the number of contaminated servings estimated by the model;

 $N_{\rm s}$ is the total servings (i.e., $N_{\rm s} = N_{\rm m}$ * number of serving).

$$FD_x (\%) = \frac{N_x}{n_s}$$

Where,

 FD_x is the percent of contaminated serving from source (*x*) (i.e. *x* = broiler, crosscontaminated item, or both);

 N_x is the number of contaminated serving from source (x);

*n*_s is total number of contaminated serving.

$$\boldsymbol{P_{iii}} = \frac{\sum \boldsymbol{P_{iii}}}{N_c}$$

*P*_{ill} is the probability of illness;

 $\sum P_{ill}$ is the mean probability of illness estimated by the model;

 $N_{\rm c}$ is the number of contaminated servings estimated by the model.

$$IP_{i||} = S * P_s * P_{i||}$$

Where,

IP_{ill} is individual (i.e. a whole broiler consumer) probability of illness; S is number of whole broiler serving/year (i.e. annual individual consumption attributed to whole broilers).

Where,

RE is risk estimate (per serving) which demonstrate the probability of illness from consuming a random whole broiler serving.

2) Risk Severity:

Risk characterization inputs were collected and optimized (see chapter II, section 2.6.2.2). Those inputs were modeled with exposure assessment and hazard characterization outputs (i.e. risk estimate) to estimate salmonellosis severity. Salmonellosis severity is characterized by its impact on the U.S. population (i.e. number

of illnesses, hospitalizations, deaths, DALYs, and COI), and was estimated as follows:

ARE is the annual risk estimate;

Po is population of interest;

CC is proportion of chicken consumer;

AC is annual whole broiler consumption attributed to whole broiler (serving).

Where,

AI is annual illnesses;

AWB is annual whole broiler production;

S is the mean number of servings per broiler.

$$AH = \left(\frac{AI}{URM}\right) * HR$$
$$AD = \left(\frac{AI}{URM}\right) * DR$$

Where,

AH is annual hospitalization due to salmonellosis;

AD is annual death due to salmonellosis;

HR is salmonellosis hospitalization rate;

DR is salmonellosis death rate;

URM is under-reporting multiplier.

DALY = YLL + YLD

Where,

DALY is Disability-Adjusted Life Years;

YLL is Years of Life Lost;

YLD is Years Lost due to disability. (WHO, 2001)

NOTE: DALY calculation considers a 3% time discounting rate.

$$YLL = \frac{N}{r} (1 - e^{-rL})$$

Where,

YLL is years life lost due to premature death;

N is number of deaths;

r is discount rate (r = 0.03);

L is life expectancy. (WHO, 2001)

$$YLD = \frac{I * DW * (1 - e^{-rL})}{r}$$

Where,

YLD is years lost due to disability;

I is number of incident cases;

DW is disability weight;

L is length of disability. (WHO, 2001)

COI = Direct Cost + Indirect Cost + Cost of Premature Death

Where,

COI is Cost of Illness;

OP is salmonellosis outpatient cost;

AI is annual illnesses;

IP is salmonellosis inpatient cost;

AH is annual hospitalization;

CDL is cost of day lost;

TDL is total days lost;

CD is cost of premature death;

AD is annual death. (CDC, 2010)

3. RESULTS AND DISCUSSION

The constructed QMRA model predicts the likelihood and severity of salmonellosis (e.g. RE, ARE, AI ... etc.), among other outputs. However, the predicted likelihood and severity of salmonellosis are affected by the attendant uncertainties. Therefore, the QMRA model should be validated by comparing the QMRA model's outputs (i.e. predicted results) with relevant reported data such as epidemiological data (e.g. annual salmonellosis reported by CDC) and/or observational data (e.g. prevalence and concentration of Salmonella at retail in the U.S. reported by USDA). It is important to note that due to the large uncertainties associated with risk assessment outputs, risk assessment model validation is often difficult (FAO/WHO, 2002b). If the predicted outputs do not match reported data, the QMRA needs to be calibrated. There is no specific approach for calibrating QMRA models, however, several approaches may be used including, but not limited to, data revision, calculation revision, uncertainty analysis, and/or sensitivity analysis. Moreover, @RISK can be used to evaluate outputs uncertainties propagated from input uncertainties by performing Monte Carlo simulation and sensitivity analysis.

Generally, a QMRA model's inputs contain either known or unknown variability and uncertainty which means that a model's inputs are a range of values which follow a specific probability distribution. However, @RISK is capable to include variability and/or uncertainty present in the model's inputs to generate results that show all possible outcomes (i.e. outputs probability distribution). @RISK uses Monte Carlo simulation technique to combine all identified uncertainties (i.e. inputs' probability distributions) in

the model using Excel's modeling capability. However, it will use all possible inputs' values to estimate all possible outcomes for each output by simulating the model thousands of times (i.e. thousands of iterations). Therefore, the model will be run thousands of times under different sets of conditions (i.e. different inputs' values) to deal with associated uncertainties and to improve our picture about the results.

@RISK outputs are monitored during simulation and reported as probability distributions (i.e. histogram and statistics) that show how the outputs changed due to inputs distribution. @RISK outputs (i.e. the model's outputs) are assigned using the "Add Output" function in @RISK. Furthermore, @RISK inputs can be any cell with any @RISK distribution (i.e. any model's inputs). Inputs can be assigned by "Define Distributions" function in @RISK. The assigned inputs are used by @RISK to perform simulation within the specified probability distribution. Identification of @RISK inputs will help in performing sensitivity analysis, risk optimization, and goal seeking.

@RISK's Monte Carlo simulation consists of two parts; inputs cells (i.e. distributed variables) and outputs cells (i.e. monitored outcomes). The simulation can be performed without identifying the inputs, however, some useful outcomes (e.g. sensitivity of inputs) will not be calculated. @RISK's simulation helps in estimating outcomes distribution and the statistics (i.e. mean, standard deviation, mode, percentiles, kurtosis ...etc.) of monitored outcomes. In Monte Carlo simulation, @RISK generates a random value for each identified input cell within the identified distributions (an iteration). The number of iterations is identified when setting up the simulation. In this project, each iteration is considered as a *Salmonella*-positive flock. For instance,

performing 100 iterations means that 100 random *Salmonella*-positive flocks were sampled.

@RISK observes and records all possible values for each output and generates a report for each monitored cell (i.e. each outputs). When simulation results are ready, distributions can be fitted to identify how the monitored outcomes are distributed using "Fit Distribution" function within a @RISK output window. Simulation results can be saved within the Excel file (which can cause future calculations to run slowly) or can be saved in a separate file with the @RISK file extension "*.RSK5".

3.1 Review, Test, and Calibrate the QMRA Model

At this stage, the QMRA model is constructed and all collected data is incorporated in the model as inputs. However, the final version of the QMRA model (i.e. revised version with revised and optimized inputs) is reviewed, tested, and calibrated before its final and used for decision-making. The review process was performed by preparing the model for Monte Carlo simulation and then running a simulation to check the initial results (i.e. QMRA results before model calibration). Furthermore, the implemented modeling approach was tested to ensure that modeling approach does not significantly affect RAs results. Testing the modeling approach was performed by comparing results of different QMRA model versions to quantify the effect of the implemented modeling approach on the QMRA results. The effect of modeling order (i.e. cross-contamination event first or growth/reduction event first) and the effect of distributions used (i.e. Excel or @RISK distributions) were tested.

The review and testing process was performed using five different versions of the QMRA models. For each version, Monte Carlo simulation (2000 iterations) were performed and the result for Annual Illnesses (AI) (i.e. central statistics and 90% CI) were compared with CDC reported illness estimates as follows:

- QMRA-A1: cross-contamination modeled first and all EA distributions are modeled using Excel functions.
- QMRA-A2: cross-contamination modeled first and all EA distributions are modeled using @RISK functions. Only RAs inputs are marked with "RiskCollect" function to avoid considering EA distributions in sensitivity analysis.
- QMRA-B1: growth or reduction modeled first and all EA distributions are modeled using Excel functions.
- QMRA-B2: growth or reduction modeled first and all EA distributions are modeled using @RISK functions. Only RAs inputs are marked with "RiskCollect" function to avoid considering EA distributions in sensitivity analysis.
- QMRA-20,000: the EA is based on 20,000 broilers (i.e. estimated flock sized), growth or reduction modeled first, and all EA distribution are modeled using Excel functions.

The CDC estimates 222,537 (60,358 – 693,333; 90% CI) annual salmonellosis attributed to whole broilers (Figure 3.1). The QMRA-A1 estimates too small AI as 4,114 (0 - 23,307; 90% CI), while the QMRA-A2 estimates a smaller AI as 134 cases annually

(Figure 3.2). However, the QMRA-B1 estimates 137,844 (0 – 794,000; 90% CI) cases of salmonellosis, while the QMRA-B2 estimates 111,686 (0 – 654,000; 90% CI) cases annually (Figure 3.3). The QMRA models where growth/reduction event modeled first (i.e. QMRA-B1 and QMRA-B2) estimate AI 38 – 50% less than CDC numbers, however, the estimated AI distribution (i.e. 90% CI) is corresponding to CDC estimated AI distribution. Furthermore, it was noticed that in both cases when EA was modeled using @RISK distribution, the QMRA models estimate lesser AI.

Furthermore, when the flock size was increased to 20,000 broilers/flock (i.e. mean number of birds within a flock) there was a ~13.5% increase in predicted AI (Figure 3.4) comparing to the QMRA-B1. However, the number of broilers simulated within a flock (i.e. flock size) may affect the result. Moreover, modeling of the chilling tank step is critical and it greatly affects the RAs results. However, to confirm this notice, another QMRA model version was constructed (QMRA-C) which is basically the QMRA-A2 with reduction modeled first only in chilling tank step. The QMRA-C model estimated the AI as 124,965 (0 – 716,000 CI) (Figure 3.5). This may indicate that cross-contamination should not be modeled first especially in steps with high log reduction (G/R > -2 log).

Consequently, based on the above results, the model QMRA-B2 was chosen as the baseline, thus, it will be calibrated before performing sensitivity analysis. This model is more stable because of using @RISK distributions and modeling growth or reduction events first. Additionally, the random probability was generated using "RiskUniform" distribution within @RISK rather than using "RAND" function within Excel. "RAND" function is not seeded, thus, it may not give each number (i.e. between 0 - 1) the same

probability of occurrence and may also follow a different trend (i.e. the lower bits tend to cycle). However, "RiskUniform (0, 1)" within @RISK is better especially in high resolution Monte Carlo simulation.

At this stage, the QMRA-Baseline is identified and ready for calibration. Calibration was performed using the Risk Optimizer function of @RISK considering exposure assessment inputs with high uncertainty (i.e. wide range of triangular distribution). However, data entry for scalding (minimum log reduction), de-feathering (minimum and mode log reduction), washing (minimum and mode log reduction), and chilling tank (minimum and mode log reduction) were targeted for calibration. The optimization was set up by assigning these inputs as "Changing Cells", and Annual Illnesses as target cells with "Optimization Goal" equal to 223,000 cases. The optimization mode was set to perform 10 trials with 1000 iterations each.

Based on optimization results (Figure 3.6), the reduction mode of washing and chilling steps were the same as the original inputs. The reduction mode of scalding step was decreased from 2 log reduction to 1.3 log reduction. The maximum reduction of preparation (cooking) step was also decreased from 22 log reduction to 17 log reduction. Lastly, maximum growth of the grading and packaging step was increased from 0.01 log growth to 0.06 log growth. Furthermore, after optimization result was implemented, the baseline model was simulated one last time (5000 iterations) to ensure the efficiency of the calibration. The QMRA-baseline model estimated the AI as 220,257 cases (0 – 1,750,000 CI) (Figure 3.7). This range overlaps the CDC estimated range, while the means are similar.

Finally, the last step in reviewing and testing the QMRA-baseline model is comparing some QMRA model's secondary outputs with similar reported data, if applicable. This comparison was conducted for six steps as follows:

Transport to Plant: van der Fels-Klerx et al. (2008) reported that during transport to abattoir the prevalence of *Salmonella* increased by 0.1 - 1.8% (~ 2 – 30.5% relative differences). The QMRA model estimates the change in prevalence as 31% (2.8 – 88.1% Cl). This wide reported range may related to transportation temperature which vary between seasons. Additionally, according to FAO/WHO (2002b), the prevalence of *Salmonella* (feather and skin) at the stun and kill step (i.e. after transport to plant) ranged between 27 – 75%. However, the QMRA model estimates the prevalence after transport to plant as 62.5% (30.7 – 84.3% Cl).

Scalding: literature review conducted by FAO/WHO (2002b) demonstrates that *Salmonella* population at scalding was 3 – 3.5 log MPN/carcass. However, the QMRA model estimates the mean *Salmonella* concentration after scalding as 2.92 log cfu/carcass (2.49 – 3.78 log CI).

De-feathering: the FSIS Microbiology Division (2008) reported the percentage of *Salmonella*—positive samples at Re-Hang as 40.7% with a concentration of 2.99 \pm 0.85 MPN/ml. Other research estimated *Salmonella* prevalence after de-feathering as 43 – 55% with concentration 2.77 \pm 0.59 log₁₀ MPN at rehang (Berghaus et al., 2013; Finstad et al., 2012). However, the QMRA model estimates the prevalence after de-feathering as 68.3% (34 – 88.7% CI) with a mean concentration of 2.26 log cfu/carcass (1.84 – 3.12 log CI).

Chilling (Tank): in FSIS Microbiology Division (2008) baseline data collection program, the percent of positive sample at Post-Chill was 5.19% with a concentration of 0.7 ± 0.14 MPN/ml. A literature review conducted by FAO/WHO (2002b) reported that the prevalence of *Salmonella* before chilling was 6 – 13%, and 2 – 29% after chilling; with concentrations estimated as <0.4 MPN/g. However, the QMRA model estimates post-chilling prevalence as 10% (3.5 – 23.1% Cl) with mean concentrations of 0.4 log (0.15 – 1 log Cl).

Grading and Packaging: FSIS Microbiology Division (2008) estimated the prevalence of *Salmonella* at the end of processing as 7.5%. Prevalence of *Salmonella* on finished carcasses and portions in the U.S. was estimated between 3% and 21.4% with a population range from <12 to 1200 MPN/carcass (FAO/WHO, 2002b). According to Oscar (2004) the population of *Salmonella* at a processing plant ranged from 1 - >300 MPN/chicken. However, the QMRA model estimates the prevalence after grading and packaging as 10.9% (3.5 – 27% CI) with a mean concentration of 0.42 log cfu/carcass (0.15 – 1 log CI).

Storage at Retail: according to the 2010 executive report from the National Antimicrobial Resistance Monitoring System (NARMS) of the FDA, the prevalence of *Salmonella* in retail chicken breast was 13.0% (Thakur et al., 2013). Oscar (2004) reported that the *Salmonella* concentration at retail ranged from 10 - 1100 MPN/chicken. However, the QMRA model estimates the prevalence at retail as 11.4% (3.5 - 27.8% CI) with a mean concentration of 0.41 log/carcass (0.14 - 0.99 log CI).

From the above information, it can be noticed that the QMRA model is capable of estimating salmonellosis from whole broilers that is similar to CDC reported salmonellosis (i.e. after attribution to whole broiler). Additionally, the QMRA model was able to make good estimation for some secondary outputs in different stages. At this stage, the QMRA-baseline model has been created, revised, tested, and calibrated; and ready for sensitivity analysis.

3.2 Sensitivity Analysis

Sensitivity analysis influences risk assessors' confidence in the outputs robustness. It generates important risk assessment information (i.e. sensitive inputs and data gaps) that can help improve the QMRA results. Such information may be used to direct future research and data collection, and/or suggest some steps for food safety intervention. However, it can reduce uncertainties by identifying sensitive inputs with relatively larger effects on results. It is important to note that, sensitivity analysis results can be considered as the first level of QMRA results. These might be used by risk managers to make risk analysis and/or food safety decisions. However, risk managers may consider waiting to improve risk assessment results until they gather more information (i.e. which may be identified by sensitivity analysis) or by spending more resources to acquire such data to make more informed food safety decision(s) (FAO/WHO, 2009b).

It is important to note that, accurate and detailed sensitivity analysis should be performed using the "Advanced Sensitivity Analysis" function within @RISK rather than

the sensitivity analysis performed within Monte Carlo distribution. This analysis is conducted for a single input each time, however, detailed sensitivity analysis is beyond the scope of this project. Therefore, sensitivity analysis was performed in the QMRAbaseline model by @RISK during Monte Carlo simulation to identify sensitive inputs and data gaps as follows:

- 1- Eliminate source of variability by fixing broilers type to be "chilled" and broilers destination to be "home". Any other combination may be tested (e.g. frozen broilers going to food service facility).
- 2- None of the hazard and risk characterization inputs were considered.
- 3- Exposure assessment inputs that include variability were not considered in the sensitivity analysis to avoid calculating the effect of variability.
- 4- Initial contamination maximum and minimum were distributed within <u>+</u>10%.
- 5- G/R events mode for steps that do not incorporate variability were distributed within <u>+</u>10%.
- 6- Maximum and minimum transfer rates for all steps were distributed within 10%.
- 7- Cross-contamination was marked with "RiskMakeInput" which allows equations to be considered as @RISK inputs.
- 8- The mode of percent of protected cells was distributed within 10%.
- 9- All the above inputs were marked with the "RiskCollect" function. This function allows @RISK to only consider marked inputs in sensitivity analysis to avoid unnecessary consideration for EA distributions in the analysis.

- 10-After identifying inputs for sensitivity analysis, the QMRA-Baseline model was simulated for 2000 iterations.
- 11- Although all the identified @RISK outputs will have sensitivity analysis results, only annual illnesses (AI) sensitivity will be discussed and reported as a representative output.

Data gaps: the "Tornado – Change in Output Mean" graph resulted from sensitivity analysis (Figure 3.8) demonstrates the 10 inputs that significantly affect the annual illnesses uncertainty and their effect on AI mean. All of the reported inputs are considered as data gaps. However, uncertainties related to the following inputs are found to have a significant effect on the overall uncertainty (i.e. data gaps). Therefore, to improve the QMRA results these data gaps need to be minimized either by collecting more information or by directing future research to those topics. The following data gaps have been identified by sensitivity analysis:

- 1) Cross-contamination during grading and packaging,
- 2) Cross-contamination during preparation (cooking),
- 3) Maximum transfer rate during storage at home and grading and packaging,
- Minimum transfer rate during preparation (cooking), distribution, and grading and packaging,
- 5) Temperature abuse during storage at retail and transport to home, and
- 6) Prevalence between flocks (PBF).

It is important to note that, sensitivity analysis results will be misleading if variability and uncertainty are combined into a single dimension. That means if variability is considered, sensitivity analysis results will report both the effect of variability and uncertainty on RAs results not only data gaps that affected by uncertainty. However, the two sources of variability (i.e. broilers type and destination) were fixed to eliminate the effect of variability. The effect of variability can then be estimated by testing different combinations (e.g. frozen broilers going to home).

Sensitive Inputs: the "Tornado – Correlation Coefficients" graph resulted from sensitivity analysis (Figure 3.9) demonstrates the 16 inputs with the highest correlation coefficients with the annual illnesses (i.e. observed output). Inputs with higher correlation coefficients may be identified as sensitive inputs and may be considered for potential food safety interventions as they are expected to yield higher effects on AI.

It was found that only cross-contamination during grading and packaging (correlation coefficient = 0.73) is statistically significant and has a linear correlation with annual illnesses (AI). The other 15 reported inputs have a correlation coefficient that is equal to or less than 0.09 which indicate they have no statistical significance and no linear correlation with (AI). However, conducting a complete sensitivity analysis—that capable of capturing non-linear correlation—may capture more sensitive inputs with higher accuracy.

3.3 QMRA-Baseline Model Results

At this stage, the QMRA-baseline model is established, reviewed, calibrated, and ready to use. The final outcome of the risk assessment process is the baseline model which describes the current magnitude of salmonellosis. It can be used to evaluate the performance of the broiler production system and to inform the food safety decision-making process. Such a QMRA model is usually highly informative with several dozen outputs. However, all the QMRA outputs are assigned as @RISK outputs to be observed by @RISK during Monte Carlo simulation. The simulation reports all the possible values of an output in graphs (e.g. cumulative frequency chart). Additionally, "Fit Distribution" function within @RISK is used to identify results distribution, however, results will be presented in the form of bounded distributions. The minimum and maximum values are assigned based on the 90% CI of resulted distributions.

In this section, the QMRA-baseline model's results will be categorized, while the final results will be discussed in detail in Chapter IV. The QMRA results will be divided into three groups based on their intended use as follows:

A. Evaluating current practices (107 outputs):

At this stage, the QMRA baseline model is ready to evaluate the U.S. whole broilers production system and to assist relevant food safety decisions. The QMRA model aims to observe *Salmonella* prevalence and concentration in broilers flocks from farm to fork to enable quantitative estimation of the performance of the U.S. whole broiler production system (i.e. the current food safety control system which is

demonstrated by in-place sanitary and process measures). Additionally, because the risk assessment was based on the idea of performance criteria, the baseline model can demonstrate the current effort in controlling *Salmonella*.

The estimated performance evaluates the current practices and provides valuable information that may be communicated through a Risk Communication process to inform all relevant parties (i.e. farm, process, retail, and consumer) about broilers' microbial quality from farm to fork. The following outputs are predicted by the QMRA model and can be used to evaluate the current performance of the production system and to estimate the effect of interventions on broilers contamination (e.g. evaluate performance improvement opportunities). This group of outputs results from the exposure assessment model; and demonstrates exposure of whole broilers to *Salmonella* due to the current production practices. However, it is characterized by two groups of outputs as follows:

1) Microbial load (90 outputs): this group of outputs comprises three groups of outputs for each step, from farm to fork, which describe the performance of each step in controlling *Salmonella* load on whole broilers (Figure 3.10). For each step the following outputs will be estimated:

a) <u>Prevalence</u> (2 outputs/step): this group of outputs demonstrates the prevalence of contaminated broilers within *Salmonella*-positive flocks at each step from farm to fork. It also demonstrates the performance of each step in controlling *Salmonella* prevalence by calculating the percent of prevalence change due to a step, and can be used to evaluate the effect of potential

intervention(s) on the prevalence. It also used to estimate PCs (prevalence) and POs (prevalence). It can be compared with reported data (i.e. experimental data) to validate and/or calibrate the model (i.e. check model accuracy in estimating *Salmonella* prevalence).

- b) Concentration (4 outputs/step): this group of outputs demonstrates the concentration of Salmonella cells in externally contaminated broilers at each step from farm to fork. It characterizes Salmonella concentration by three values: minimum, maximum, and mean. Note that, the mean is reported in two formats: arithmetic and log formats. Mean concentration illustrates the performance of each step in controlling Salmonella concentration; and can be used to evaluate the effect of potential intervention(s) on concentration, and to estimate PCs (concentration), POs (concentration), and MCs. It can be compared with reported data (i.e. experimental data) to validate and/or calibrate the model (i.e. check model accuracy in estimating Salmonella concentration). The minimum concentration expected for a contaminated broiler at each step can be used to evaluate the threshold of Salmonella method of detection for inspection reason. The maximum concentration expected for a contaminated broiler at each step may be used to estimate POs and MCs.
- c) <u>Source of contamination</u> (1 output/step): this group of outputs demonstrates the percentage of broilers that were contaminated at each step and remained contaminated to the time of consumption (i.e. contribution in the final dose).

They can be used to identify the riskiest steps (based on its contribution in the final dose) which may be the best step for a mitigation option.

2) Food control system performance (21 outputs): this group of outputs is used to evaluate the current food control system (i.e. current practices and policies) in controlling *Salmonella* for each stage from farm to fork (i.e. farm, processing, retail, and consumer kitchen) (Figure 3.11). Estimating the performance at each stage generates valuable information for the whole food continuum such as broiler acceptance criteria and performance objective (e.g. CCPs). This group of outputs demonstrates the current performance of the U.S. whole broilers production system:

- a) <u>Prevalence</u> (1 input/stage): this group of outputs demonstrates the performance of each stage in controlling *Salmonella* prevalence. It can be used to estimate *Salmonella* prevalence (i.e. percent and numbers) in contaminated flocks at the end of each stage and the effect of potential interventions on each stage's performance in controlling *Salmonella* prevalence. In the consumer kitchen stage, however, the prevalence represents *Salmonella* prevalence at time of consumption. Note that, the effect of cross-contamination is not considered in this number (i.e. only accounts for cells coming from cooked broiler), however, the effect of cross-contaminated meal.
- b) <u>Concentration</u> (1 input/stage): this group of outputs demonstrates the performance of each stage in controlling *Salmonella* concentration. It can be used to estimate *Salmonella* concentration on contaminated broilers at the

end of each stage and the effect of potential interventions on each stage's performance in controlling *Salmonella* concentration.

- c) <u>Effect on prevalence</u> (1 input/stage): this group of outputs demonstrates the effect of each stage on *Salmonella* prevalence (i.e. % of increase or reduction). It can be used as an overall performance criteria (i.e. PC prevalence) for each stage, and can also be used to estimate the effect of potential interventions on a stage's performance in *Salmonella* reduction.
- d) Effect on concentration (1 input/stage): this group of outputs demonstrates the effect of each stage on Salmonella concentration (i.e. % of increase or reduction). It can be used as an overall performance criteria (i.e. PC concentration) for each stage, and can be used to estimate the effect of potential interventions on a stage's performance in Salmonella reduction.
- e) <u>Dose contribution</u> (1 output/stage): this group of outputs demonstrates the percentage of broilers that became contaminated at each stage and remained contaminated to the time of consumption. It estimates the effect contamination at farm, and the effect of cross-contamination at processing and retail. It can be used to determine if an intervention is required to reduce cross-contamination at retail and/or processing and/or the farm.
- f) <u>Probability of contaminated meal</u>: this output demonstrates the percentage of Salmonella-contaminated meals (i.e. broiler and other food) at time of consumption. This output as well as other information regarding consumption patterns such as serving size are used to calculate the probability of a contaminated serving. It is important to note that this number and the

estimated probability of contaminated serving are considering the effect of cross-contamination, however, they include other contaminated foods where broilers were the original source of contamination.

B. Estimating Risk Likelihood (9 outputs):

Risk likelihood (or measures of probability) demonstrates exposure of humans to *Salmonella* due to consumption of whole broilers produced in the United States. The Risk Estimate (RE) quantitatively describes salmonellosis likelihood. This group of outputs can be used to estimate Annual Risk Estimate (ARE), Annual Illnesses (AI), Food Safety Objective (FSO) frequency (probability of contaminated serving), and FSO concentration (mean dose) (Figure 3.12).

1) Probability of contaminated serving: this number demonstrates the likelihood of consumer exposure to *Salmonella* due to whole broiler consumption. Additionally, it demonstrates the overall performance of the U.S. whole broiler production system in controlling *Salmonella* prevalence. It estimates the percentage of *Salmonella*-contaminated servings (i.e. piece of chicken and other food) at time of consumption, and can be used to evaluate the effect of potential intervention(s) on the final prevalence of *Salmonella* (i.e. at time of consumption); and the effect of prevalence on public health. Importantly, this number is used to calculate the Risk Estimate.

2) Source of final dose (3 outputs): this group of outputs demonstrates sources of contamination (i.e. for contaminated servings). It can be used to communicate risks

(i.e. inadequate cooking and cross-contamination) to consumers and food service facilities; and to generate consumer related decisions (e.g. training, publishing guidelines and/or recommendation ...etc.). The QMRA model estimates the percent of contaminated servings and the source(s) of the final dose:

- a) <u>Contamination from broiler serving</u> (%): cells that survived broiler cooking (i.e. inadequate cooking) may be used to estimate the effect of inadequate cooking on public health.
- b) <u>Contamination from cross-contaminated materials</u> (%): cells transferred from broiler during preparation to meal through cross-contamination may be used to estimate the effect of cross-contamination on public health.
- c) <u>Contamination from both routes</u> (%): represents the percent of contamination from both inadequate cooking and cross-contamination. It may be used to avoid bias when quantifying the role of inadequate cooking and cross-contamination in public health.

3) Dose quantity (2 outputs): this group of outputs demonstrates the overall performance of the U.S. whole broiler production system in controlling *Salmonella* concentration. It estimates the mean and maximum number of *Salmonella* cells in a contaminated serving at time of consumption (i.e. digested dose). It can be used to evaluate the effect of potential intervention(s) on the final concentration of *Salmonella* (i.e. at time of consumption); and to estimate the effect of final concentration on public health. Importantly, these numbers may be used in establishing FSOs.

4) Probability of illness (2 outputs): The dose quantity output quantifies the human exposure to *Salmonella*, however, the effect of that exposure is estimated by calculating the probability of illness. This output results from the hazard characterization process (i.e. from dose-response model). The probability of illness is addressed by two outputs as follows:

- a) <u>Mean probability of illness</u>: demonstrates the probability of illness resulting from consumer exposure to *Salmonella* due to consuming whole broilers. It is a function of *Salmonella* concentration at time of consumption. It can be used to evaluate the effect of potential intervention(s) on the probability of illness.
 Importantly, this number is used in calculating Risk Estimate.
- b) <u>Individual probability of illness</u>: demonstrates the probability of a random consumer in the U.S. contracting salmonellosis due to whole broiler consumption each year. It can be used to assess the individual risk of salmonellosis from whole broilers (i.e. compare it with other source of salmonellosis).

5) Risk Estimate (RE): this number demonstrates the overall performance of the U.S. whole broiler production system in controlling *Salmonella* prevalence and concentration. The Risk Estimate is the result of multiplying the probability of contaminated serving (i.e. prevalence) and probability of illness (i.e. concentration). It addresses the overall likelihood of salmonellosis resulting from the current U.S. whole broiler performance (i.e. sanitary and process measures) and estimates the likelihood of illness due to consuming a random serving of broiler. RE is a result of exposure

assessment and hazard characterization processes; and is used in risk characterization to estimate salmonellosis impact.

C. Estimating Risk Severity (6 outputs):

Risk severity (or measures of impact) demonstrates the impact of salmonellosis on the U.S. population. However, salmonellosis severity is characterized by estimating annual salmonellosis, hospitalization and death resulted from salmonellosis; and salmonellosis socio-economic impacts (i.e. DALYs and COI) (Figure 3.12). The severity of salmonellosis, especially the public health impact, should be the primary basis for decision making. This group of outputs is used to assess the current practices and to estimate the effect of potential food safety interventions. It also used to calibrate the baseline model against official epidemiological studies' results. The effect of interventions on society (i.e. change in quality of life) can be estimated by achieving a reduction in Disability-Adjusted Life Years (DALYs). The feasibility of interventions can be estimated by any reduction achieved in Cost of Illness (COI).

1) Public health impact (4 outputs): this group of outputs demonstrates the model's estimation of public health impact (risk severity) due to salmonellosis. However, public health impact is addressed by four outputs as follows:

 a) <u>Annual Risk Estimate</u> (ARE): this number demonstrates the model estimation of annual number of salmonellosis (i.e. population RE) cases within the U.S. population (including underreported cases). It is characterized by risk likelihood (i.e. RE) and the U.S. population broiler consumption pattern. It is
the primary metric for public health, and therefore should be the primary basis for decision-making. Furthermore, ARE is used to estimate the effect of intervention(s) in public health. Moreover, it can be used to estimate the risk of salmonellosis in a specific sub-population, but in this case the doseresponse model should also be adjusted for the object sub-population.

- b) <u>Annual Illnesses</u> (AI): this number illustrates the total annual number of salmonellosis (i.e. including underreported cases) within the U.S. population estimated by the QMRA model. It is characterized by risk estimate (RE) and the U.S. annual whole broiler production (i.e. number of whole broilers that produced and sold locally). It should be the primary parameter for food safety decision-making. It is used to estimate the effect of intervention(s) in public health. It is used to estimate annual hospitalization and death as a result of salmonellosis using hospitalization and death rates. It should be compared with the reported epidemiological data (i.e. CDC data) to validate and/or calibrate the model. Moreover, annual illnesses can be used as an ALOP for morbidity (along with annual hospitalization).
- c) <u>Annual hospitalization</u>: this number demonstrates the model estimation of annual hospitalization due to salmonellosis. It is used to calculate DALYs and COI. It can be used to evaluate the effect of some interventions (e.g. reducing percent of hospitalization caused by salmonellosis or to reduce inpatient cost) in DALYs and COI.
- <u>Annual deaths</u>: this number demonstrates the model estimation of annual death resulting from salmonellosis. It is used in the calculation of DALYs and

COI. It can be used to evaluate the effect of some interventions (e.g. reducing the death rate associated with salmonellosis) in DALYs and COI. Moreover, annual death can be used as an ALOP for mortality.

2) Socio-economic impact (2 outputs): These outputs demonstrate the model's estimation of socio-economic impact (risk severity) due to salmonellosis, as follows:

- a. <u>DALYs</u> (years): this number demonstrates the number of annual years lost from the U.S. society due to disabilities resulting from salmonellosis (i.e. premature death, hospitalization, and illness). It is used to determine the societal burden and the effect of salmonellosis on the quality of life. It can be used to evaluate the effect of intervention(s) on the society's quality of life. Generally, DALY is used for risk ranking and prioritizing potential intervention(s) for its role in risk-benefit analysis. Moreover, DALY can be used as an ALOP for societal impact.
- b. <u>COI</u> (\$): this number demonstrates the number of U.S. dollars lost due to salmonellosis (i.e. premature death, inpatient, outpatient, and disability). It estimates the cost that government would pay to cure salmonellosis and the cost of lost productivity due to disability due to salmonellosis. It can be used to evaluate the effect of intervention(s) on the economy; and to evaluate potential intervention(s) feasibility. Generally, COI is used for risk ranking and prioritizing potential intervention(s) for its role in risk-benefit analysis. Moreover, COI can be used as an ALOP for economic impact.

3) CDC reported numbers: this group of outputs demonstrates the CDC estimation of annual salmonellosis. The published numbers represent the total salmonellosis, however, they were attributed. Because CDC numbers are published with a 90% confidence interval and attribution factors also have some uncertainty, these numbers are presented as distribution. Even though the CDC numbers are reported with 90% CI, the full distribution (100% CI) should be considered. Finally, this group of outputs was used to calibrate the QMRA model by comparing predicted results with published results.

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5. FIGURES AND TABLES



Figure 3.1: Annual Illnesses estimated by CDC and attributed to whole broilers.

Figure 3.2: Annual Illnesses relative frequency estimated by the QMRA-A1 (Upper

graph) and the QMRA-A2 (Lower graph) models *



* In these models cross-contamination was modeled first; upper graph (QMRA-A1) illustrates AI when EA was conducted by Excel distributions; lower graph (QMRA-A2) illustrates AI when EA was conducted by @RISK distributions.

Figure 3.3: Annual Illnesses relative frequency estimated by the QMRA-B1 (Upper

graph) and the QMRA-B2 (Lower graph) models *



* In these models growth/reduction was modeled first; upper graph (QMRA-B1) illustrates AI when EA was conducted by Excel distributions; lower graph (QMRA-B2) illustrates AI when EA was conducted by @RISK distributions.



Figure 3.4: Annual Illnesses relative frequency estimated by the QMRA-20,000 model *

* This model is a copy of QMRA-B1, however, the EA was modeled with 20,000 broiler rather than 1000 broilers.



Figure 3.5: Annual Illnesses relative frequency estimated by the QMRA-C model *

* In this model cross-contamination was modeled first EXCEPT in chilling (tank) step and EA was conducted by @RISK distributions.

Figure 3.6: Risk Optimization Results (as reported by @RISK).

Goal	
Cell to Optimize	'Sheet1'!S40
Statistic to Optimize	Mean
Type of Goal	Target Value
Target Value	223,000
Results	
Valid Trials	10
Total Trials	10
Original Value	124,175
+ soft constraint penalties	0.00
= result	124,175
Best Value Found	224,199
+ soft constraint penalties	0.00
= result	224,199
Best Trial Number	9
Time to Find Best Value	0:31:56
Reason Optimization Stopped	Number of trials
Time Optimization Started	8/7/2014 15:17
Time Optimization Finished	8/7/2014 15:52
Total Optimization Time	0:35:04

Trial	Elapsed Time	Iterations	Result	Goal Cell Statistics Std.			Adjustable Cells					
				Mean	Dev.	Min.	Max.	110	113	114	J15	H21
1	0:04:10	1000	124,175	99,616	0	99,616	99,616	-2.00	-1.30	-2.30	0.01	-22
3	0:10:59	1000	214,735	32,568	0	32,568	32,568	-1.50	-1.10	-2.30	0.06	-17
9	0:31:56	1000	224,199	12,641	0	12,641	12,641	-1.30	-1.30	-2.40	0.1	-22

* highlighted numbers are used for QMRA model calibration

Figure 3.7: Estimated annual illnesses (AI) of the QMRA-baseline model after calibration.



Figure 3.8: Sensitivity Analysis: inputs ranked by their uncertainties' effect on annual illnesses mean.



Figure 3.9: Sensitivity Analysis: annual illnesses correlation coefficients.



Exposure Assessment										
"Microbial Load"										
Process	Prevalence	Prevalence	Con	centration (Mean	Source of				
FIOCESS	(%)	change (%)	Min	Mean	Max	(log)	Cont. (%)			
Farm										
Rearing	0.348		258	14,141	77,025	4.16	0.389			
Transport to Plant	0.553	58.9	22	100,868	3,752,625	5.01	0.000			
Processing										
Scalding	0.588	6.3	1	3,703	266,837	3.57	0.019			
Defeathering	0.616	4.8	1	811	63,778	2.91	0.056			
Evisceration	0.664	7.8	0	805	64,669	2.91	0.037			
Washing	0.482	-27.4	1	66	6,126	1.82	0.019			
Chilling (Tank)	0.184	-61.8	1	9	33	0.95	0.259			
Grading & Packaging	0.224	21.7	1	8	34	0.88	0.000			
Retail (FS)										
Distribution	0.235	4.9	1	7	34	0.87	0.000			
Storage at Retail	0.245	4.3	1	7	34	0.86	0.000			
Consumer Kitchen										
Transport to Home	0.245	0.0	1	7	34	0.86	0.000			
Storage at Home	0.245	0.0	1	7	34	0.86	0.000			
Preparation (Cooking)	0.054	-78.0	1	1	7	0.14	0.000			
		Number of	cont. Meal	54						

Figure 3.10: RAs results from exposure assessment as reported by the QMRA model *

* These inputs describe *Salmonella* load (prevalence and concentration) on broilers for each step from farm to fork. The effect of prevalence (% prevalence change) and source of contamination (%) for each step is also reported. **Figure 3.11:** The current performance of the Food Control System as reported by the QMRA model ^{*}

	Stage	Prevalence	Effect (P)	Concent.	Effect (C)	(%) Dose	Overall
Food Contro System Performance	Farm	0.187	58.9	5.01	20.4	0.389	A. W. Broiler Production
	Processing	0.076	-59.5	0.88	-82.4	0.389	831,281,125
	Retail	0.083	9.4	0.86	-2.3	0.000	P. of Contaminated Meal
	Consumption	0.018	-78.0	0.14	-83.7	0.000	0.0182

* The Effect (P) demonstrates the current PC prevalence for each stage. The effect (C) demonstrates the current PC concentration for each stage. The proportion (%) of final dose for each stage is also reported as an additional indicator for performance.

Figure 3.12: RAs results from risk characterization as reported by the QMRA model *

Hazard & Risk Characterization								
Risk Likeliho	od (Probabili	ty)	Risk Severity (Impact)					
P. of Contaminated Serving 0.0119			Public Health Impact					
	Serving (%)	0.981	Annual Risk	Estimate (ARE)	765,739		
Source of Final Dose	X.C. (%)	0.000	Annual IIIne		695,860			
	Mix (%)	0.019	Annual Hosp	1,377				
Doco Quantity (colle)	Mean	1	Annual Death			22		
Dose Quantity (cens)	Max	2	Socio-economic Impact (D			Y)		
D. of Illnoor	Mean	0.0141		265	YLD	9		
P. OF IIIIIess	Individual	0.002762	TLL	505		3,087		
Risk Estimate (RE)		0.000167	DA	LYs	3,460			
			Socio-economic Impact (COI)					
Attributed (CDC) Numbers (2010)			Cost of lost days (\$)		41,766,155			
			Cost of Outpatient (\$)		6,270,204			
A. Illnesses	253,686		Cost of Inpatient (\$)		21,14	3,167		
A. Hospitalization	502		Cost of Death (\$)		84,13	6,658		
A. Death	8		COI (\$) 153,			16,184		

* This group of outputs demonstrates the magnitude of salmonellosis from whole

broilers by describing salmonellosis likelihood and severity.

CHAPTER IV: RISK MANAGEMENT ACTIVITIES (DESIGN INTERVENTION PLAN)

ABSTRACT

Risk management activities (RMAs) identify and select microbial risk management (MRM) options using the QMRA model. The selected MRM options should be then implemented in accordance with an established plan. RMAs also aim to establish a monitoring plan to ensure the effectiveness of MRM activities.

The QMRA model was prepared for MRM activities by transforming some QMRA results to MRM metrics. A complete set of MRM metrics (i.e. ALOPs, FSOs, POs, and PCs) were calculated including a sampling plan to test the compliance of farm, processing, and retail stages with the established POs for prevalence and concentration. These metrics form the food safety control system for reducing salmonellosis from whole broilers. The MRM metrics are used to identify and plan food control interventions such as risk communication, auditing, inspection, and monitoring. However, because the POs are the bases for inspection, sampling plans, and monitoring plans, it was possible to combine both auditing and inspection within the monitoring plan to optimize resource consumption.

The QMRA model was also used to identify some potential food safety interventions (non-specific interventions) and to quantitatively evaluate their effect on public health. Identified interventions can then be used to direct future research. The effect of potential food safety interventions is estimated by three different @RISK functions (i.e. advanced sensitivity analysis, goal seek, and risk optimizer). An example

for each method is discussed. Moreover, an example of evaluating a specific food safety intervention is also presented.

1. INTRODUCTION

According to a FAO/WHO (1997) risk management is "the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures." It should ensure the scientific integrity of risk assessment, while considering attendant uncertainties. Additionally, risk management should ensure a functional separation from risk assessment, while promoting interactive risk communication with all parties. Risk management should be an ongoing process to ensure up-to-date data and to continually evaluate and review risk management activities (FAO/WHO, 1997). As recommended by Codex, risk management should follow a structured approach, however, risk management can be conducted in accordance with a framework that consists of four elements as follows: preliminary risk management activities (or risk evaluation), identification of MRM options, implementation of selected MRM options, and monitoring and review (Codex, 2007a). Risk managers should ensure that selected MRM options are adequate to promote public health, scientifically justifiable, practicable, enforceable, and are not trade restrictive (Codex, 2007a). Implemented options should be monitored for their effectiveness to ensure the achievement of food safety and public health goals (FAO/WHO, 1997).

Food safety microbial risk management (MRM) metrics such as the Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC) are intended to link the traditional food safety metrics (i.e. MC, PcC, and PdC) to public health protection. However, the WTO/SPS agreement addresses public health by the

Appropriate Level of Protection (ALOP) (Codex, 2007a). Generally, establishing ALOP aim to articulate the current level of risk in population delivered by the current food safety control system. This established ALOP represent the baseline degree of control of which future public health goals will be set against (Stringer, 2004). The MRM metrics are used to articulate the control required (i.e. intervention stringency) of a food safety system at different steps from farm to fork to achieve established ALOP.

ALOP quantification was not described in the SPS agreement, however, risk managers may need to decide what level of risk is adequate, appropriate, or tolerable to estimate ALOP. ALOP may be addressed as the maximum number of illnesses per year associated with a hazard/commodity combination. It should be science-based, should minimize trade restriction, and should include socio-economic factor. Nonetheless, it is difficult to utilize ALOP to establish food safety control measures. However, FSOs translate the ALOP into a measurable and controllable food safety parameter that can be monitored by government. In other words, ALOP expresses public health risk; and FSO expresses the maximum level of a hazard (FAO/WHO, 2002a).

The FSO can be used by risk managers to clearly communicate to industry the expected criteria (i.e. prevalence and concentration) of food produced under properly managed practices. Communicating the expected microbial criteria (i.e. based on FSOs) will enhance the flexibility of food organizations to establish and maintain their own food safety practices (e.g. GMP and HACCP) to achieve the established FSOs (de Swarte and Donker, 2005).

A FSO is a transparent food safety parameter that can be used to organize trade within WTO members in accordance with SPS agreements. Risk managers must

confirm that the established FSOs are technically achievable through sound implementation of a food safety code of practices (e.g. GMP, HACCP ...etc.). However, establishing effective and achievable ALOPs and FSOs requires close interaction and communication among risk managers, industry professionals, consumers, and other stakeholders. If the established FSOs are not technically achievable, either the food production system and/or the FSOs should be modified. If modification is not possible the affected product may be banned. Similarly, if an exporting country was unable to meet an importing country FSO and the importing country is not willing to modify its FSO, then in this case the product cannot be exported (FAO/WHO, 2002a).

A FSO establishes the stringency of a food control system by identifying the maximum level of a hazard (i.e. frequency and concentration) that should not be exceeded. Moreover, POs describe the required performance of a specific segment of the food system to achieve a FSO. Generally, established FSOs are usually not monitored by microbiological testing at point of consumption to verify its compliance. However, the FSO can be achieved by implementing efficient control measures throughout the food chain. Therefore, hazard observation and analysis should be performed throughout the food chain to ensure compliance with established FSOs (Stringer, 2004). Consequently, POs throughout the food chain may be observed to ensure the achievement of FSOs and ultimately ALOPs.

Safe food may be produced by adhering to food safety practices (e.g. GAP, GMP, and GHP) and by implementing a food safety risk management system (e.g. HACCP). However, the effect of implementation of such practices cannot be quantitatively evaluated. Therefore, FSOs and POs are established to provide food

chain organizations with quantitative targets or standards. Food industry may use established POs to periodically verify their food safety control measure effectiveness. Furthermore, a competent authority may perform inspection—which is usually done by microbiological testing—to assess the adequacy of and the compliance with FSOs and POs.

Microbiological criteria (MC) may be established to set up a planned program to conduct inspection. Generally, within-lot MC is used to statistically compare the level of detected hazard against specified limit (i.e. POs). MC are usually established to test the adequacy of and adherence to in-place food safety code of practices, however, MC should be established only when there is a need to ensure compliance (van Schothorst et al., 2009). According to Codex (1997) MC may consist of the following components:

- The food, microorganism, and point of food chain to which the MC applies;
- The analytical methods for their detection and/or quantification;
- Number of samples to be taken and the size of the analytical unit;
- Microbiological limits considered appropriate;
- The number of analytical units that should conform to these limits;
- Any actions to be taken when the criterion is not met.

QMRA is recognized as a systematic science-based decision-support tool that can inform risk managers decision in relation to food safety. Recently, the idea of using MRA outputs to develop practical microbial risk management strategies (i.e. MRM metrics) was elaborated. This includes the use of a QMRA model to establish quantitative science- and risk based microbial metrics (i.e. FSO, PO, and PC). One concern is that, the current definitions of FSO, PO, and PC should be fully compatible with the QMRA outputs used to derive them. MRM metrics can be used to identify and quantify the required food control stringency to achieve relevant public heath goals. The FAO/WHO expert meeting considers the MRM metrics as MRA intermediate targets. FSOs may be used to translate in-place food safety control measures into public health outcomes. However, POs and PCs may be used to identify required stringency (i.e. set microbial standards) of the food control system in steps where control measures can be implemented and verified. POs and PCs can be achieved, maintained, and verified through the implementation of MC, PcC, and PdC (FAO/WHO, 2006b).

2. MATERIALS AND METHODS

At this stage, the risk assessment phase has been completed, and the QMRA model has been developed, reviewed, tested, and calibrated. The QMRA model is used to coordinate risk management activities in an effort to reduce the risk of salmonellosis from whole broilers consumption. From the QMRA model, model outputs were reviewed to derive Microbial Risk Management (MRM) metrics based on their definitions. Derived MRM metrics will later be used to establish a food safety control system for controlling *Salmonella* from whole broilers. The risk management phase was implemented in three steps as follows:

- 1) Transform risk assessment results to risk management metrics (section 2.1),
- 2) Identify and implement MRM options (section 2.2.1 and section 2.2.2),
- 3) Develop MRM monitoring and review plan (section 2.2.4).

2.1 Microbial Risk Management Metrics (MRM Metrics)

This step transforms some important RAs results to MRM metrics which will greatly facilitate the understanding of the U.S. whole broiler production system performance. MRM metrics also enable quantifying the significance of each step from farm to fork in controlling *Salmonella*. Exposure assessment results (i.e. microbial load and food safety system performance) will be transformed to PCs, POs and FSOs; while risk characterization results (i.e. risk likelihood and severity) will be transformed to ALOPs. The following MRM metrics were derived from the QMRA model:

Appropriate Level of Protection (ALOP): risk managers may set up sanitary and/or phytosanitary measures to achieve the planned ALOP. However, ALOPs can be used to identify the current and required level of protection from salmonellosis, the required intervention to achieve planned ALOPs, and the optimal allocation of food safety resources. In this project, seven ALOPs are established as follows:

- ALOP overall risk = Risk Estimate (RE) This demonstrates the maximum probability of getting salmonellosis due to consuming a random whole broiler serving within the United States.
- b) ALOP Morbidity = Annual Illnesses (AI)
- c) ALOP Mortality = Annual Death
- d) ALOP Social = DALYs
- e) ALOP cost of DALY = $\frac{\text{COI}}{\text{DALY}}$
- f) ALOP Economic = COI

g) ALOP cost of illness case = $\frac{COI}{AI}$

Food Safety Objectives (FSO): FSOs translate ALOPs into food safety targets by estimating the acceptable exposure (i.e. prevalence and concentration) to *Salmonella* from whole broilers. However, the established FSOs demonstrate the overall performance of the U.S. whole broiler production system in achieving intended public health goals. They can be used to estimate the effect of mitigation options on consumer exposure to *Salmonella*. FSOs are delivered to industry (i.e. by competent authority) in from of MCs, POs, and PCs. In this project, two food safety objectives are established as follows:

- a) FSO frequency (%) = probability of a contaminated serving
- b) FSO concentration (log) = log maximum dose of a contaminated serving

The FSO frequency demonstrates the maximum percent of *Salmonella*contaminated servings (could be calculated for meals) that are deemed acceptable and estimated to achieve the established ALOPs. The FSO concentration estimates the maximum number of *Salmonella* cells in contaminated servings—at time of consumption—that are deemed acceptable to achieve the established ALOPs.

Microbial Criteria (MC): MCs demonstrate the maximum permitted microbial load at a specific segment in the food chain, thus, it can be used to identify the performance of whole broiler production stages for *Salmonella* reduction. Additionally,

MCs can be used to estimate the effect of potential interventions on broilers' microbial quality within the food chain.

Usually, competent authorities audit food chain stages to assure compliance with established MCs by implementing a sufficient and representative sampling plan for microbial testing. Food chain stages (i.e. farm, processing, retail, consumer kitchen) can achieve compliance with the established MCs by implementing PCs and monitoring POs. In this project, four MCs (one for each stage) are established as follows:

- a) Farm MC = log of maximum concentration at end of transport to plant.
- b) Processing MC = log of maximum concentration at end of grading and packaging.
- c) Retail MC = log of maximum concentration at end of storage at retail.
- d) Consumer Kitchen MC (usually not audited) = log of maximum concentration at time of consumption.

Performance Criteria (PC): PCs estimate the required performance of each step from farm to fork in controlling *Salmonella* on whole broilers. Each step has two PCs, first, the PC prevalence which estimates the required percent of decrease (or maximum percent of increase) in prevalence of *Salmonella*-contaminated broilers that should be accomplished to achieve the established FSO frequency and PO prevalence. The second PC is the PC concentration which estimates the required log reduction (or maximum log increase) in *Salmonella* population in contaminated broilers that should be accomplished to achieve the established FSO frequency.

Generally, PCs are directly applied to the processing industry, while they are established by the competent authority. In this project, PCs prevalence and concentration for each step—except the first step rearing—are established as follows:

a) PC prevalence =
$$\left(\left(\frac{\text{prevalence at specific step}}{\text{prevalence at previous step}}\right) - 1\right) * 100$$

b) PC concentration =

maximum conc. at specific step - maximum conc. at previous step

Performance Objectives (PO): POs demonstrate the maximum prevalence and concentration of *Salmonella* on broilers at each step in the food chain that are deemed acceptable. Each broiler production stage should adhere to and comply with any established POs that contribute in achieving FSOs. Farms, processing facilities, and retailers may need to assure their compliance with intended POs by conducting microbial tests. Although consumers (including food service facilities) are not required to test their compliance to POs, food service facilities should show their compliance with process criteria (PcC) and product criteria (PdC) to ensure compliance with POs. In this project, POs (prevalence and concentration) for each step are established as follows:

- a) PO prevalence = the prevalence at each step
- b) PO concentration = Log₁₀ maximum concentration at each step

Sampling plan: microbiological testing is an important tool that can be used to evaluate implemented food safety control measures. However, the number, frequency and size of representative samples is always controversial, thus, in many cases higher number of samples are taken causing unnecessary deployment of available resources.

Any samples collected should be stored, transported, and analyzed in accordance with applicable guidance, standards, and regulations.

These outputs estimate the required number of samples to be collected to monitor the compliance of each food chain stage with established POs and MCs. The estimated number of samples is the minimum number that are required to detect prevalence and/or concentration above established criteria and within a pre-determined confidence limit (CL). Furthermore, a competent authority should collect and analyze samples to assure the achievement of planned POs, MCs, and FSOs. However, noncompliant batches should be considered for further action(s).

In this project, sample sizes are estimated to test a lot compliance with established POs prevalence and concentration for the first three stages (farm, processing, and retail). Calculation of sample size was based on the ICMSF method for establishing sampling plans. The estimated sample size is the number of samples required to reject a non-compliant lot (van Schothorst et al., 2002; van Schothorst et al., 2009; Whiting et al., 2006). However, in this case the estimated sample size will demonstrate the required samples to detect non-compliance. This sample size can be calculated as:

$$\boldsymbol{N}_{\text{freq.}} = \frac{LOG(1-CL)}{LOG(1-PO_P)}$$

Where,

N freq. is the required sample size to test compliance with PO prevalence; *CL* is the desired confidence limit to reject a noncompliant lot; *PO_P* is the maximum accepted PO prevalence (van Schothorst et al., 2009).

Or, calculated as:

$$\boldsymbol{N}_{conc.} = \frac{LOG(1-CL)}{LOG(1-P_m)}$$

Where,

N conc. is the required sample size to test compliance with PO concentration (or MC);

 P_m is the probability of exceeding MC concentration, and represents the distribution area (%) (i.e. the probability) between μ and established MC (Whiting et al., 2006).

$DS = NORM.DIST (MC, \mu, SD, 1)$

$$P_m = 1 - DS$$

Where,

DS is distribution area (%) under the established MC (or PO concentration) (i.e.

the probability of getting number smaller that MC);

MC is the established microbial criteria (i.e. PO concentration);

 μ is mean Salmonella concentration estimated by the QMRA model;

SD is the standard deviation of Salmonella concentration estimated by the

QMRA model;

1 is to set the distribution to return the cumulative distribution function.

If P_m is less than ~14%, the number of required samples will become larger.

However, if P_m is larger than ~45%, the number of required samples becomes smaller.

If $14 < P_m < 45$, the number of required samples will be approximately between 5 and 30 samples (Whiting et al., 2006). Therefore, it may be appropriate to set test sensitivity (TS) to avoid a large estimated sample size. TS represents the minimum P_m that needs to be considered. Test sensitivity may be set based on the desired confidence limit (i.e. TS = 1 - CL). In this case, any P_m less than TS will be disregarded and the TS will replace the estimated P_m when calculating ($N_{conc.}$). Generally, P_m is characterized by the number of standard deviations between μ and established MC (z-score). The z-score can be calculated as follows:

$$z = \frac{MC - \mu}{SD}$$

At this stage, all microbial risk management metrics are established to enable a food safety control system for the U.S. whole broiler production system. Two tables were constructed in Sheet1 within the QMRA model where first table demonstrates the MRM metrics and the second demonstrates the suggested sampling plan.

2.2 Risk Management Activities

Risk Management Activities (RMAs) help to identify, select, and implement MRM options and to monitor and review the MRM activities. In this project, RMAs were conducted to design an intervention plan (i.e. identify and select MRM options) that takes into consideration most of the possible Microbial Risk Management options (MRM options) including both food safety interventions and food control interventions. In accordance with Codex recommendations for conducting risk management, the RMAs were conducted in four steps as described in 2.2.1 to 2.2.4.

2.2.1 Identify MRM Options

Salmonella on whole broilers can be mitigated by a variety of interventions (i.e. MRM options) that can be implemented by different participants of the food system such as a regulatory authority, a competent authority, and/or industry sector. In the light of this point, the following MRM options can be derived from the QMRA model:

1) Regulatory authority level MRM options: due to the nature of regulatory authority's (i.e. risk manager) tasks, interventions at this level can be considered as food control interventions. Although interventions implemented in this level will not affect the prevalence and concentration of *Salmonella* on whole broilers, they would improve public health by promoting the application of science- and risk based regulations. However, two food control interventions are identified in this level using the QMRA results as follows:

a) Improving the QMRA model: The identified sensitive data, data gaps, and the reported uncertainty around the QMRA results (mainly AI) are used to identify data required to improve the QMRA results. Identified data can be acquired by directing scientific research, expert elicitation, and/or national microbial baseline data collection programs. Such intervention may be deemed necessary when risk managers are not fully satisfied with QMRA's inputs and/or results uncertainties.
b) Risk communication: The QMRA results are used to identify some important information related to *Salmonella*/whole broilers that needs to be communicated to interested parties. However, POs can be used to identify the need for more communication intended for assisting a food chain organization. For example, an organization with 10% higher POs (i.e. detected by inspection) may be targeted for training. Additionally, the PCs and how to comply with them (i.e. GAP, GMP, GHP, and HACCP) will always be a potential communication topic. For example, during auditing, organizations with less awareness regarding their established PCs (i.e. based on achieved PCs and POs) may also be targeted for training.

2) Competent authority level MRM options: due to the nature of competent authority's tasks, intervention at this level can be considered as food control interventions. In other words, the following intervention would not affect *Salmonella* prevalence or concentration, however, such intervention will improve public health by promoting food safety control. However, two food control interventions are identified in this level using the QMRA results as follows:

a) Auditing and inspection: QMRA results are used to establish an auditing and inspection plan based on the established PCs and POs, respectively. Food organizations should understand, document, and maintain related PCs. And, activities conducted to ensure compliance with PCs should also be verified, documented, and observed by the organizations. Furthermore, an inspection plan can be conducted on each stage with the calculated sampling plan to

observe food stages' compliance with the established POs prevalence and concentration.

b) Emergency preparedness program: Processing POs are used to identify actions such as discontinuing production and organization shutdown, while retail POs are used to identify the need for recall. For example, a 20% increase in processing POs may require an organization to stop a production line to perform corrective action(s), while a 50% increase in processing POs may result in organization shutdown. Moreover, a product lot (i.e. chilled or frozen whole broilers) may be recalled (or rejected at the border) if it exceeds a retail POs by 20%, for example.

3) Industry level MRM options: industry level MRM options or food safety interventions are directly affecting *Salmonella* prevalence and/or concentration. Such interventions are usually new policy, process, and/or procedure. The QMRA model is built to function as a decision-making tool. However, food safety interventions are identified by the model in two scenarios as follows:

a) Non-specific food safety interventions: The QMRA model can identify potential food safety interventions. Sensitive inputs identified by the sensitivity analysis can be considered as potential interventions. However, the QMRA model can be used to identify other food safety interventions. The following section (2.2.2) demonstrates how non-specific food safety interventions can be identified and evaluated for selection.

b) Specific food safety interventions: When a new technology, process, process aid, process modification, or any other suggested improvement emerges, its effect on public health may need to be estimated for regulatory purposes (i.e. to issue a policy alternative). The effect of the suggested improvement on a growth reduction event or cross-contamination should be identified. The new performance (i.e. G/R and cross-contamination after intervention) should then replace the baseline performance within the QMRA model to examine any change in annual illnesses. If the results are satisfactory, the suggested improvement might be implemented as a policy alternative.

2.2.2 Select MRM Options

The above MRM options include food safety interventions and food control interventions. Although food control interventions are known to promote public health, their effect on public health (i.e. on annual salmonellosis) cannot be quantitatively identified. However, these interventions should be an ongoing process regardless of their effect on public health. The QMRA results are used to plan and direct these interventions without estimating their effect on annual salmonellosis. On the other hand, food safety interventions have a direct influence on the prevalence and concentration of *Salmonella* on whole broilers. However, the effect of these interventions on public health can be quantitatively estimated, thus, best option(s) can be selected based on its/their effect on public health.

In this project, food safety interventions are evaluated with different methods, using @RISK functions, to inform the decision-making process as follows:

1) Sensitivity Analysis: Sensitivity analysis when performed within Monte Carlo simulation estimates the sensitivity of @RISK outputs to inputs. It can be used to identify data gaps, so, sensitive inputs with large uncertainty can be identified using a "Change in Output Mean" tornado graph. However, data collection and future research can be directed to reduce such data gaps and to improve QMRA results. Moreover, a "Correlation Coefficient" tornado graph can be used to identify inputs that significantly affect outputs. Inputs with high correlation coefficients indicates statistically significant linear correlation and may be used to identify best step for potential intervention. However, non-linear correlations between RAs inputs and observed output will not be captured by this sensitivity analysis.

Furthermore, the "Advanced Sensitivity Analysis" function runs a series of simulations—each consists of a series of iterations—with different values in the tested input cell(s) (i.e. "changing cell" as named in @RISK). The number of simulations, iterations, and inputs are customized. This can be set up with a maximum of 16 observed inputs, however, @RISK will deal with only one input value at a time (i.e. one change to one input cell for each simulation or trial). This function can be used to estimate the effect of improving a specific step's performance on public health. For example, the optimum improvement in rearing performance can be estimated by testing outputs (e.g. ARE) sensitivity to different PWF values or percentiles (e.g. 10%, 20%, and 30% reduction in PWF). If the 70th percentile (i.e. 30% reduction) was found to achieve a significant improvement in public health, then the PWF at 70th percentile will be considered as a food safety control system goal, if practical. Risk managers can then direct research and expert elicitation toward achieving the 30% reduction in PWF.

2) Goal Seek: this function estimates the required change in a specific input to achieve a determined goal in a specific output. It can be used to identify and quantify interventions based on a pre-determined public health goal. For example, if a public health goal was to reduce salmonellosis by 10% by implementing an intervention in the farm stage to reduce PBF, then in this case, the "Goal Seek" function can be used to estimate the required reduction in PBF to achieve the public health goal. Such a decision can help optimize allocation of food safety resources.

3) Risk Optimizer: The "RISK Optimizer" function combines simulation and optimization to optimize models with uncertainty factors. It is used to optimize an output cell by changing the value of one or more input cell(s). In other words, it estimates the possible values of a monitored cell (i.e. an output) for each combination of values of identified input cell(s). This function, can be used to quantify a combination of interventions to achieve a pre-determined public health goal. The number of trials, iterations, inputs, and value of changes are customized. For example, the change in annual illnesses could be examined by testing a combination of different values of PBF, PWF, and Initial Contamination. Risk optimization can also be used to calibrate the QMRA model by optimizing all sensitive inputs (i.e. performed after sensitivity analysis) to reduce their uncertainty.

2.2.3 Implement MRM Options

After identifying all possible MRM options including food safety and food control interventions, the QMRA model is used to identify the extent of food control interventions and to select optimum food safety intervention(s). At this stage, MRM options are identified and ready to be implemented. The identified MRM options should be implemented in accordance with an established implementation strategy or plan. An implementation plan may include the identified MRM options (from above), rationales, implementation methods, verification plans, time frames, resources available, and any other information that will improve the process of implementing MRM options. However, to promote transparency, a risk manager should communicate the implementation plan with interested parties in a timely manner.

All food system segments (i.e. industry, retail, consumer, competent authority, and regulatory authority) may be involved in an implementation plan. The government should ensure the availability of an appropriate regulatory framework, infrastructure, and monitoring program (including sampling plans) to conduct the implementation plan. The competent authority should ensure the compliance of industry with the plan. The industry should develop, apply, and maintain established control measures to ensure a successful implementation plan. The consumer should follow communicated food safety instructions (Codex, 2007a). In this project, although some valuable information that facilitates the implementation of identified MRM options is provided, no implementation plan will be established due to the scope of the project.

2.2.4 Monitoring and Review of MRM activities

Codex recommends establishing a monitoring plan to ensure the effectiveness of the MRM activities (Codex, 2007a). Monitoring can confirm the ability of a risk analysis to accurately estimate the current practices and to predict the effect of changes in the whole broilers production system on public health. In this project, POs are the bases for calculating sampling plans, directing inspection activities, and monitoring implemented intervention(s). However, it was possible to merge inspection and monitoring into one plan to optimize food safety resources consumption.

3. RESULTS AND DISCUSSION

Two major outcomes were derived from the QMRA model: 1) a food safety control system for the U.S. whole broilers production system and 2) a decision-making tool that can be used to identify food safety decisions that will improve the established food safety control system. The QMRA model identifies the MRM metrics and the sampling plan from the QMRA results. However, to be able to examine the results of MRM tables, a Monte Carlo simulation was performed with 5000 iterations. The results of this simulation will be reported in this section. However, the QMRA model outcomes are as follows:

3.1 Food Safety Control System

Salmonella is not a zero tolerance microbe, however, its presence in whole broilers is acceptable in some level. Additionally, because whole broilers are always cooked, sufficient cooking should eliminate remaining *Salmonella*. However, to the best of the author knowledge, there is no standard (e.g. POs) for *Salmonella* presence in whole broilers at any stage of the food chain was published. Therefore, predicted *Salmonella* load (i.e. prevalence and concentration) at each stage are used to establish microbial standards based on the current practices. Moreover, salmonellosis likelihood and severity are used to establish exposure and public health standards based on the current exposure. The baseline model simulates the current whole broilers production

practices, and, it estimates the current food safety control system. The QMRA model quantitatively estimates the current food safety control system in two steps as follows:

1) Current Performance:

The current performance of the U.S. whole broilers production system: this step predicts the current exposure to *Salmonella* from whole broilers and the resulted risk (i.e. magnitude of salmonellosis resulted from current level of exposure). The current performance of the U.S. whole broilers production system in controlling *Salmonella* was estimated as follows:

a) Farm stage: Farm is the major source of *Salmonella* on whole broilers as *Salmonella* can occur naturally in live broilers either internally or externally. The performance of farm stage (rearing and transporting to plant) in controlling *Salmonella* on whole broilers was estimated (Table 4.1). The overall prevalence of *Salmonella*-contaminated broilers at the end of farm stage was estimated as 24% (12.2 – 35.7% CI), with mean concentration of 4.35 log (3.9 – 5.2 log CI). Additionally, the transport to plant step was predicted to increase the prevalence of contaminated broilers by 31% (2.2 – 91.5% CI) and to increase the concentration of *Salmonella* cells by 5.1% (0 – 26% CI). It was also predicted that 32.6% (1.7 – 97.6% CI) of final dose was originated from farm (Figure 4.1).

b) Processing stage: Processing consists of all activities from stun to packaging (i.e. 6 steps are modeled in the QMRA model). If appropriately conducted,

processing will significantly reduce *Salmonella* prevalence and concentration (Table 4.1). At the end of processing, the overall *Salmonella* prevalence was predicted as 4.17% (1.2 - 9.8% CI), with mean concentration around 0.42 log ($0.12 - 1 \log$ CI) (Table 4.1). Moreover, it was estimated that processing would reduce *Salmonella* prevalence by 82.5% (61.3 - 93.2% CI), while reduce the concentration by 91% (80.4 - 97% CI). Finally, it was predicted that 20% (1 - 60.5% CI) of final dose is originated from processing (Figure 4.2).

c) Retail stage: The final product (i.e. chilled or frozen broilers) is either to delivered to retail (e.g. conventional store) or to food service facility (e.g. restaurant). In both cases, broilers will be distributed and stored for some time. However, temperature abuse may occur resulted in *Salmonella* growth. The retail stage was predicted to increase *Salmonella* prevalence by 12.1% (3.2 - 26.4% CI), while reduce the concentration by 4.8% (-11.9 - 3.2% CI). This change in population is resulted due to cross-contamination. The prevalence of *Salmonella* at the end of retail stage was predicted as 4.6% (1.4 - 10.6% CI), with mean concentration of $0.4 \log (0.11 - 1 \log CI)$. Furthermore, it was predicted that <1% (0 - 1% CI) of final dose is originated from retail stage (Table 4.1; Figure 4.3).

d) Consumer stage: Cooking chicken by consumers is considered a major step in *Salmonella* reduction. The prevalence of contaminated broilers at time of consumption was predicted as 0.62% (0 – 1.9% CI) with mean concentration of $0.09 \log (0.01 - 0.3 \log CI)$. Furthermore, consumer stage was estimated to

reduce the prevalence of *Salmonella* by 92.7% (78.3 – 99.6% CI) and the concentration by 85.5% (56.7 – 99.3% CI). Moreover, it was predicted that consumer stage does not contribute to the final dose (Table 4.1; Figure 4.4).

e) Salmonellosis likelihood: The likelihood of salmonellosis due to the consumption of whole broilers within the U.S. is considered as a major indicator for the overall performance of the U.S. whole broilers production system. It was predicted that the current performance will result in 0.63% (0.1 - 1.9% CI) of contaminated meals containing a whole broiler and any other cross-contaminated food, if applicable. The percent of contaminated serving (part of broilers with other food) was predicted as 0.4% (0.01 - 1.1% CI) with mean *Salmonella* cell of 1 cell (0.3 - 2 cell CI). The probability of salmonellosis resulted from the above exposure was estimated as 0.74% (0.01 - 2.2% CI). Finally, Risk Estimate of salmonellosis from whole broilers was predicted as 5.5E-05 (equal to 5.5 case/100,000 capita) (Table 4.1; Figure 4.5).

f) Salmonellosis severity: The severity of salmonellosis attributed to whole broilers demonstrates the public health and socio-economic burden resulting from exposure to Salmonella due to whole broilers consumption within the United States. The QMRA model estimated the annual salmonellosis from whole broilers as 220,257 case of salmonellosis annually (11,000 – 660,000 case CI) (Table 4.1). The number of hospitalizations was predicted as 428 cases annually (22 –

1,280 case CI), while death was estimated as 13 per year (1 – 38 CI) (Table 4.1; Figure 4.6).

The social burden (i.e. DALY) of salmonellosis from whole broilers was estimated by the QMRA model; it was predicted that the U.S. population lose 953 years (49 - 2,853 years CI) of healthy life annually due to salmonellosis from whole broiler. Furthermore, the economic burden of salmonellosis was predicted as 72.6\$ million (4 - 218\$ million CI) annually (Table 4.1; Figure 4.6).

The above information demonstrates the current performance of the U.S. whole broilers production system in controlling *Salmonella*. The performance of the four stages demonstrate the exposure of broilers to *Salmonella* and the resultant consumer exposure (i.e. prevalence and concentration of *Salmonella* at time of consumption). Furthermore, salmonellosis magnitude (i.e. likelihood and severity) resulting from consumer exposure to *Salmonella* demonstrates the public health and socio-economic burden from such exposure. The current performance can be utilized to achieve the following:

 Conduct a monitoring plan to ensure the accuracy of QMRA model results. Monitoring results should be compared with predicted results to review and calibrate the QMRA model. Calibrating the QMRA model using a monitoring plan is more accurate than calibration using "Risk Optimizer" function of @RISK. In the U.S., monitoring may performed by the USDA and results should be reported to risk managers.

- The predicted prevalence and concentration at each stage can be considered as POs.
- 3. The effect of each stage on *Salmonella* prevalence and concentration can be used as PCs.
- 4. Salmonellosis likelihood and severity can be used as a basis for decisionmaking. The effect of potential intervention should be based on changes to these numbers. Additionally, these numbers can be used for risk ranking, so other hazard/commodity combinations can be compared with the *Salmonella*/whole broiler combination for food safety risks.

2) Current food control system:

This step predicts the MRM metrics required to maintain the current performance. The MRM metrics is the required tool to establish and maintain food safety control system to control the risk of salmonellosis from whole broilers. They aim to generate science- and risk-based food control interventions (section 3.2) and to provide the required control to ensure achieving the established ALOPs. A complete set of MRM metrics is derived from the QMRA results (section 2.1). Although the established MRM metrics are reported as distributions (i.e. reported as @RISK outputs), only the means are reported (Table 4.2). These metrics are considered as the required standards that need to be accomplished to achieve the required public health goals. However, the food safety control system (i.e. MRM metrics) estimated by the QMRA model to maintain the current public health status is as follows: a) Appropriate Level of Protection (ALOPs): These metrics are used by the regulatory authority to set up the acceptable baseline risk that should not be exceeded. From the QMRA results, seven ALOPs were established. These ALOPs demonstrate the maximum risk accepted (i.e. baseline risk) from the *Salmonella*/whole broiler combination. The ALOPs estimated by the QMRA model were as follows (Table 4.2; Figure 4.7):

- 1. ALOP overall risk = 5.5E-05 (or 5.5 case / 100,000 capita / year)
- 2. ALOP mortality = 13 death case / year
- 3. ALOP morbidity = 220,257 salmonellosis case / year
- 4. ALOP DALY = 953 years lost / year
- 5. ALOP cost of DALY = 114,669 / DALY (year)
- ALOP COI = ~72.6 million US dollar / year
- 7. ALOP cost of salmonellosis case = 730 US dollar / salmonellosis case

These ALOPs can be used for risk ranking, however, regulatory authority may compare other hazard/commodity ALOPs with *Salmonella*/whole broilers ALOPs. Additionally, ALOPs should be used as the bases for food safety decision-making in the regulatory level. However, intervention with estimated satisfactory effect on public health and socio-economic burden may be considered for final revision by the regulatory authority. Final revision at the regulatory level would include establishing implementation plan—including policies—and feasibility study. Moreover, these ALOPs should always be monitored by the regulatory authority. For example, in the U.S., the CDC could perform the monitoring plan and report the actual numbers based on its epidemiological studies. Monitoring results should be reported to risk managers and compared with predicted results.

b) Food Safety Objectives (FSOs): These metrics demonstrate the maximum *Salmonella* prevalence and concentration at time of consumption that are required to be maintain to achieve the established ALOPs. Regulatory authority should report the established FSOs to the competent authority to take the required actions to achieve and maintain them.

The QMRA model estimated that the maximum percent accepted of *Salmonella*-contaminated serving (FSO freq.) is 0.38%, with maximum concentration (FSO conc.) of 0.35 log (Table 4.2; Figure 4.8). In the U.S., the USDA may conduct a monitoring plan to verify and validate the established FSOs. When validated, the USDA may deliver the FSOs to interested parties along with the standards (i.e. POs and PCs) that need to be implemented to ensure the compliance with the established FSOs. The established FSOs should be the bases for food safety decision-making in the competent authority level. For instance, risk factors—related to *Salmonella*/whole broilers that are reported in literature—should be identified and their effect on FSOs should be quantified. Risk factors with significant effect on FSOs should be regulated and monitored by food safety control measures (e.g. HACCP plan).

c) Performance Objectives (POs): These metrics demonstrate the required microbial load (i.e. prevalence and concentration) at each stage to achieve the established FSOs. It serves as the bases to conduct microbial testing to ensure compliance with POs, then FSOs. These metrics should be communicated (by competent authority) with interested parties (industry stages) to highlight their roles in achieving the desired public health goals.

The QMRA results are used to estimate the POs for each stages (Table 4.2). The maximum percent of contaminated broilers at the end of farm stage (PO prev.) was estimated as 62.5%, with maximum concentration (PO conc.) of 5.5 log (Figure 4.9). Moreover, the maximum percent of contaminated broilers at the end of processing stage was estimated as 10.9%, with maximum concentration of 0.86 log (Figure 4.10). Additionally, the maximum percent of contaminated broilers at the end of retail stage was estimated as 12%, with maximum concentration of 0.86 log (Figure 4.11). Finally, at consumer kitchen stage, the maximum prevalence was estimated as 1.63%, with maximum concentration of 0.47 log (Figure 4.12).

d) Performance Criteria (PCs): These metrics demonstrate the required performance of each stage in controlling *Salmonella* contamination. PCs are reported as the mean percent of reduction (or growth) in *Salmonella* load (i.e. prevalence and concentration) that need to be accomplished to achieve the established POs. It was estimated that during transport to plant (which represent farm stage as there is no PCs were estimated for rearing), *Salmonella*

prevalence should not increase more than 31% (PC prev.) while the concentration should not increase more than 5.1% (PC conc.) to ensure achieving farm POs. However, processing stage should achieve 82.5% reduction in *Salmonella* prevalence and 91% reduction in concentration to ensure achieving processing POs. Moreover, the prevalence of contaminated broilers should not increase more than 12.1% and the concentration should not increase more than 3.2% during retail stage to achieve retail POs. Finally, consumer kitchen stage should achieve 92.7% reduction in prevalence and 85.5% reduction in concentration of *Salmonella* to achieve consumer kitchen stage POs (Table 4.2). It is important to note that, all the above POs should be achieved to establish the FSOs.

Each stage is responsible for achieving its established PCs by implementing the required food safety measures. Therefore, as the POs should be inspected, the PCs should be audited. Food organization efforts in understanding, documenting, controlling, and maintaining PCs should audited by the competent authority. However, PCs can be achieved by:

- Reducing cross-contamination events- which can be done by implementing recommend code of practices such as GAP, GMP, and GHP. However, some PcC may reduce cross-contamination (e.g. packaging).
- Controlling Salmonella growth and/or reduction events- which can be done through achieving the required PcC and PdC.

NOTE: A HACCP plan requires the implementation of a prerequisite program (i.e. GAP, GMP, and/or GHP) and the identification of the critical control points

(CCPs) (i.e. PcC and PdC). The QMRA results may be used to establish a HACCP plan—with a list of CCPs and CLs—for each food chain stage.

NOTE: The QMRA model also estimates POs and PCs for each steps. These metrics should be used by the relevant stage to inspect and audit their processes performance. They might be used for investigation, process evaluation, and/or problem identification and solving.

3.2 Food Safety Decision-making Tool

In this project, the QMRA results are used to identify and quantify suggested MRM options (i.e. to establish intervention plan) that would improve public health by reducing the risk of salmonellosis from whole broilers consumption within the United States population. At this step, the current performance are used to generate food safety intervention (i.e. industry level intervention), while the current food safety control system are used to generate food control interventions (i.e. regulatory and competent authorities levels interventions). However, the QMRA results are used for decisionmaking as follows:

1) Identify and select MRM options (RMAs 1 and 2)

a) Food control interventions: These interventions are based on MRM metrics, and aimed to be implemented in the regulatory and competent authority levels.

Although such interventions do not directly affect *Salmonella* prevalence and/or concentration, they are known to improve public health by promoting scienceand risk-based regulation and by improving food safety control. From the established food control system (section 3.1), four food control interventions were planned as follows:

1. <u>Improving the QMRA model</u>: The regulatory authority (i.e. risk manager) is the owner of the QMRA model. The QMRA is an important tool for risk manager as it promotes generating science- and risk-based interventions. However, risk manager should ensure that the QMRA model is up-to-date, while working to reduce uncertainty. To perform such task, sensitivity analysis results are used to identify possible interventions to improve the QMRA model.

The sensitivity analysis performed (Chapter III, section 3.2) demonstrated that there are 10 RAs inputs where their uncertainties significantly affect the overall uncertainty. However, to improve the QMRA results the overall uncertainty should kept to the minimum. Therefore, the reported data gaps should be minimized either by collecting more data or by directing research to those topics. The following data gaps were identified:

- Cross-contamination during grading and packaging,
- Cross-contamination during preparation (cooking),
- Maximum transfer rate during storage at home and grading and packaging,

- Minimum transfer rate during preparation (cooking), distribution, and grading and packaging,
- Temperature abuse during storage at retail and transport to home, and
- Prevalence between flocks (PBF).

A sensitivity analysis should be performed each time a change has been incorporated to the QMRA model. Also, a complete sensitivity analysis should be performed rather than rely on the sensitivity analysis performed within Monte Carlo simulation. The complete sensitivity analysis (can also be called uncertainty analysis) is a lengthy process where a simulation should be done to test the effect of each input uncertainty, which means 100+ simulations will be performed, on the overall uncertainty.

Here, the overall uncertainty was measured around the estimated annual illnesses (AI) as it is considered the major output of the model. Annual salmonellosis was predicted between 11,000 – 660,000 cases (mean = 220,257 case). However, CDC salmonellosis attributed to whole broilers was estimated between 60,358 – 693,333 cases (mean = 222,537 case). Thus, it can be noticed that the QMRA uncertainty around AI corresponds to the uncertainty around CDC number. However, it was assumed that the overall uncertainty of the QMRA model is satisfactory. It is also recommended to examine the overall uncertainty each time a change has been incorporated the QMRA model. Additionally, a minoring plan that aim to verify and validate the QMRA model may be conducted. The monitoring plan may target stages POs and some steps POs. monitoring results should be compared with QMRA results review and evaluate the QMRA model accuracy, and to calibrate it when necessary. It is important to note that, calibrating the QMRA model based on monitoring is more accurate than calibrating the model using "Risk Optimizer" function of @RISK. More details about planning and scoping the monitoring plan is given in the next section.

Moreover, the QMRA model should regularly reviewed. Risk managers may seek public comment and/or expert elicitation to improve the QMRA model. Because of the complexity of the QMRA model, experts from different disciplines may review the QMRA model.

2. <u>Risk communication</u>: This risk communication (i.e. communicating QMRA results) is different from risk communication between risk managers, risk assessors, stakeholders, and the public during PRMAs. Risk communication is a food control intervention which would improve public health if the right information was delivered in suitable format to the relevant party in a timely manner. It is an ongoing task for regulatory authority which can be improved and planned by risk analysis. However, most of risk communication activities are conducted through the competent authority. Risk communication aims to deliver professional assistance to all relevant parties to facilitate understanding the established food control system to promote

compliance with the food control system requirements. Generally, ALOPs, FSOs, POs, PCs, and risk profile are communicated to relevant parties. It is important to note that, different food chain stage would require a different communication channel such as publishing guidelines, training, and outreach program. However, the QMRA results are used to plan risk communication as follows:

- Communication with competent authority: the current performance of the U.S. whole broilers production system along with the established food control system should be communicated to competent authority. These information will help the competent authority to plan and scope monitoring, auditing (based on PCs), and inspection (based on POs) plans.
 Additionally, risk profile should also be communicated with the competent authority to ensure that it is accurate and up-to-date. Regulatory authority should also communicate the established ALOPs and FSOs to ensure that the competent authority is aware about public health goals and acceptable baseline risk. Finally, because of the high expert level expected in the competent authority level, communication with competent authority may be done by granting it access to the QMRA model.
- Communication with industry: this communication may be conducted by the competent authority. Usually, PCs and POs are communicated to relevant stage. These information may be used by food organizations to conduct internal audit and inspection plan. It also help food organizations

to identify control measures (e.g. CCPs) required to achieve PCs and then POs. However, communicating PCs and POs to industry may involve publishing standards, code of practices, training, and/or outreach program. This is due to the science and experience required to understand and implement PCs. Additionally, information related to previous stage may also be communicated. For instance, processing facilities may be informed about the current performance of farm stage to help processing facilities expecting the amount of *Salmonella* contamination coming from farm. These information may help processing facilities to set up a rejection standards (or corrective and preventive actions plan) for *Salmonella*positive flocks.

- Communication with consumer: although consumer stage PCs and POs should be communicated to consumer, communicated information should be simple to facilitate understanding. Generally, consumer are communicated through product labelling or by advising signs. However, food service facilities may additionally be communicated by training (e.g. ServSafe[®] training program). For instance, the QMRA model estimated the PCs for consumer stage as 80% reduction in *Salmonella* prevalence and concentration. These PCs may be communicated to consumers as instructions in:
 - Best practices when shopping for whole broilers,

- Best practices to store whole broilers (consumer and food service facilities),
- Best practices to prepare and cook whole broilers (consumer and food service facilities).

3. <u>Auditing and inspection</u>: An audit is a systematic examination performed to determine the compliance of organization activities with a planned arrangement; and whether these arrangements are effectively implemented to achieve objectives. Thus, auditing is targeting the implementation of PCs. Food organizations should understand, document, and maintain their relevant PCs. However, achieving and maintaining PCs requires a strategy that should be based on science and experience. Therefore, a competent authority should conduct auditing to ensure that such strategy is in-place and implemented, documented, verified, and maintained. Moreover, as mentioned above, PCs can be achieved through the implementation of food safety practice such as GAP, GMP, GHP, and HACCP. However, the competent authority may audit the implementation of those food safety practices and their adequacy to achieve the established PCs.

Moreover, inspection includes testing any aspect of food and/or environment to verify compliance with applicable requirements. However, inspections target the achievement of POs. Generally, inspection is performed by taking representative samples (i.e. product or environment) to verify environmental compliance (i.e. sanitation) and product safety and quality through lab analysis. In the U.S., the USDA (i.e. competent authority) may establish an inspection plan by performing microbial testing to inspect the compliance of food chain stages with the established POs. However, a sampling plan that ensures detection of nonconformity was established for this research. The MCs were derived from the first simulation (90 percentile of estimated MCs), then a second simulation (2000 iterations) was performed with the established MCs to calculate the number of samples (N) required to detect non-compliant lots. The mean number of samples (N) required to detect a Salmonella-positive flock at farm stage is 5 (mode = 3), while 53 samples (mode = 59) are required to detect a non-compliant flock with the established PO concentration. Moreover, it was estimated that 41 samples (mode = 36) are required to detect a contaminated lot at processing stage, while 59 samples (mode = 59) are required to detect a non-compliant lot with the established PO concentration. Finally, 36 samples (mode = 36) are required to be collected to detect a contaminated lot at retail stage, while 59 samples (mode = 59) are required to detect a non-compliant lot with the established PO concentration. It is important to note that the number of samples required are characterized by POs tested and confidence required.

The percent of contaminated samples estimates the percent of *Salmonella*-contaminated broilers within the tested flock or lot. However, the mean number of cells in contaminated samples estimates the mean number of *Salmonella* cells within the tested flock or lot. Consequently, it may be

appropriate to perform the suggested sampling plan to ensure the compliance of food chain stages with the established POs. However, a plan to deal with nonconformity (i.e. when observed microbial load is higher than the established POs) should be in-place.

NOTE: Both auditing and inspection should always be conducted on all food chain stages to detect noncompliance with applicable requirements (i.e. PCs) and standards (i.e. POs). However, the stringency of the audit and inspection (i.e. sample size) may vary due to the magnitude of risk posed by the stage being audited and/or inspected.

NOTE: Auditing and inspection may result in capturing a food safety issue that needs more investigation to be resolved. Investigations may include conducting further inspections, auditing, and/or other activities on one or more food organization(s) to discover, observe, and/or solve a food safety issue.

4. Emergency preparedness program: In some cases, industry may lose control of a process causing an increased or new food safety risk or even an illness outbreak. In such urgent cases, an adequate intervention should be implemented to minimize or eliminate the risk. This intervention includes actions such as discontinuing production, product recall, and/or organization shutdown. It is important to note that the Food Safety Modernization Act enacted in 2011 empowers the competent authority to initiate recall, while

requiring decisions—including initiating recall—to be science- and risk based. However, the estimated POs are used to set up criteria for urgent situations that may significantly affect the established FSOs.

NOTE: The effect of deviation in POs on FSOs (based on each stage PCs) can be estimated. However, the correlation between POs and PCs for each stage needs to be identified to allow such evaluation. This will enable quantifying the unsatisfactory change in FSOs based on POs deviation. Such information is valuable and can be used to identify actions based on inspection results and to identify emergency preparedness actions (i.e. rejecting criteria, discontinuing production, organization shutdown, and recall). For example, it may be predicted that a 20% increase (from established PO) in prevalence at processing stage will increase FSOs by 10%. However, risk managers may relate inspection and emergency actions to the magnitude of change on FSOs.

b) Food safety interventions: Food safety interventions can affect the prevalence and/or concentration of *Salmonella* on whole broilers. Such interventions are directly related to public health by their ability to reduce exposure of consumers to *Salmonella* from whole broilers and thereby reduce annual salmonellosis illnesses. In some cases, risk managers may deem the current ALOPs are satisfactory and fulfilling a determined goal, thus, the resulting intervention may be "Do Nothing" which means no intervention is needed. In most cases, risk managers seek continual improvement of public health, thus,

new control measures are deemed necessary. Risk managers may undertake such decisions by comparing *Salmonella*/whole broilers ALOPs with other hazard/commodity ALOPs.

Specific food safety interventions such as emerging technology, processes, process aids, process modifications, procedures, or any other suggested improvements may be quantitatively evaluated by the QMRA model. For example, the performance of air chilling in broiler processing (i.e. log reduction and cross-contamination percent) in controlling *Salmonella* may replace the performance of water chilling in the QMRA model. The model should then be re-simulated and the effect on public health can be estimated. If the results are satisfactory, then risk managers may require industry to conduct air chilling as a policy alternative to water chilling, if feasible.

Non-specific food safety interventions may be identified and evaluated for selection in different ways using the QMRA model (section 2.2.2). In this case, potential interventions are reported as PCs which are then translated to PdC and PcC. PCs for each step are represented by G/R (log) and cross-contamination (%) events. However, predictive models can be used to identify required PcC and PdC that achieve the required PCs (using goal seek function within predictive model), if applicable. Furthermore, risk managers may direct research, expert elicitation, professional recommendation, and/or inspection results to figure out how to achieve new PCs.

Example 1: sensitivity analysis shows that the cross-contamination percent during grading and packaging has a statistically significant correlation with AI. However, risk managers may direct research to find the best way to decrease cross-contamination during grading and packaging. The effect of reduction on AI can be quantified by performing Monte Carlo simulation.

Example 2: in this example a public health goal is established as 20% reduction in annual salmonellosis (i.e. target annual salmonellosis = 180,000 \pm 5%). An intervention was sought to reduce cross-contamination during chilling. Goal Seek function was used to identify the required reduction in cross-contamination during chilling to achieve the sought goal. The cross-contamination predictive model used to predict cross-contamination in the chilling tank estimated the cross-contamination percent as 3.4 - 14.8 % (mean 8.7%) (Figure 4.13). However, the Goal Seek function estimated that reducing cross-contamination in the chilling tank to 6.9% would reduce annual salmonellosis to 176,784 cases/year (Figure 4.13), thus, this reduction would achieve the sought goal. This result should then be communicated to academia and experts (e.g. relevant scientific association) to figure out how to reduce cross-contamination in chilling tank to a maximum 6.9%.

Example 3: "Risk Optimizer" function can be used to evaluate a group of interventions or one intervention with multiple inputs (e.g. G/R event has 3 inputs minimum, mode, and maximum). Risk optimizer was used to examine the required intervention during the rearing step to achieve a 25% reduction in annual salmonellosis (165,000 case). Initial contamination, PWF, and PBF were

tested to evaluate required interventions to achieve a desired public health goal. Optimization results show different possibilities to achieve this goal (Figure 4.14). The most practical combination of interventions may be identified, implemented, and used to direct research and expert elicitation. However, annual salmonellosis can be reduced to 172,410 cases by implementing the following combination of interventions:

- 1) Maximum initial contamination: 4.9 log no intervention required,
- 2) PBF: reduce the mean PBF from 38.6% (original) to 34.2% (intervention),
- 3) PWF: reduce the mean PWF from 57.3% (original) to 33.8% (intervention).

2) Monitor and review MRM activities (RMAs 4)

Monitoring is conducting a planned sequence of observations or measurements to obtain information about compliance with applicable requirements. This includes ongoing gathering, analyzing, and interpretation of data related to MRM activities (Codex, 2007a). Monitoring is used to evaluate, verify, and validate in-place control measures and/or newly implemented MRM options.

Monitoring MRM activities (i.e. current practices) should be regularly conducted to ensure the appropriateness and effectiveness of the current practices in achieving the desired public health goals. It aim to update the QMRA model and to improve its results by verifying the QMRA inputs and modeling approach; and validating the QMRA results (by comparing with monitoring results). Moreover, a monitoring plan may be implemented to verify and validate that newly implemented MRM options are effective in

achieving established public health goals. The plan can also test the accuracy of the QMRA model in estimating the effect of interventions in public health.

Reviewing MRM activities can be done by comparing monitoring results (or any other information collected during monitoring that is relevant to risk analysis) with QMRA results. Additionally, the MRM activities (including the QMRA model) can be reviewed by scientific assessment, expert elicitation, and/or public comment (Codex, 2007a). However, based on the review, any aspect of MRM activities may be subject to amendment.

The MRM metrics can be the bases for planning a monitoring program. In this project, POs are the bases for calculating sampling plans, directing inspection activities, and monitoring implemented intervention(s). However, it is possible to merge inspection and monitoring into one plan to optimize food safety resource consumption. The following monitoring plan is suggested:

a) As suggested above, the established inspection plan covers 3 stages (i.e. farm, processing, and retail). Inspections may test of (PO prev.) and (PO conc.) of each food production system stage. Inspecting a food organization would result in an action, however, all routine inspections results should be collected, maintained, and assembled. However, if inspection was conducted as suggested and all results were saved, then, overall inspection results (e.g. results of an inspection program that last for a year) can be considered as a part of monitoring plan. In this case, overall inspection results can be considered as a monitoring plan for *Salmonella* prevalence and concentration

on whole broilers. Inspection results may be used to verify and validate the established POs.

- b) An auditing plan that ensures the compliance of a food organization based on their established PCs can also be part of monitoring plan. Similar to inspection, the overall results of auditing program may report important information regarding established PCs. Audit findings may be used to verify and validate the established PCs. Furthermore, if planned from the beginning, auditing programs may identify the required control measures including PcC and PdC to achieve the established PCs.
- c) The first and last stages (i.e. farm and consumer kitchen) may have other points to be monitored. For instance, initial contamination, prevalence between flocks, and prevalence within flock may be monitored at farm stage to verify and/or update the QMRA inputs. Additionally, monitoring *Salmonella* prevalence and concentration at consumer stage may also conducted to verify and/or update the QMRA model's inputs related to this stage. Finally, risk manager can add any point for monitoring plan (i.e. monitor any step in the food chain) and use the estimated POs (i.e. POs estimated by the model for that specific step) as a bases for monitoring.
- d) The established ALOPs may also be monitored to confirm that public health goals are accomplished. The public health authority may need to conduct this part of monitoring. The results of this monitoring may be used to validate established ALOPs; and to re-calibrate the QMRA model. Additionally,

monitoring results may also be used to verify socio-economic inputs and to validate estimated DALYs and COI.

e) When there is/are any intervention(s) implemented, the step(s) where the intervention(s) is/are implemented should be added to the monitoring plan to evaluate the appropriateness and effectiveness of the implemented intervention(s). This monitoring will estimate the new POs (i.e. after the implementation of intervention(s)), however, monitoring results will be used to validate the estimated POs (i.e. the QMRA estimation of the new POs after intervention(s) implementation).

4. RECOMMENDATIONS

- 1- The major limitation that always related to risk analysis is the quality of data and the resulted uncertainty. Risk analysis is a multi-disciplinary process, however, in this project the benefit of a multi-disciplinary risk assessment team was not granted. Therefore, this resulted in some limitations as follows:
 - a) Although the author practiced most care to identify and collect data that is recent and represent the U.S. production system, a more comprehensive data collection program will improve the quality of the QMRA results.
 - b) Data optimization was simple, however, a more sophisticated tool such as meta-analysis may be used to better optimize data for RAs use.
 - c) Although a farm to fork continuum was considered, only three variability
 (i.e. season, broiler storage, and destination) were considered due to the scope of project.
 - d) In order to avoid un-true growth, 4 temperature abuse scenarios (during distribution, storage at retail, transport to home, and storage at home) was assumed. To the best of author knowledge, those numbers were not reported in literature.
- 2- Conducting a complete risk analysis that include risk ranking, epidemiological data, risk assessment, and MRM metrics will facilitate food safety problem understanding and will results in informative model. Performing risk assessment phase only will not involve PRMAs and RMAs. However, PRMAs greatly improve performing risk assessment, while RMAs greatly utilize the

constructed QMRA model. Therefore, it is recommended to conduct risk analysis rather than only performing risk assessment.

- 3- Conduct risk analysis based on performance criteria as each step from farm to fork has its effect on a food safety hazard that can be measured. Doing so, will enable exposure assessment model to predict PCs for each stage as percent of reduction in both prevalence and concentration. At each step, cross-contamination percent and growth/reduction event (which achieved by implementing PcC and PdC) represent each step performance. Furthermore, modeling a food lot (e.g. a broiler flock) within exposure assessment rather than a single item will improve simulating PCs and risk exposure result. Performance criteria should be considered as a basis for exposure assessment; and to improve simulation of PCs by modeling a food lot rather than a single item.
- 4- Cross-contamination is an important part of food processing which significantly affects contamination prevalence. It is important to include crosscontamination in any risk assessment to fully address performance. However, at the time of preparing this project, the author believes that crosscontamination is not adequately explained in literature. That led to construction of a predictive model to estimate cross-contamination percent based on level of contamination and number of physical contacts. Additionally, there was inadequate information to quantify transfer rate which

characterized any cross-contamination event. Additional research is needed to better understand and quantify cross-contamination.

- 5- Microbial predictive models (PM) will facilitate risk analysis as they inform the exposure assessment model. Although there is a good amount of research considering predictive microbiology, their implementation within risk assessment was rarely discussed. However, to facilitate using a predictive model to inform exposure assessment, it should be built in iterative approach to account for attendant uncertainty. It is recommended to improve PMs range, accuracy, and implementation to better inform exposure assessment to improve risk analysis results.
- 6- The QMRA model should be valid for use, as long as it is up-to-date, as an important tool to control the risk of salmonellosis from whole broiler consumption. Regulatory and competent authorities are always required to implement science- and risk-based interventions. However, using the QMRA model to identify and plan MRM options may enhance the compliance with the FSM Act which requires the competent authority to undertake science- and risk-based actions. Therefore, the QMRA model should continually improve as follows:
 - a) Conduct monitoring to verify QMRA inputs and to validate QMRA outputs.
 - b) Exposure assessment can be modeled in different ways depending on risk assessors understanding of the food chain continuum and the available data and information. However, it is recommended to maintain ongoing
improvement to exposure assessment (EA) as new data and/or information is available.

- c) Conduct RAs data collection program to ensure that QMRA inputs are always updated; and to reduce uncertainty.
- d) Conduct sensitivity analysis each time an aspect of the QMRA model is changed (i.e. new input, change in modeling approach ... etc.). Sensitivity analysis can identify sensitive inputs and data gaps.
- e) Review of the QMRA model by scientists, experts, and public comment.
- 7- Many possible interventions can be identified by using the QMRA model as a decision-making tool. Every RAs input can be targeted to examine the effect of its change on public health. However, the QMRA model can also be used to evaluate the following:
 - a) Annual Illnesses (AI) can be used to evaluate aspects related to whole broiler production. For instance, the effect of increasing whole broilers production by 10% on the number of annual salmonellosis can be estimated. Other production aspects such as proportion of whole broilers and/or frozen/chilled broilers can also be evaluated.
 - b) Annual Risk Estimate (ARE) can be used to evaluate risk of salmonellosis for specific population. In this case, all affected population inputs (6 inputs) within the QMRA model should be customized to the tested population. This can be done as follows:
 - 1. Identify targeted population and quantify.

- 2. Quantify the susceptible population within the targeted population.
- Quantify the proportion of the targeted population that consumes whole broilers, and quantify their consumption pattern (annual serving consumption).
- Replace the above information in the QMRA model under "Affected Population + Consumption Pattern" in the risk characterization table in Sheet1.
- Identify the (β) for targeted population to modify the dose-response model for the targeted population. Replace the (β) in the QMRA model under "Dose-response Model" in the risk characterization table in Sheet1.
- If targeted population has different hospitalization and death rate, these inputs should be updated within the QMRA model.
- 7. Annual hospitalizations, deaths, DALY, and COI are calculated based on AI. However, they should be calculated based on ARE to estimate the effect. This can be done by replacing AI with ARE within those outputs equations. It is important to note that, in this case, only hazard and risk characterization outputs, ALOPs, and FSOs can be reported. All other results will not be representative.
- c) The QMRA model can be used to assess the risk of any other microbial hazard (e.g. *Campylobacter*) on whole broilers. However, in this case, all inputs should be replaced with values that relate to the hazard of concern.

Only "Production Characteristic" and "Affected Population" inputs will not need to be changed.

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6. FIGURES AND TABLES

Table 4.1: The current performance of the U.S. whole broiler production system asestimated by the QMRA model.

	Salm	onella	Salmonella	Effect on	Effe	ct on	Contribution
Stage	pro	ev.	conc.	prev.	CO	nc.	in Dose
	mean	• (CI) *	mean (CI)	mean (CI)	mear	n (CI)	mean (CI)
Farm	23.9	97%	4.35 log	+ 31%	+ 5.	13%	32.6%
1 ann	(12.2 –	35.7%)	(3.9 – 5.2 log)	(2.2 – 91.5%)	(-5.4 –	26.1%)	(1.7 – 97.6%)
Processing	4.2	2%	0.42 log	- 93%	- 82	.5%	20.2%
Trocessing	(1.2 –	9.8%)	(0.12 – 1 log)	(76 – 99.5%)	(80.4 -	- 97%)	(1 – 60.5%)
Rotail	4.6	5%	0.4 log	+ 12.4%	- 4.	8%	<1%
Netan	(1.4 –	10.6%)	(0.12 – 1 log)	(3.2 – 26.4%)	(-11.3 -	- 3.2%)	(0 – <1%)
Consumer	0.6	5%	0.09 log	- 92.7%	- 85.5%		0
Consumer	(0 – 2	1.9%)	(0.01 – 0.3 log)	(78.4 – 99.6%)	(56.7 – 99.3%)		Ŭ
Salmonellosis Likelihood			Salmonellosis Severity				
	mear	n (CI)		mean (CI)			
% of cont mea	I		0.63%	Annual salmonellosis		220,257 cases	
		(0).1 – 1.9%)			(11,000 – 660,000)	
% of cont servi	ina		0.4%	Annual hospitalization		428 cases	
	ing	(0.0	002 – 1.14%)		(2 – 1,280)
Mean dose (cell)		1 cell		Annual death		13 case	
		(0	.3 – 2 cell)			(1 – 39)	
Probability of Illness		0.74%		DALYs (annually)		ç	953 years
	neee	(0.0	0004 – 2.2%)			(4	9 – 2,853)
Risk Estimate			5 5E-05	Cost of Illness ((\$)	\$7	2.6 million
INION LOUITIOLE			0.02 00			(\$4 – 218 million)	

* 90% Confidence Interval

Table 4.2: The food safety control system (MRM metrics) as estimated by the QMRA model.

Regulatory Level (ALOPs + FSO)						
Overall Risk	5.5E-05	DALYs	953	\$ / Case	730	
Mortality	13	\$ / DALY	114,688	FSO freq.	0.38%	
Morbidity	220,257	COI (\$)	72.64 m	FSO conc.	0.35 log	

Competent Authority Level (PO)						
	Prev. (%)	Conc. (log)		Prev. (%)	Conc. (log)	
Farm	62.5	5.48	Retail	12	0.9	
Processing	10.9	0.9	Consumer	1.63	0.47	

Sampling Sizes for Testing POs Mean # samples per flock or lot (mode #)						
Farm		Proce	Processing		tail	
PO prev.	PO conc.	PO prev.	PO conc.	PO prev.	PO conc.	
5 (3)	53 (59)	41 (36)	59 (59)	36 (36)	59 (59)	

Industry Level (PC) *						
	Prev. (%)	Conc. (%)		Prev. (%)	Conc. (%)	
Farm	+ 31	+ 5.1	Retail	+ 12.14	- 4.8	
Processing	- 82.5	- 91	Consumer	- 92.7	- 85.5	

* Derived from the effect of each stage on *Salmonella* prevalence and concentration



Figure 4.1: Farm stage performance as estimated by the QMRA model.







Figure 4.2: Processing stage performance as estimated by the QMRA model.







Figure 4.3: Retail stage performance as estimated by the QMRA model.















Figure 4.5: The likelihood of salmonellosis from whole broilers within the U.S.







Figure 4.6: The severity of salmonellosis from whole broilers within the U.S.





Figure 4.7: The seven ALOPs estimated by the QMRA model as a part of the established food control system.





















Figure 4.11: Retail stage POs.







Figure 4.12: Consumer kitchen stage POs.







Upper graph shows the predicted cross-contamination percent in chilling tank.

Lower box show Goal Seek result (cell \$E\$14 is cross-contamination % at chilling tank).

Figure 4.14: Risk Optimizer example.

\$		RISKO	RISKOptimizer- Model 🛛 🗕 🗖 💌				
Optimization Goal		Target Value		•	165000		
<u>C</u> ell		=S40					
<u>S</u> tatistic		Mean			-		
Adj <u>u</u> stable Cell Ra	nges						
Minimum		Range		Maximum	Values	<u>A</u> dd	
- Recipe						(Delete)	
3	<=	=G5	<=	5 🎽	Step(0.5) 🔻	L	
0.25	<=	=F6	<=	0.35	Any 🔻		
0.3	<=	=F7	<=	0.5	Any 🔻		
						Group	
Co <u>n</u> straints							
Description		Form	nula		Туре	A <u>d</u> d	
						<u>E</u> dit	
						Delete	
0					ОК	Cancel	

Trial	Flansed Time	Iterations	Result	Adjustable Cells		
mar	Elapsea fille	iterations	Result	G5	F6	F7
1	0:03:39	1000	N/A	4.9	0.3860	0.5730
2	0:06:21	1000	133,256	4	0.3000	0.4000
3	0:09:13	1000	98,643	3	0.2500	0.3000
4	0:12:27	1000	199,088	5	0.3500	0.5000
5	0:15:37	1000	148,491	5	0.2569	0.4944
6	0:18:38	1000	139,348	5	0.2500	0.4916
7	0:21:39	1000	131,262	3	0.3326	0.3099
8	0:24:36	1000	132,841	5	0.2713	0.3083
9	0:27:35	1000	172,410	5	0.3419	0.3383
10	0:30:39	1000	177,658	5	0.3500	0.3533

Upper box shows the establishment of Risk Optimized model. Lower table shows optimization results (G5: maximum initial contamination; F6: mean PBF; and F7: mean PWF).

PPENDICES

APPENDIX A: QMRA: MODELS AND INPUTS LISTS

Table A.1: Models List

	Model	Source	References
1	Transmission model	L	(FAO/WHO, 2009a)
2	Cross-contamination model	Α	Adopted from: (FAO/WHO, 2009a); (Bucher et al., 2012)
3	Transportation contamination	L	(Bucher et al., 2012)
4	Growth model	L	(Polese et al., 2011); (Carrasco et al., 2012a); (Koseki, 2009); (Fakruddin et al., 2011); (Baranyi et al., 1996)
5	Inactivation model	L	(FAO/WHO, 2009a); (Oscar, 2004); (Murphy et al., 2004a); (Murphy et al., 2004b)
6	Exposure assessment model	Α	Based on performance criteria.
7	Dose-response model	L	(FAO/WHO, 2002b)
8	Annual Illness	Α	Based on production volume.
9	Risk Estimate	L	Based on consumption pattern. (FAO/WHO, 2002b); (FAO/WHO, 2009b); (FAO/WHO, 2009a); (Mataragas et al., 2008)
10	DALYs model	L	(Fox-Rushby and Hanson, 2001); (WHO, 2004); (WHO, 2001); (CDC, 2013)
11	Cost of Illness model	L	(CDC, 2010); (WHO, 2001)
12	MRM metrics model	Α	Based on EA results (performance criteria).
13	Sampling Plan	L	(van Schothorst et al., 2009); (Whiting et al., 2006); (FAO/WHO, 2002a)
14	Case-study model	Α	EA without distribution (deterministic model).

Source: A= author assumption; L= literature

Table A.2: Exposure Assessment Inputs (Performance Criteria)

	Input		References
1	Transfer rate	L	Chapter III; Section 2.2.2
Rea	ring		
2	Prevalence between flocks	L/P	
3	Prevalence within flock	L/P	Chapter II; Section 2.6.2.1; Subsection A
4	Initial Contamination at rearing	L	
Tra	nsport to Plant		
5	Season	Α	Randomly generated with 0.25 possibility for each season
6	Cross-contamination (%)	L/P	Chapter II: Section 2.6.2.1: Subsection A
7	Growth/Reduction (log)	Р	Chapter II, Section 2.6.2.1, Subsection A
Sca	lding		
8	Cross-contamination (%)	Р	Chapter II: Section 2.6.2.1: Subsection P
9	Growth/Reduction (log)	L/P	Chapter II, Section 2.6.2.1, Subsection B
De-	feathering		
10	Cross-contamination (%)	L/P	Chapter II: Section 2.6.2.1: Subsection P
11	Growth/Reduction (log)	L/P	Chapter II, Section 2.6.2.1, Subsection B
Evis	sceration		
12	Cross-contamination (%)	L/P	Chapter II: Section 2.6.2.1: Subsection P
13	Growth/Reduction (log)	Α	Chapter II, Section 2.6.2.1, Subsection B
Was	shing		
14	Cross-contamination (%)	Р	Chapter II. Costion 2 C 2 4. Cubecation D
15	Growth/Reduction (log)	L/P	Chapter II, Section 2.6.2.1, Subsection B
Chi	lling (Tank)		
16	Cross-contamination (%)	Р	Chapter III Section 26.24. Subsection D
17	Growth/Reduction (log)	L/P	Chapter II, Section 2.6.2.1, Subsection B

Gra	Grading & Packaging					
18	Cross-contamination (%)	L/P	Chapter III Section 2.6.2.4. Subsection P			
19	Growth/Reduction (log)	L/P	Chapter II, Section 2.6.2.1, Subsection B			
Dist	ribution					
20	Cross-contamination (%)	A/P/L				
21	Temperature Abuse (%)	Α	Chapter II; Section 2.6.2.1; Subsection C			
22	Growth/Reduction (log)	Р	4			
Sto	rage at Retail					
23	Cross-contamination (%)	A/P/L				
24	Temperature Abuse (%)	Α	Chapter II; Section 2.6.2.1; Subsection C			
25	Growth/Reduction (log)	Р	4			
Tra	nsport to Home					
26	Cross-contamination (%)	A/L				
27	Temperature Abuse (%)	Α	Chapter II; Section 2.6.2.1; Subsection D			
28	Growth/Reduction (log)	Р				
Sto	rage at Home					
29	Cross-contamination (%)	A/L				
30	Temperature Abuse (%)	Α	Chapter II; Section 2.6.2.1; Subsection D			
31	Growth/Reduction (log)	Р				
Preparation (cooking)						
32	Cross-contamination (%)	L				
33	Proportion of XC with materials that eaten raw (%)	L				
34	Growth/Reduction (log)	L/P	Chapter II; Section 2.6.2.1; Subsection D			
35	Under-cook (%)	L				
36	Protected cells (%)	L / (A)				

Total Inputs = 36

Source: A= author assumption; L= literature; P= predictive model

Table A.3: Hazard	and Risk	Characterizations	Inputs
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	Input	Source	References				
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Dos	Dose-Response model inputs:						
1	(α) Parameter	L					
2	(β) Parameter (normal & susceptible)	L	Chapter II; Section 2.6.2.2				
Epi	demiological Data:	,					
3	Annual illness	L					
4	Hospitalization rate	L					
5	Death rate	L	Chapter II; Section 2.6.2.3; Subsection A				
6	Under-reporting Multiplier	L					
7	Attribution factor to Broiler	L					
Pro	duction Characteristics:						
8	Annual Broilers Production	L					
9	Flock Size (Mean)	L					
10	Domestic Broiler (%)	L	Chapter II: Section 2.6.2.3: Subsection B				
11	Whole Broiler (%)	L					
12	Broilers going to Home (%)	L					
13	Frozen broiler (%)	L					
Aff	Affected Population:						
14	U.S. Population	L					
15	Chicken Consumer (%)	L					
16	Annual broiler consumption	L	Chapter II; Section 2.6.2.3; Subsection C				
17	Annual Serving from whole broiler	L					
18	Susceptible Population (%)	L					

Socio-economic Information: DALYs and COI			
19	Lost Life Year (life expectancy)	L	
20	Disability weight (2 inputs)	L	
21	Disability duration (2 inputs)	L	Chapter II, Section 2.6.2.2, Subsection D
22	Cost of illness (4 inputs)	L	Chapter II, Section 2.6.2.3, Subsection D
23	Proportion of outpatient (3 inputs)	L	
24	Number of day lost (2 inputs)	L	

Total Inputs = 32

Source: L= literature;

APPENDIX B: QMRA PREDICTED OUTPUTS

Step	Outputs	
Rearing Transport to Plant Scalding De-feathering Evisceration Washing Chilling (Tank) Grading & Packaging Distribution Storage at Retail Transport to Home Storage at Home Preparation (cooking)	 For each of these step, the model will predict the following outputs; 1- Prevalence of contaminated broiler (%) 2- Effect on prevalence (%) (except rearing step). 3- Mean population of <i>Salmonella</i> (log). 4- Mean population (cell). 5- Minimum population of <i>Salmonella</i> (cell). 6- Maximum population of <i>Salmonella</i> (cell). 7- Source of contamination: percentage of broilers that got contaminated in this step and contributed in the final dose (i.e. contamination last to the time of consumption). 	
Total Outputs = 90		

Table B.1: Outputs that demonstrate whole broiler microbial load from farm to fork

Table B.2: Outputs that demonstrate broiler production system performance

Stage	Outputs	
Farm Processing Retail Consumer Kitchen	 For each of these stages, the model will predict the following: 1- Prevalence of contaminated broilers (%). 2- Effect of stage on prevalence (%). 3- Concentration of <i>Salmonella</i> (log). 4- Effect of stage on <i>Salmonella</i> concentration (%). 5- Contribution in final dose (%). 	
Number of cont. meal	Number of contaminated meals resulted from a <i>Salmonella</i> -positive flock. It consider cross-contamination. It used to calculate source of contamination (%)	
Prob. of cont. meal	The probability of getting a <i>Salmonella</i> -contaminated meal—full broiler & other food with 1 or more cell(s)—within the U.S. (covers all flocks).	
Total Outputs = 22		

Table B.3: Outputs that demonstrate salmonellosis likelih	lood
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Output	Description
Probability of contaminated Serving	This number demonstrates the likelihood of consumer exposure to <i>Salmonella</i> due to whole broiler consumption. Estimates the percentage of <i>Salmonella</i> -contaminated servings (i.e. piece of chicken and other food) at time of consumption. Importantly, this number is used in calculating Risk Estimate.
Amount of Final Dose (2 outputs)	Estimated mean and maximum number of <i>Salmonella</i> cells in a contaminated serving
Source of Final Dose (3 outputs)	 Percentage of contaminated servings where the dose comes from broilers (i.e. inadequate cooking). Percentage of contaminated servings where the dose comes from other food (i.e. cross-contamination). Percentage of contaminated servings where the final dose comes from broilers and other food.
Probability of illness (2 outputs)	 Demonstrates the probability of illness resulting from consumer exposure to <i>Salmonella</i> due to consuming whole broilers. It is a function of <i>Salmonella</i> concentration at time of consumption. It can be used to evaluate the effect of potential intervention(s) on the probability of illness. Importantly, this number is used in calculating Risk Estimate. Individual probability of illness: demonstrates the probability of a random consumer in the U.S. to get salmonellosis due to whole broiler consumption per year. It can be used to assess the individual risk of salmonellosis from whole broiler (i.e. compare it with other source of salmonellosis).
Risk Estimate (RE)	This number demonstrates the overall performance of the U.S. whole broiler production system in controlling <i>Salmonella</i> prevalence and concentration. Result from multiplying the probability of contaminated serving (i.e. prevalence) and probability of illness (i.e. concentration). It addresses the overall likelihood of salmonellosis resulting from the current U.S. whole broiler performance (i.e. sanitary and process measures). Estimates the likelihood of illness due to consuming a random serving of broiler. A result of exposure assessment and hazard characterization processes; and it is used in risk characterization to estimate salmonellosis impact.

Table B.4: Outputs that demonstrate salmonellosis severity

Output	Description
Annual Illnesses	Demonstrates the model estimation of annual number of salmonellosis cases within the U.S. population (including underreported cases). Characterized by risk likelihood (i.e. RE) and U.S. whole broiler production. It is the primary metric for public health and used to estimate annual hospitalization and death as a result of salmonellosis. It should be compared with the reported epidemiological data (i.e. CDC data) to validate and/or calibrate the model. It can be used as an ALOP for morbidity (along with annual hospitalization).
Annual Hospitalization	Demonstrates the model estimation of annual hospitalization due to salmonellosis. Used to calculate DALYs and COI. It can be used to evaluate the effect of some interventions (e.g. reducing percent of hospitalization or to reduce inpatient cost) in DALYs and COI.
Annual Death	Demonstrates the model estimation of annual death resulting from salmonellosis. It is used to calculate DALYs and COI, and can be used to evaluate the effect of some interventions (e.g. reducing the death rate) in DALYs and COI. Moreover, annual death can be used as an ALOP for mortality.
Annual Risk Estimate (ARE)	Demonstrates the model estimation of annual number of salmonellosis (i.e. population RE) within the U.S. population (including underreported cases). It is characterized by risk likelihood (i.e. RE) and the U.S. population broiler consumption pattern. Can be used to estimate the risk of salmonellosis in a specific sub-population, but in this case the dose-response model should also be adjusted for the object sub-population.
DALYs (years)	Demonstrates the number of years lost from the U.S. society due to disabilities resulting from salmonellosis (i.e. premature death, hospitalization, and illness). Used to determine the societal burden and the effect of salmonellosis on the quality of life. Generally, DALY is used for risk ranking and prioritizing potential intervention(s) for its role in risk-benefit analysis. It can be used as an ALOP for societal impact.
COI (\$)	Demonstrates the number of U.S. dollars lost due to salmonellosis (i.e. premature death, inpatient, outpatient, and disability). It estimates the cost that government would pay to cure salmonellosis and the cost of lost productivity due to disability due to salmonellosis. Can be used to evaluate potential intervention(s) feasibility, risk ranking, and prioritizing potential intervention(s) for its role in risk-benefit analysis. And, can be used as an ALOP for economic impact.
	Total Outputs = 6

Step	Output	Description
Rearing	POs	ALOPs: Appropriate Level Of Protection. Demonstrates
Transport to Plant	PO/MC + PCs	the maximum level of risk that deemed acceptable.
Scalding	POs + PCs	FSO frequency: the maximum number of <i>Salmonella</i> - contaminated servings, at time of consumption, to achieve ALOPs.
De-feathering	POs + PCs	FSO concentration: the maximum number of Salmonella
Evisceration	POs + PCs	achieve ALOPs.
Washing	POs + PCs	MCs: the maximum <i>Salmonella</i> concentration (log) required at the end of each food chain segment that
Chilling (Tank)	POs + PCs	achieve the intended FSO. Food chain segments should be regulated and inspected in accordance with MCs by competent authority. However, MCs could be regulated
Grading & Packaging	PO/MC + PCs	and inspected in food service facilities, but not in consumer kitchen. However, consumer should be
Distribution	POs + PCs	educated and instructed to contribute in achieving FSO.
Storage at Retail	PO/MC + PC	POs prevalence: the maximum <i>Salmonella</i> frequency (%) required, at each step, to achieve FSO.
Transport to Home	POs + PCs	POs concentration: the maximum <i>Salmonella</i> concentration (log) required, at each step, to achieve
Storage at Home	POs + PCs	FSO.
		PCs prevalence: mean of targeted change required in prevalence of <i>Salmonella</i> , at each step, by the application of control measures.
Preparation (cooking)	PO/MC + PCs + FSOs + ALOPs	PCs concentration: mean of targeted change required in concentration of <i>Salmonella</i> , at each step, by the application of control measures.
Stage	Output	Description

 Table B.5: Outputs that demonstrate the food safety control system (MRM metrics)

Stage	Output	Description
Farm Processing	$N_p + N_c$ $N_p + N_c$	N_{P} = number of samples required to test compliance with PO prevalence (%) at a specific segment (i.e. stage).
Retail	$N_p + N_c$	N_c = number of samples required to test compliance with MC (log) at a specific segment (i.e. stage).
Total Outputs = 62		

APPENDIX C: QMRA MODEL SETTINGS

1) QMRA Model Construction (Excel File Name: QMRA-Baseline):

- 1- Sheet 1: where all inputs are entered and all outputs are presented.
- 2- Sheet 2: where EA and HC are modeled.
- 3- Sheet 3: where microbial predictive models are constructed.

NOTE: user need only to use Sheet 1. However, Sheet 2 may be visited to review modeling EA and HC for future improvement. Sheet 3 may be visited to re-estimate a RAs input when new data is available; or when an intervention is needed to be translated to PcC or PdC.

2) QMRA Model Inputs:

All inputs are entered in the orange table in Sheet 1, and are assigned as @RISK inputs (distributions were set by @RISK functions). However, to allow @RISK to include RAs inputs in sensitivity analysis, it should be marked with "RiskCollect" function.

3) Modeling Risk Assessment:

Modeling starts in exposure assessment stage because hazard identification is considered as a semi-qualitative risk assessment. EA and HC are modeled in Sheet 2, while RC is modeled in Sheet 1 (green tables). Microbial predictive models were used to inform EA without being incorporated within EA framework (i.e. not part of the EA model). In other words, some EA inputs were predicted using PMs in Sheet 3, then optimized and entered in Sheet 1 as RAs inputs. This was done to minimize overall complexity.

Cross-contamination percent for steps from transport to plant to storage at retail (9 steps) were predicted in the side of Sheet 1. The adopted contamination model was used to estimate cross-contamination percent based on prevalence of contaminated broilers and the possible number of contact among broilers during those steps. However, cross-contamination events are characterized by cross-contamination percent and transfer rate.

4) Running the QMRA Model:

- 1- Operate @RISK first and then open the QMRA model (i.e. Excel file "QMRA-Baseline").
- 2- All inputs should be entered in the input table (i.e. the orange tale in Sheet 1).
- 3- Set up a Monte Carlo simulation using @RISK function with the following settings;
 - a) Number of iteration = minimum 2000 iterations (this was tested to give stable results each run \pm 3%)
 - b) Number of simulation = 1
 - c) Multiple CPU support = Enable
 - d) Sampling type = Monte Carlo (this will not affect results, but maintains consistency).
 - e) Generator = Mersenne Twister (this will not affect results, but maintains consistency).
 - f) Initial seed = choose randomly
 - g) Multiple simulation = any choice because one simulation will be performed (see b).
 - h) Collect distribution samples = Input marked with collect (this because only RAs inputs are aimed for sensitivity analysis, so distribution given in EA will not be considered for sensitivity analysis. This will also speed up the simulation).
 - i) Smart sensitivity analysis = Enable
 - j) Update statistic functions = At end of each simulation (to speed up simulation).
 - k) Other options can be set, but they will not affect results and should express user preference only.
- 4- After running the simulation, the results will be saved on outputs cells. Put the cursor on the desired output cell and the result will show up. However, outputs distribution should be tested to identify how the result is distributed (e.g. normally distributed).
- 5- Results can be saved as the same Excel file or can be saved separately in a "*.RSK5" file. You can continue working with the model by opening the "*.RSK5" file.
- 6- The QMRA model is iterative, thus, step 1 5 can be repeated with different inputs.

5) QMRA Model Outputs:

QMRA-baseline model outputs are estimated using Monte Carlo simulation in @RISK. After several thousand iterations, the outputs will be presented as relative frequencies, however, different distributions can be tested to identify which distribution best fits the results.