Interagency Risk Assessment:

Listeria monocytogenes in Retail Delicatessens

Technical Report

The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup

September 2013

Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup

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Acknowledgments

The Interagency Retail *Listeria monocytogenes* Workgroup thanks the many contributions made by others in the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS); the U.S. Food and Drug Administration (FDA); and the Centers for Disease Control and Prevention (CDC). We are also grateful for coordination of an independent peer review by Versar, Inc.; focus studies conducted by members of academia, to fulfill specific data needs in this risk assessment; and input from both consumer groups and industry throughout this risk assessment. Specific recognition includes the following.

We acknowledge and thank FSIS scientists and risk managers for their input and support throughout the development of this risk assessment: Kristina Barlow, Phil Bronstein, Vivian Chen, Phil Derfler, Denise Eblen, Daniel Engeljohn, David Goldman, Steve Mamber, Evelyne Mbandi, Tim Mohr, and William Shaw. We acknowledge and thank the members of the FDA Risk Management team, including Elizabeth Calvey, Ted Elkin, Faye Feldstein (retired), Mary Losikoff, Mickey Parish, Jenny Scott, Kevin Smith, Mark Wirtz, and Donald Zink, for advice throughout the process. We also thank our colleagues from the CDC for their valuable input: Ezra Barzilay, Patricia Griffin, Martha Iwamoto, K. Liane Ong, Benjamin Silk, and Robert Tauxe.

We are grateful to the following individuals for their contributions to the success of the public meeting that initiated this risk assessment and that actively included stakeholder and public input: Frederick Angulo[1], Daphne Brown[2], John Butts[3], Greg DiNapoli[2], Frances Ann Draughon[4], Amanda Eamich[2], Linda Eckrich[2], Rachel Edelstein[2], Atiya Khan[2], Ndidi Mojay[2], Amirhossein Mokhtari[5], Laura Reiser[2], Peggy Riek[2], and Robert Tynan[2]. We thank the many individuals from industry and consumer groups who provided useful input in the development and refinement of this risk assessment: Susan L. Backus[6], Betsy

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[2] Food Safety and Inspection Services, U.S. Department of Agriculture
[3] Land O'Frost
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[6] American Meat Institute Foundation

Booren[6], Pat Buck[7], Caitlin Catella[8], Tony Corbo[9], Joe Corby[10], Nancy Donley[11], Jill Hollingsworth[12], Susan Kendrick[13], Sara Klein[8], Larry Kohl[12], Felicia Nestor[9], Tanya Roberts[7], Caroline Smith DeWaal[8], Warren Stone[14], Kimberly Stryker[15], Hilary Thesmar[12], and Carol Tucker-Forman[16].

We thank the following individuals for their roles in studies involving retail deli employee behavior, longitudinal study/risk mapping of *L. monocytogenes* in the retail grocery deli environment, and transmission of *L. monocytogenes* in retail delis: Shirley Bohm[17], Renee Boyer[18], Laura Brown[2], Elizabeth Calvey[19], Benjamin Chapman[20], Philip G. Crandall[21], Susan Duncan[18], Joseph Eiffert[18], Caren Kieswetter[17], Brenda Le[1], Jessica Maitland[18], Jianghong Meng[19], Haley Oliver[22], Carol Selman[1], Courtney Simmons[23], Martin Wiedmann[23], and Denita Williams[1]. We also thank Vangelia Campbell[2] for her tireless support and oversight of FSIS contracts with Cornell University to develop a risk map of *L. monocytogenes* in the retail deli environment [FSIS contracts: AG-3A94-C-09-0027; AG-3A94-C-09-0028; and AG-3A94-C-10-0016] and with Virginia Polytechnic Institute and State University for both the study of *L. monocytogenes* transmission in retail delis [FSIS contract: AG-3A94-C-10-0007] and quantitative risk assessment modeling support [FSIS contract: AG-3A94-P-08-0166]. We also thank Kristin Holt[2] for facilitating an interagency agreement between FSIS and CDC to collect nationwide information on worker behaviors in retail delis.

[7] Center for Foodborne Illness Research & Prevention
[8] Center for the Science in the Public Interest
[9] Food & Water Watch
[10] Association of Food and Drug Officials
[11] STOP Foodborne Illness
[12] Food Marketing Institute
[13] Oregon Department of Agriculture
[14] Grocery Manufacturers Association
[15] Alaska Division of Environmental Health
[16] Consumer Federation of America
[17] Center for Food Safety and Applied Nutrition, Food and Drug Administration
[18] Virginia Polytechnic Institute and State University (Virginia Tech)
[19] Joint Institute for Food Safety and Applied Nutrition
[20] North Carolina State University
[21] University of Arkansas
[22] Purdue University
[23] Cornell University

We are grateful for insights from peer reviewers Leila M. Barraj[24], Edmund A.C. Crouch[25], and Renata Ivanek-Miojevic[26]. We thank David Bottimore[27], Kathy Coon[27], Keith Drewes[27], Ruth Holt[2], Lori Papadakis[17], and Stephanie Sarraino[27] for facilitating and organizing the FDA-FSIS co-funded independent peer review.

We thank Mike Mikailov[28], Brian Fitzgerald[28], Stuart Barkley[28], and Luo Fu-Jyh[28] for their invaluable contributions to programming and supercomputing. We also thank Eric Ebel[2], Mike Williams[2], Yong Cao[29], and Jennifer Hoeting[29] for providing additional high-performance computer capacity.

We acknowledge Wendy Fanaselle[17], David Weingaertner[17], David LaBarre[2], and Stacy Kish[2] for support in the development and preparation of this report.

We thank Susan Mary Cahill[17] for careful review and editing of the draft report.

This project was supported, in part, by appointments to the Research Participation Program at the Center for Food Safety and Applied Nutrition, administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the U.S. Food and Drug Administration.

The considerable help and valuable expertise provided by the aforementioned notwithstanding, responsibility for the content of this report rests solely with the U.S. Department of Agriculture, Food Safety and Inspection Service; and the Food and Drug Administration, Center for Food Safety and Applied Nutrition.

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List of Abbreviations

AFDO	Association of Food and Drug Officials
AMIF	American Meat Institute Foundation
ARS	Agricultural Research Service
cfu	colony forming units
CDC	Centers for Disease Control and Prevention
CFA	Consumer Federation of America
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CSPI	Center for Science in the Public Interest
DHHS	Department of Health and Human Services
EHS-Net	Environmental Health Specialists Network
EO	eating occasion
FAO	Food and Agriculture Organization of the United Nations
FCS	food-contact surface(s)
FDA	Food and Drug Administration
FMI	Food Marketing Institute
FSIS	Food Safety and Inspection Service
GI	growth inhibitors
GMA	Grocery Manufacturers Association
GT	generation time
IAFP	International Association for Food Protection
MPN	most probable number
NAFSS	National Alliance for Food Safety and Security
NCBI	National Center for Biotechnology Information
NFCS	non-food-contact surface(s)
NFPA	National Food Processors Association
NHANES	National Health and Nutrition Examination Survey
NIFA	National Institute of Food and Agriculture
OMB	Office of Management and Budget
ppm	parts per million
QRA	quantitative risk assessment
RAC	raw agricultural commodities
RTE	ready-to-eat
sd	standard deviation
U.S.	United States
USDA	United States Department of Agriculture
Virginia Tech	Virginia Polytechnic Institute and State University
WHO	World Health Organization

List of Abbreviations for Baselines and Scenarios

The Table below introduces the abbreviations used to identify the various risk assessment model baselines and scenarios denoted in the figures of the Results and Discussion section of this report (Section 7).

Abbreviations	Description
Baselines	
Multiple Niche 100W	A retail deli with multiple niches on slicers, utensils, food-contact surfaces (FCS), and non-food-contact surfaces (NFCS). Each niche contaminates its associated site, at a mean frequency of once per week, with a mean of 100 colony forming units (cfu) per event.
No niche	A retail deli without any niches or environmental *L. monocytogenes* transfer.
Temperature Control	A retail deli without any niches that maintains its deli case at ≤5°C (≤41°F)
Incoming Growth Chub	A retail deli without any niches, with one incoming ready-to-eat (RTE) product (a) whose mean *L. monocytogenes* $\log_{10}$ concentration of -5 $\log_{10}$ cfu per gram is greater than baselines (-9.2 $\log_{10}$ cfu per gram) and (b) that supports the growth of *L. monocytogenes*.
Incoming Non-Growth Chub	A retail deli without any niches, with one incoming RTE product (a) whose mean *L. monocytogenes* $\log_{10}$ concentration of -5 $\log_{10}$ cfu per gram is greater than baselines (-9.2 $\log_{10}$ cfu per gram) and (b) that does <u>not</u> support the growth of *L. monocytogenes*.
Niche & Temperature Control	A retail deli with "Multiple Niche 100W" (see above) that maintains the temperature of the deli case at ≤5°C (≤41°F)
Scenarios: Worker Behaviors, Sanitation, and Cross Contamination	
Wash & Sanitize	Increase the effectiveness of retail deli cleaning from simply washing to washing and sanitizing.
Clean 8 Sporadic	Doubling the number of retail deli sites sporadically cleaned from 4 to 8.
No Sanitation	Do not conduct any wiping, washing, or sanitizing.
No Sporadic Cleaning	Retail deli workers clean FCS as required by the 2009 FDA Food Code, but do not conduct any additional sporadic cleanings.
No Glove	Retail deli workers do not use gloves when serving customers.
Gloves Every Serving	Retail deli workers change gloves for every sale of RTE products.
NFCS as FCS	Retail deli workers clean deli NFCS as if they were FCS (i.e., every 4 hours in accordance with the 2009 FDA Food Code).
Transfers to 0	Scenario in which *L. monocytogenes* cross contamination in the retail deli would only result from the deli slicer (i.e., set cross contamination transfer coefficients to 0 for all sites except the slicer).
Transfers and Slicer to 0	Scenario in which there is no *L. monocytogenes* cross contamination in the retail deli (i.e., set cross contamination transfer coefficients to 0; i.e., no cross contamination occurs for all sites, including the slicer).
No-Contact Glove Case	Retail deli workers do not use their hands (gloved or ungloved) to open the retail deli case (e.g., if a floor switch is used).
Reduce Level	Lower the mean incoming *L. monocytogenes* $\log_{10}$ concentration on all RTE products from the observed mean of -9.2 $\log_{10}$ cfu per gram to a mean of -9.5 $\log_{10}$ cfu per gram.
Pre-slice	Retail deli workers pre-slice all chubs of RTE product (deli meat and deli cheese) in the morning, after cleaning.

Scenarios: Worker Behaviors, Sanitation, and Cross Contamination (Continued)	
Separate Slicer	Retail deli workers use a separate slicer for RTE products that support growth of *L. monocytogenes* versus RTE products that do not.
Separate Slicer Case	Retail deli workers use a separate slicer and a separate deli case for RTE products that support growth of *L. monocytogenes* versus RTE products that do not.
Lower Env Cont	Reduce transfer of *L. monocytogenes* among RTE products, FCS, and NFC (i.e., reduced transfer coefficients by 50%) in the retail deli.
Do Not Slice Onto Gloves	Retail deli workers collect slices of RTE products directly on tissue paper, rather than on their gloves.
Scenarios: Temperature Control and Growth Inhibition	
Temp = 5°C	Set the retail deli case temperature for all retail delis to 5°C (41°F) (i.e., in compliance with the 2009 FDA Food Code), rather than using real-world deli-case temperatures reported by Ecosure.
No Growth (T = -5°C)	Set all retail deli-case temperatures to -5°C (23°F). At this temperature, no *L. monocytogenes* growth will occur.
Temp <= 5°C	Use the retail deli-case temperatures observed in the Ecosure dataset at or below 5°C (41°F). This implies that all retail delis with deli-case temperatures exceeding the 2009 FDA Food Code recommendation come into compliance.
Shorten time in retail deli	Retail delis reduce the length of time RTE products are held before they are sold or disposed of from 7 to 4 days.
All GI	Reformulate all RTE products sold at the retail deli that would otherwise support *L. monocytogenes* growth to include growth inhibitors, to restrict the growth [same growth inhibitor (GI) formulation as cured ham with GI].
No GI	Reformulate all RTE products that support *L. monocytogenes* growth that are sold at the retail deli to not include GI that would restrict *L. monocytogenes* growth.

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Executive Summary

The "Interagency Risk Assessment: *Listeria monocytogenes* in Retail Delicatessens" provides a scientific assessment of the risk of foodborne illness associated with consumption of ready-to-eat (RTE) foods commonly prepared and sold in the delicatessen (deli) of a retail food store and examines how that risk may be impacted by changing common or recommended practices. This quantitative risk assessment (QRA) was conducted collaboratively by the Department of Health and Human Services' (DHHS) Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA/CFSAN) and the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), in consultation with the DHHS Centers for Disease Control and Prevention (CDC) and input from industry, academic institutions, and consumer advocacy group stakeholders. The White House Food Safety Work Group identified this risk assessment as a priority. It provides information useful to those responsible for implementing policies, programs, and practices that target prevention of listeriosis.

Background

Listeria monocytogenes (*L. monocytogenes*) is a food-safety concern, and control of this pathogen has long been an objective of the public health community. The CDC has estimated that *L. monocytogenes* causes approximately 1,600 illnesses, 1,500 hospitalizations, and 260 deaths annually. When compared with other major foodborne diseases, listeriosis is a rare occurrence, but the fatality rate is very high (i.e., approximately 16%, compared with 0.5% for either *Salmonella* or *Escherichia coli* O157:H7).

Cross contamination in the deli environment is thought to contribute to *L. monocytogenes* contamination of RTE foods, but little is known about the transfer of this pathogen in the retail setting. *L. monocytogenes* is present in the environment and can survive and grow in foods held at ambient and refrigeration temperatures. Therefore, adequate preventive controls must take into account contamination as well as survival and proliferation of the organism. *L. monocytogenes* can contaminate foods via cross contamination from one product to another or from the environment, or both.

Overview of Risk Assessment

The QRA simulates the retail deli environment and evaluates how various sanitary and food handling practices may influence the U.S. risk of listeriosis associated with consuming RTE foods that are sliced, prepared, or packaged in retail grocery delis. The model is unique in its ability to quantitatively link activities within a retail deli directly to predicted public health outcomes. The model simulates *L. monocytogenes* concentration and prevalence in products sold to customers, predicts changes in concentrations during customer home storage, and estimates the risk of listeriosis from consumption of these products in the home. The population was divided into two subpopulations, for the purposes of this risk assessment: (1) the population with increased susceptibility (including neonates, older adults, and the immunocompromised) and (2) the remaining population (referred to as the general population).

Risk Management Questions

The questions initially posed to the Interagency Retail *L. monocytogenes* Risk Assessment Workgroup were:

1. What is the exposure to *L. monocytogenes* from consuming RTE foods prepared in retail delis?
2. What are the key processes that increase contamination of RTE foods in retail delis?
3. How much is the relative risk per serving reduced according to specific risk management options?

The above questions are very broad in nature and were further refined as a list of more specific questions evaluated through scenario analyses within this risk assessment. Some of the specific 'what if' scenarios were generated by FSIS and FDA risk managers, while others were provided by stakeholders. Examples include:

- What impact does improved compliance with the cold holding and storage duration requirements found in the FDA Food Code have on the predicted listeriosis risk?
- What impact does improved compliance with food-contact-surface sanitation have on the predicted listeriosis risk?
- What impact does using dedicated slicers for specific products have on the predicted listeriosis risk?
- What impact does reducing the presence and level of *L. monocytogenes* on incoming RTE foods have on the predicted listeriosis risk?

Key Findings of the Risk Assessment

The key findings from this assessment of risk of listeriosis associated with RTE foods prepared and served in retail deli operations include:

- **Control Growth**. Employing practices that prevent bacterial growth dramatically reduced the predicted risk of listeriosis, as observed in other *L. monocytogenes* risk assessments. The use of growth inhibitors for suitable products prevents growth of *L. monocytogenes* in RTE foods, both at retail and during consumer home storage. In this risk assessment, use of growth inhibitors led to an overall dramatic reduction in the predicted risk of listeriosis (ca. 95%). Strict temperature control during refrigerated storage in retail delis did reduce the predicted risk (5-20% reduction, according to the baseline and the scenario). It should be noted that the impact of this control is lower than the impact from use of growth inhibitors, which mitigate growth of *L. monocytogenes* in RTE foods beyond the retail setting.
- **Control Cross Contamination**. Cross contamination of *L. monocytogenes* in the retail environment dramatically increases the predicted risk of listeriosis. Cross contamination during the routine operation of the retail deli is not amenable to a simple solution.
- **Control Contamination at its Source**. Increasing the concentration and transfers of *L. monocytogenes* from incoming products, the environment, or niches directly increases the predicted risk of illness. Increasing *L. monocytogenes* concentration in incoming product increased the predicted risk of listeriosis whether or not the contaminated RTE product itself supported growth. The increase in predicted risk was greater when the equivalent contamination occurred on product that supported the growth of *L. monocytogenes*.
- **Continue Sanitation.** Sanitation practices that eliminate *L. monocytogenes* from deli area food-contact surfaces result in a reduction in the predicted risk of illness. Cleaning and sanitizing food-contact surfaces reduced the predicted *L. monocytogenes* levels in the deli area. Wearing gloves while serving customers reduced the estimated risk of listeriosis.
- **Identify Key Routes of Contamination**. The slicer is a primary source of *L. monocytogenes* cross contamination to deli meats and cheeses. Control of *L. monocytogenes* cross contamination at this point during retail preparation of RTE foods reduced the predicted risk of listeriosis.

In summary, this QRA improves our understanding of *L. monocytogenes* in the retail deli and should encourage improvements to retail food-safety practices and mitigation strategies to further control *L. monocytogenes* in RTE foods. The 'what if' scenarios modeled in this QRA provide insight on how cross contamination, sanitary practices, and temperature control impact the predicted risk of listeriosis. This QRA is based on an extensive amount of information gathered through partnerships with academia and input from stakeholders. Additional data would be useful to further explore how more specific retail practices and conditions (e.g., equipment design) impact the risk of listeriosis.

Interagency Risk Assessment:
Listeria monocytogenes in Retail Delicatessens

The "Interagency Risk Assessment: *Listeria monocytogenes* in Retail Delicatessens" provides a scientific assessment of the risk of foodborne illness associated with consumption of ready-to-eat (RTE) foods prepared in retail delicatessens (delis) and examines how that risk may be impacted by changes to current practices. This risk assessment was conducted collaboratively by the Department of Health and Human Service (DHHS), Food and Drug Administration's Center for Food Safety and Applied Nutrition (FDA/CFSAN), and United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), in consultation with the DHHS Centers for Disease Control and Prevention (CDC), and input from industry, academic institutions, and consumer advocacy group stakeholders. The conduct of this risk assessment was identified as a priority by the White House Food Safety Work Group [1] and will be used to evaluate current policies, programs, and practices intended to protect public health through the prevention of listeriosis.

1. Background

L. monocytogenes is a food safety concern, and control of this pathogen has long been an objective of the public health community, including government, academia, industry, and consumer advocacy groups. The CDC [2] has estimated that *L. monocytogenes* causes approximately 1,600 illnesses, 1,500 hospitalizations, and 260 deaths annually. When compared with other major foodborne diseases, listeriosis is a rare occurrence, but the fatality rate is very high (i.e., approximately 16% compared with 0.5% for either *Salmonella* or *Escherichia coli* O157:H7).

To prevent listeriosis in the U.S., it is important to identify the foods that pose the greatest risk of the illness, the most effective retail practices for controlling *L. monocytogenes*, and the changes in processing, handling, and/or preparation practices that can improve the safety of foods associated with the illness. Risk assessment provides a useful framework for integrating scientific research and data and evaluating the public health implications of changes in food safety practices and policies.

During the past decade, FSIS and FDA have conducted several risk assessments to guide federal policies intended to control and prevent listeriosis in the United States. In 2003, the FDA and FSIS developed a

QRA to determine the relative risk of listeriosis that 23 categories of RTE foods pose to the total U.S. population and 3 age-based subpopulations [3]. That 2003 risk assessment supported the findings of epidemiologic investigations of sporadic illnesses and outbreaks of listeriosis. The risk assessment identified and quantified the factors that affect exposure to *L. monocytogenes*, including (1) amount and frequency of consumption of the food, (2) frequency and levels of *L. monocytogenes* in the food, (3) potential of the food to support growth of *L. monocytogenes*, (4) refrigerated storage temperature, and (5) duration of refrigerated storage before consumption. The 2003 risk assessment identified several RTE foods as posing a high risk, per serving, including deli meats, soft cheeses, pâté, and smoked seafood. Of these RTE foods, deli meats were estimated to account for the most – approximately 67% – of all listeriosis cases per year in the U.S. [3].

Following the release of the FDA/FSIS risk assessment in 2003, FDA and CDC issued an Action Plan to reduce the risk of *L. monocytogenes*, which was subsequently updated in 2008 [4]. The 2008 update provides a list of FDA's activities within six areas: (1) develop and revise guidance for processors that manufacture or prepare RTE foods, for retail and food service, and for institutional establishments; (2) develop and deliver training and technical assistance for industry and food safety regulatory employees; (3) enhance consumer and health care provider information and education efforts; (4) review, redirect, and revise enforcement and regulatory strategies; (5) enhance disease surveillance and outbreak response; and (6) coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities. FDA's activities related to the 2008 Action Plan are publicly available [4]. Examples of these activities include (1) two draft guidance documents issued for public comment in 2008: a draft "Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes*" and a draft "Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen ready-To-Eat Foods," (2) modification of the 2005 FDA Food Code to amend the date-marking provisions and cold-holding times and temperatures, and (3) a public health education campaign to provide advice to consumers about refrigerator temperatures, to prevent foodborne illness, including listeriosis.

Also in response to the findings of the 2003 FDA/FSIS risk assessment, FSIS conducted a complementary risk assessment to evaluate which food safety interventions during the processing of RTE meat and poultry products are most effective in preventing listeriosis [5]. This FSIS QRA revealed that formulating RTE products with growth inhibitors and using post-lethality interventions, combined, were more effective in preventing foodborne illness, compared with using either of these interventions alone or with testing and sanitizing food-contact surfaces (FCSs). These findings directly formed the scientific basis of

FSIS's interim final rule for *L. monocytogenes*, which encourages federal establishments to adopt more effective food safety interventions during the production of RTE meat and poultry products (9 CFR 430, 68FR 3422; June 6, 2003). FSIS also used these findings and those from the 2003 FDA/FSIS risk assessment to guide its verification sampling programs, whereby RTE meat and poultry processing establishments (9 CFR 430) with less effective *L. monocytogenes* controls are sampled more frequently [6]. These findings were used to inform FSIS' compliance guidance to industry [7]. To aid in implementation of the interim final rule, FSIS provided specialized training to its inspection workforce. These policies and programs have resulted in industry adoption of more stringent *L. monocytogenes* controls during the processing of RTE meat and poultry products in the U.S. Correspondingly, FSIS has observed a steady decline in the number of *L. monocytogenes*-positive samples from its in-plant testing programs, an indication that interventions during processing to mitigate risks from RTE meat and poultry products are succeeding (Figure 1).

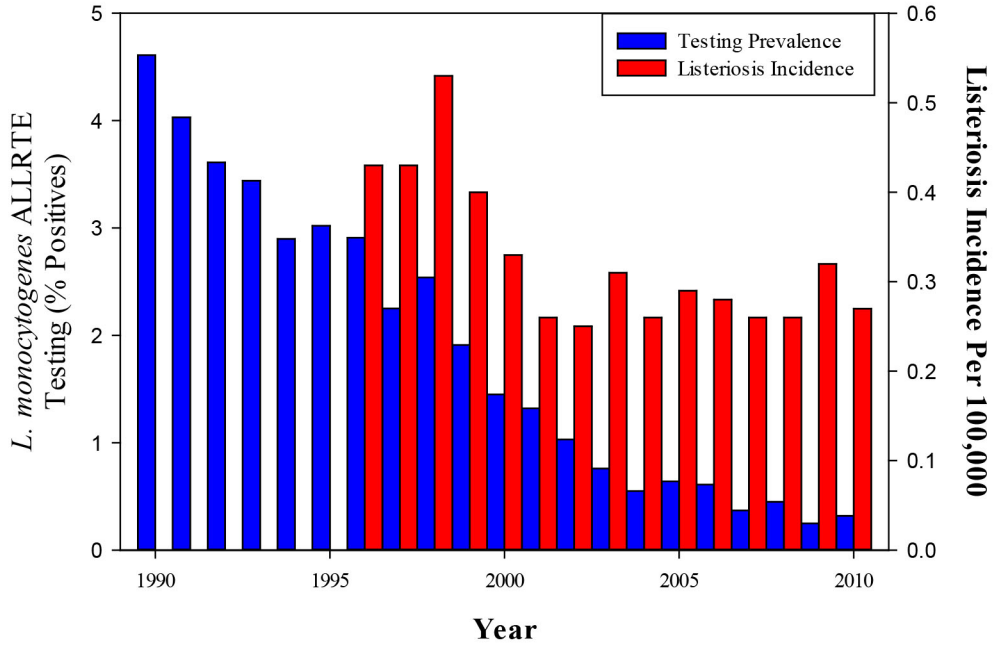


Figure 1: Percentage of RTE meat and poultry products testing positive for *L. monocytogenes* in FSIS-inspected facilities, compared with incidence of listeriosis per 100,000, from CDC FoodNet surveillance
(Source: [8] and [9]).

Despite a decline of *L. monocytogenes* in RTE meat and poultry products tested in processing plants over the past several years, epidemiologic data from the CDC have shown a steady incidence of listeriosis in the U.S. [10, 11] (Figure 1). Recent estimates of listeriosis incidence did not meet the Healthy People

2010 target of 0.24 cases per 100,000 population [12]. [Note: The 2020 target is 0.20 cases per 100,000 population [13].

The lack of a decline in listeriosis cases in the U.S. – despite a concurrent, dramatic decline in the percentage of RTE meat and poultry products (primary foodborne vehicles for *L. monocytogenes* [3]) that test positive for *L. monocytogenes* in meat- and poultry-production facilities – suggests contamination of RTE products at retail or in the consumer's home. Surveillance studies conducted by industry and academia [14, 15] have indicated that the prevalence of *L. monocytogenes* is approximately seven times higher in deli meats sliced at retail, compared with those sliced and packaged at federally inspected processing facilities. These surveys also indicated higher levels of *L. monocytogenes* on RTE meats sliced or packaged at retail. This difference in *L. monocytogenes* contamination was further quantified by an FSIS comparative risk assessment that indicated that approximately 83% of the listeriosis cases attributed to deli meat were associated with deli meats sliced at retail [6, 16]. An independent study by Cornell University also showed that the majority of listeriosis cases attributed to deli meats were associated with those sliced and served at retail delis [17].

In addition, as part of a 10-year study of the occurrence of foodborne illness risk factors in retail and food-service establishments, FDA collected data on food safety practices in food stores, including retail delis, in 1998, 2003, and 2008. The authors of the study looked for trends that would indicate whether practices were improving or regressing over the 10-year timeframe. The report on the 2008 data collection revealed that, for retail delis, the foodborne illness risk factor most in need of attention was "Improper Holding for Time and Temperature" [18]. In 60% of the 98 delis visited, at least one observation was made in which food requiring temperature control was not held at 41ºF (5ºC) or below, as specified in the FDA Food Code [18]. Similar non-compliance with temperature control of retail deli cases was suggested in a study by Ecosure [19].

Moreover, the analysis of trends in retail practices during the 10-year study period revealed no statistically significant change in the overall percentage of compliance with the FDA Food Code for all risk factors combined [20]. However, a statistically significant improvement in the poor personal hygiene risk factor was observed, including an improvement in preventing bare-hand contact with RTE foods. Despite this positive trend, in roughly 50% of the 98 delis visited in 2008, at least one employee was observed failing to wash his or her hands at the time or to wash them in the manner recommended in the FDA Food Code. Also, improper temperature holding is one of several factors that may contribute to an

increased risk of listeriosis [3]. Another is improper sanitation of slicers [21-23]. The extent to which these contribute to listeriosis is not well understood.

Prior to this QRA, little was known about how *L. monocytogenes* contamination of RTE foods occurs in retail delis. *L. monocytogenes* strains are regularly found and often widely distributed in retail facilities [24, 25]. Retail practices may result in cross contamination either from one RTE product to another or through contamination from the retail environment, or both. Retail practices may also contribute to higher levels of *L. monocytogenes* on RTE foods [14, 15]. A recent QRA suggests that retail cross contamination of RTE foods has the potential to increase the risk of listeriosis considerably and that frequency of cross contamination has the greatest impact on the risk [26]. In addition to cross contamination, likely contributors to *L. monocytogenes* contamination and to growth of the bacteria on RTE foods at retail include improper holding temperatures and insufficient sanitary practices [27]. Retail food establishments are required to comply with a number of food safety requirements that are designed to mitigate the risk of foodborne illness (e.g., cold holding, date marking, specified methods and frequency of cleaning surfaces). However, the extent to which these requirements and other industry best practices mitigate the risk of listeriosis is not well understood.

Given that there are several studies identifying retail delis as contributing to the risk of listeriosis from RTE foods in the U.S., and given the limited understanding of the extent to which certain retail food safety practices mitigate these food safety risks, the White House Food Safety Work Group identified the conduct of a food safety risk assessment as a priority, to guide efforts to prevent *L. monocytogenes* cross contamination at retail, for protection of the public health[30]. This interagency risk assessment fulfills this White House priority through in-depth evaluations of the extent to which certain retail food safety practices mitigate the risk of listeriosis and identifies practices that contribute to the risk.

[30] In 2009, the Federal Food Safety Workgroup identified the conduct of this interagency risk assessment as a food safety priority involving efforts to collaborate across federal agencies, with industry and consumer groups, and with the states. This risk assessment has remained a priority as highlighted in the Federal Food Safety Work Group Progress Report (December 2011).

2. Process for Conducting This Risk Assessment

In the planning and conduct of this risk assessment, the Working Group pursued a unique partnership of government agencies, academia, industry, and consumer groups. The Working Group had four primary goals for the conduct of this risk assessment:

1) Shared partnership between FSIS and FDA in all aspects of the development of the project (e.g., planning, budgeting, data acquisition, model development, peer review, and outreach);
2) Engagement of consumer groups, retail and food industry [including Consumer Federation of America (CFA), Center for Science in the Public Interest (CSPI), American Meat Institute Foundation (AMIF), Food Marketing Institute (FMI), Grocery Manufacturers Association (GMA), and the Association of Food and Drug Officials (AFDO)], throughout the entire process;
3) Collaboration with academia and researchers [including Cornell University, the University of Maryland, Virginia Polytechnic Institute and State University (Virginia Tech)] to fill identified, specific data needs; and
4) Scientific input and review through frequent presentations of the model and data analyses at scientific conferences and through a rigorous, independent peer review.

2.1. Partnership

FSIS and FDA formed an interagency workgroup, shared resources, and collaborated in the development of this risk assessment. The group met frequently and worked together to commission, collect, and analyze data; obtain stakeholder and public input; develop and refine the risk assessment model; co-fund the peer review; and develop presentations, written communications, and reports.

2.2. Ensuring public participation in the process

In June 2009, FSIS and FDA held a meeting to garner input from the public and engage stakeholders at the outset. The Agencies discussed the scope and objectives of the risk assessment (74 Federal Register, Vol 74, No 109, June 9, 2009 27276-27278) and invited public comment and submission of scientific data and information (Federal Register Notice, Vol 74, No 12, January 21, 2009. 3617-3619; Federal Register Notice, Vol 74, No 165, August 27, 2009. 43714-3619). Comments were received from AMIF, GMA, and CSPI.

During the course of the risk assessment, the project was presented to various stakeholders; notably AMIF, FMI, GMA, CSPI, CFA, and AFDO. Stakeholder recommendations and suggestions were taken into consideration.

2.3. Collaboration with academia

Studies to collect data for this risk assessment were undertaken in collaboration with the University of Maryland, Virginia Tech, and Cornell University. Trade associations, including FMI and AMIF, contributed to the planning and conduct of some of these studies. Specific studies include:

- **Retail employee behavior studies.** FDA, the University of Maryland, and the Joint Institute for Food Safety and Applied Nutrition conducted an observational study of retail deli food handling and sanitation practices in nine retail delis in the D.C. metro area [28]. This time-series study of retail behaviors over the course of a day formed the basis for the sequential "events" modeled at retail in this risk assessment. The FMI was instrumental in facilitating the conduct of this study. Additional data from 300 retail delis in 5 states (New York, including New York City, Tennessee, California, Minnesota, and Rhode Island) are currently being gathered through a follow-on study conducted through a collaborative effort between FSIS and the CDC with Environmental Health Specialists Network (EHS-Net) state partners. This subsequent study was cleared by the Office of Management and Budget (OMB) in December 2012, and data from this study will be used in future updates of this risk assessment.

- ***L. monocytogenes*** **transmission studies.** A mock deli was set up at Virginia Tech, to study the dynamics of *L. monocytogenes* by semi-quantitatively evaluating transfer during events and actions as RTE deli products are prepared, sliced, and/or packaged in retail delis [29]. Additional work was funded by the National Institute of Food and Agriculture at the University of Arkansas [30].

- ***L. monocytogenes*** **contamination in the retail environment**
  - A risk mapping of *L. monocytogenes* in a retail environment was developed by Cornell University through elicitation of expert opinion, to validate where *L. monocytogenes* occurs in a retail facility [31];
  - Cornell University also collected data on environmental *L. monocytogenes* contamination in 30 retail delis in Indiana, New York, and North Carolina, during pre-operational and operational activities. This study has been completed, and a manuscript is in preparation. AMIF and FMI have extended this study, in collaboration with Purdue University, to further evaluate the effectiveness of interventions to prevent or control *L. monocytogenes* in retail delis.

2.4. Scientific input and peer review

In keeping with OMB's Final Information Quality Bulletin for Peer Review (Federal Register Notice, Vol. 70, No. 10, January 14, 2005. 2664-2677), FDA and FSIS are committed to ensuring the quality, objectivity, utility, and integrity of all agency-disseminated scientific information. Peer review is an important procedure used to ensure that the quality of published scientific information meets the standards of the scientific and technical community. The OMB bulletin describes peer review requirements for influential scientific information. A scientific assessment is defined by OMB as "an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information."

Consistent with the OMB peer review guidelines, the draft model of the "Interagency Risk Assessment: *L. monocytogenes* in Retail Delicatessens" was independently peer reviewed in 2010, through an external contract with Versar, Inc. The review focused on an evaluation of the design, logic, and mathematics of the risk assessment. The risk assessment model was further amended and modified in response to peer-reviewer comments and input from the scientific community. The reports from this external peer review, as well as the specific FSIS and FDA answers to the various comments, are publicly available[31].

The risk assessment model and related analyses also were presented at technical scientific meetings, including the 2009 and 2012 Society for Risk Analysis annual meetings (December 8, 2009, Baltimore, Maryland; December 11, 2012, San Francisco, California), the XVIIth International Symposium on Problems of Listeriosis (May 6, 2010, Porto, Portugal), the 2010 Conference on Modeling for Public Health Action (Centers for Disease Control and Prevention, December 10, 2010, Atlanta, Georgia), the 2010, 2012, and 2013 International Association for Food Protection annual meetings (June 1-4, 2010, Anaheim, California; July 22-25, 2012, Providence, Rhode Island; July 28-31, 2013, Charlotte, North Carolina), and the 2012 Conference for Food Protection (April 13-18, 2012, Indianapolis, Indiana).

[31] FDA http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments; FSIS: http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments/risk-assessments

3. Scope and Objectives / Risk Management Questions

3.1. Charge for the Interagency Risk Assessment, and Risk Management questions

Among the essential duties of risk managers are to determine what hazards or practices present more risk than society is willing to accept and to consider what control options are available [32]. These options must be effective and efficient in mitigating risks. The risk managers usually present the risk assessors with several options (posed in the form of questions) to be evaluated. The risk assessors evaluate the options, to determine and compare the extent to which they may reduce the public health risk.

At the outset of this risk assessment, three questions important to risk managers were considered:

1. What is the exposure to *L. monocytogenes* from consuming RTE foods prepared in retail facilities?
2. What are the key processes that increase RTE food contamination at retail?
3. How much is the relative risk per serving reduced when specific risk management practices are implemented?

These broad risk management questions were further expanded as a list of more specific questions to be evaluated (e.g., via scenario analyses) within the risk assessment. Some of the questions were generated by FDA and FSIS risk managers, and others were provided by stakeholders. These include risk management questions related to sanitation, retail behavior, and levels of *L. monocytogenes* on RTE products entering retail delis for further preparation.

1) What is the public health impact of more frequent or extensive retail deli cleaning procedures than those specified in the 2009 FDA Food Code?
2) What is the potential public health impact of increasing the use of single-service gloves in the retail environment?
3) What if scale touch pads, refrigerator and deli case handles, and other frequently touched non-food-contact surfaces were considered food-contact surfaces and were therefore required to be cleaned and sanitized at a minimum frequency?
4) What if practices were in place so that no cross contamination occurred in delis (i.e., no further *L. monocytogenes* were added to incoming RTE products)?
5) What if display cases were not touched with gloved or bare hands (i.e., tissues or automatic door open/shut were used)?

6) What would be the potential public health impact if the level of *L. monocytogenes* contamination on RTE foods coming into the retail deli were at higher level (cfu/gram)?[32]
7) What would be the potential public health impact of "pre-slicing" all RTE products *vs*. "slicing to order" (hypothesis: less cross contamination occurring in the morning prior to other cross contamination events)?
8) What would be the potential public health impact of using separate slicers and/or separate counters for RTE products that permit growth of *L. monocytogenes* and for those RTE products that do not support growth of *L. monocytogenes*?
9) What would be the potential public health impact of lowering the level of environmental transfers from environment to food?
10) What if food workers did not slice RTE products directly onto their gloved hands?
11) What is the potential public health impact of *L. monocytogenes* growth in retail delis?
12) What would be the potential public health impact of complete compliance to the cold-holding requirements for certain RTE foods in deli cases [i.e., 2009 FDA Food Code guidance: hold at 41°F (5°C) or less]?
13) What would be the public health impact of shortening the time a RTE product can be used in a deli department (i.e., before it is discarded)?
14) What would be the potential public health impact if all (or no) RTE products (e.g., deli meats and deli salads) coming into the deli were formulated with growth inhibitors?

3.2. Scope and objectives of the risk assessment

The objective of this risk assessment is to assess the risk of foodborne illness associated with current practices and to examine how that risk may be impacted by mitigations that may reduce or prevent *L. monocytogenes* growth or contamination in RTE foods prepared in retail deli settings.

The risk assessment is designed to cover RTE foods that are: *i*) regulated by both FSIS and FDA; *ii*) sliced, prepared, and/or packaged in the retail deli environment and consumed in the home, such as deli meats, cheeses, and deli-type salads; *iii*) sold in a retail deli environment, which refers to a range of retail types, such as delicatessen departments of major and large grocery chains, supermarket facilities, and other groceries (i.e., multipurpose, independent, small, or local facilities). Restricting the scope of the risk

[32] This scenario would evaluate the potential increased risk posed from an increased contamination level of *L. monocytogenes* in RTE foods at retail delis.

assessment to foods that are intended to be "consumed in the home" means that restaurants or other establishments where the RTE foods are consumed on-site were not included.

The risk assessment model simulates the retail environment and evaluates how changes in various retail sanitary and food handling practices may influence the U.S. risk of listeriosis from consuming RTE foods that were sliced, handled, or prepared in retail grocery delis. The model also predicts which mitigation strategies confer the greatest benefits in reducing the risk of listeriosis. This may provide risk managers with information needed to inform retail food safety decisions regarding policy changes for retail facilities and promote industry "best practices."

This risk assessment is intended to be used to refine retail food safety practices and mitigation strategies, to further control *L. monocytogenes* in RTE foods.

4. Conceptual Model and Framework

The risk assessment model is unique in its ability to quantitatively link activities and changes in retail deli practices to public health outcomes. Model inputs are the stochastic working routines of deli workers, *L. monocytogenes* concentrations of incoming product, environmental contamination of food-contact sites, and cross contaminations among those sites. The model simulates the *L. monocytogenes* concentrations and prevalences in products sold to customers, predicts changes in concentrations during customer home storage, and estimates the risk of listeriosis from these sales. By serving as a "virtual deli," the model allows for quantitative assessment of listeriosis risks from activities or proposed changes to the retail deli operation.

To estimate risk per serving, the processes (notably, cross contamination, bacterial growth, and/or bacterial inactivation/removal) that lead to the level of bacterial contamination present when the RTE product is sold have to be considered. A specific discrete-event simulation model was developed for this purpose. The output of the discrete-event model is a distribution of number of *L. monocytogenes* per RTE product sold by the retail deli. An estimate of growth of *L. monocytogenes* on RTE product includes growth during transport from the retail deli to the home, as well as growth during storage in the home's refrigerator. The risk of listeriosis, per serving, is eventually derived from the concentration in the RTE product at the time of consumption, the serving size, and a dose-response model.

4.1. A discrete-event simulation to track L. monocytogenes in the retail environment

Cross contamination is an important process to model in food safety risk assessments. Cross contamination at retail has the potential to change the final dose at consumption and to lead to a greater number of contaminated servings of food leaving the deli. Because *L. monocytogenes* can grow at refrigerated temperatures, initial low levels of bacteria resulting from cross contamination could grow to higher levels during retail storage and consumer transport and storage. Cross contamination also can increase the level of *L. monocytogenes* on food already contaminated with the bacterium, again increasing risk of illness. Given these various factors, risk assessments that incorporate cross contamination modeling have greater data needs and require simulation of a broader number of variables than do typical quantitative microbial risk assessments.

Cross contamination is defined here as the transfer of bacteria from one food compartment or site to another. It is commonly used to describe the transfer of pathogens among different food groups and

environmental surfaces during food production. Cross contamination models affect the analysis of exposure in the risk assessment directly. In addition to the time-temperature growth modeling common to most risk assessments, models of cross contamination in food usually distinguish between variables or compartments that need to be simulated and events or handling procedures that allow the bacteria to transfer from one compartment to another [e.g., 33, 34-37]. For each compartment, the bacterial concentrations are modeled through time. Examples of compartments for a retail environment might include:

- different food groups, with possible distinction of surface concentrations versus interior concentrations;
- workers' hands and clothing;
- slicers and other equipment;
- food-contact surfaces, such as countertops; and
- other environmental locations (e.g., refrigerated storage areas and floors).

The compartments established for a food processing plant may be different from those established when modeling a retail deli environment.

Events over time that cause bacteria to be transferred from one compartment to another also must be simulated. Examples of events in the retail environment might include:

- handling chubs while transferring from storage to countertop and then from countertop to slicer;
- slicing a chub;
- washing hands;
- cleaning equipment; or
- cleaning food-contact surfaces.

The compartments that are impacted and the frequency of each event are part of the cross contamination model input.

A discrete-event-type model was selected as the most appropriate framework for the charge of this risk assessment. In discrete-event simulation, the operation of a system is represented as a chronological sequence of events. Each event occurs at an instant in time and marks a change of state in the system. Cross contamination occurs when specific sites are brought in contact (e.g., when a chub is placed on a slicer). Bacterial transfer occurs only at these discrete events. A major advantage of this framework is the flexibility and granularity that the approach provides. Additional events can be inserted or several events can be merged into one without changing the overall model. The process is illustrated in Figure 2. A

major event is selected stochastically (e.g., serving a customer or cleaning the deli area). If appropriate, this major event can be broken down into a series of more granular activities (e.g., removing a chub from the case or slicing a chub). This sequence of events can also be developed stochastically, as shown in Figure 3.

Each 'YES/NO' branch can be based on probabilities. The level of granularity can be modified as needed. This flexibility is especially important, because it enables risk management questions to be added.

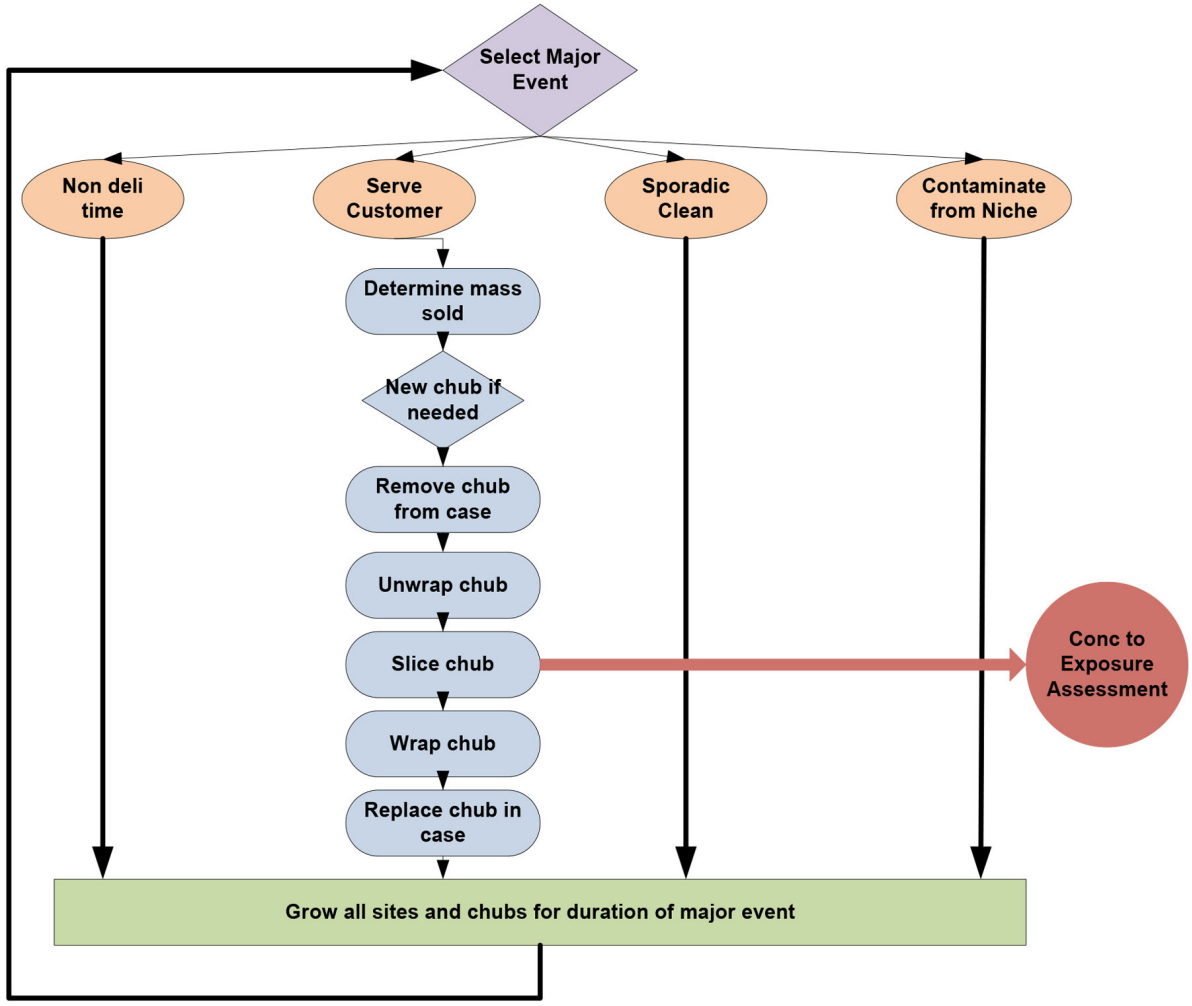


Figure 2: Illustration of the discrete-event cross contamination model component of the Interagency Risk Assessment: *L. monocytogenes* in Retail Delicatessens

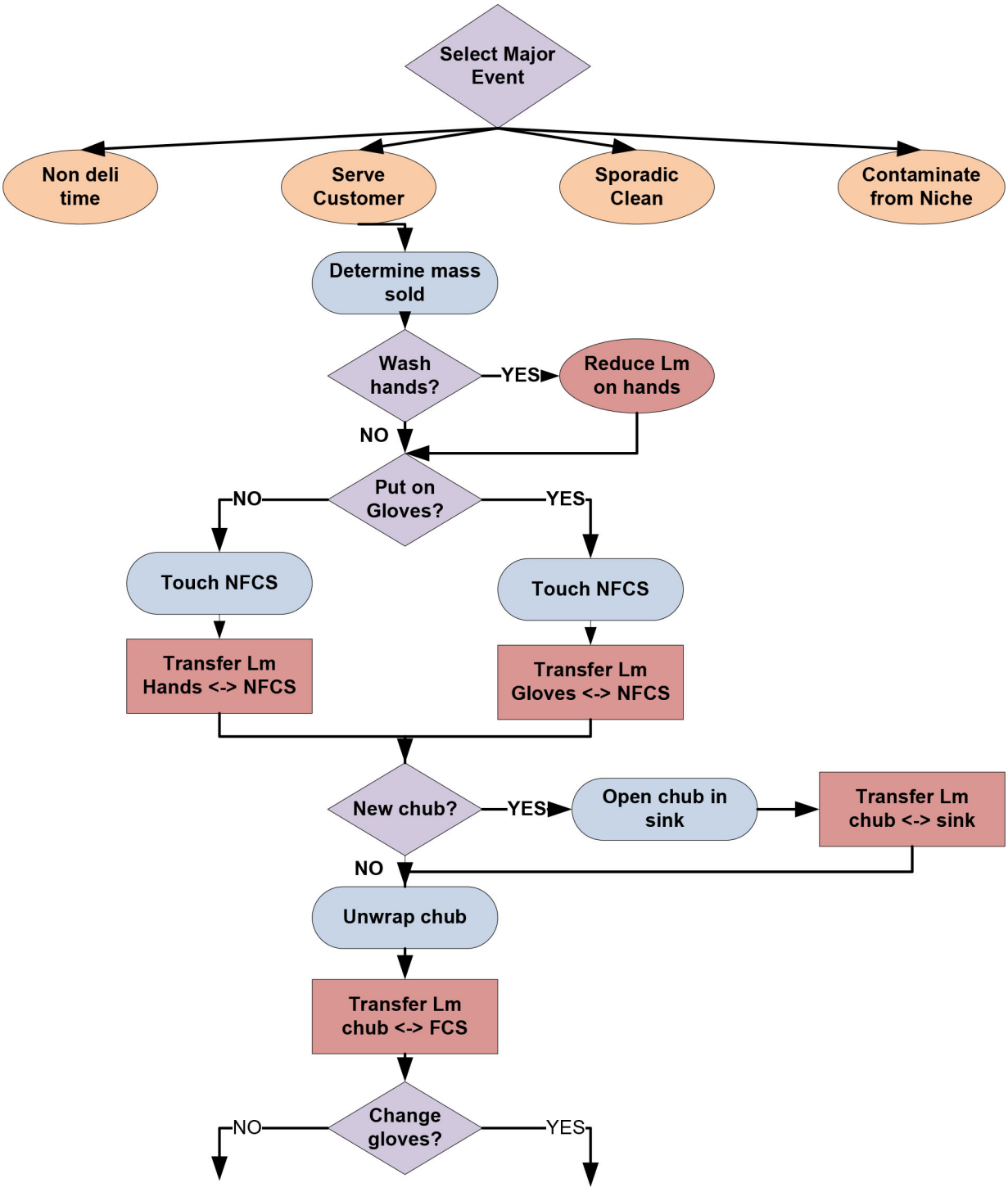


Figure 3: Illustration of stochastic decision tree within the discrete-event model of the Interagency Risk Assessment: *L. monocytogenes* in Retail Delicatessens

4.2. Overview of the "virtual deli," its operation, and the impact on L. monocytogenes

A graphical depiction of the "virtual deli" model, along with possible *L. monocytogenes* transfer routes, is provided in Figure 4. The retail deli food worker is depicted on the lower left.

Food RTE products are shown on the left. The current model is designed for three major food categories: deli meats, deli cheeses, and deli salads. Although not shown here, each of these food categories is broken down into more specific types. Each of these specific RTE products has associated growth rates and probability of being sold. Each RTE food also is tracked for age of the product. Older product is disposed of in this model (see section 6.5.2).

Sites within each retail deli are shown on the right. Vertical arrows at a site indicate the possibility of *L. monocytogenes* growth (up arrow) or removal by cleaning (down arrow). In practice, only *L. monocytogenes* growth for RTE products was actually used for model scenarios. Asterisks at a site indicate the possibility of a niche. The model is flexible, in that any site may harbor a niche. Those shown are illustrative of the multiple niche scenarios described below. Arrows between sites, workers, and RTE products indicate the potential cross contamination routes. RTE food servings leaving the retail deli (i.e., RTE products sold) are depicted in the upper left.

The risk assessment model is flexible also in that it readily allows the addition of new RTE products, sites, or transfer routes. For example, this risk assessment model currently includes a floor as one of the sites, but no transfer of *L. monocytogenes* route exists from the floor to RTE food, based on a retail deli observational study [28]. However, such a site, event, and transfer could be readily added to this flexible risk assessment model.

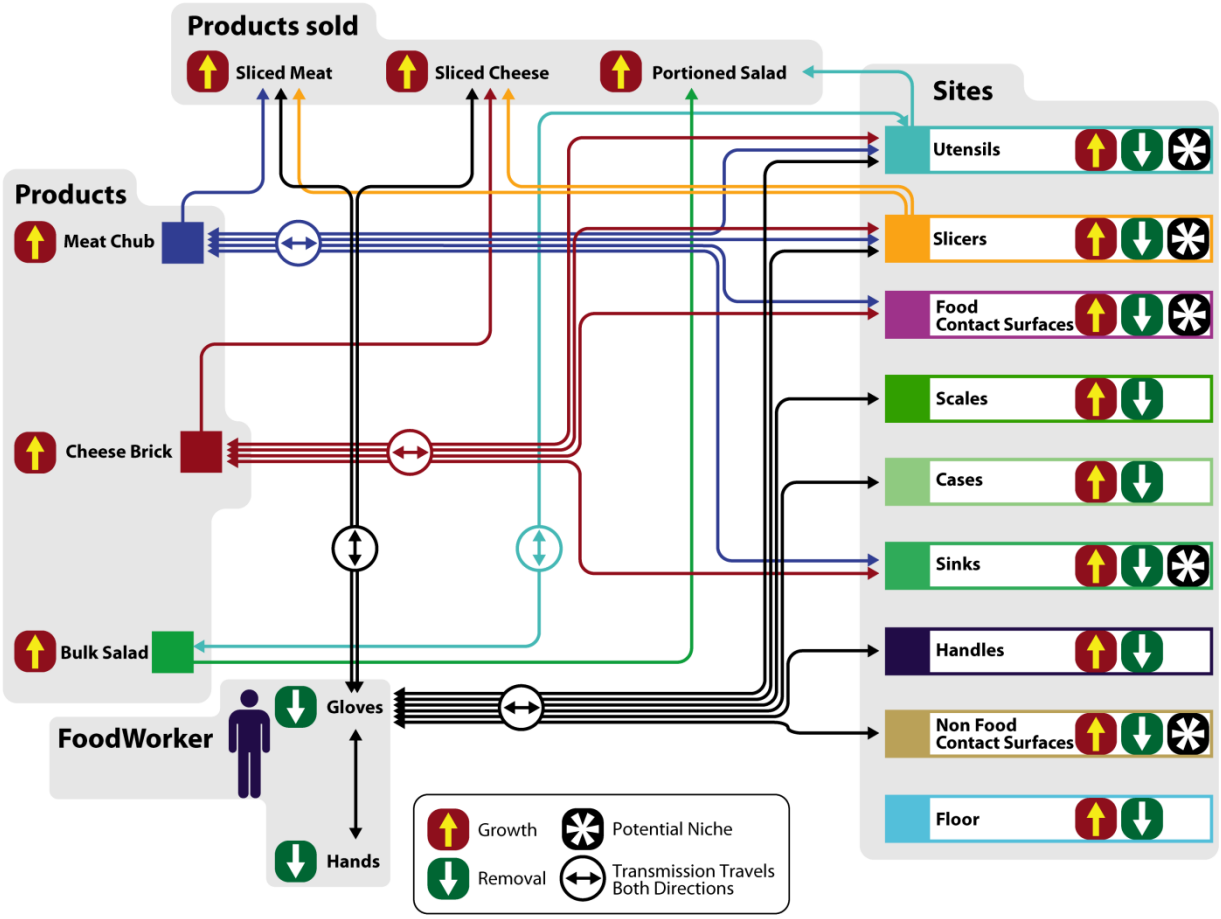
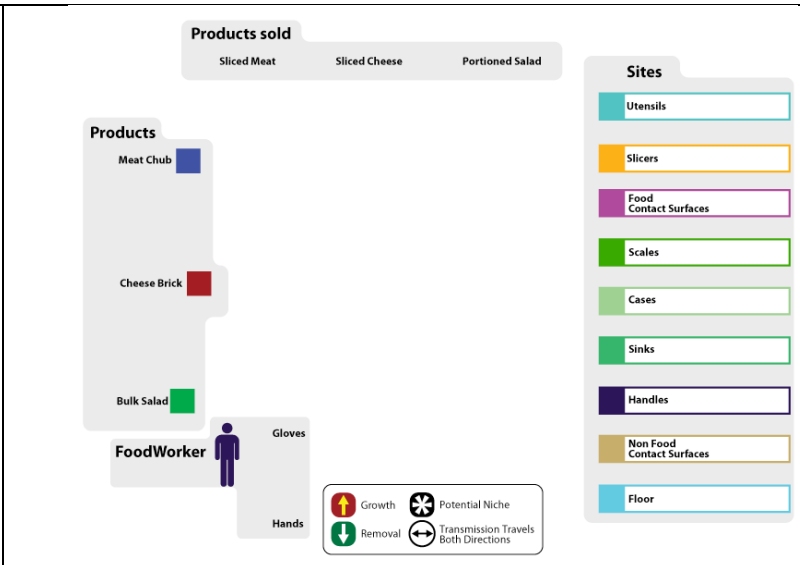


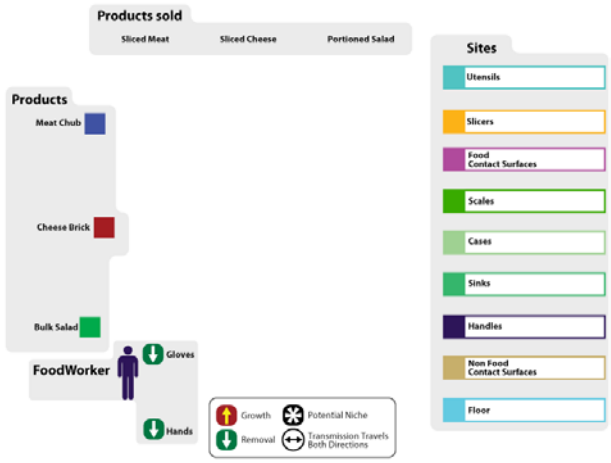
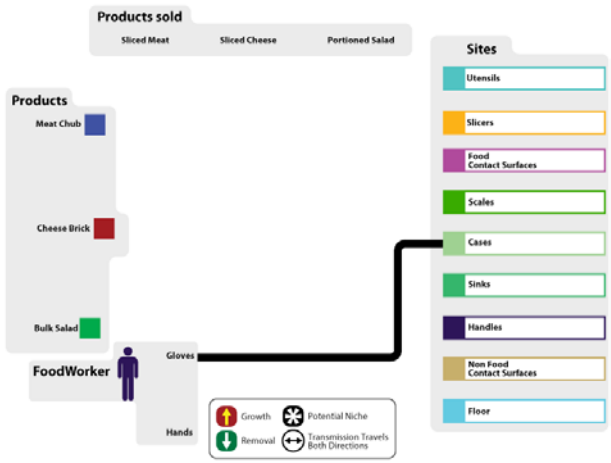
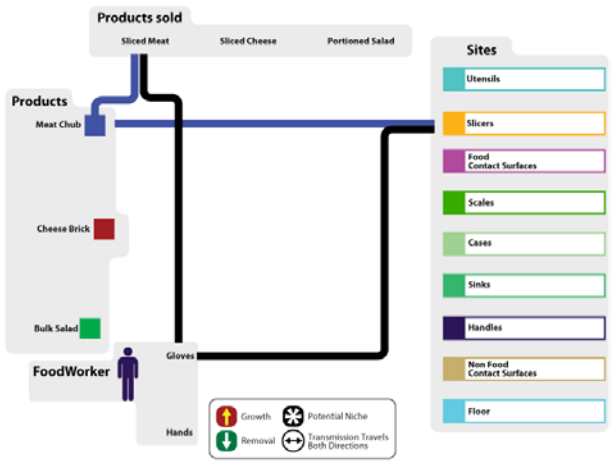
Figure 4: Diagram of "virtual deli" and cross contamination routes within the model of the Interagency Risk Assessment: *L. monocytogenes* in Retail Delicatessens

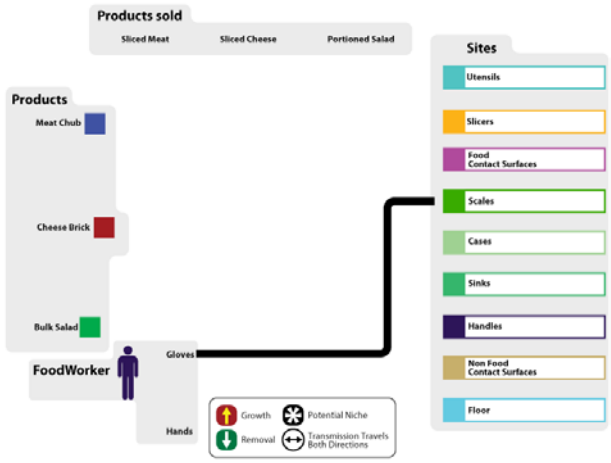
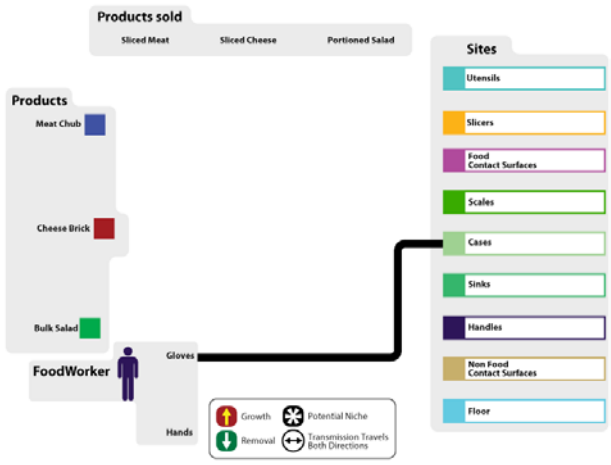
The diagram in Figure 4 appears complicated, with a large number of cross contamination routes. However, the discrete-event model framework considers a limited number of site interactions at any time, over a long period. Table 1 depicts this scenario for a "serving a customer" event. At the beginning of the event, the *L. monocytogenes* concentrations for each site and chub are known. The first activity is to wipe down the slicer, which reduces the concentration of *L. monocytogenes* at that site (note the down arrow). The next activity is for the worker to wash his or her hands and put on gloves. This reduces the concentration on the worker's hands and adds a new location (glove) to track. The third activity is to get the chub from the case. This brings in contact the worker's gloves and the case handle, with subsequent potential cross contamination between worker's gloves and the case handle. The fourth activity is to slice the chub. This allows cross contamination among the worker's gloves, slicer, chub, and future serving. The fifth action is to weigh the serving and touch the scale. Cross contamination can occur between the

worker's gloves and the scale. Finally, the chub is placed back in the case, with a contact between the gloves and the case. At each stage, the number of sites involved and level of contamination being updated is small, but the cumulative effect is a mechanistic model of cross contamination, over time, in a retail environment.

Table 1: Illustration of site interactions and cross contamination while serving a customer

Example: Serve Customer Event	
1. Wipe Slicer Removes some bacteria from the slicer.	

2. Wash hands and change gloves Removes some bacteria from hands	
3. Open case, remove chub, and close case Cross contamination between gloves and case	
4. Slice onto gloves Cross contamination among gloves, slicer, and chub	

5. Touch scale Cross contamination between gloves and scale	
6. Open case, replace chub, and close case Cross contamination between the gloves and the case	

4.3. Considering model variability and uncertainty

According to international scientific recommendations [38, 39], a quantitative food safety risk assessment should reflect the variability in the risk and evaluate separately the uncertainty associated with the risk estimates. Variability represents temporal, geographic, and/or individual heterogeneity of the food safety risk for a given population. Uncertainty is understood as stemming from a lack of perfect knowledge about the risk assessment model structure and associated parameters. Variability and uncertainty should be treated separately, because each has different risk management implications.

Variability explains differences from one retail deli to another – both in terms of size of the retail deli and corresponding amount of equipment (e.g., number of slicers, etc.) and the operating procedures used. Additionally, operations in the retail deli, bacterial growth, cross contamination, consumption, etc., are simulated individually using stochastic processes. For each retail deli, a time-series (i.e., a series of

L. monocytogenes concentrations at each location within the retail deli and for all servings sold chronologically) is developed. The time series includes a sufficiently large number of servings to evaluate specific operating practices (i.e., the statistics of the time series have stabilized).

The model is written as a full second order Monte Carlo model that distinguishes variability from uncertainty [40] (Figure 5). It was assumed that the uncertainty surrounding the existence and the "behavior" of the niches overwhelmed the other sources of uncertainty. It was thus decided to illustrate this uncertainty through the comparison of various baselines (e.g., by comparing the various scenarios within a retail deli with multiple niches versus within a retail deli without niches) (see section 7).

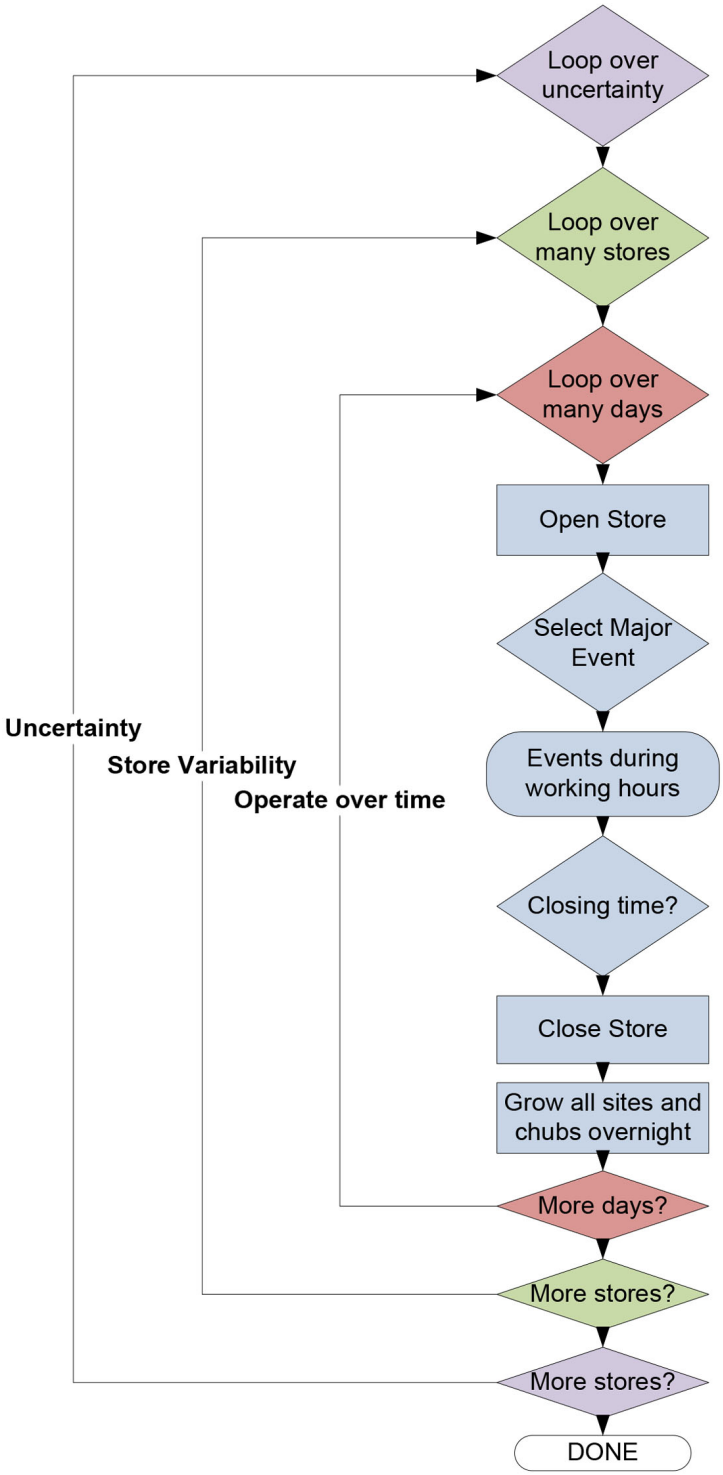


Figure 5: Illustration of developed time-series based on variability within and among retail delis and uncertainty of existence and location of niches within the retail deli

5. Data Collection

The Interagency Retail *L. monocytogenes* Risk Assessment Workgroup commissioned a number of studies to fill specific data needs for the conduct of this risk assessment. These studies were listed in Section 2.3 and include retail worker behavior data (University of Maryland and CDC/EHS-Net studies), environmental sources of *L. monocytogenes* in retail delis (Cornell University), and simulation of the transmission of *L. monocytogenes* in mock retail delis (Virginia Tech).

In addition, the Interagency Retail *L. monocytogenes* Risk Assessment Workgroup conducted a systematic review of the literature regarding the various domains covered by the considered model. This systematic review included scientific literature on bacterial transfer (including during the slicing process), bacterial growth, bacterial inactivation through cleaning and disinfection, retail data, and consumer handling of food. The group synthesized the available scientific evidence to derive probability distributions and mathematical models.

For that purpose, the relevant peer-reviewed scientific literature was identified using the National Center for Biotechnology Information (NCBI) PubMed database, cross references in related published manuscripts, and auxiliary data sources, such as the Google® search engine. Literature searches for transfer coefficients (including those specific to slicers) and for cleaning and sanitizing were performed in June 2009 and December 2010, respectively. Initial queries for transfer coefficients were run in the NCBI PubMed database using the terms 'cross contamination,' 'transfer,' and 'bacteria,' followed by identification of additional manuscripts through cross-referencing in the studies identified in the initial query. For studies of cleaning and sanitization, the NCBI PubMed database and Google were searched using 23 relevant keywords, screening all NCBI PubMed results and the first 15 pages in the Google® database for each query. This meta-analysis of available data was published as a scientific paper in the International Journal of Food Microbiology [37]. The probability distributions and mathematical models derived within this study were used to predict *L. monocytogenes* cross contamination and inactivation in the current model.

Other in-house data collection and meta-analyses were developed in the framework of this study. These meta-analyses included studies on bacterial growth, including the presence of growth inhibitors, consumption data, temperature data, dose-response models, etc. The results are provided within this report, in the corresponding sections or as appendixes.

6. Comprehensive Description of the Risk Assessment Model

6.1. Modeling the basic processes for L. monocytogenes

Within an exposure assessment, Nauta [41, 42] suggests describing and modeling the RTE product pathway as a succession of "basic processes" impacting the prevalence and level of bacteria in the RTE product. The basic processes are the six fundamental events that may affect the prevalence and/or level of any microbial hazard in food processing. The basic processes used in the current model are:

- cross contamination: a transmission of bacteria from one unit (object or food) to another one. The terms "cross contamination" and "transfer" will be used interchangeably;
- bacterial growth: the multiplication of microorganisms (or growth of the population); this basic process is a typical characteristic of quantitative microbial risk assessment;
- bacterial inactivation: sanitation process is frequently an applied food safety and food preservation strategy. The chemical inactivation and physical removal of bacteria *via* washing and wiping, as well as the removal of bacteria *via* the disposal of contaminated objects (e.g., putting gloves in the trash) are included in this basic process within this risk assessment;
- partitioning: occurs when a large unit is split into several units.

In the current model, bacterial growth may occur in food all along the RTE product pathway, from entry into the deli through to consumption. Bacterial inactivation occurs during sanitizing, washing, and wiping. Partitioning will be encountered during the slicing of cheese and deli meat, as well as during the scooping of salad from a bulk container. Eventually, transfer of bacteria from the environment, i.e., cross contamination, occurs in the deli.

This section describes the general rules, models and data used to model these basic processes. The transfer of bacteria is a transfer of a finite number of cells. As a consequence, the number of bacteria per site / food / niche is considered, and not the concentration of bacteria. In other words, bacteria are tracked as colony forming units (cfu) at a location, not as a representative mass or area-based concentration.

6.1.1 Cross contamination

In this report, the definition of cross contamination is enlarged to include any transfer of bacteria from one site, food, or niche to another.

Cross contamination between two objects

The probabilistic derivation of the model is as follow [37]: given N_1, the initial number of bacteria on a given object (#1), and N_2, the initial number of bacteria on another object (#2). T_{12} is the transfer coefficient ($0 \leq T_{12} \leq 1$) from object #1 to object #2, and T_{21} is the transfer coefficient ($0 \leq T_{21} \leq 1$) from object #2 to object #1. F_1, the final number of bacteria on object #1, and F_2, the final number of bacteria on object #2, are derived stochastically using the following algorithm:

$$x_{11} \sim \text{binomial}(N_1, 1 - T_{12})$$

$$x_{21} \sim \text{binomial}(N_2, T_{21})$$

$$F_1 = x_{11} + x_{21}$$

$$F_2 = N_1 + N_2 - (x_{11} + x_{21})$$

The underlying assumptions for this model are:

1) the two populations N_1 and N_2 "act" independently;
2) within each population (N_1 and N_2), each bacterium "acts" independently (i.e., the probability of transfer for all bacteria from one object to the other is equal and constant for a given cross contamination). Using a binomial process assumes that the result is the sum of N_1 independent Bernoulli assays;
3) no bacteria are lost during the transfer; and
4) the transfer coefficients T_{12} and T_{21} are independent of the initial number of bacteria.

Various transfer models have been developed and used in the literature [5, 33-35, 43-49]. In most, the independence of transfer (i.e., assumption #2) is assumed. The most discussed assumption is linked to the independence of the transfer coefficient and the initial number of bacteria (i.e., assumption #4). Montville and Schaffner [50] and Fravalo et al. [51] suggest that the transfer from contaminated objects is inversely related to the initial load. Rodriguez et al. [52] did not confirm this observation. Eventually, Nauta [53] shows that the observation of a relationship between the transfer rate and the initial level of contamination can be explained by an artifact linked to the limit of detection. He concludes that "so far, there is no evidence that bacterial transfer rates are inversely related to the initial level of contamination," and this assumption is used in the model.

Transfer coefficients were thus considered as independent of the number of bacteria, while variable from transfer to transfer. A complete literature review was performed [37], to develop the distribution of

transfer coefficients for various source-recipient couples (e.g., Stainless steel - Meat). The $\log_{10}$[33] normal distribution was eventually chosen on the basis of published data and our assays' ability to reflect the variability of transfer coefficients for a given source-recipient couple. Given M_{Tij} (i.e., the mean of the $\log_{10}$ of transfer coefficient from the object *i* to the object *j*) and S_{Tij} (i.e., its standard deviation), a transfer coefficient T_{ij} is sampled for each new transfer using:

$$\log_{10}(T_{ij}) \sim \text{Normal}(M_{Tij}, S_{Tij}).$$

If the sampled value leads to $T_{ij} > 1$, then T_{ij} is set to 1 (and thus all bacteria are transferred).

Cross contamination between more than two objects

The model can be extended to transfers between *k* objects [37]. Let N_i equal the initial number of bacteria on object *i* before transfer, and N_j equal the initial number of bacteria on object *j* before transfer, with $i,j \in [1, k]$. Following the same notation and rationale as above,

$$x_{ii} \sim \text{binomial}\left(N_i, \prod_{j \in K, j \neq i}\left(1 - T_{ij}\right)\right)$$

with $K = (1, .., k)$, and $x_{ij,}$ the number of bacteria transferred to object *j* from object *i*, is distributed as

$$x_{ij, j \neq i} \sim \text{multinomial}\left(N_i - x_{ii}, \frac{T_{ij, j \neq i}}{\sum_{j \in K, j \neq i} T_{ij}}\right).$$

For the same reasons as above, $F_{i,}$ the final number of bacteria on object *i* after transfer, equals:

$$F_i = \sum_{j=1}^{k} x_{ji}.$$

Cross contamination during the slicing process

Slicing is a complex process in terms of bacterial transfer [54]. The objective here was to derive a model that could mimic the cross contamination linked to the use of a slicer in retail and that could be in accordance with the studies developed on the subject [21-23, 54-58]. Modeling the slicing process may indeed be challenging: "The following are the factors that can impact the transfer of *L. monocytogenes*: (1) the compositions of deli meat (moisture, fat content, formulation, and so on), (2) the cut surface characteristics (texture, homogeneity) of deli meat, (3) the rotational speed or revolutions per minute (rpm) of the cutting blade, (4) the diameter of the blade, (5) the sharpness (or profiles) and material of the

[33] Note: in this document, ln is the logarithm of base e (natural logarithm) and $\log_{10}$ is the logarithm of base 10.

blade, (6) the back pressure from meat loaf (weight force exerted to contact blade surface by gravity and/or the end weight attachment), (7) the slicing speed (for example, slices per minute), (8) the contact angle, area, and slice thickness, (9) the microorganism (age, strain, inoculum size, capability to adapt different stresses, adhesion to surfaces, and so on), and (10) the environmental condition (for example, temperature and so on)." [58].

The experimental assays provided in the literature are not sufficient to model the impact of all these covariates. The models that are developed in the literature are empirical and cannot be used in a stochastic discrete-event model. A general compartmental model that is in accordance with the literature observations had to be derived instead.

The model considers two parts for the chub (both meat and cheese):

- the head of the chub (*HC*), contaminated by the blade during the slicing process,
- the remainder of the chub (named here "core of the chub" *CC*), which may be contaminated due to introduction of *L. monocytogenes* at the manufacturing stage or due to cross contamination after opening.

The bacteria that are involved in the system have three origins:

- the contamination of the core of the chub;
- the contamination of the head of chub;
- the contamination of the slicer.

The following simulation process is used:

1. Given CC_0, the number of bacteria in/on the core of the chub of mass M_0, given m the mass of a slice and assuming a homogeneous distribution of the *L. monocytogenes* on/in the chub, the number of bacteria newly involved in the process is $I_0 \sim \text{binomial}(CC_0, m/M)$. The remaining number of bacteria in/on the core of the chub is then $CC_1 = CC_0 - I_0$. The remaining mass of the chub is $M_1 = M_0 - m$.
2. The number of bacteria from the chub, C_0, eventually involved in the slicing process is the newly involved number of bacteria I_0 and the number of bacteria on the head of the chub HC_0: $C_0 = I_0 + HC_0$.
3. During the slicing process,
    - a part of these C_0 bacteria are transferred to the slicer following $C_s \sim \text{binomial}(C_0, a)$, with $0 \leq a \leq 0.5$, a parameter. The remaining stay on what becomes the slice $C_y = C_0 - C_s$;

- a part of the S_0 bacteria stays on the slicer $S_s \sim \text{binomial}(S_0, 1 - 2a)$. On average, half of the bacteria transferred from the slicer are transferred to the (new) head of the chub according to $HC_1 \sim \text{binomial}(S_0 - S_s, 0.5)$, and the remaining are transferred to the slice $S_y = S_0 - S_1 - HC_1$.
- $Y = C_y + S_y$ is the number of bacteria on the slice. $S_1 = S_s + C_s$ is the number of bacteria on the slicer at the end of the slicing process.

The process is repeated n times to obtain n slices.

Figure 6 illustrates this model, also described in Hoelzer et al. [37]. This process is in accordance with the experimental data that *i*) generally show a log linear decrease of the number of bacteria, which contaminates successive slices of RTE products; and *ii*) suggest a cross contamination between the slicer, the chub, and the RTE product that is sold [21-23, 54-58].

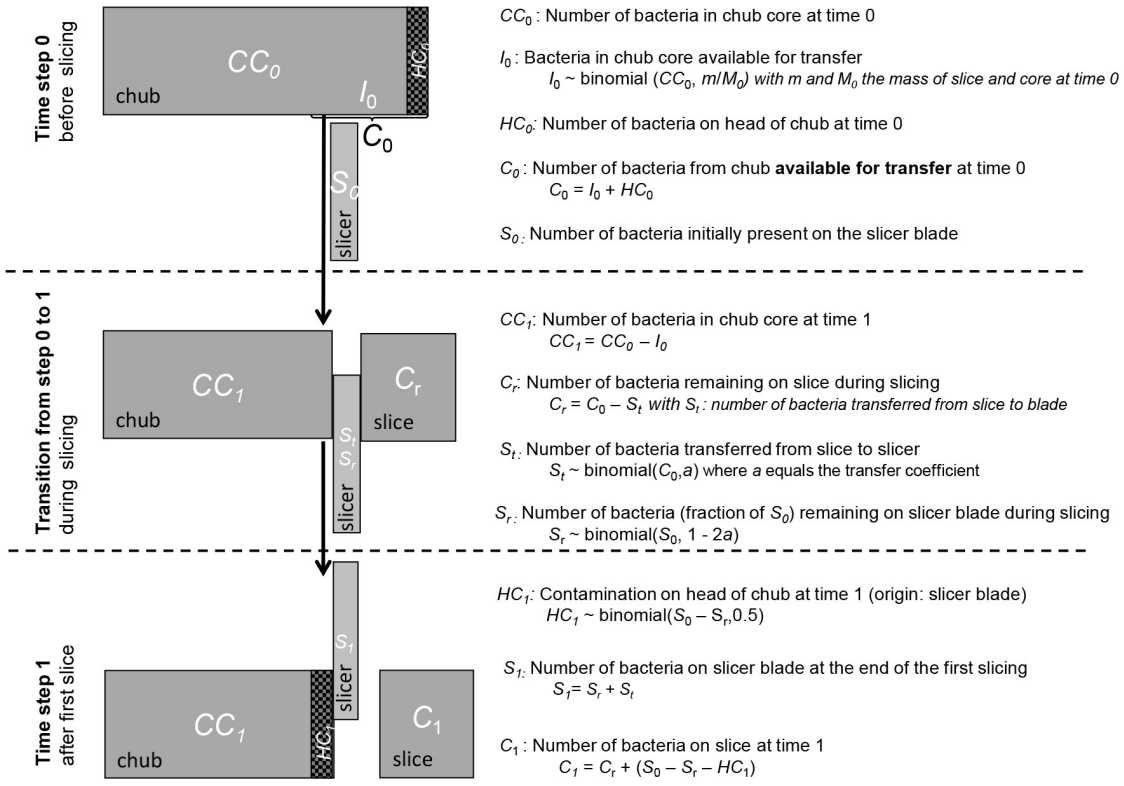


Figure 6: The slicer model

(Source: [37])

A literature review of the available scientific articles dealing with slicers was performed. The exhaustive review is detailed in Hoelzer et al. [37]. The only experimental designs considered were those in which *i*) a blade is artificially contaminated, and *ii*) RTE products are contaminated by the blade during the slicing process [23]. The inferred distribution for the parameter a is a logistic distribution with location parameter 0.07 and scale parameter 0.03. The mean and median of the distribution for a are 8.1% and 7.7%, respectively.

Cross contamination during scooping process

Similarly, a model was derived for the specific process of scooping deli salad from the bulk container.

The following simulation process is used:

1. Given CC_0, the number of bacteria in/on the salad bulk of mass M_0, and given m the mass of the serving and assuming a homogeneous distribution of the *L. monocytogenes* on/in the salad, the number of bacteria newly involved in the process is $C_0 \sim \text{binomial}(CC_0, m/M)$. The temporary remaining number of bacteria in/on the core of the salad bulk is then $(CC_0 - C_0)$. The remaining mass of the salad bulk is $M_1 = M_0 - m$.
2. During the scooping process:
    - The utensil contaminates the serving and the remaining bulk salad: a part of the U_0 bacteria present on the utensil will stay on the utensil according to $U_u \sim \text{binomial}(U_0, 1 - TC_{us})$, where TC_{us} is the transfer coefficient from the utensil to the salad. It is assumed that, on average, half of $(U_0 - U_u)$ bacteria transferred from the utensil are transferred to the top of the salad according to $TS_1 \sim \text{binomial}(U_0 - U_u, 0.5)$, and the remaining are transferred to the serving $S_u = U_0 - U_u - TS_1$.
    - The serving contaminates the utensil: a part of the C_0 bacteria present in the serving are transferred to the utensil following $C_s \sim \text{binomial}(C_0, TC_{su})$, where TC_{su} is the transfer coefficient from the salad to the utensil;
    - The remaining bulk salad contaminates the utensil: it is assumed that the utensil is in contact with a m/M_1 part of the remaining salad (i.e., to $R_0 \sim \text{binomial}(CC_0 - C_0, m/M_1)$ bacteria). A part of these bacteria, $R_1 \sim \text{binomial}(R_0, TC_{su})$, will be transferred to the utensil;
3. The remaining number of bacteria in the bulk container of salad is the initial number of bacteria in the bulk minus the number of bacteria that were in the serving minus the number of bacteria that contaminate the utensil plus the number of bacteria transferred from the utensil, (i.e., $CC_1 = CC_0 - C_0 - R_1 + TS_1$);

4. The number of bacteria in the serving is the original number of bacteria from the bulk salad minus those that transferred to the utensil plus those that transferred from the utensil, (i.e., $S_1 = C_0 - C_s + S_u$).
5. The number of bacteria on the utensil at the end of the scooping process is the number of bacteria that were not transferred to the salad or the serving plus the number of bacteria transferred from the serving plus the number of bacteria that transferred from the remaining salad, (i.e., $U_1 = U_u + C_s + R_1$).

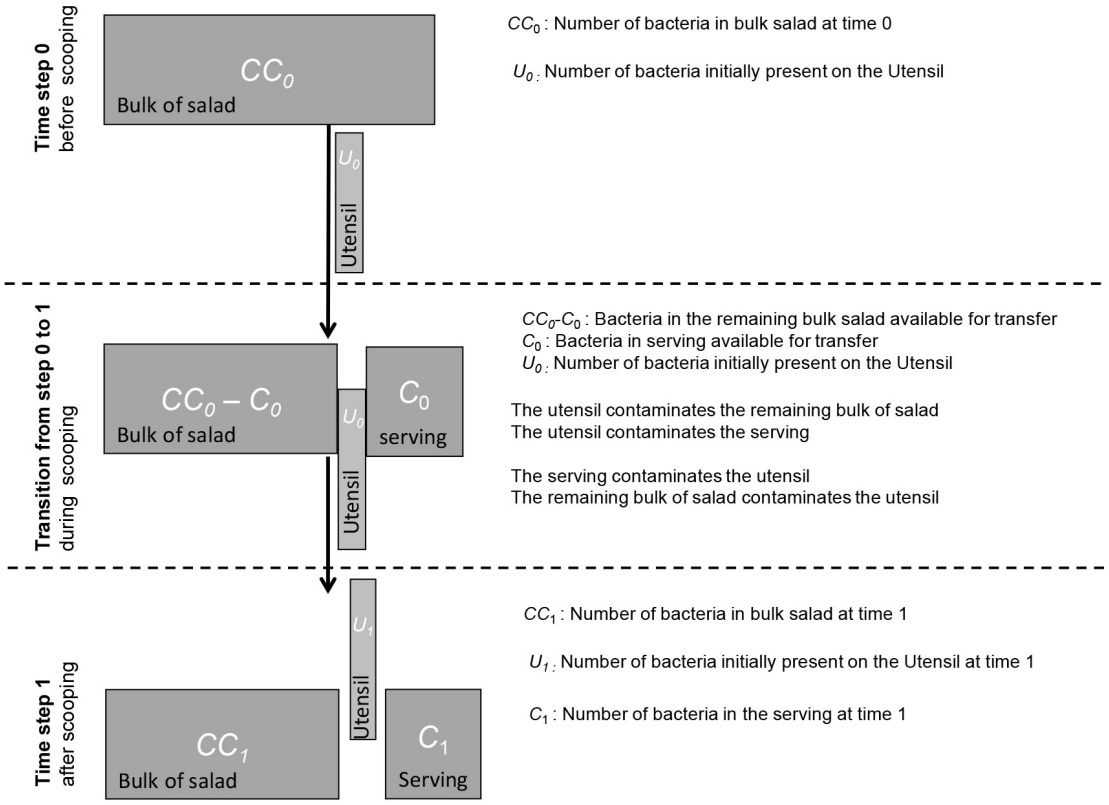


Figure 7: Illustration of the scooping model

Cross contamination from a niche / Contamination from the environment

A niche or harborage site is a location associated with a site where bacteria can reside and resist normal cleaning and sanitation procedures. Existing literature provided little insight into the development of a conceptual model for the transfer of *L. monocytogenes* from niches to RTE foods. As such, a very simplified model was developed to consider the presence of niches in the retail environment:

- Each niche is associated with an existing site within the model. Transfer from the niche only occurs to its associated site. Once bacteria transfer out of the niche to the associated site, they

become part of the site's bacteria count and can move to other sites through classical cross contamination;

- The probability for a site to have a niche is specified by the user;
- From time to time, the niche releases a fixed number of bacteria to the site. This number is specified by the user; and
- The occurrence of release is assumed to follow a Poisson process. The time to the next release from the niche is then assumed to follow an exponential distribution with mean λ also specified by the user.

As an example, the user can specify a probability of having a niche associated with a deli case as 0.5, a number of transferred bacteria as 1,000 cfu, with a release of bacteria occurring, on average, every 168 hours of operation. In this context, if a niche is present, 1,000 cfu will be transferred to the corresponding case, on average, every 168 hours of operation.

Note that this concept could either simulate the presence of a niche or, similarly, the presence of a regular contamination from an external source. This could mimic, as an example, a food worker who would regularly (on average, every 168 hours of operation) place a contaminated object, such as a milk crate, on the food-contact surface, with a transfer of 1,000 cfu.

6.1.2 Bacterial growth

Bacterial growth is one of the important basic processes that leads to exposure to, and risk from, *L. monocytogenes* [3, 59].

Growth models in food

Predictive microbiology is a science whose object is to predict the size of a bacterial population according to the environment of the bacteria. Predictive microbiology in food has expanded in recent years and now provides interesting tools for risk assessment purposes [60, 61].

In predictive microbiology, a "primary model" is a model that predicts the evolution of the size of the bacterial population according to time in a given environment. The "secondary model" is a model that evaluates the evolution of the parameters of the primary model according to the environment.

Primary growth model

The primary model predicts the number of cells with time. A popular growth model is the exponential "tri-linear" model [61, 62]:

$$\begin{cases} y(t) = y(0) & t < \lambda \\ y(t) = \min\left(y(0) + EGR \times (t - \lambda), y_{\max}\right) & t \geq \lambda \end{cases}$$

where $y(t)$ ($\log_{10}$ cfu/g) is the bacterial concentration at time t (day), λ (days) is the lag time, EGR is the exponential growth rate ($\log_{10}$ cfu day^{-1}), and y_{max} ($\log_{10}$ cfu/g) is the maximum achievable concentration in the media (Figure 8). $EGR = \frac{24 \times \mu}{\ln(10)}$, where μ is the specific growth rate (h^{-1}). This model has been described as a simple but sufficiently complex model to be used in predictive microbiology and in risk assessment [61, 62].

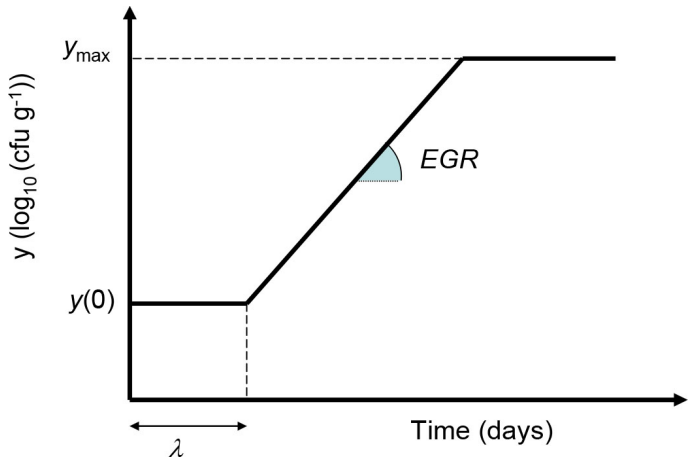


Figure 8: The "tri linear" primary growth model and its parameters

A lag time in the growth is observed in case of rapid change in the bacterial environment.

This model is purely deterministic (i.e., is suitable for a large number of bacteria). The stochastic (i.e., for a small number of bacteria) analog of the exponential phase of this model is the Yule pure birth growth model [63], as described by Vose [64], with the following premise: *i*) that individual bacteria have offspring on their own (e.g., by division), *ii*) that they procreate independently, *iii*) that procreating is a Poisson process in time, and *iv*) that all individuals in the population are the same. The expected number of offspring from an individual per unit time (over some infinitesimal time increment) is defined as μ. This leads to the result that an individual will have, after time t, a number of offspring that follow a geometric(exp(-μt)) distribution. Starting with $x(0)$ individuals (cfu),

$$x(t) \sim x(0) + NegBin(x(0), \exp(-\mu t))$$

where NegBin(n, p) is the negative binomial distribution[34] with size parameter n and probability parameter p. Note that, as desired, the expected value of $x(t)$ is[35] $x(0)\exp(\mu t)$. Then, $y(t) = y(0) + EGR \times t$ and the expectation of the stochastic model is the deterministic model.

Secondary growth model on EGR or μ

The Gamma concept [65]

The secondary models predict the change in the primary model parameters according to a change in the growth environment. Many secondary models are available [60, 61]. Most of these models may be grouped either as polynomial models or models from the gamma concept family.

The gamma concept considers the impact of multiple environmental factors on bacterial growth. The principles of the gamma concept [65] are:

- A μ_{opt} (or an $EGR_{opt} = \frac{24 \times \mu_{opt}}{\ln(10)}$) parameter is specified. This is the growth rate obtained when all environmental parameters are optimal for the bacterial growth;
- For each considered environmental parameter x_i (e.g., temperature (T), pH, water activity (a_w), nitrite concentration (*nit*), lactic acid concentration (LAC), and diacetate concentration (DAC)), a function $\gamma_i(x_i)$ is defined, with $0 \le \gamma_i(x_i) \le 1$ reflecting the impact of this environmental parameter on the growth. An additional function ξ_{int} is defined, to consider the interaction among parameters.
- Then, $\mu = \mu_{opt}\left(\prod_i \gamma_i(x_i)\right)\xi_{int}(x_1,...,x_n)$ in the considered environment; i.e.,

$$\mu = \mu_{opt} \cdot \gamma_T(T) \cdot \gamma_{pH}(pH) \cdot \gamma_{a_w}(a_w) \cdot \gamma_{nit}(nit) \cdot \gamma_{LAC}(LAC) \cdot \gamma_{DAC}(DAC) \cdot \xi_{int}(T, pH, a_w, nit, LAC, DAC)$$

The advantage of the gamma concept is that it allows independent consideration of a large number of environmental parameters. It is extensively used in the predictive microbiology domain and claimed to be universal, allowing *Listeria* growth to be modeled in a variety of different RTE products, if some of their

[34] Because the sum of n independent geometric distributions with parameter p is a negative binomial distribution with parameter n and p.

[35] The expected value of a NegBin(n, p) distribution is $n(1-p)/p$. The expected value of $x(t)$ is then $x(0)(1-\exp(-\mu t))/\exp(-\mu t) + x(0) = x(0)(\exp(\mu t) - 1) + x(0) = x(0)\exp(\mu t)$

characteristics are known [66]. This gamma concept has already been used in QRAs (e.g., in an Australian risk assessment for *L. monocytogenes* in RTE meats [67]).

The alternatives would be:

- the use of one exponential growth rate per food category, as was done within the 2003 FDA/FSIS risk assessment [3]. Nevertheless, it might be difficult to obtain some data for all kinds of RTE food (e.g., with and without growth inhibitors);
- the use of only the minimum of the γ_i factors. This is more common in environmental modeling, because of concerns that the multiplicative model is overly restrictive as more factors are considered and that μ_{opt} thus becomes a function of the number of factors;
- the use of polynomial models that predict the bacterial growth. The major drawback of these later models is that they are only applicable to the situation for which they were developed [61]. The polynomial models are of great interest for one or a limited number of food RTE products, but could not be incorporated into this model.

The disadvantage of this gamma concept approach is that the chemical characteristics of the RTE products are needed to evaluate the potential for *L. monocytogenes* growth in a RTE product, (i.e.at least the pH and a_w, if no preservative is present).

The Mejlholm and Dalgaard model

The gamma concept was extended, over time, to include more and more parameters, as well as their interactions [68-74]. In 2009, Mejlholm and Dalgaard gathered and evaluated those modules to build an extensive model for growth [75]. This model included the impact of the temperature; water activity (calculated from the concentration of NaCl in the water phase of the RTE product); pH, concentration in smoke components (phenol); concentration in nitrite; concentration of dissolved CO_2 at equilibrium; and concentrations of undissociated lactic acid, diacetate, acetic acid, benzoic acid, citric acid, and sorbic acid. The Mejlholm and Dalgaard model [75] was used in this study, but limited to temperature, pH, water activity, nitrites, sodium lactate, potassium lactate, and sodium diacetate concentration and their interactions. The model, its parameterization, and its parameters are fully described in Appendix 1.

Validation of the model

In the original paper, Mejlholm and Dalgaard [75] obtained bias and accuracy factors [76] of 1.4 and 1.6, respectively, after evaluating growth rates of *L. monocytogenes* in different types of meat products with added organic acids obtained by various authors [77-80]. A second publication from these authors compared the predictive values of this model against concurrent ones [66, 81, 82] for various RTE foods

[83]. For that purpose, 1,014 growth responses of the pathogen in meat, seafood, poultry, and dairy products were used for validation. For the Mejlholm and Dalgaard [75] model, bias and accuracy factors for growth rate predictions were 1.0 and 1.5, respectively. The performance of three other models, including the effect of five to seven environmental parameters, was lower, with bias factors of 1.2 to 1.3. Less complex models that did not include the effect of acetic acid/diacetate and lactic acid were unable to predict growth responses of *L. monocytogenes* accurately in a wide range of food.

Results

Table 2 illustrates the use and results of the growth model in various RTE foods simulated in this risk assessment (i.e., deli meat, cheese, and deli salad). The growth rates (h^{-1}) and the generation time (time for the population to double) is affected by the intrinsic properties of the products, as well as the inclusion of growth inhibitors.

Table 2: Growth rate (μ, h^{-1}) and generation time (GT) of various RTE foods modeled in this risk assessment

RTE product Type (example*)		pH	a_w	Nitrites (ppm)	Sodium Lactate (%)	Potassium Lactate (%)	Sodium Diacetate (%)	T = 4°C (39.2°F) μ (/h)	T = 4°C (39.2°F) GT (h)	T = 10°C (50°F) μ (/h)	T = 10°C (50°F) GT (h)
Deli Meat	(Uncured Ham)	6.4	0.97	0	0	0	0	0.015	47	0.052	13
Deli Meat Low Growth	(Cured Ham)	6.4	0.97	150	0	0	0	0.003	210	0.017	41
Deli Meat No Growth	(Cured Ham w growth inhibitor [GI])	6.4	0.97	150	0	1.65	0.12	0.000	Inf**	0.009	78
Deli Meat	(Uncured Turkey)	6.3	0.96	0	0	0	0	0.012	60	0.041	17
Deli Meat Low Growth	(Cured Turkey)	6.3	0.96	150	0	0	0	0.002	376	0.013	52
Deli Meat No Growth	(Cured Turkey w GI)	6.3	0.96	150	0	1.65	0.12	0.000	Inf	0.004	183
Deli Meat	(Uncured Bologna)	6.3	0.93	0	0	0	0	0.000	Inf	0.006	121
Deli Meat Low Growth	(Cured Bologna)	6.3	0.93	150	0	0	0	0.000	Inf	0.000	Inf
Deli Meat No Growth	(Cured Bologna w GI)	6.3	0.93	150	0	1.65	0.12	0.000	Inf	0.000	Inf
Deli Meat No Growth	(Pepperoni)	4.7	0.83	0	0	0	0	0.000	Inf	0.000	Inf
Deli Meat No Growth	(Salami)	5.0	0.91	0	0	0	0	0.000	Inf	0.000	Inf
Deli Cheese Low Growth	(Colby)	5.2	0.95	0	0	0	0	0.002	460	0.013	54
Deli Cheese No Growth	(Monterey Jack)	5.3	0.93	0	0	0	0	0.000	Inf	0.001	522
Deli Cheese No Growth	(American)	5.6	0.92	0	0	0	0	0.000	Inf	0.000	Inf
Deli Cheese No Growth	(Provolone)	5.2	0.91	0	0	0	0	0.000	Inf	0.000	Inf
Deli Cheese Low Growth	(Swiss)	5.2	0.92	0	0	0	0	0.000	Inf	0.000	Inf
Deli Salad	(Potato)	4.6	0.998	0	0	0	0	0.000	Inf	0.000	Inf
Deli Salad Low Growth	(Potato w GI)	4.6	0.998	0	0	1.65	0.12	0.000	Inf	0.000	Inf
Deli Salad	(Protein)	5.0	0.998	0	0	0	0	0.000	Inf	0.003	252
Deli Salad Low Growth	(Protein w GI)	5.0	0.998	0	0	1.65	0.12	0.000	Inf	0.000	Inf

*Note that the example is provided only as illustration purpose; **: infinite. The generation time is infinite since the growth rate is 0.

Stochasticity in the μ parameter

The secondary model mentioned above is deterministic, in the sense that one set of environmental parameter leads to one expected value for μ. Augustin et al. [84] quantified the variability of growth parameters of *L. monocytogenes* obtained by challenge testing in five RTE products (vacuum-packed pork pie, vacuum-packed smoked herring, sliced cooked ham packed under modified atmosphere, cooked chicken, and surimi salad). The total variance obtained when adding different sources of variability (residual, between-batch, and between-manufacturer) led to a total coefficient of variation[36] for μ of 45%.

[36] The coefficient of variation is the ratio of the standard deviation to the mean.

In order to consider these sources of variability, the $\mu_{ref,i}$ parameter (the specific growth rate at a reference temperature) for a given RTE product *i* (chub, or deli salad bulk) was sampled from a normal distribution with mean μ_{ref} and standard deviation ($0.45 \times \mu_{ref}$). Negative values were set to 0. Table 3 illustrates the distribution of the predicted growth during 7 days of storage at 10°C.

Table 3: Distribution of the predicted growth (log_{10} increase) during a 7-day storage at 10°C (50°F)

	Example*	1st Quantile	Median	Mean	3rd Quantile
Deli Meat	(Uncured Ham)	2.66	3.82	3.82	4.97
Deli Meat Low Growth	(Cured Ham)	0.87	1.25	1.25	1.63
Deli Meat No Growth	(Cured Ham with GI)	0.69	0.98	0.98	1.28
Deli Meat	(Uncured Turkey)	2.08	2.98	2.98	3.87
Deli Meat Low Growth	(Cured Turkey)	0.68	0.97	0.97	1.27
Deli Meat No Growth	(Cured Turkey with GI)	0.32	0.45	0.46	0.59
Deli Meat	(Uncured Bologna)	0.29	0.42	0.42	0.55
Deli Meat Low Growth	(Cured Bologna)	0.00	0.00	0.00	0.00
Deli Meat No Growth	(Cured Bologna with GI)	0.00	0.00	0.00	0.00
Deli Meat No Growth	(Pepperoni)	0.00	0.00	0.00	0.00
Deli Meat No Growth	(Salami)	0.00	0.00	0.00	0.00
Deli Cheese Low Growth	(Colby)	0.65	0.93	0.94	1.22
Deli Cheese No Growth	(Monterey Jack)	0.07	0.10	0.10	0.13
Deli Cheese No Growth	(American)	0.00	0.00	0.00	0.00
Deli Cheese No Growth	(Provolone)	0.00	0.00	0.00	0.00
Deli Cheese Low Growth	(Swiss)	0.00	0.00	0.00	0.00
Deli Salad	(Potato Salad)	0.00	0.00	0.00	0.00
Deli Salad Low Growth	(Potato Salad with GI)	0.00	0.00	0.00	0.00
Deli Salad	(RTE Meat Deli Salad)	0.00	0.00	0.00	0.00
Deli Salad Low Growth	(RTE Meat Deli Salad with GI)	0.00	0.00	0.00	0.00

*Note that the example is provided only for illustration purposes.

Other parameters

Lag time

A lag time is observed in bacterial growth when an abrupt change in the bacterial environment is observed. No abrupt change in the bacterial environment in retail, during transport, and at home is considered in the model. The considered process consists only of slicing or scooping at retail and storage at home. The shifts in temperature are probably not abrupt enough to induce a lag [3]. No consensual model in the literature predicts lag time following transfer from a surface to food. As a conservative choice favoring the model that leads to a higher risk [59, 85], this risk assessment model does not take into account a potential lag phase in bacterial growth that may occur upon transfer of bacteria from one surface to another. A lag after a transfer from FCS or NFCS to food could be considered in future versions of this risk assessment.

y_{max} (Maximum Population Density)

The maximal population density is a very important parameter for prediction of the risk associated with *L. monocytogenes* [86, 87]. Nevertheless, few studies have evaluated this parameter. Within the 2003 FDA/FSIS risk assessment, for example [3], the maximal population density was related to the temperature. For deli meat, deli-type salads, and cheeses, the growth was limited to 5 $\log_{10}$ cfu/g, if the temperature was <5°C (41°F); to 6.5 $\log_{10}$ cfu/g, if the temperature was 5-7°C (41-44.6°F); and 8 $\log_{10}$ cfu/g, if temperature was >7°C (44.6°F). As a safe choice, it was considered that growth can reach 8 $\log_{10}$ cfu/g in all RTE products, including those with growth inhibitor, whatever the storage temperature.

Growth models on sites

The growth model used on sites is the stochastic derivation of an exponential model without lag, as the one used for food:

$$x(t) \sim x(0) + NegBin\left(x(0), \exp\left(-\frac{egr}{\ln(10)}t\right)\right)$$

with $egr \geq 0$, the exponential growth rate on the considered site. *egr* could be a function of the temperature. Currently, *egr* is set to 0, meaning that no growth is considered on sites. Note that a decrease in the number of bacteria with time may be observed on the various sites [88].

6.1.3 Inactivation

In the current risk assessment model, inactivation is limited to the removal and reduction of *L. monocytogenes* on surfaces as the result of cleaning operations, (i.e., wiping, washing, and sanitization). The inactivation process is modeled as follows. Given N, the initial number of bacteria on the site being treated, and W, the efficacy of the inactivation process ($0 \leq W_i \leq 1$), F, the final number of bacteria on the site is derived stochastically using:

$$F \sim \text{binomial}(N, W)$$

This assumes that the bacteria are inactivated independently. W is currently sampled at each inactivation process from:

$$\log_{10}(W) \sim \text{Pert}(\text{min}, \text{mode}, \text{max})$$

where Pert is the Pert distribution [64], *min, mode*, and *max* are specific to *i*) the object and *ii*) the level of inactivation. Currently, three levels of inactivation are implemented: "Wipe," "Wash," "Wash and Sanitize." Note that W is minus the expected $\log_{10}$ reduction of the process. If $\log_{10}(W)$ is -1, then W is 0.1 and the expected $\log_{10}$ reduction is 1; this leads to an expected 10-fold decrease of the number of bacteria on the object. Following a complete literature review [37], (*min*, *mode*, *max*) is set to (-1, -0.5, 0) for all

"wiping" processes, to (-1.5, -0.5, 0) for all "washing" processes, and to (-8, -6, -1.5) for all "washing and sanitizing" processes.

6.1.4 Partitioning

The only partitioning processes in the model are:

- partitioning a chub to a slice; and
- partitioning a serving of salad from a bulk container.

The partitioning process has already been described in the subsection dealing with cross contamination during the slicing process and scooping process. Indeed, a homogeneous contamination of the chub and the salad is assumed. As a consequence, given N_0, the number of bacteria in the chub (or the salad bulk), M is the mass of the chub (or the salad bulk) and m the mass of the slice (or the salad serving), while the number of bacteria in the slice (or the salad serving) is

$$N_1 \sim \text{binomial}(N_0, m/M)$$

The number of bacteria in the remaining chub (or the salad bulk) will then be $N_1 - N_0$.

6.2. Objects in the model

6.2.1 Food

Three categories of food were considered in the model: deli meat, deli cheese, and deli salad. Deli meat and deli cheese were served following a slicing process. Deli salads were served by scooping from a bulk container.

Any type of RTE products within these categories may be simulated in the risk assessment model. For example, deli meat could be ham with high potential of *L. monocytogenes*, uncured ham, ham with growth inhibitor, salami, etc. The model is flexible enough to support the addition of new RTE products. The following characteristics must be known or estimated for each RTE product:

- "category": "chub" or "salad." When served, a "chub" will imply a process of slicing, while a "salad" will imply a process of scooping. "Chubs" are meats and cheeses;
- sale characteristics summarized by
    - the probability of being present in the retail deli (for rare RTE products) or the number of chub/salad bulk in the retail deli (for RTE products that are present in all deli departments), and
    - the relative frequency of sales of the RTE product and the mass of a slice (for "chubs");

- some physical characteristics (i.e., the mean and the standard deviation of the mass of the chub / bulk);
- some chemical characteristics [i.e., pH, water activity, nitrites (ppm), as well as the proportion (w/w) of sodium lactate, potassium lactate and sodium diacetate]. Those factors are used to estimate the growth rate in the RTE product (see section 6.1);
- mean and standard deviation of the initial $\log_{10}$ concentration of *L. monocytogenes*;
- number of days the RTE product can be held in the retail deli after opening or preparation;
- mean and standard deviation of the $\log_{10}$ of the transfer coefficients (see p. 29) of bacteria from these food categories to other food or sites;
- probability of having this food item pre-sliced in the morning, with a mean and standard deviation of the weight of RTE product that would be pre-sliced.

6.2.2 Sites

Sites are potentially contaminated objects that are present in a deli department. Those sites were chosen following the observational study specifically developed for this model [28]. Currently, the following objects are considered: "floor," "sink," "handle," "case," generic "non-food-contact surface" (NFCS), "utensil" (and its "handle"), "slicer," generic "food-contact surface," (FCS), and "scale." Two additional "sites" are associated with food workers: "hands" and "gloves."

The sites are characterized by:

- their initial contamination at the beginning of the simulation;
- the probability of having a niche compartment/of being contaminated from the environment and, in this case, the number of bacteria transferred to the considered site during a release of bacteria from the niche/environment and the average time of operation between two releases (see p. 34);
- the mean and the standard deviation of the $\log_{10}$ reduction of *L. monocytogenes* when the sites were wiped, washed, sanitized, or washed and sanitized (see p. 42);
- the mean and standard deviation of the $\log_{10}$ of the transfer coefficients (see p. 29) of bacteria from these sites to other sites or food;
- the exponential growth rate (*egr*) of *L. monocytogenes* on this object, currently $egr = 0$.

More than one site in each category may be present in the retail deli. Additional objects could easily be implemented, as soon as they are associated with specific events (potential cross contamination from/to this object).

Structure of the deli departments

In the model, the user can build a variety of retail-deli-department layouts or, using an associated relative probability, may run simulations using a set of specific deli-department layouts. A layout is characterized by:

- its hours of operation;
- its number (≥1) of various sites present in the deli-department (floor, sink, handle, scale, utensil, slicer, FCS, NFCS);
- the probability ($0 \leq p \leq 1$) that gloves are worn by an employee handling unpackaged foods when serving customers;
- the probability ($0 \leq p \leq 1$) the niche / environmental contamination occurs in the department,
- the time in hours between cleaning the food-contact surfaces;
- the number of objects that are cleaned during a sporadic cleaning event.

Moreover, a matrix of contact has to be specified for a given retail deli. This matrix of contact allows one to specifiy which objects or food worker can be in contact with which category of food. For example, in a complex retail deli including three slicers, it is possible to specify that slicer #1 is used only for cheese, slicer #2 for meat with no growth, slicer #3 for all kinds of RTE products. This matrix of contact allows one to study various deli-department patterns.

6.3. Events in the model

It is important to note that the model tracks only the actions made by, and the transfers resulting from, the actions of a single food worker. More complex models could be derived for multiple food workers.

6.3.1 Main events

The main events simulated within the model are "Opening the deli," "Closing the deli," and "Operating the deli." Each is described below.

Opening the deli

The virtual deli is open 7 days a week, during a given number of hours. This number of hours is specified at the retail deli level.

When the retail deli opens, the food items that were opened or prepared more than a specified number of days prior (e.g., 7 days for refrigerated RTE foods) [27]) are discarded. This mimics a date-marking system [27]. Additionally, when the retail deli opens, some food items may be "pre-sliced" in large quantity. Afterwards, pre-sliced items will be sold throughout the day. A food item is pre-sliced or not

according to a probability of pre-slicing defined by the user (if 1: some amount of RTE product will be pre-sliced each morning; if 0: this food item will never be pre-sliced; if > 0 and <1: a random value will be drawn each morning to decide whether or not the RTE product will be sliced). The amount of RTE product (>0 g) that will be pre-sliced will be randomly sampled from a normal distribution with mean and standard deviation defined by the user. Then the RTE product will be pre-sliced using the same process as if a serving of this RTE product of that size were requested by a customer.

Closing the deli

When the retail deli closes (or every 24 hours of operation, if the deli is open 24/7), all hard surfaces and equipment in the deli are washed and sanitized. The remaining pre-sliced RTE products are discarded.

Bacterial growth on all sites and food is considered during the time the deli is closed.

Operating the deli

Within the operating hours, three main events are considered: i.e., "Non Deli Time," "Sporadic Clean," and "Serve Customer." Additionally, *i*) the FCS are washed and sanitized regularly, according to a planned schedule; *ii*) some transfer of bacteria from the niches may occur, according to a random schedule.

During the "Non Deli Time" event, nothing happens concerning our considered process (except bacterial growth; see below).

During the "Sporadic Clean" event, some sites are cleaned within the deli. The number *n* of objects cleaned during a sporadic clean event is characteristic of the retail deli (defined by the user). The algorithm selects the *n* sites that have not been cleaned since the longest time, with a random selection in case of ties. Those objects are then "washed" (i.e., not "washed and sanitized").

Before all major events, the algorithm checks whether or not one transfer occurred from one niche to its corresponding site (see p.34).

At the end of a main event, the algorithm checks the "FCS clock." This clock is set to 0 at the opening time. Regularly, as specified by the user (in the baseline, every 4 hours, according to the 2009 FDA Food Code), the FCS [in the baseline: the slicer(s), the generic FCS(s), the scale(s), and the utensil(s)], are washed and sanitized. The FCS clock is then reset.

At the end of each main event, the bacterial growth that occurred during that period is evaluated, and bacterial population numbers are updated, according to the growth models.

Serve a customer

When this main event is chosen by the algorithm, the first action is the choice of the RTE product to be sold. The choice of a RTE product is proportional to the global sale of this RTE product, compared with the other ones present in the retail deli. The mass sold is selected. Then the process varies if the RTE product is to be sliced (meat or cheese) or is to be served (deli salad).

Serving meat or cheese

In Lubran et al.'s study of deli employee behavior [28], a regular baseline behavior sequence was commonly observed in employees serving customers in deli departments [28]. The food employee would change gloves, open the deli case, pick up the chub, close the case, unwrap the chub, slice the RTE product onto his or her gloves, put the RTE product on a deli tissue, put the deli tissue on the scale, touch the scale, put the deli tissue in a plastic bag, put the label on the plastic bag, give the plastic bag to the consumer, rewrap the chub, open the case, put the chub in the case, close the case. Of course, some deviations from this baseline were observed. The frequencies of these alternatives were evaluated from the observational study and incorporated into the risk assessment model (Table 4).

Table 4: Sequence of events when serving deli meat or deli cheese (derived from [28])

Event	Number of times observed / total observations
Wipe the Slicer	7/83
Wash Hands and Change Gloves OR Do not Wash Hands and Change Gloves OR Do not Wash Hands and Do not Change Gloves	33/83 22/83 28/83
Touch a NFCS	4/83
Open the Case	68/83
Close the Case	if had opened it
Touch the Refrigerator Handle	2/66
Open a New Chub	if the mass of the chub < mass to be sold
	If open a new Chub
No contact OR Contact New Chub - Sink OR Contact New Chub – FCS OR Contact New Chub - Slicer	6/17 4/17 1/17 1/17
Pick up a Chub	83/83
Change Gloves	1/83
Touch the Knob of the Slicer	18/83
Slice onto Gloves or Slice onto Deli Tissue	82/83 1/83
Touch the Scale	83/83
Contact Chub –- FCS	1/83
Open Case	If had opened/closed it previously
Put Chub in Case	83/83
Close Case	If had opened it previously
Wipe the Slicer	if had not done it at the beginning 15/68

Serving salad

A similar baseline sequence was used for the main event "serve a deli salad." The baseline sequence, as observed in retail delis [28], consists of change gloves, open the case, take salad bulk, close the case, pick up utensils, serve salad, put the RTE product on the scale, open the case, put salad bulk in case, close the case, touch the scale, wash utensils. Alternatives are provided in Table 5.

Table 5: Sequence of events when serving deli salad (derived from [28]).

Event	Frequency / Condition
Wash Hands and Change Gloves	1/11
or Do Not Wash Hands and Change Gloves	6/11
or Do Not Wash Hands and Do Not Change Gloves	4/11
Touch a NFCS	1/11
Open the Case	9/11
or Open the Case Twice	1/11
or Open the Refrigerator	1/11
Open a New Bulk of Salad	if the remaining mass < mass to be sold
Pick up Salad Bulk	11/11
Pick up Utensils	11/11
Serve Salad	11/11
Close the Case	If it had been opened
Touch the Scale	11/11
Wash and Sanitize the Utensil	6/11
or Sanitize the Utensil	2/11
or Do not Wash or Sanitize the Utensil	2/11

Customer Serving Times

The duration of a serving (h) is assumed proportional to the serving size. Serving times were measured through buying individual sales of various deli RTE products at different retail delis across different times of the day. Weights and times are shown in Table 6. Times represent the time from when the order was placed until the chub was returned to the case.

Table 6. Observed data for calculation of customer serving time

RTE product	Ordered weight		Serving time	
	Pounds	Grams	minutes	hours
American cheese	0.5	227	1.2	0.0200
Turkey	0.5	227	1.22	0.0203
Ham	0.5	227	3.03	0.0506
American cheese	1	454	2.33	0.0389
Turkey	1	454	2.67	0.0444
American cheese	1	454	4.27	0.0711
Turkey	1	454	3.02	0.0503
Ham	0.25	113	2.45	0.0408
American cheese	0.5	227	1.17	0.0194

A regression to predict time based on ordered weight was generated. Times were quite variable, depending on whether a new chub needed to be opened, the deli worker could easily find the chub ordered, etc. Consequently, the regression fit is rather poor. This high variability is captured by including a residual standard error from the regression in the time generation within the risk assessment model.

Time (hr) = 0.00007017 weight (g) + 0.01745

$R^2 = 0.30$

Residual standard error: 0.0155

A minimum time of 0.02 hours (1.2 minutes) was assumed for any size serving. An example random draw of this approach is shown in the red symbols in Figure 9. The solid black circles represent the observed data.

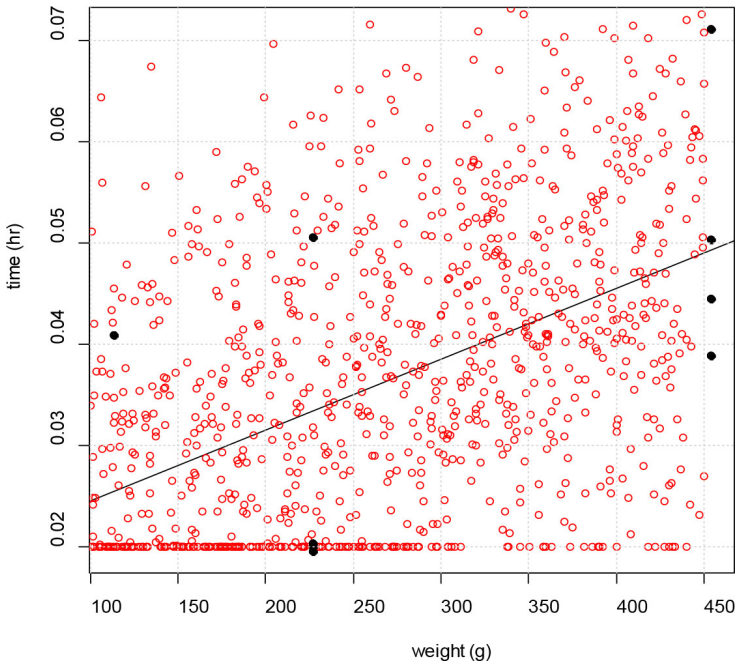


Figure 9: Simulation of customer serving times

Thus, the customer serving time is modeled as

duration = max(0.02, 0.01745 + 0.00007017 × *SS* + Normal(0, 0.0155)).

where *SS* is the serving size (g).

The duration of a deli-salad serving is also assumed to be proportional to the serving size. It is assumed that the time a serving takes follows a normal distribution with a mean of 4 minutes and standard deviation of 0.4 minutes per pound, with a minimum of 30 s; that is, for a duration expressed in hours and a serving size in grams,

duration = max(0.0083, SS × Normal(0.0001468, 0.00001468)).

6.3.1 Sites

In the baseline and all alternatives, no bacterial growth is considered on the sites. It is considered that the sites are not contaminated at the beginning of the simulation. However, the first 1% or 10,000 in 1,000,000 servings are removed from the simulation prior to analysis (burn-in period).

6.3.2 Basic processes

The main events are a single process or a succession of basic processes. Table 7 provides the correspondence between the main events used in the current model and the basic processes.

Table 7: Translation of the basic events in terms of basic processes

Basic event	***Basic process***	***Objects involved***
Remove Glove	Remove all Bacteria	Glove
Change Glove	Cross contamination[a]	Glove – Hand
Put on Glove	Changes Site for Hand/Glove Cross Contamination with Other Sites.	Glove
Close Case	Cross Contamination	Case – Hand or Glove[b]
Open Case	Cross Contamination	Case – Hand or Glove
Open Chub with Contact Chub FCS	Cross Contamination	Chub – FCS
Open Chub with Contact Chub Sink	Cross Contamination	Chub – Sink
Open Chub with Contact Chub Slicer	Cross Contamination	Chub – Slicer
Pick-up Utensil	Cross Contamination	Utensil Handle – Hand or Glove
Put Chub on FCS	Cross Contamination	Chub – FCS
Serve Salad	Cross Contamination Partitioning	RTE Product – Utensil RTE Product – RTE Product Sold
Slice	Slice	Chub - RTE Product Sold– Slicer
Slice onto Glove	Cross Contamination	First Slice – Hand or Glove
Touch Knob	Cross Contamination	Slicer – Hand or Glove
Touch NFCS	Cross Contamination	NFCS – Hand or Glove
Touch Refrigerator Handle	Cross Contamination	Handle – Hand or Glove
Touch Scale	Cross Contamination	Scale – Hand Or Glove
Touch Scale	Cross Contamination	Scale – Hand or Glove
Wash Hands	Inactivation/Removal (Wash)	Hands
Wash Utensil	Inactivation/Removal (Wash)	Utensil and Utensil Handle
Wash and Sanitize Utensil	Inactivation/Removal (Wash and Sanitize)	Utensil and Utensil Handle
Wipe Slicer	Inactivation/Removal (Wipe)	Slicer

[a]: "Cross contamination":[a]: Possible cross contamination if one object carries some bacteria. [b]: "Hand or Glove": Hand or glove according to the current hand status of the food employee.

6.3.3 Temperature in display cases

Temperature of a RTE product is assumed equal to the temperature in the cases in which it is displayed.

Data

Temperature of the RTE products in the display cases were inferred from a study conducted by Ecosure [19]. The display case temperatures of a variety of RTE products were recorded in this study as follows: "When reaching a desired display case within their normal shopping pattern, some participants removed the RTE product to be purchased and inserted a thermometer directly into the RTE product. Participants left the thermometer in the RTE product until the temperature stabilized and then recorded the RTE product temperature and time of day" [19]. Among the tested RTE products, the data obtained for "Sliced meat" (Bologna) were used to derive a temperature distribution for deli cases in the model. Recorded temperatures ranged from -3.33°C (26°F) to 18.33°C (65°F). The raw data are reported in Table 8.

Table 8: Raw storage temperature data for "Sliced Meat" (°F and °C.)

°F	**26**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**
°C	**-3.33**	**-1.11**	**-0.56**	**0.00**	**0.56**	**1.11**	**1.67**	**2.22**	**2.78**	**3.33**	**3.89**	**4.44**	**5.00**	**5.56**
n	1	2	1	9	8	11	11	23	23	68	45	120	51	61

°F	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**	**51**	**52**	**53**	**54**	**55**	**56**
°C	**6.11**	**6.67**	**7.22**	**7.78**	**8.33**	**8.89**	**9.44**	**10.00**	**10.56**	**11.11**	**11.67**	**12.22**	**12.78**	**13.33**
n	25	64	54	47	30	73	22	63	10	20	7	9	6	7

°F	**57**	**58**	**60**	**62**	**65**
°C	**13.89**	**14.44**	**15.56**	**16.67**	**18.33**
n	1	5	10	2	2

(Source [19])

An analysis of the data leads to the conclusion that the collected data should be used directly, as an empirical distribution, rather than as a parametric one.

Model

In the risk assessment model, every morning the temperature of each display case is randomly sampled as being -1°F, +0°F, or +1°F as the day before, using an algorithm preserving the empirical distribution issued from the Ecosure dataset. For that purpose, a Metropolis-Hastings-like algorithm was used. Given T_n the current temperature (e.g., 40°F), T_{n+1} the temperature of the following day, the algorithm is as follows:

- draw a proposed new temperature T_{prop} that is equal to the next higher temperature observed in the dataset (e.g., 41°F) or equal to the next lower temperature observed in the dataset (e.g., 39°F) with equal probabilities; say that the draw is 41°F;

- The number of observations of the temperature T_n in the dataset is E_n (e.g., 120), the number of observed temperature T_{prop} in the dataset is E_{prop} (e.g., 51). Calculate the ratio: $r = E_{prop} / E_n$; here: $r = 51/120 = 0.425$.
- Accept the proposed move to T_{prop} with probability min(1, r). Here, draw a value uniformly between 0 and 1 and accept the proposal, if this value is lower than 0.425. If the proposal is not accepted, then $T_{n+1} = T_n = 40$; else $T_{n+1} = T_{prop} = 41$.

It is possible to slow down the shift of temperature by moving only occasionally, using either a regular shift (example: one shift every week) or using a probability of proposal of shift that is independent of the current temperature. In the baseline model, a shift is proposed every day.

Figure 10 illustrates the use of this method for the Ecosure data [19] as well as the concordance between the Ecosure empirical distribution and the simulated distribution.

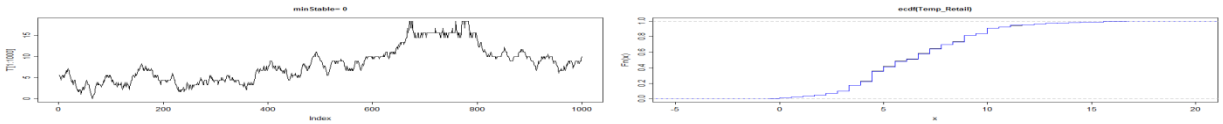


Figure 10: Illustration of the Monte Carlo Markov Chain used to simulate the temperature changes in retail deli cases

Left panel: time series for 1,000 days, Right Panel: empirical cumulative density function from Ecosure [19] and simulated empirical cumulative density function.

6.4. From the retail deli to foodborne illness

The output of the risk assessment model is a distribution of number of *L. monocytogenes* per serving of RTE products. *L. monocytogenes* growth may occur during the transport from the retail deli to the home and during the storage in the refrigerator at home. This growth will be a function of the RTE product characteristics and the time and temperature of storage. No cross contamination at home was considered.

The final output is, then, the risk per serving of RTE food. This output is evaluated considering the consumption data and, eventually, the dose-response model.

6.4.1 Transport

Time, temperature, and model

The most pertinent datasets for time and temperature during transport are the Ecosure 2007 dataset [19]. The protocol within this study was as follows: when reaching a desired display case, participants recorded the temperature of the RTE food and the time of day. "Immediately before placing products in the home refrigerator or freezer, the temperature of each product was taken and the time recorded. The change in temperature from the retail case to home is considered to be short-term high-temperature abuse resulting from shopping, excessive ambient temperatures, and delays between removal of product from its display and re-refrigeration at home." See details in [19] and corresponding data on www.FoodRisk.org.

Time to reach home

The best parametric distribution fitting the Ecosure data [19] on the duration between refrigerated storage at the retail deli and refrigerated storage at home Δt (h) is a ln-normal distribution (Table 9), as compared to a normal, a Weibull, a gamma, a logistic, and a log-logistic distribution on the basis of the Anderson-Darling statistic (results not shown).

Table 9: Parameter of the fitted ln-normal distributions

Delay to get home (h)	mean (s.e. Wald) [95% CI Bootstrap]	sd (s.e. Wald) [95% CI Bootstrap]	ρ spearman ($p = 0$)
Deli meat	0.132 (.0143) [.104, .159]	.403 (.0101) [.384, .422]	-.06 ($p = .03$)

Increase in temperature: Deli Meat

A linear model was developed using Ecosure data. In this model, the explained variable was the increase of temperature (ΔT, °F) of the deli meat product. The duration of the transport (Δt, h), the weight of the product (w, oz.), and the initial temperature (T_0, °F) were explaining variables. The residuals are important, and the adjusted R^2 is only 0.09. Given these variables, the variation of temperature is eventually modeled as:

$$\Delta T = \max\left(0, 13.27 - .1276 \times T_0 + 2.131 \times \Delta t - .2961 \times w + \varepsilon\right) \text{ with}$$
$$\varepsilon \sim Normal\left(0, 5.19\right)$$

Increase in temperature: Deli Salad

A similar linear model using the variation in temperature as the explained variable and the temperature at t_0, the transport duration and weight of the product, show that the weight is not a significant parameter for deli salad. This model leads to the following model for deli salad:

$$\Delta T = \max(0, 10.52 - .1482 \times T_0 + 1.748 \times \Delta t + \varepsilon) \text{ with}$$
$$\varepsilon \sim Normal(0, 4.70)$$

No data are available for deli cheese; the model developed to predict the increase in temperature for deli meat was used for these cheeses.

Growth during transport

The growth during transport of duration Δt, starting at a temperature of T_0 and ending at a temperature of $T_f = T_0 + \Delta T$, may be approximated by the growth that would occur during the same duration at a fixed temperature of $T_0 + \Delta T/2$. The growth models used are the same as those used in the deli department.

Nevertheless, the growth occurs only when the temperature is higher than the minimal temperature of growth $T_{\min}$. A linear increase of the temperature during the transportation is assumed from T_0, the temperature at retail to T_f, the temperature when the product arrives at home ($\geq T_0$). T_0 and T_f are possibly lower than $T_{\min}$. The mean temperature during which the growth occurs is then

$$m = \frac{\max(T_{\min}, T_0) + \max(T_{\min}, T_f)}{2}.$$

The effective time of growth (time when $T > T_{\min}$) is

$$\Delta t_{eff} = \Delta t \times \frac{\left(\max(T_f, T_{\min}) - \max(T_0, T_{\min})\right)}{(T_f - T_0)}.$$

6.4.2 Home

The time-temperature characteristics of home storage have been studied extensively by Kosa et al. [89]. Classical parametric survival modeling was used to derive parametric distributions from the RTI International storage practices dataset [90]. Time-temperature during home storage was modeled using the distributions proposed in Table 10 and Table 11. As an example for Deli Meat, the algorithm to draw a storage time at home is as follows (from Table 11):

- draw a sample $x \sim$ Uniform(0, 1) distribution
- if $x < 0.04$ (i.e., 4%): the serving is eaten at the opening of the package. The time to consumption (days) is drawn from an exponential(1/0.457) distribution;

- else, the serving is eaten at the last occasion. The time to consumption (days) is drawn from a Weibull(2.08, 8.33) distribution.

Note that no data on hard cheese sliced to order are available. Soft cheese data were used instead. All simulated temperatures <0°C (32°F) were set to 0°C. The bacterial growth was modeled as detailed on pages 35-42.

Table 10: Fitted Laplace distribution of the refrigerator temperature data in Fahrenheit and Celsius

	Location	Scale
Fahrenheit	39.3	4.23
Celsius	4.06	2.31

From [90]

Table 11: Fitted distribution of time to first consumption of RTE food, using RTI International data

	Time to first consumption (day)	Ate package at one time: weighted %	Time to last consumption (day)
	Fitted Distribution		Fitted Distribution
Deli Meat – Sliced to Order	Exponential(.457)	4%	Weibull(2.08, 8.33)
Soft Cheese	Weibull(.873, 5.34)	8%	Weibull(1.34, 18.7)
Deli Salad	Exponential(.475)	14%	Weibull(1.34, 7.49)

From [90]. Exponential(x) is the exponential distribution with mean x.

6.4.3 Consumption

Specific consumption data were extracted from the 1999-2006 National Health and Nutrition Examination Survey (NHANES, a USDA/DHHS survey), using the FARE™ Program (Food Analysis and Residue Evaluation Program, v. 8.63) developed by Exponent®. Details are given in Appendix 2. Figure 11 is the empirical cumulative distribution function of the serving size per eating occasion obtained from this analysis for deli salad, deli meat, and deli cheese. Table 12 provides some basic statistics from this distribution.

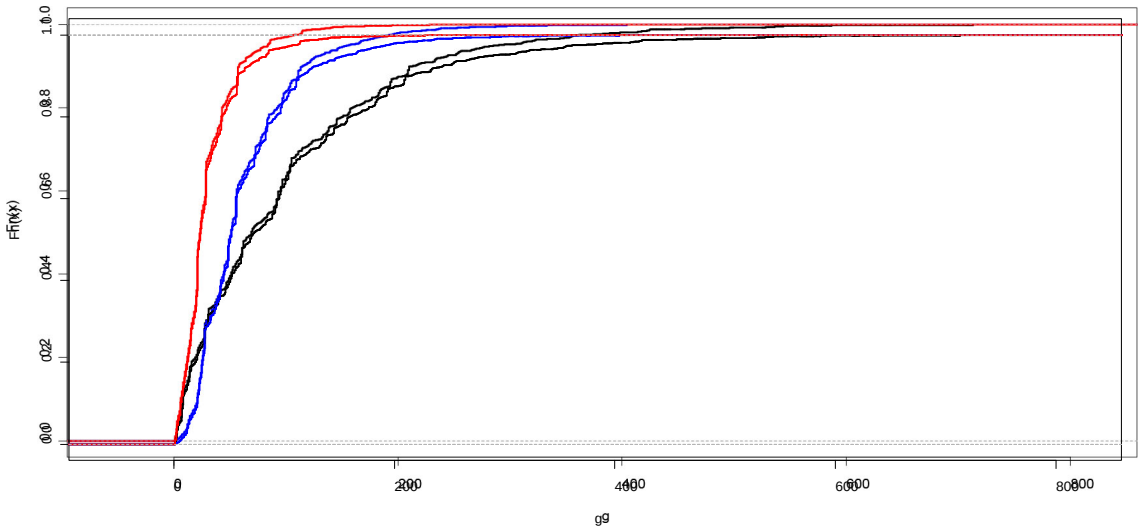


Figure 11: Distribution of serving size for deli salad (black), deli meat (blue) and deli cheese (red) for the total population

Table 12: Summary statistics of the empirical distribution of serving sizes, as simulated in the *L. monocytogenes* retail model (g/eating occasions)

	Deli Meat	Deli Salad	Deli Cheese
Minimum	1	1	1
1st Quartile	28	28	15
Median	51	69	24
Mean	63	99	31
3rd Quartile	83	138	39
Maximum	775	763	982

6.4.4 Dose-response model

The number of bacteria in the serving sold, after transport and growth in the refrigerator, is converted into a concentration using the mass of the serving sold. This concentration is then multiplied by the serving size (gram per serving) to obtain the ingested dose. Note that, at this level, the dose is not a discrete number but a continuous one, representing the mean of a Poisson distribution of the number of ingested cfu for the exponential dose-response [91].

The dose response model is a function that links the ingested dose to the probability of a given specified endpoint. A general review of the hazard characterization process may be obtained in FAO/WHO [92]. A specific review for the characterization of *L. monocytogenes* (i.e., characterization of severity and selection of appropriate biological end points to be modeled, factors that affect dose-response relations for

L. monocytogenes, approaches to modeling dose-response may be obtained in the FAO/WHO risk assessment of *L. monocytogenes* in RTE foods [59].

Relative to a "general" population, an increased susceptibility is commonly associated with:

- pregnant women and neonates, resulting in stillbirth or neonatal infection;
- older adults; and
- persons with particular conditions, including cancer and immunosuppressive therapy, AIDS, cardiovascular disease, congestive heart failure, diabetes, cirrhosis, and alcoholism [93, 94].

To date, two major dose-response models for humans scaled on epidemiological data are available: one developed within the 2003 FDA/FSIS quantitative assessment of relative risk to public health from foodborne *L. monocytogenes* among selected categories of RTE foods [3] and one developed within the FAO/WHO risk assessment of *L. monocytogenes* in RTE foods [59]. The second model uses the latter dose-response relationship. All details on the dose-response can then be obtained in the FAO/WHO risk assessment [59].

The FAO/WHO risk assessment considers invasive listeriosis as endpoint. It considers two subpopulations: the population with "increased susceptibility" [59] (including neonates, older adults and immunocompromised), and the population with "decreased susceptibility" [59] (all others). The model is an exponential dose-response model [91] that might be written as

$$\Pr(\text{inf}|D)=1-\exp(-r\,D)$$

where $\Pr(\text{inf}|D)$ is the marginal probability of invasive listeriosis in a population that ingests a food when the serving-to-serving variability of contamination follows a Poisson distribution of mean D. The exponential dose-response model is a single-hit model; it considers that pathogens act independently and that ≥1 pathogen is enough within the host to evoke the endpoint [91]. Parameter r, the unique parameter of this model, is the probability that one cell evokes the endpoint in a consumer at random from the reference population. It is considered in the exponential dose-response model that r is a constant for the specific population to which the model is applied. Note that the marginal dose-response relationships in the FAO/WHO [59] and the 2003 FDA/FSIS [3] risk assessment models closely compare, because they rely mostly on the same data. These models are almost linear at low-to-medium dose.

Indeed, the unique r parameter per subpopulation of the FAO/WHO [59] model is estimated from exposure data issued from a draft FDA/FSIS report [95] and from the annual number of cases of listeriosis estimated in the U.S. [96]. The point estimates for r used in this model are 1.06×10^{-12} for the

susceptible population and 2.37×10^{-14} for the other population [see Table 2.17, p. 56 and Table 2.20, p.58, 59].

Uncertainty for the *r* parameters was derived based on four parameters that influence the dose-response relations; namely the percentage of the population in the U.S. with increased susceptibility to *L. monocytogenes*, the percentage of cases of total severe listeriosis cases associated with the increased-susceptibility population in the U.S., the total number of cases in the U.S., and the maximum achievable dose of *L. monocytogenes* per serving [59]. Using the FAO/WHO [59] assumptions, a Monte Carlo simulation was built to derive an empirical distribution of uncertainty for each of the two *r* parameters. A median *r* estimate is 7.76×10^{-13} [1.32×10^{-13}; 6.98×10^{-12}] for the susceptible population and 1.76×10^{-14} for a 95% CI of [2.07×10^{-15}; 2.10×10^{-13}] for the other population. Note the scale of the uncertainty. The fraction of the population in the two subpopulations also is uncertain. No uncertainty is included for any dose-response parameter for this risk assessment, because the emphasis is on comparing outputs for different deli operating rules. Because this confounding uncertainty is not the purpose of this study, it was chosen to use the point estimates for *r*.

6.5. Additional baseline inputs

6.5.1 Retail deli characteristics

Two categories of retail deli are currently considered: a retail deli A type (20% of simulated retail delis) and retail deli B type (80% of simulated retail delis). Retail deli A type includes one of each considered category of object, (i.e., one Floor, one Sink, one Refrigerator [handle], one Scale, one Case, one Utensil (and its handle), one Slicer, one Food-Contact Surface, and one Non-Food-Contact Surface). The retail deli B type includes two of each considered category of object. Each retail deli is opened 14 hours per day.

In the baseline risk assessment model, food-contact surfaces are washed and sanitized once every 4 hours of operation. When food workers engage in sporadic cleaning, it is assumed that they wash four objects. Also, it is considered that food workers wear gloves while serving customers 100% of the time (as observed by Lubran et al. [28] in States with the glove policy).

In the baseline, it is assumed that one slicer is used only for deli meat and that the other slicer is used for deli cheese in larger retail delis with two slicers. There is no separation of deli cases or any other type of

objects according to the type of RTE food (e.g., cheese, deli salad, deli meat). When multiple sites can be used in the retail deli, the specific sites (e.g., slicer, utensil) used for that serving are randomly picked.

6.5.1 General operation

In all baselines and scenarios, the probability of occurrence of a Non Deli Time event among the main events ("Non Deli Time," "Sporadic Clean," and "Serve Customer") is 30%. Its duration follows a normal distribution with mean 3 minutes and standard deviation 0.3 minute. The probability of occurrence of a Sporadic Clean event among the main events is 5%. Its duration follows a normal distribution with mean 10 minutes and standard deviation 1 minute. The main event "Serve a Customer" occurs with a probability of 65%.

6.5.2 RTE products

A retail deli from the baseline model includes 20 different RTE products. The sales characteristics are presented in Table 14. The relative frequency of sales for most of the RTE products are from "What's in store 2010" [97]. The sizes of the servings sold are sampled from the empirical distribution observed by Ecosure [19] from sales of 787 various deli meats. The empirical cumulative distribution is provided in Figure 12.

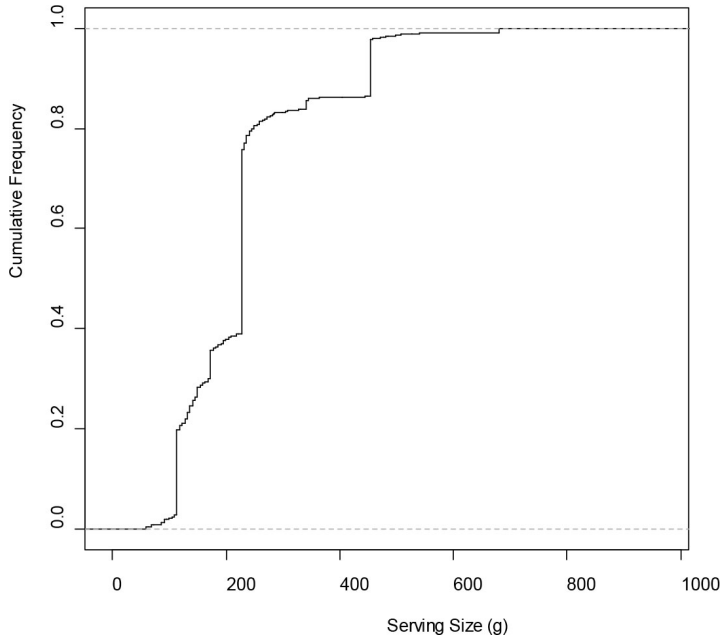


Figure 12: Empirical cumulative distribution of the size of RTE food serving in a retail deli
(Source: [19])

It is important to note that the initial concentration distribution (cfu/gram) for all RTE products is assumed to be a $\log_{10}$ normal distribution. The mean and standard deviation of this $\log_{10}$ normal distribution are assumed to be issued from a multinormal distribution with mean (-9.228, 2.923) and covariance matrix $C = \begin{pmatrix} 0.232 & -0.085 \\ -0.085 & 0.032 \end{pmatrix}$. These parameters are maximum likelihood estimates from the FSIS *L. monocytogenes* verification sampling program data [8, 98]. Data from 2006–2010 were used to estimate this distribution [99]. The dataset consisted of 56,985 samples, with an observed prevalence of 0.42% (239 positives). Twenty-two of the samples had quantifiable concentrations above the detection limit. The highest observed concentration was 230 MPN/g. A maximum likelihood estimation algorithm, which accounted for the censoring of the data due to the multiple detection limits [16], was used to fit the lognormal model to the data. To avoid any unrealistic concentration using this unbounded, heavily tailed, $\log_{10}$ normal distribution, it was truncated to 500 cfu per gram

For a 2,270 gram chub, and assuming a Poisson-lognormal(-9.228, 2.923) distribution of the bacteria, this distribution leads to a prevalence (percentage of chubs containing >0 bacteria) of 2.97%. Table 13 presents some characteristics of this distribution and of distributions that were used in some of the alternatives.

Table 13: Characteristics of the distribution of bacteria in contaminated chubs (2,270 grams) according to the mean of the $\log_{10}$ normal-Poisson distribution

	Mean	sd	prevalence (prob > 0 cfu)	prob > 2270 cfu (1 cfu/g)	prob > 22,700 cfu (100 cfu/g)
Baseline	-9.228	2.923	2.97%	0.08%	0.01%
Alternatives	-9.529	2.923	2.35%	0.06%	0.00%
	-8.928	2.923	3.71%	0.11%	0.01%
	-7.000	2.923	12.71%	0.83%	0.10%
	-5.000	2.923	31.94%	4.36%	0.83%
	-3.000	2.923	58.04%	15.24%	4.36%

The characteristics of the various RTE products are reported in Table 15. These characteristics are extracted from the chemical analysis results provided in the predictive microbiology literature [72, 77, 79, 80, 82, 100-120].

Table 14: Sales and characteristics of the RTE products

RTE Product Type	(Example*)	Number of Chub/Bulk in each Retail Deli	Sales quantity (Relative Quantity)	Mass of a Chub/Bulk in g.	(Sd)
Deli Meat	(Uncured Ham)	2	4.7	2724	(227)
Deli Meat Low Growth	(Cured Ham)	2	4.7	2724	(227)
Deli Meat No Growth	(Cured Ham w GI)	1	4.7	2724	(227)
Deli Meat	(Uncured Turkey)	2	5	2724	(227)
Deli Meat Low Growth	(Cured Turkey)	2	5	2724	(227)
Deli Meat No Growth	(Cured Turkey w GI)	1	5	2724	(227)
Deli Meat	(Uncured Bologna)	1	1	2724	(227)
Deli Meat Low Growth	(Cured Bologna)	1	1	2724	(227)
Deli Meat No Growth	(Cured Bologna w GI)	1	1	2724	(227)
Deli Meat No Growth	(Pepperoni)	1	1	2724	(227)
Deli Meat No Growth	(Salami)	1	3	2724	(227)
Deli Cheese Low Growth	(Colby)	1	1	3178	(227)
Deli Cheese No Growth	(Monterey Jack)	1	1.4	3632	(227)
Deli Cheese No Growth	(American)	1	7.6	3632	(227)
Deli Cheese No Growth	(Provolone)	1	1.4	3632	(227)
Deli Cheese Low Growth	(Swiss)	1	1.4	3632	(227)
Deli Salad	(Potato)	1	5	4540	(227)
Deli Salad Low Growth	(Potato w GI)	1	5	4540	(227)
Deli Salad	(Protein)	1	2	4540	(227)
Deli Salad Low Growth	(Protein w GI)	1	3	4540	(227)

* Examples are proposed for illustrative purposes

Table 15: Characteristics of the RTE products

RTE Product Type	(Example*)	pH	aw	Nitrites (ppm)	Potassium Lactate (w/w %)	Sodium Diacetate (w/w %)
Deli Meat	(Uncured Ham)	6.4	0.97	0	0	0
Deli Meat Low Growth	(Cured Ham)	6.4	0.97	150	0	0
Deli Meat No Growth	(Cured Ham w GI)	6.4	0.97	150	1.65	0.12
Deli Meat	(Uncured Turkey)	6.3	0.96	0	0	0
Deli Meat Low Growth	(Cured Turkey)	6.3	0.96	150	0	0
Deli Meat No Growth	(Cured Turkey w GI)	6.3	0.96	150	1.65	0.12
Deli Meat	(Uncured Bologna)	6.3	0.93	0	0	0
Deli Meat Low Growth	(Cured Bologna)	6.3	0.93	150	0	0
Deli Meat No Growth	(Cured Bologna w GI)	6.3	0.93	150	1.65	0.12
Deli Meat No Growth	(Pepperoni)	4.67	0.83	0	0	0
Deli Meat No Growth	(Salami)	5	0.91	0	0	0
Deli Cheese Low Growth	(Colby)	5.2	0.95	0	0	0
Deli Cheese No Growth	(Monterey Jack)	5.25	0.93	0	0	0
Deli Cheese No Growth	(American)	5.6	0.92	0	0	0
Deli Cheese No Growth	(Provolone)	5.2	0.91	0	0	0
Deli Cheese Low Growth	(Swiss)	5.2	0.92	0	0	0
Deli Salad	(Potato)	4.6	0.998	0	0	0
Deli Salad Low Growth	(Potato w GI)	4.6	0.998	0	1.65	0.12
Deli Salad	(Protein)	5	0.988	0	0	0
Deli Salad Low Growth	(Protein w GI)	5	0.988	0	1.65	0.12

* Examples are proposed as illustrative purposes

The FDA Food Code [27] specifies that RTE, potentially hazardous food prepared and held refrigerated for more than 24 hours in a food establishment must be marked at the time the original container or package is opened in a food establishment, to indicate the date by which the food shall be consumed or

discarded. In the baseline model, chubs of ham, turkey, bologna, and salads are discarded if they are not used 7 days after the date they are opened. Foods that do not require a 7-day limit after opening, according to the FDA Food Code [27] [e.g., pepperoni, salami, and cheese (Colby, Monterey Jack, American, Provolone, Swiss)] are discarded after 30 days, if they are not used.

In the baseline model, RTE products are not pre-sliced; they are sliced and served at the consumer's request.

6.5.3 Transfer coefficients

The current values of the parameters defining the transfer coefficient distributions (M_{Tij} and S_{Tij} ;see section 6.1.1), following the analysis described in Hoelzer et al. [37], are reported in Table 16. The parameters are shown only for the transfers that are currently simulated in the model. See Hoelzer et al. [37] for details.

Table 16: Mean (standard deviation) of the $\log_{10}$ of the transfer coefficients for *L. monocytogenes* at retail

	To Meat	Cheese	Salad	Floor	Sink	Handle	Case	Utensil	Utensil Handle	Slicer	Scale	FCS	NFCS	Glove	Hand
From Meat					-0.28 (0.2)			-0.28 (0.2)		-0.28 (0.2)		-0.28 (0.2)	-0.28 (0.2)	-1.69 (0.81)	-1.69 (0.81)
Deli Cheese					-0.28 (0.2)			-0.28 (0.2)		-0.28 (0.2)		-0.28 (0.2)	-0.28 (0.2)	-1.69 (0.81)	-4.96 (0.37)
Salad								-0.28 (0.2)		-0.28 (0.2)		-0.28 (0.2)	-0.28 (0.2)	-1.69 (0.81)	-4.96 (0.37)
Floor														-1.84 (0.87)	-1.84 (0.87)
Sink	-0.28 (0.2)	-0.28 (0.2)												-1.84 (0.87)	-1.84 (0.87)
Handle														-1.84 (0.87)	-1.84 (0.87)
Case														-1.84 (0.87)	-1.84 (0.87)
Utensil	-0.28 (0.2)	-0.28 (0.2)	-0.28 (0.2)											-1.84 (0.87)	-1.84 (0.87)
Utensil Handle														-1.84 (0.87)	-1.84 (0.87)
Slicer	-0.28 (0.2)	-0.28 (0.2)												-1.84 (0.87)	-1.84 (0.87)
Scale														-1.84 (0.87)	-1.84 (0.87)
FCS	-0.28 (0.2)	-0.28 (0.2)	-0.28 (0.2)											-1.84 (0.87)	-1.84 (0.87)
NFCS	-0.28 (0.2)	-0.28 (0.2)	-0.28 (0.2)											-1.84 (0.87)	-1.84 (0.87)
Glove	-4.96 (0.37)	-4.96 (0.37)	-4.96 (0.37)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-3.43 (0.79)	-3.43 (0.79)
Hand	-1.69 (0.81)	-4.96 (0.37)	-4.96 (0.37)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-1.84 (0.87)	-3.43 (0.79)	-3.43 (0.79)

6.6. Implementation

The model is written in open-source language R version > 2.11.1 [121], which is free and available for download at http://www.r-project.org/. The parameters are specified in a Microsoft® Excel workbook read by R through an ODBC (Open Database Connectivity)(RODBC package).

The major disadvantage of discrete-event models is that their computing times are long. Any state being dependent on the preceding one, this prevents vectorization and requires loops in R, which run much slower. A lot of effort has been made while writing the code in order to *i*) be able to launch the code on parallelized processors, using the R SNOW package; ii) profile the time of computing.

The Interagency Retail *L. monocytogenes* Risk Assessment Workgroup has access to High Performance Computing (HPC) tools brought by the Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA. This allowed the group to run the model on up to 2,016 cores (Figure 13). Running the code in parallel greatly reduced run time and was used to provide results.

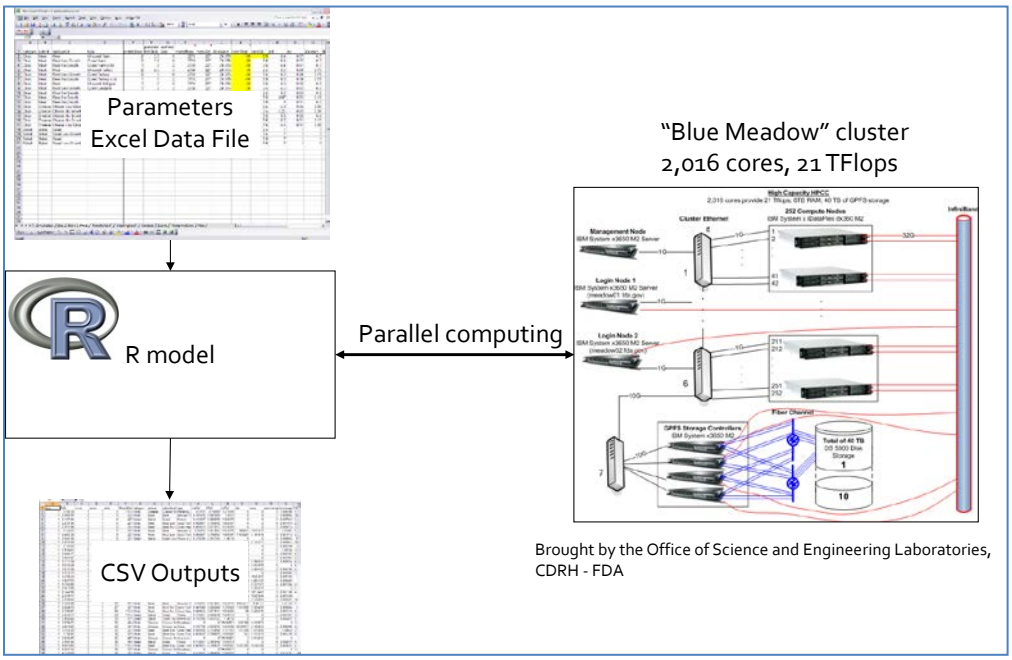


Figure 13: General scheme of simulations

The current general algorithm is as provided in Figure 13. On 101 cores, it takes about 0.45 hour to run 100 retail delis in parallel; 1,100,000 sales for each retail deli.

6.7. Studying the model

6.7.1 RTE products

Given that each simulation is run for periods measured in years (1,000,000 servings) for 100 retail delis, a resulting output file size that would record each sale would be too large to be handled. Thus, the risk assessment model outputs include summary statistics of the servings and events for each simulation. The summary for the serving includes, for each retail deli and food sub category:

- number of servings;
- number of contaminated servings;
- mean number of *L. monocytogenes* cfu among positive RTE product servings;
- mean number of *L. monocytogenes* cfu per gram of RTE product among positive servings;
- mean *L. monocytogenes* concentration among positive RTE product servings when sold and when eaten;
- mean ingested dose of *L. monocytogenes*;
- mean risk of invasive listeriosis in the two subpopulations;
- mean of the $\log_{10}$ of these outputs;
- sum of square of these outputs.

These few statistics are sufficient to build various other statistics, such as the mean for all servings (negative and positive), the variance, the standard error, within sub-category of RTE food, within uncertainty loop, within repetition, etc. It also is sufficient to build an analysis of variance.

Moreover, in order to better characterize the cumulative density function of these outputs, another summary provides the number of contaminated servings that falls in some contamination level bins. These statistics count the number of deli sales that fall in the (-∞; 0.001), [0.001; 0.01), [0.01; 0.1),... [1E6, 1E7), [1E7, ∞) bin of contamination (in cfu/g of RTE products). Knowing these counts, it is easy to rebuild the interval-based cumulative density function within sub-category of food, within repetition, etc.

If needed, a file containing a record for each of the simulated servings may be built. It includes all characteristics of the product sold (e.g., growth characteristics, final size, associated risk). This file is usually too large to be handled, but may be built and studied for shorter runs, to study a very specific situation.

6.7.2 Sites

A file is provided to track the contamination of the sites: the summary reports for each retail deli and for each site, the kind of retail deli (e.g., "A" or " B"), the fraction of time a site is contaminated, and the mean number of events during which the given site stays contaminated.

The model also can output the time series of *L. monocytogenes* counts at each site each time an event occurs or for one selected type of event. This file is usually too large to be handled for a complete run.

6.7.3 Transfer matrix

Within the risk assessment model, a matrix was developed to track each transfer of *L. monocytogenes* during a simulation. The structure of the matrix is depicted in Figure 14.

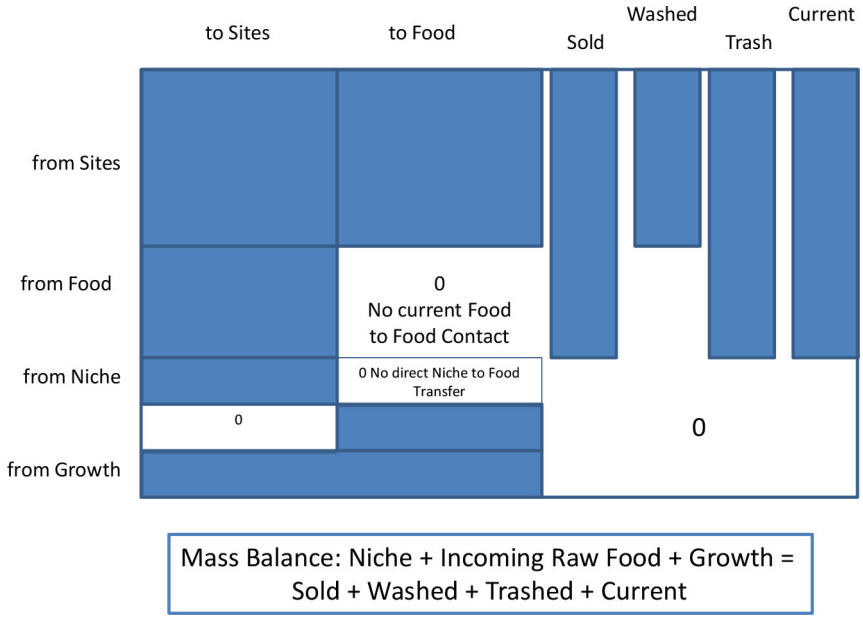


Figure 14: Structure of the *L. monocytogenes* transfer matrix in the model of the Interagency Risk Assessment: *L. monocytogenes* in Retail Delicatessens

The risk assessment model summarizes the information from a run by proving *i*) the number of contacts between objects, *ii*) the number of effective contacts (i.e., number of contacts with at least one cfu involved), *iii*) the average number of *L. monocytogenes* cfu transferred per contact, and *iv*) the overall number of transferred *L. monocytogenes* cfu.

The intensity of the transfers occurring in a model may be graphically illustrated as in Figure 20, to study the dynamics of the transfer of *L. monocytogenes* in the risk assessment model as well as the impact of changes in deli practices on each *L. monocytogenes* transfer.

7. Risk Assessment Results and Discussion

7.1. Risk management questions and model approaches

7.1.1 Baseline retail deli and RTE product conditions

The model requires the input of bacterial loadings and frequencies of bacterial transfer from the niches and the mean bacterial $\log_{10}$ concentration in the contaminated product type. Baseline conditions had to be established to evaluate the public health impact of changes in retail deli practices. The conditions in different retail stores and within a single retail deli at different times may vary a great deal in terms of *L. monocytogenes* levels of environmental and product contamination. A sensitivity analysis was conducted, in section 7.2.1, of the levels and frequencies of *L. monocytogenes* contamination from niches and the mean levels of *L. monocytogenes* on RTE products entering the retail deli for further preparation (e.g., slicing) before being sold to the consumer.

The approach used in this risk assessment was to evaluate the public health effect of various under six different baseline conditions that may characterize a retail deli and the RTE product it serves at different times over the course of operations. These six baseline conditions are:

- A retail deli with multiple niches that release *L. monocytogenes* to food-contact surfaces. This approach would also represent retail delis where general environmental contamination of non-food-contact surfaces is transferred to surfaces that may be in contact with food. This baseline assumes that, on average, 100 *L. monocytogenes* are released to food-contact surfaces periodically, with an average period of one week (**W**) between two releases. The level selected for this specific baseline was selected among other levels (see section 7.2.1). This baseline was denoted **Multiple Niche 100W** (1st baseline model condition).
- A retail deli with no niches or environmental *L. monocytogenes* transfer. This baseline was denoted **No niche** (2nd baseline model condition).
- A retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product contaminated at levels higher than those of other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs. -9.2 $\log_{10}$ cfu/g) [99]. These baselines assume a mean of the $\log_{10}$ normal distribution of the concentration in that incoming RTE product of -5 $\log_{10}$ cfu/g, higher than the baseline (-9.2 $\log_{10}$ cfu/g). The *L. monocytogenes* contamination level selected for these specific baselines were selected to generate a readily observable increase in the predicted public health risk and were further evaluated by a sensitivity analysis (see section 7.2.1). Two types of retail deli situations are examined, including:

  - The incoming contaminated RTE product supports growth. (Sales volume and other RTE product-specific data based on available data on RTE food that support *L. monocytogenes* growth). This baseline was denoted **Incoming Growth Chub** (3rd baseline model condition).
  - The incoming RTE product does not support growth. (Sales and other RTE product-specific data were based on available data on RTE food that does not support *L. monocytogenes* growth). This baseline was denoted **Incoming Non-Growth Chub** (4th baseline model condition).
- A retail deli compliant with the 2009 FDA Food Code guidance to maintain deli cases at ≤41°F (≤5 °C).
  - A retail deli with multiple niches and compliant temperature control. This baseline was denoted **Niche & Temperature Control** (5th baseline model condition).
  - A retail deli without any niches with compliant temperature control. This baseline was denoted **Temperature Control** (6th baseline model condition).

When evaluating the impact of incoming contaminated product, sales and product composition were taken from typical high-sale deli meat and cheese food products. The incoming concentrations were selected as a range to be higher than actually observed, so that the potential public health impact of these higher levels could be evaluated.

In the absence of *ad-hoc* data, the specific values defining each baseline type are merely representative. For example, the **Multiple Niche 100W** baseline considers that niches transfer 100 cfu on an average weekly frequency. The baseline values are thus representative of a type of retail delis. A range of values for niche characteristics and levels of contamination of incoming products are evaluated in a sensitivity analysis in Section 7.2.1.

7.1.2 Scenarios: Changes in retail deli practices

Various scenarios were evaluated to inform the specific risk management questions posed for this risk assessment (see Section 3). The food safety intervention scenarios that were run for each of the baseline conditions are given below. The abbreviations used on the graphs are shown first in bold, followed by a brief explanation. The reader can refer to a list of these abbreviations in the Table on page vi. These scenarios are grouped according to the risk management question the scenario illustrates.

Because of the large number of scenarios considered in this risk assessment, they were divided into two categories:

- Category 1: scenarios primarily based on sanitation.
- Category 2: worker/industry behavior and scenarios primarily directed at impacting growth through time and temperature control.

Risk assessment model scenario analyses were conducted to inform specific risk management questions as follows:

1) What would be the potential public health impact of practicing more frequent or more extensive cleaning procedures for FCS and/or NFCS than is currently specified in the 2009 FDA Food Code [27] on (1) the prevalence of *L. monocytogenes* in RTE products sold in retail delis and (2) the corresponding mean risk of invasive listeriosis? The corresponding tested scenarios were:

- **Wash & Sanitize**: Increase the effectiveness of retail deli cleaning from simply washing to washing and sanitizing [i.e., from an average $\log_{10}$ reduction obtained from a Pert(-1.5, -0.5, 0) to a Pert(-8, -6, -1.5)].
- **Clean 8 Sporadic**: double the number of retail deli sites sporadically cleaned from 4 to 8;
- **No Sanitation**: do not conduct any wiping, washing, or sanitizing of retail deli FCS;
- **No Sporadic Cleaning**: retail deli workers clean FCS as required by the 2009 FDA Food Code, but do not conduct any additional sporadic cleanings, as observed by Lubran et al. [28].

2) What would be the potential public health impact of increasing the use of single-service gloves in retail delis?

- **No Glove**: retail deli workers do not use gloves when serving customers;
- **Gloves Every Serving**: retail deli workers change gloves for every sale of RTE products.

3) What if scale touch pads, refrigerator and deli case handles, and other frequently touched NFCS were considered food-contact surfaces and were therefore cleaned and sanitized at a minimum frequency, per FDA Food Code [27] requirements?

- **NFCS as FCS**: retail deli workers clean deli NFCS as if they were FCS (i.e., every 4 hours, in accordance with the 2009 FDA Food Code).

4) What if practices were in place so that no cross contamination occurred in delis (i.e., no further *L. monocytogenes* added to incoming RTE products)?

- **Transfers to 0**: scenario in which *L. monocytogenes* cross contamination in the retail deli would result only from the deli slicer (i.e., set cross contamination transfer coefficients to 0 for all sites except the slicer);
- **Transfers and Slicer to 0**: scenario in which there is no *L. monocytogenes* cross contamination in the retail deli (i.e., set cross contamination transfer coefficients to 0, meaning no cross contamination occurs for all sites, including the slicer).

5) What if display cases were not touched with gloved or bare hands (i.e., use of tissues or automatic door open/shut)?

- **No-Contact Glove Case**: retail deli workers do not use their hands (gloved or ungloved) to open the deli case (e.g., if a floor switch is used).

6) What would be the potential public health impact if the level of *L. monocytogenes* contamination were reduced in RTE foods coming into the retail deli?

- **Reduce Level**: lower the mean incoming *L. monocytogenes* concentration on all RTE products from a mean of the $\log_{10}$ of -9.2 to a mean of the $\log_{10}$ of -9.5 (see Section 7.2.1). This leads to an average prevalence for a 2,270 g chub of 2.35% *vs*. 2.97% in the baseline.

7) What would be the potential public health impact of "pre-slicing" all RTE products vs. "slicing to order" (hypothesis: less cross contamination occurs in morning, prior to other cross contamination events).

- **Pre-slice**: retail deli workers pre-slice all chubs of RTE product (deli meat and deli cheese) in the morning, after cleaning. A quantity equal to the median of the daily sales is pre-sliced every morning. When a consumer orders a RTE product, the food worker serves the pre-sliced RTE product, until all of the pre-sliced quantity is sold. If needed, additional RTE product is sliced to order. At the end of the day, the remaining pre-sliced RTE product is discarded.

8) What would be the potential public health impact of using separate slicers and/or separate counters for RTE products that permit growth of *L. monocytogenes* and for RTE products that do not?

- **Separate Slicer**: retail deli workers use a separate slicer for RTE products that support growth of *L. monocytogenes* versus RTE products that do not;
- **Separate Slicer Case**: retail deli workers use a separate slicer and a separate deli case for RTE products that support the growth of *L. monocytogenes* versus RTE products that do not.

9) What would be the potential public health impact of lowering the level of environmental contamination of food-contact surfaces?

- **Lower Env Contam**: reduce transfer of *L. monocytogenes* among RTE products, FCS, and NFCS (i.e., reduce transfer coefficients by 50%) in the retail deli.

10) What if food workers did not slice RTE products directly on their gloved hands?

- **Do Not Slice Onto Gloves**: during the observational study, it was observed that the food worker usually gets the slices on his or her gloves before putting the slices on the deli tissue (rather than slicing directly onto the deli tissue). In this alternative, retail deli workers collect the sliced RTE products directly on tissue paper, rather than on their gloves.

11) What is the potential public health impact of bacterial growth in retail delis?

- **Temp = 5°C:** set the retail deli case temperature for all retail delis to 5°C (41°F) (i.e., in compliance with the 2009 FDA Food Code), rather than using real-world deli case temperatures reported by Ecosure [19];
- **No Growth (T = -5°C)**: set all retail deli case temperatures to -5°C (23°F). At this temperature, no *L. monocytogenes* growth will occur.

12) What would be the potential public health impact of complete compliance to the cold-holding requirements for certain RTE foods in deli cases (hold at ≤41°F i.e., ≤5 °C)?

- **Temp ≤ 5°:** use the retail deli case temperatures observed in the Ecosure dataset [19] at or below 5°C (41°F). This implies that all retail delis with deli case temperatures exceeding the 2009 FDA Food Code recommendation come into compliance.

13) What would be the impact of shortening the time a RTE product can be used in a deli department?

- **Shorten time in retail deli**: retail delis reduce the length of time RTE products are held before they are sold or disposed from 7 to 4 days.

14) What would be the impact if all (or no) RTE products (e.g., RTE meat and poultry products, RTE deli salads) coming into the deli were formulated with growth inhibitors?

- **All GI**: reformulate all RTE products sold at the retail deli that would otherwise support *L. monocytogenes* growth to include growth inhibitors, to restrict growth [same growth inhibitor (GI) formulation as cured ham with GI];
- **No GI:** reformulate all RTE products that support *L. monocytogenes* growth that are sold at the retail deli and do not include GI to restrict *L. monocytogenes* growth.

7.2. Baseline analysis

This section provides the results of the various baselines and compares the various scenarios within each baseline. The following section (7.3) compares the scenarios across the various baselines.

The actual levels selected for specific baselines ("Retail deli with Multiple Niches" and "Retail delis with contaminated incoming RTE products") were selected to be large enough to show an increased predicted risk relative to the "no niche" baseline. Before providing the results of the various baselines, Section 7.2.1 provides a sensitivity analysis of the levels of specific baselines.

7.2.1 Sensitivity analysis

Figure 15 shows a sensitivity analysis of the mean predicted risk of listeriosis per serving of RTE food for a susceptible population [59] as these choices change. The blue bars to the left are for different niche loadings. "W" and "D" stand for mean weekly or mean daily transfers, respectively. The number represents the mean number of cfu transferred to the site when transfer occurs. For contaminated RTE product, the number in parentheses represents the mean $\log_{10}$ concentration [e.g., the baselines scenarios "Retail delis with contaminated incoming RTE product" are from the (-5) bars].

It is important to note that, unlike the results presented for incoming contaminated RTE products' baselines (see Sections page 88 and page 92), the estimated risk presented here specifically excludes sales of the contaminated RTE product itself. Thus, any increase in predicted public health risk is due only to consumption of RTE foods cross contaminated at the retail deli.

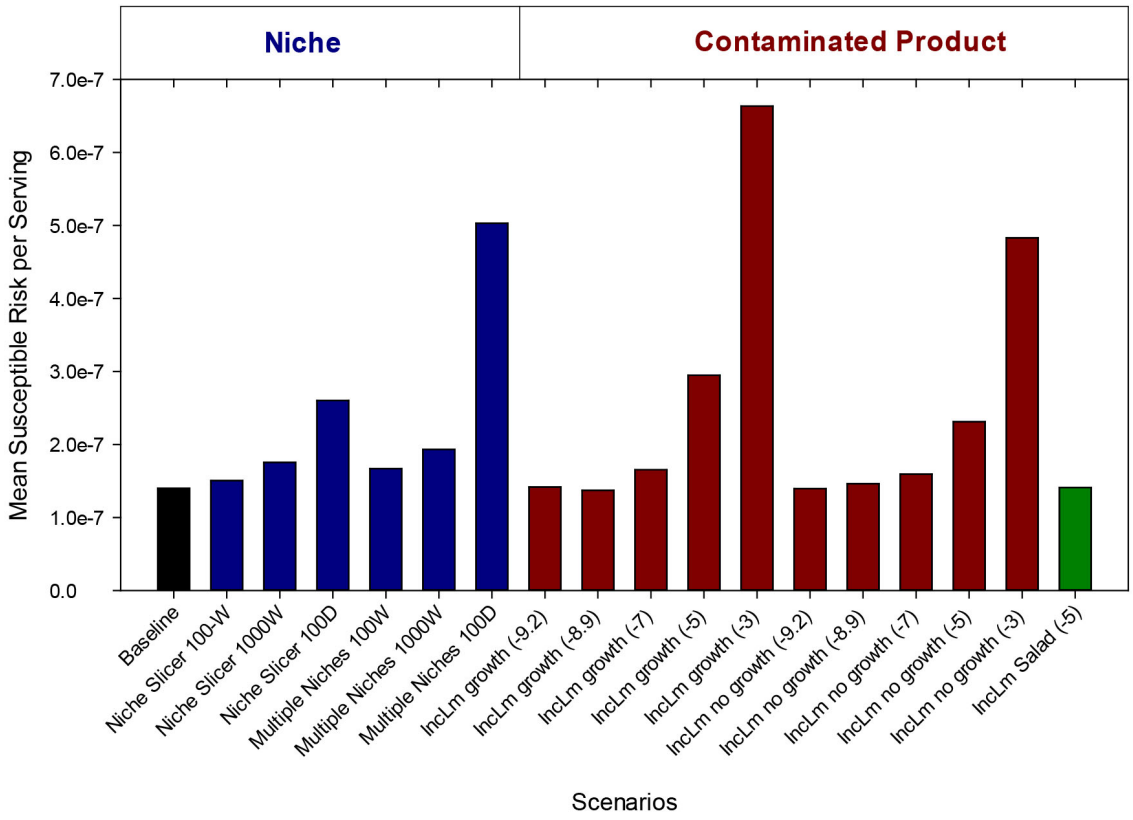


Figure 15. Sensitivity analysis for niches and contaminated RTE product

Baseline: Retail deli with no niche or environmental bacteria transfer on food-contact surfaces.

Niche Slicer 100-W: Retail deli with transfers of 100 *L. monocytogenes* cfu on the food-contact surface of the slicer, with an average frequency of one transfer per week.

Niche Slicer 1000-W: Retail deli with transfers of 1,000 cfu *L. monocytogenes* on the food-contact surface of the slicer, with an average frequency of one transfer to RTE product per week.

Niche Slicer 100-D: Retail deli with transfers of 100 cfu *L. monocytogenes* on the food-contact surface of the slicer, with an average frequency of one transfer to RTE product per day.

Multiple Niche 100-W: Retail deli with transfers of 100 cfu *L. monocytogenes* on multiple food-contact surfaces, with an average frequency of one transfer to RTE product per week.

Multiple Niche 1000-W: Retail deli with transfers of 1,000 cfu *L. monocytogenes* on multiple food-contact surfaces, with an average frequency of one transfer to RTE product per week.

Multiple Niche 100-D: Retail deli with transfers of 100 cfu *L. monocytogenes* on multiple food-contact surfaces, with an average frequency of one transfer to RTE product per day.

IncLm growth (-9.2): Retail deli with no niche or environmental bacteria transfer on food-contact surfaces, with *L. monocytogenes* average contamination of incoming RTE products equal to the current estimate of federally inspected plant (mean of the $\log_{10}$ concentration: -9.2 $\log_{10}$ cfu/g).

IncLm growth (-8.9): Retail deli with *L. monocytogenes* average $\log_{10}$ contamination of incoming RTE products that support growth of *L. monocytogenes* equal to -8.9 $\log_{10}$ cfu/g, other RTE products having an average $\log_{10}$ contamination equal to -9.2 $\log_{10}$ cfu/g.

IncLm growth (-5): Retail deli with *L. monocytogenes* average $\log_{10}$ contamination of incoming RTE products that support growth of *L. monocytogenes* equal to -5 $\log_{10}$ cfu/g, other RTE products having an average $\log_{10}$ contamination equal to -9.2 $\log_{10}$ cfu/g.

IncLm growth (-3): Retail deli with *L. monocytogenes* average $\log_{10}$ contamination of incoming RTE products that support growth of *L. monocytogenes* equal to -8.9 $\log_{10}$ cfu/g, other RTE products having an average $\log_{10}$ contamination equal to -3 $\log_{10}$ cfu/g.

IncLm no growth (-9.2): Retail deli with no niche or environmental bacteria transfer on food-contact surfaces with *L. monocytogenes* average contamination of incoming RTE products equal to the current estimate of federally inspected plants (-9.2 $\log_{10}$ cfu/g). Same situation as in S-IncLm growth (-9.2).

IncLm no growth (-8.9): Retail deli with *L. monocytogenes* average $\log_{10}$ contamination of incoming RTE products that do not support growth of *L. monocytogenes* equal to -8.9 $\log_{10}$ cfu/g, other RTE products having an average $\log_{10}$ contamination equal to -9.2 $\log_{10}$ cfu/g.

IncLm no growth (-5): Retail deli with *L. monocytogenes* average $\log_{10}$ contamination of incoming RTE products that do not support growth of *L. monocytogenes* equal to -5 $\log_{10}$ cfu/g, other RTE products having an average $\log_{10}$ contamination equal to -9.2 $\log_{10}$ cfu/g.

IncLm no growth (-3): Retail deli with *L. monocytogenes* average $\log_{10}$ contamination of incoming RTE products that do not support growth of *L. monocytogenes* equal to -8.9 $\log_{10}$ cfu/g, other RTE products having an average $\log_{10}$ contamination equal to -3 $\log_{10}$ cfu/g.

Note: For the specific objective of this sensitivity analysis, the estimated risks for the simulations that incorporated a contaminated RTE product exclude the sales of the contaminated product itself. These results should not be compared to those presented in the later sections. For example, if the mean incoming $\log_{10}$ level is increased to -5 $\log_{10}$ cfu/g, the mean risk per serving for the susceptible population with an incoming product that supports growth is estimated to be 16.6×10^{-7} when the sales of the contaminated RTE product are considered. If the contaminated product sales are excluded, the mean risk is 2.9×10^{-7} as shown in the graph. These figures are 2.8×10^{-7} vs. 2.3×10^{-7} when the incoming contaminated product does not support growth.

The main conclusions of the sensitivity analysis are that:

- allowing more *L. monocytogenes* into the retail deli environment increases the predicted risk, regardless of whether these bacteria come from a niche(s) in the retail deli environment or from *L. monocytogenes* on RTE product from the processor;
- highly contaminated RTE product cross contaminates other RTE products, leading to an increase in predicted risk per serving from consumption of the cross contaminated products. This is especially true for highly contaminated RTE products that permit growth, but it is also true for those that do not permit growth.
- allowing more frequent environmental cross contamination (daily *vs*. weekly) has proportionally more impact than allowing more bacteria per cross contamination event (100 *vs*. 1,000 cfu per contamination event);

Based on this sensitivity analysis, the following baselines were chosen:

- Retail deli with Multiple Niches/Transfers from the Environment : multiple niches/transfers, 100 cfu, with an average frequency of one transfer per week;

- Highly contaminated RTE products: mean level of *L. monocytogenes* $\log_{10}$ contamination of -5 $\log_{10}$ cfu/g.

7.2.2 Baseline conditions

Baseline Condition: Multiple Niches / Transfers from the Environment

Note that the scales are not held constant across each graph in the following sections, notably for different baselines. The baselines and changes in retail deli practices are identified using an abbreviation, as specified above. The reader can refer to the table on page vi for an extended description of these abbreviations.

For this baseline, a retail deli with multiple niches is used. Each niche contaminates its associated site with *L. monocytogenes* at a mean frequency of once per week and at a mean transfer of 100 cfu for each contamination event. This baseline would also mimic retail delis with frequent transfers from the retail deli environment.

The change in RTE products contaminated with *L. monocytogenes* and corresponding change in predicted public health risk (estimated mean risk per serving to the susceptible population) as a result of changes in sanitation and retail deli worker/industry behavior are shown in Figure 16 and Figure 17. The bottom graphs show the prevalence of *L. monocytogenes* in RTE products and the estimated risk of listeriosis. The top graphs present the relative change (%) in estimated prevalence per serving and in the estimated risk of listeriosis per serving relative to the baseline.

For each baseline, 30 simulations of 100 retail delis × 1,000,000 servings are computed with the model. The 2.5^{th} and 97.5^{th} percentiles of the mean prevalence and the 2.5^{th} and 97.5^{th} percentiles of the mean risk per serving obtained from these 30 simulations provides 95% confidence intervals for this baseline. Changes from the baseline are evaluated from the results of 1 simulation of 100 retail delis × 1,000,000 servings. Results falling within the 95% confidence interval should be considered as not significantly different from the results obtained in the baseline. The 95% confidence intervals about the baseline are shown as horizontal lines on the bottom graphs.

As can be seen in Figure 16 and Figure 17, the absence of sanitation greatly increases the estimated prevalence of *L. monocytogenes* in the sold RTE products and, therefore, the predicted public health risk resulting from these RTE products. Not conducting any sanitation increases the estimated risk by 41%

(x-axis label: No Sanitation). Risk reductions can be predicted by reducing the incoming level of *L. monocytogenes* on RTE products (Reduce Level). A reduction in incoming level of *L. monocytogenes* on RTE products yields a 22% decrease in the predicted per-serving risk from RTE products. Conceptually, preventing cross contamination by setting all the transfer coefficients to 0 (Transfers and Slicer to 0) also significantly reduces the predicted risk (34%). When the slicer transfer coefficients were not included (Transfers to 0), the predicted risk was not significantly different from the baseline, emphasizing the importance of the slicer in RTE product cross contamination. Any improvement in the design of the slicer that would reduce the transfer coefficients could have a potential beneficial impact in mitigating the predicted risk of listeriosis.

Figure 18 and Figure 19 display the effect that the growth scenarios have on the mean predicted risk per serving and the prevalence of *L. monocytogenes* in RTE product sold to the consumer when multiple niches are present. While the effects of most scenarios on prevalence are insignificant, the effects on relative risk are profound. Including a growth inhibitor in all RTE products (All GI) almost does away with any predicted risk (96% reduction). Conversely, removing growth inhibitors (No GI) increases the predicted risk by almost a factor of two (184%). These results emphasize the importance of mitigations that control the growth of *L. monocytogenes* in RTE product in the retail deli and in the home. The inclusion of growth inhibitors in RTE product that supports *L. monocytogenes* growth is a mitigation scenario that will continue to have an effect once the RTE product is sold and leaves the retail deli. While growth inhibitors have little impact on prevalence, they have a significant impact on *L. monocytogenes* concentrations at the time of consumption, and thus on the predicted risk. Proper holding temperatures and reduced holding times at home also would reduce the predicted risk, but this is out of the scope of this study, and improvement of cold holding at home was not tested here. As previously observed in *L. monocytogenes* risk assessment [3, 59], time and temperature abuse during home storage is considered a major contributor to the predicted risk of contracting listeriosis from RTE foods.

While difficult to tell because of the scales, Figure 19 also shows that improved temperature control is an effective risk reduction mitigation. Maintaining all display case temperatures at 5°C (41°F) or less resulted in a 9% reduction in the predicted risk when compared with the current estimated industry practice.

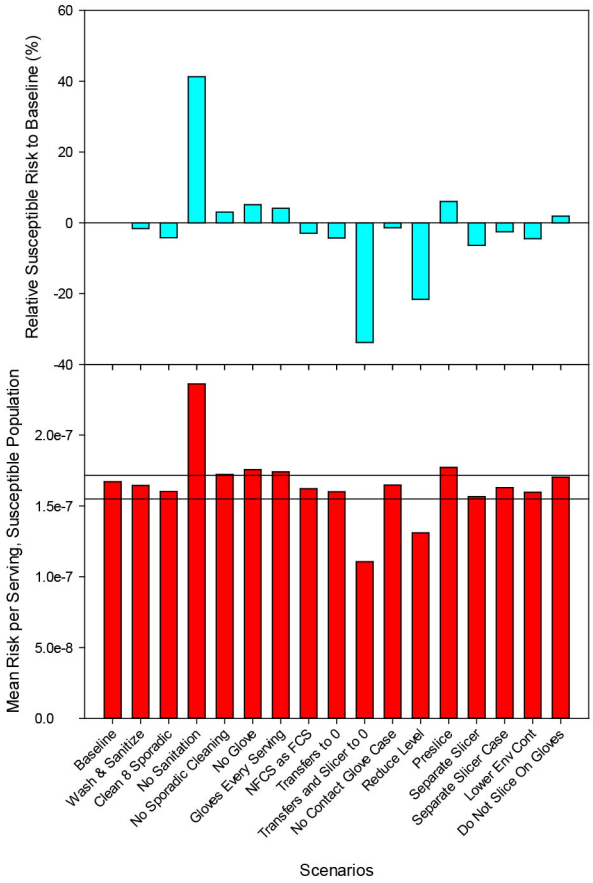


Figure 16: Effect of various sanitation scenarios on the mean risk per serving and relative risk in the susceptible population in a retail deli with multiple niches

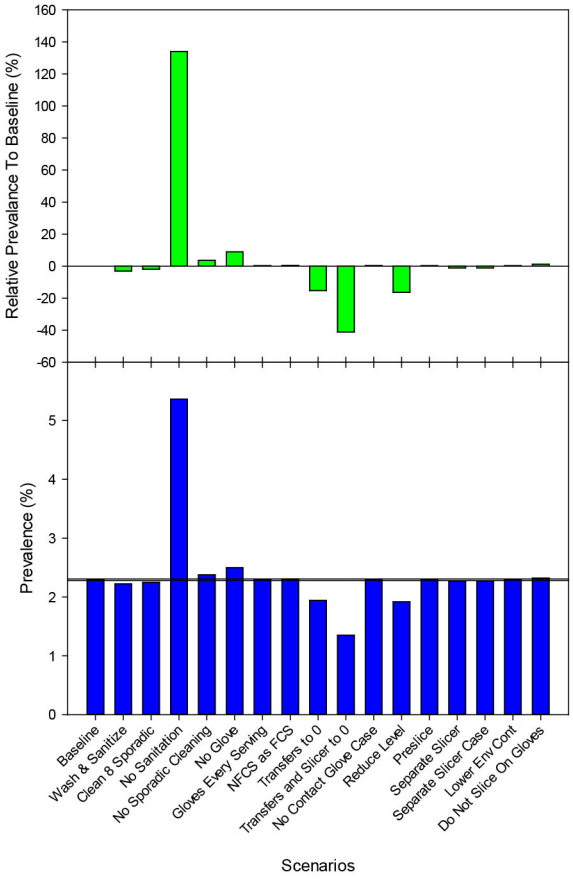


Figure 17: Effect of various sanitation scenarios on the prevalence and relative prevalence of *L. monocytogenes*-contaminated RTE products in a retail deli with multiple niches

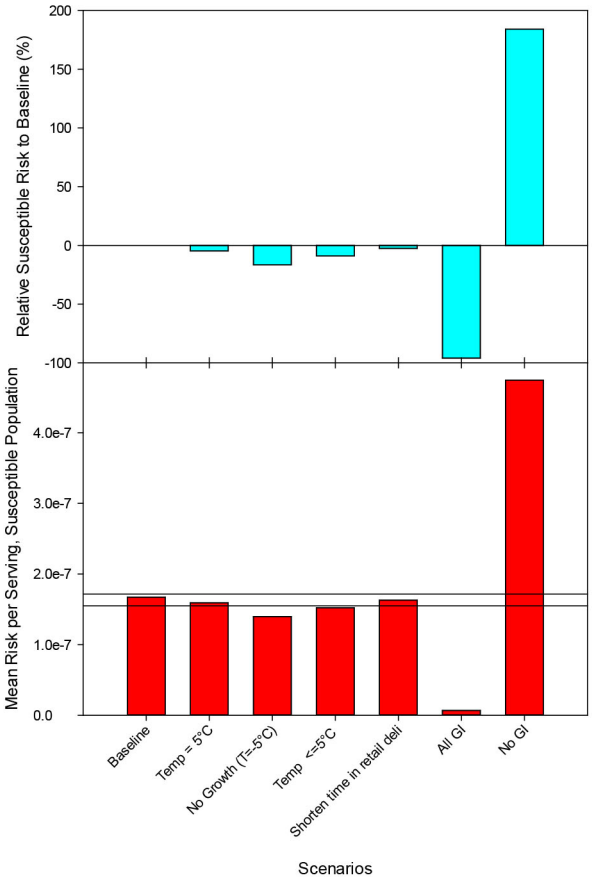


Figure 18: Effect of various growth scenarios on the mean risk per serving and relative risk in the susceptible population in a retail deli with multiple niches

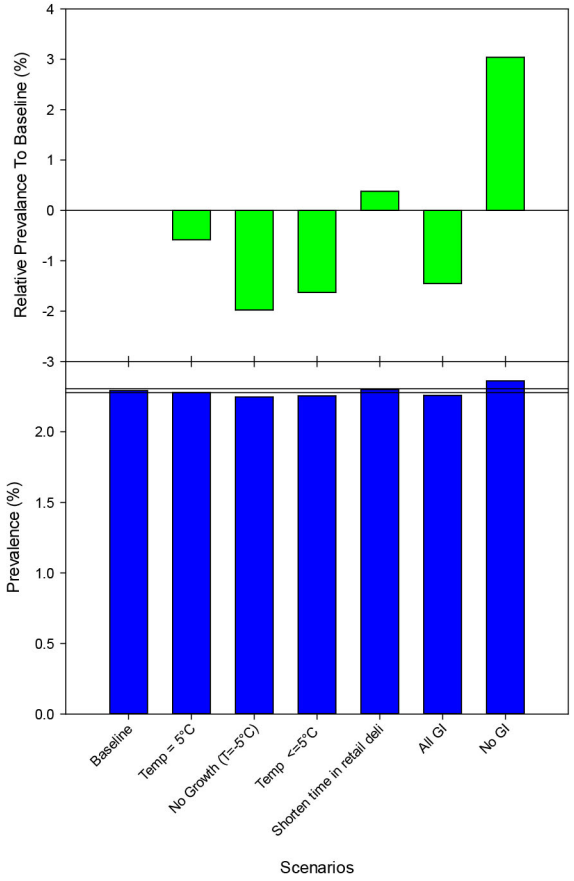


Figure 19: Effect of various growth scenarios on the prevalence and relative prevalence of *L. monocytogenes*-contaminated RTE products in a retail deli with multiple niches

Analyses of the growth, transfers, and inactivation for a typical baseline run are shown in Figure 20 and Figure 21.

Figure 20 illustrates the total number of bacteria transferred between each pair of sites as well as the total number of new bacteria from growth and the total number of bacteria that are discarded from inactivation/removal. Note that the overall number of bacteria transferred from/to RTE products (meat, cheese, and salad) is influenced by their relative sales for this figure: a RTE product rarely sold would lead to a lower total number of transferred bacteria. Significant growth is observed, particularly in deli meats. A significant number of bacteria end in the "washed" or "trashed" compartment (i.e., the compartments that count the number of bacteria that are eliminated from sanitation practices). This

reinforces the importance of sanitation. A large number of colored cells, both in the "From" and "To" category, are associated with gloves. This illustrates the importance that actual handling/touching by the worker has on cross contamination.

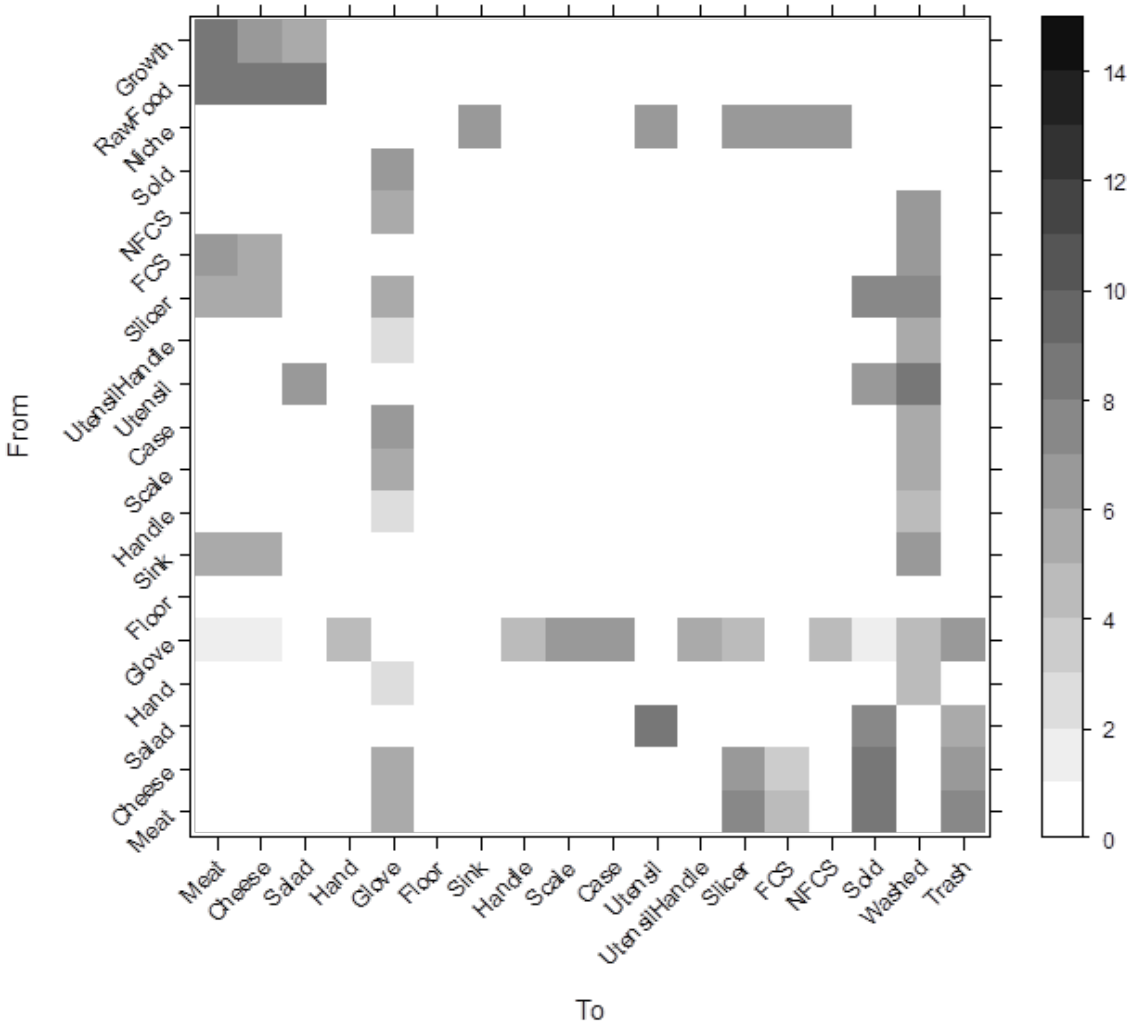


Figure 20: Total *L. monocytogenes* cfu grown, inactivated, and transferred between pairs of sites for a baseline retail deli with multiple niches (log_{10} scale). White areas indicate transfers that are not considered in the model or that are not meaningful.

Figure 21 illustrates similar matrix limited to transfers in which the bacteria transferred have been normalized by the actual number of contacts. Higher cfu transfers per contact are noted between deli meat and slicer, and to a lesser degree between deli cheese and slicer.

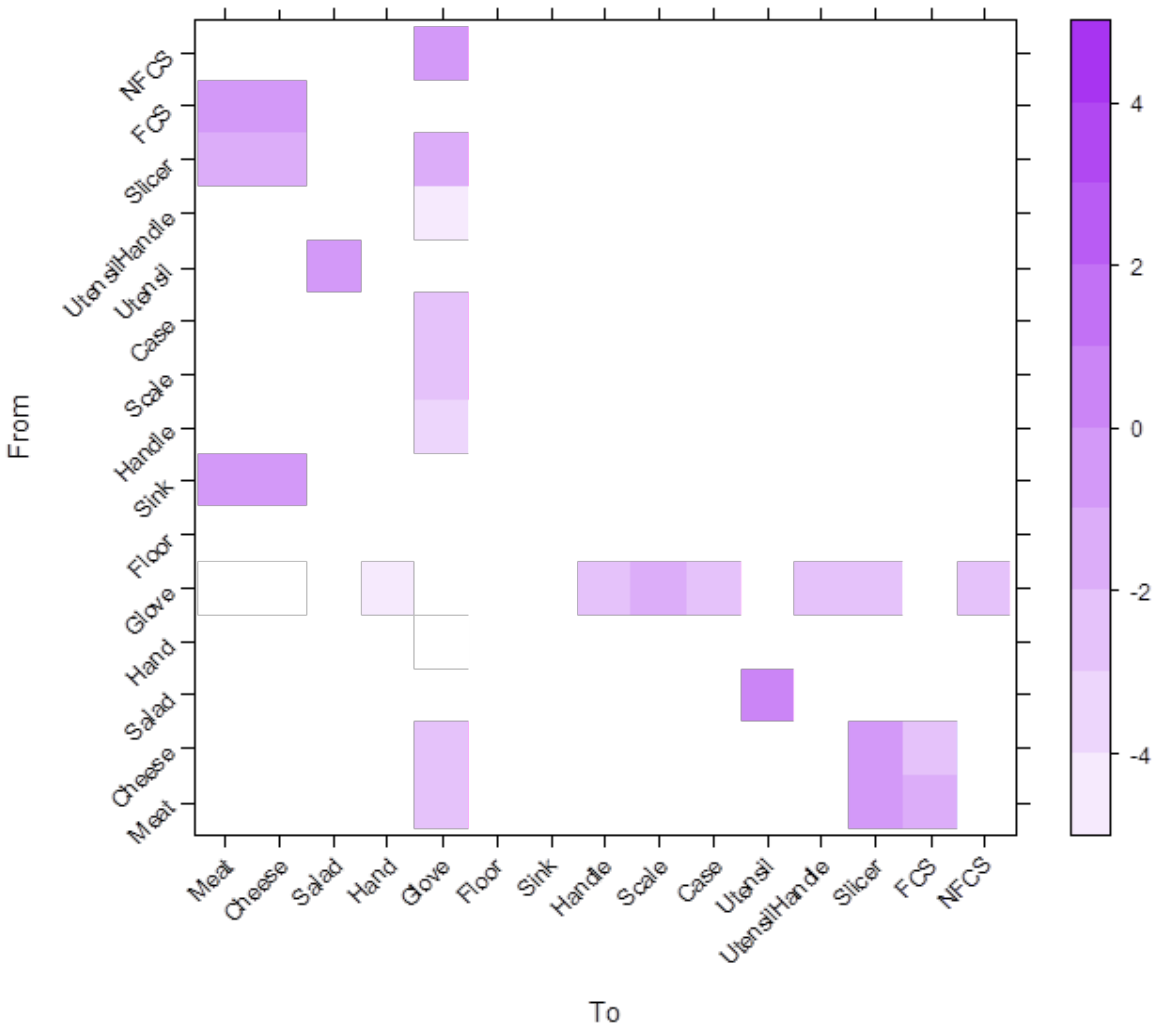


Figure 21: *L. monocytogenes* cfu transferred per actual contact between each pair of sites for a baseline retail deli with multiple niches (log_{10} scale). White areas indicate transfers that are not considered in the model or that are not meaningful.

Figure 22 evaluates the duration of site contamination. The upper graph indicates that for a retail deli with multiple niches/transfer from the environment, the NFCS are contaminated most often (upper graph). When contaminated, the contamination persists the longest (lower graph). Nevertheless, this graph shows that the contamination remains transient on sites even in the case of regular transfer from the niche/environment.

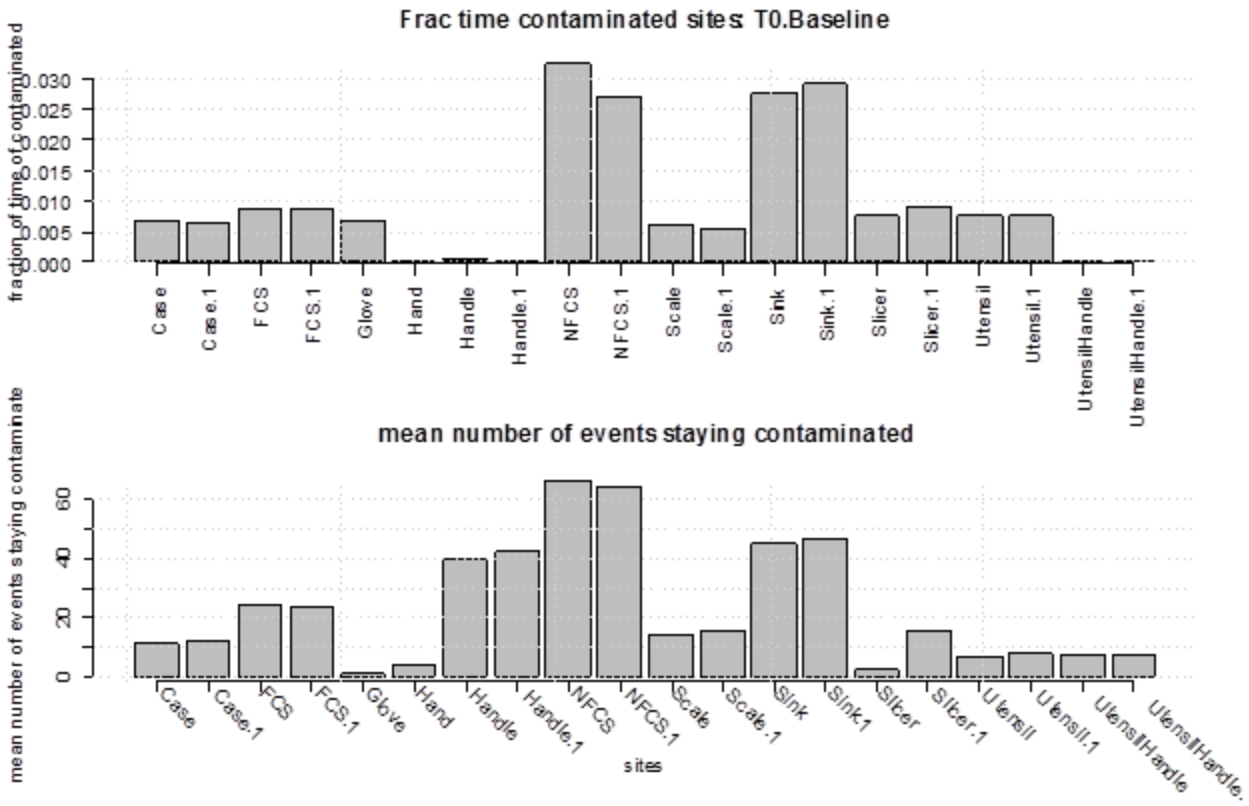


Figure 22: Contamination time analysis for sites in baseline retail deli with multiple contaminated niches. Upper graph: fraction of time each site is contaminated during a baseline simulation. Bottom graph: mean number of events during which contamination persists.

For a listeriosis case to occur through a retail deli sale, several events must occur. Contamination must be present in, or enter, the retail environment. Within this model, contamination can enter the retail deli by means of a contaminated chub or be present in the retail deli in a niche or other environmental source. Figure 23 illustrates the process leading from a contaminated chub to a high risk of listeriosis from consumption of a RTE product sold from the deli department. Thirty sales are shown from a baseline retail deli with transfer from the environment, although the environment contamination itself does not factor into this analysis. The sales and actual RTE products are shown in Figure 23a (bottom). A chub of cured ham with a high *L. monocytogenes* concentration is used for two sales: #84903 and #84909. All other RTE products sold are at much lower concentrations. When the RTE products are sliced, the total number of bacteria leaving with each sale is shown in Figure 23b. Note that these values are total cfu, not adjusted for weight of the sale. As expected, the two sales from the contaminated chub have very high cfu counts; more than 2,000 and over 6,000 cfu, respectively. The pattern after the contaminated chub is sliced changes. Sale #84904 is a deli cheese RTE product, so a different slicer was used, and cross

contamination does not occur. The two subsequent sales (#84905 and #84906) are for salami and uncured turkey, respectively. Bacterial transfers from the contaminated slicer contaminate these sales, in a typical exponentially decreasing amount, until the slicer is either sanitized or all of the available bacteria are transferred from the slicer to sales. Subsequent sales (#84907 and #84908) thus are not contaminated. Therefore, this first cross contamination event contaminates two additional sales. The second contamination event (#84909) contaminates three additional sales. Sale #84912 is potato salad, so does not contact the slicer and is not involved in the cross contamination.

The dose at consumption for each of these sales is shown in Figure 23c. For listeriosis to occur, the FAO/WHO dose-response model [59] indicates that very large numbers of bacteria must be consumed. Therefore the next process that must occur prior to a listeriosis case is significant growth during consumer handling (i.e., from the time of the sale to the time of consumption). This implies that the RTE product itself must support growth and, typically, consumer mishandling (i.e., the RTE product is in the retail deli for an extended period and/or at an elevated temperature). Only one of the sales in this example has both these features: sale #84906. On the cross contaminated uncured turkey, *L. monocytogenes* grew to its maximum concentration of 10^8 cfu/g and was consumed in an approximate 100 g serving. The other contaminated sales are either in low/non-growth RTE products or are not mishandled.

Finally, a listeriosis case usually results when a susceptible person consumes a high dose of *L. monocytogenes*. Figure 23d shows the resulting risks of invasive listeriosis following consumption of one serving from these sales. For this run, the one high dose was consumed by an individual from the general population, so the resulting risk of illness, evaluated using the corresponding dose-response model, was less than 0.03%.

Given this required chain of events for each listeriosis case, it is much more likely that retail contamination results in very sporadic cases of listeriosis, unlike the major outbreaks in which large numbers of illnesses are traced back to insanitary conditions or loss of process control. Currently, cases known to be outbreak-associated are <1% of cases reported to the Foodborne Diseases Active Surveillance Network (FoodNet) [10]

The model also illustrates the difficulty of tracing back sporadic illnesses to a specific food. Assuming RTE product was still available to be tested at the home and at the retail deli, testing the uncured turkey at the home would indicate a high concentration. However, testing at retail the exact chub the serving was taken from would find *L. monocytogenes* absent. Even without consideration of the long incubation

period for listeriosis [122], identifying contaminated RTE food and linking this to retail deli cross contamination would be very difficult.

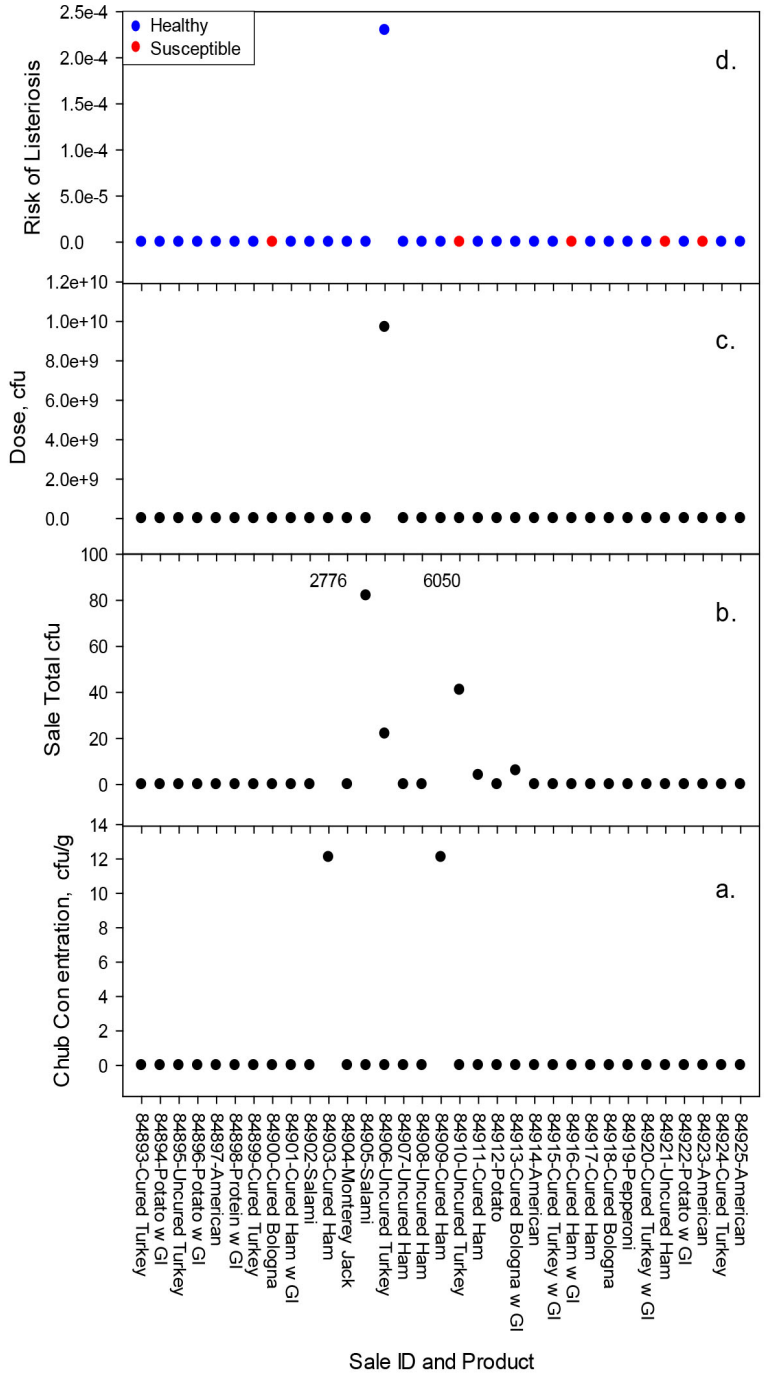


Figure 23. Timeline illustration of sales, cross contamination, and subsequent risk of listeriosis

Baseline Condition: No niche

For this baseline, a retail deli without any niches or highly contaminated RTE product was evaluated. The sanitation scenarios are shown in Figure 24 and Figure 25, and the growth scenarios are shown in Figure 26 and Figure 27. Here, sanitation has a much lower impact, because there are fewer bacteria to remove. Pre-slicing increases the predicted risk by 25%. As with the niches-contaminated retail deli, reducing incoming *L. monocytogenes* levels reduces the predicted risk (24% reduction) and preventing any cross contamination does as well (19% reduction). Only no sanitation has a noticeable impact on the prevalence.

The growth scenarios are shown in Figure 26 and Figure 27. As with a niche retail deli, the impact of using growth inhibitors was overwhelming. Temperature control was even more effective for retail delis without any niches than for niche retail delis. Simply maintaining case temperatures at less than 5°C (41°F) resulted in a 16% reduction in the predicted risk. For a retail deli without any niches, the only way for external bacteria to enter the deli area is through the incoming RTE product at low concentrations. Preventing *L. monocytogenes* from growing becomes more important. In the niche retail deli, even when growth was completely controlled, new *L. monocytogenes* regularly entered because of the niches.

A comparison of the relative effectiveness of the changes in practice in a retail deli without any niches and a retail deli with multiple niches is shown in Figure 28. The growth inhibitor options have been removed for scaling reasons. A 1:1 line (dashed) and a regression line (solid) have been added for reference. A linear regression is not expected. The predicted risks from a retail deli with multiple niches are logically higher; all the points but one fall below the 1:1 line. The degree to which they fall below this line is based on the arbitrary assumption of a frequency of contamination from a niche at 1 week, with a mean transfer of 100 cfu. Different niche loadings would have moved the points closer or farther from the 1:1 line, as evaluated in the sensitivity analysis of Section 7.2.1. This graph illustrates which scenarios perform significantly better or worse for the different retail deli types.

For example, pre-slicing falls far above the regression line. Pre-slicing in a retail deli without any niches is a relatively worse practice than in a niche-contaminated retail deli. Conversely, the three temperature control options all fall far below the regression line. Temperature control is a relatively better mitigation for retail delis without any niches than for niche-contaminated retail delis. The lack of sanitation impacts a niche contaminated retail deli more than a retail deli without any niches.

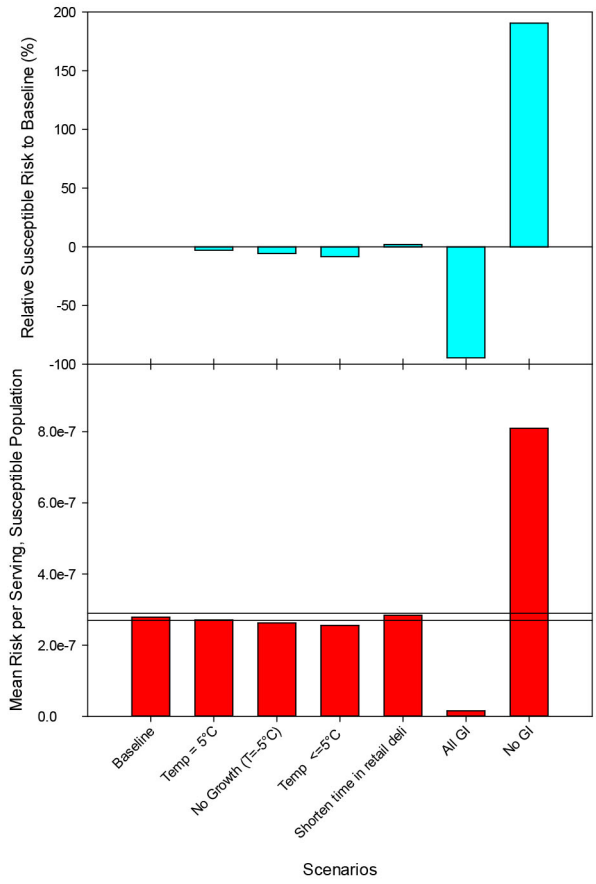


Figure 24: Effect of various sanitation scenarios on the mean risk per serving and relative risk in the susceptible population in a retail deli without any niches

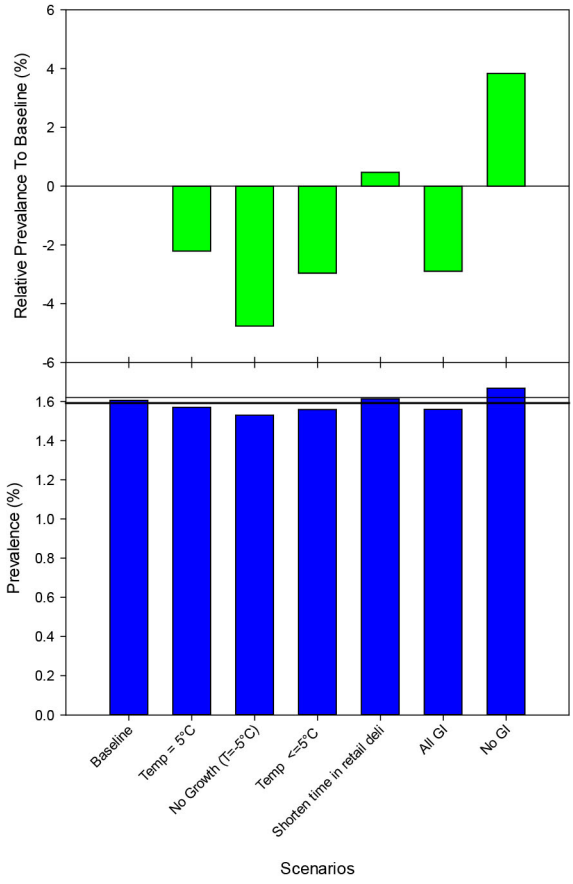


Figure 25: Effect of various sanitation scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products in a retail deli without any niches

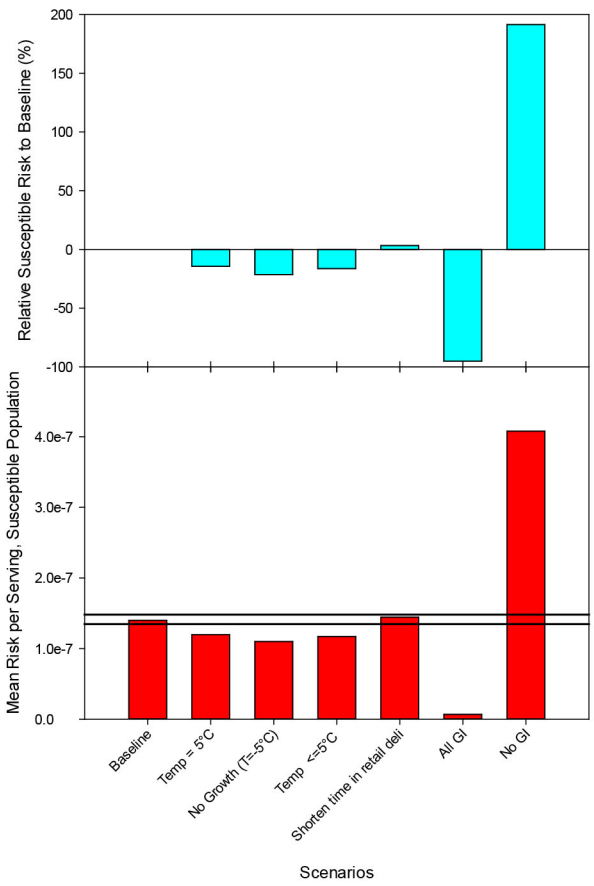


Figure 26: Effect of various growth scenarios on the mean risk per serving and relative risk in the susceptible population in a retail deli without any niches

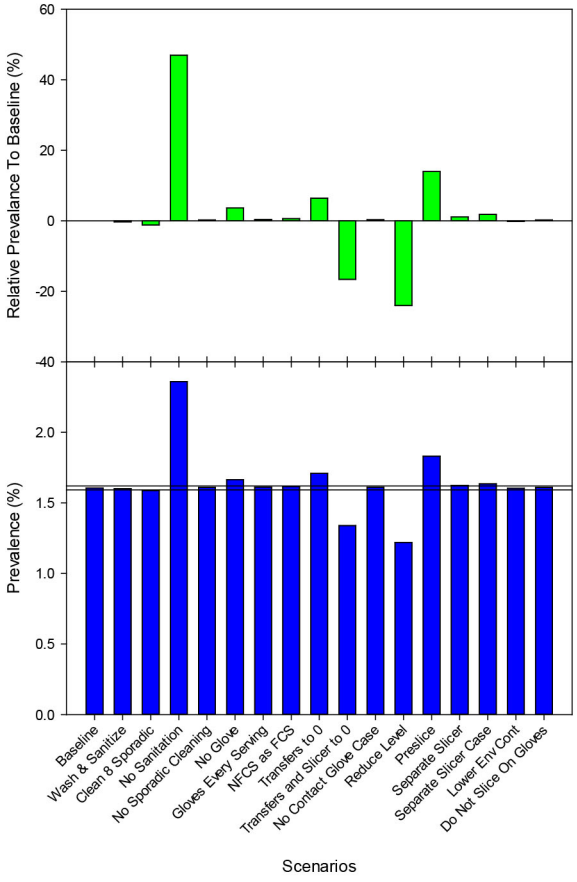


Figure 27: Effect of various growth scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products in a retail deli without any niches

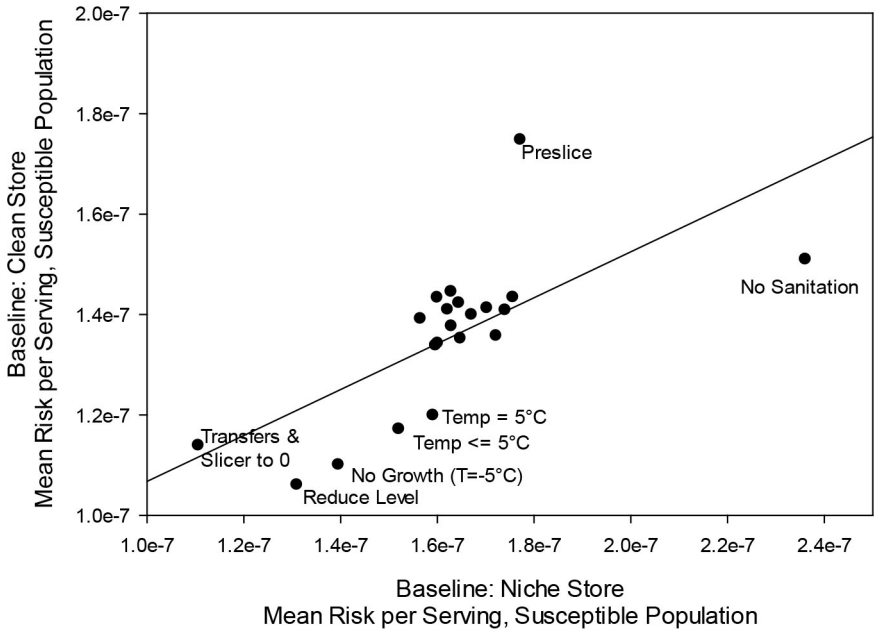


Figure 28: Risk comparisons between niche retail deli and retail deli without any niches

Baseline Condition: highly contaminated incoming RTE product that supports growth

For these scenarios, the incoming growth-supporting RTE product had the mean incoming *L. monocytogenes* $\log_{10}$ concentration increased from -9.2 $\log_{10}$ cfu/g to -5 $\log_{10}$ cfu/g. This level of contamination is fairly high. It leads to a probability for a 2,270 g chub to be positive (≥1 cfu in the chub) of 32%, and a probability for this chub to have an average concentration ≥100 cfu/g of 0.83% (Table 13). The predicted risks include the risk linked to the incoming contaminated RTE product, (i.e., the contaminated RTE product was sold and consumed), and these sales were included in the risk calculation. A different approach to contaminated RTE product was taken during the sensitivity analysis of Section 7.2.1, where sales from the contaminated RTE product were not recorded.

Sanitation scenarios are shown in Figure 29 and Figure 30, while growth scenarios are shown in Figure 31 and Figure 32. In this baseline, only pre-slicing significantly increased the predicted risk (50%). Removing all cross contamination had a slight beneficial effect (10% reduction). None of the other results were notably different from those of the baseline.

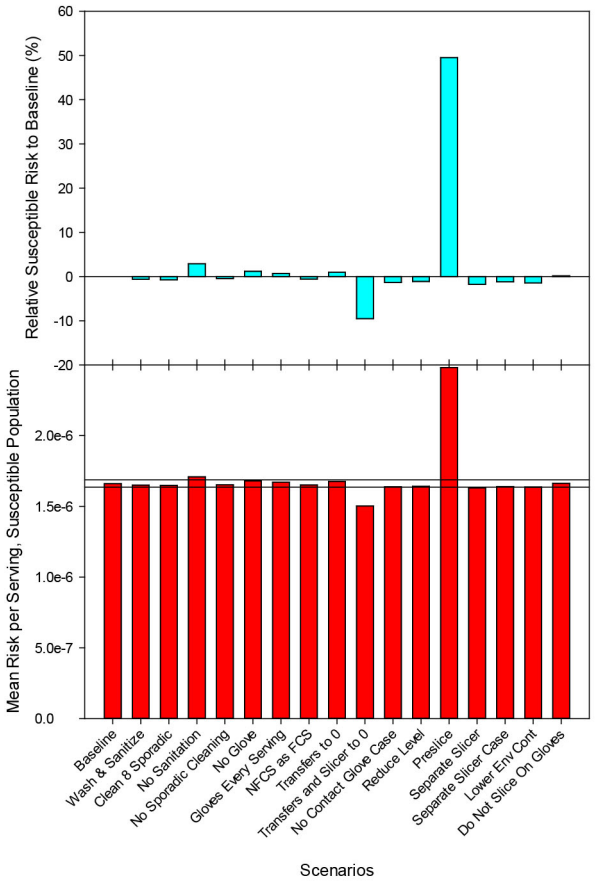


Figure 29: Effect of various sanitation scenarios on the mean risk per serving and relative risk in the susceptible population for retail delis with an incoming contaminated RTE product that supports growth

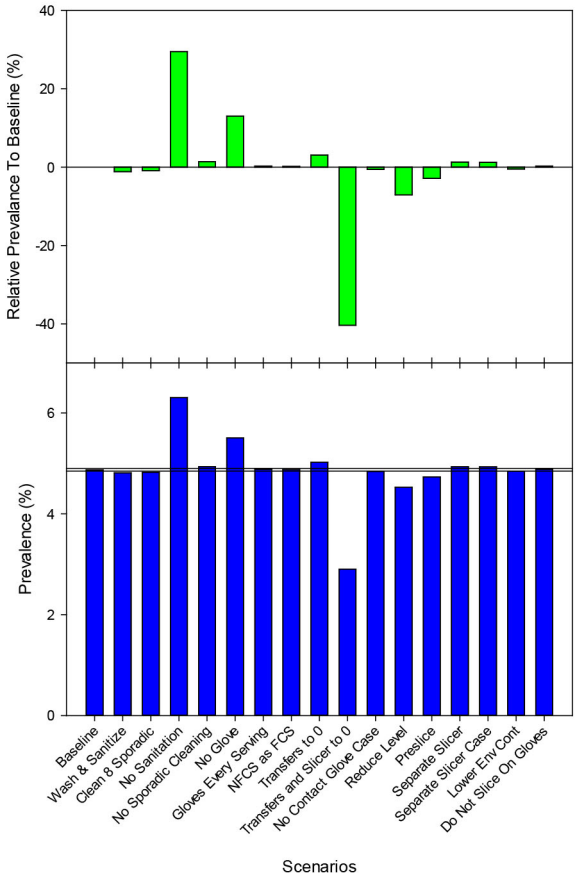


Figure 30: Effect of various sanitation scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products for retail delis with an incoming contaminated RTE product that supports growth

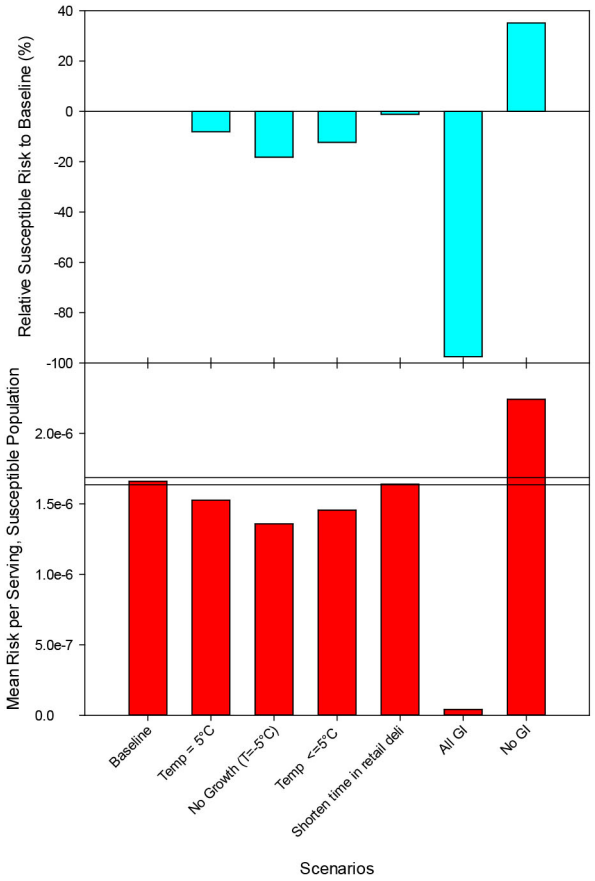


Figure 31: Effect of various growth scenarios on the mean risk per serving and relative risk in the susceptible population for retail delis with an incoming contaminated RTE product that supports growth

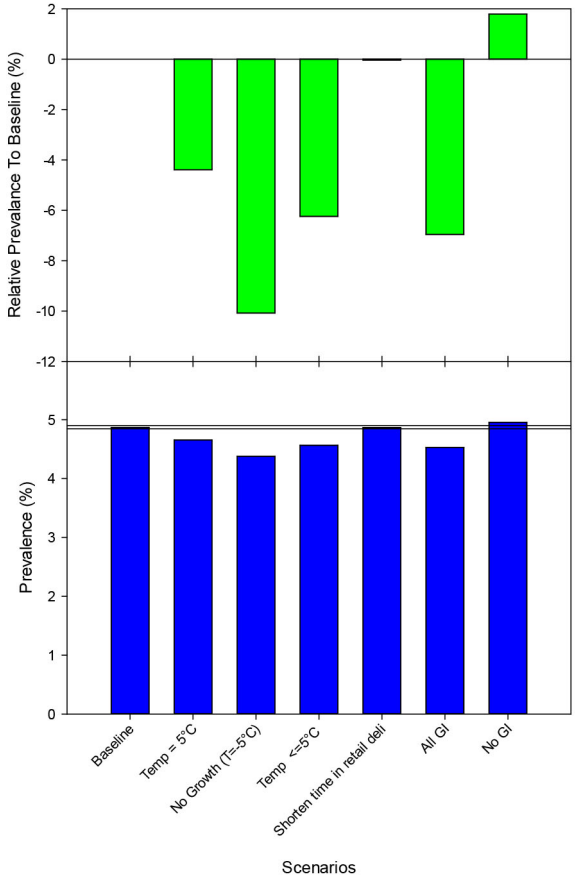


Figure 32: Effect of various growth scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products for retail delis with an incoming contaminated RTE product that supports growth

In this situation, the prevalences increase with no sanitation, even though there is little corresponding change in the predicted risk.

Growth mitigations showed more promise. As with all of the other retail deli types, use of growth inhibitors dominated the responses, and growth inhibitors for all RTE products virtually removed any risk. Controlling the case temperature to ≤5°C (41°F) resulted in a 12% reduction.

The risk comparison to a niche retail deli for different scenarios is shown in Figure 33. The growth inhibitor scenarios were not included on the graph, to allow the risk scale to focus on the remaining

scenarios. The 1:1 line is not included, because the scales are so different. Temperature controls are more effective in retail delis that have an incoming RTE food that supports growth than in retail delis with multiple niches. Pre-slicing is correspondingly worse in retail delis that have an incoming RTE food that supports growth, compared with retail delis with multiple niches.

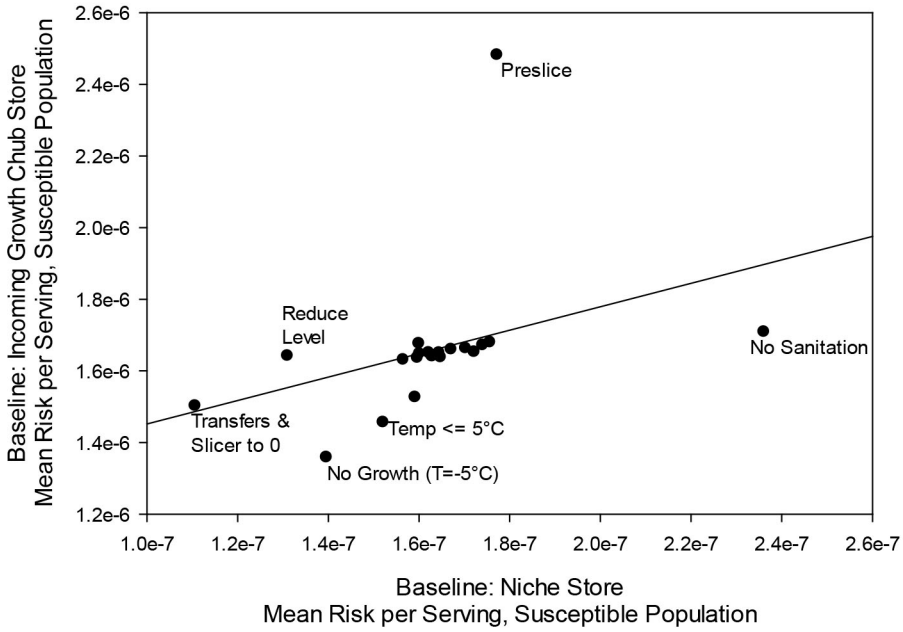


Figure 33: Risk comparison for niche retail deli versus retail deli with incoming RTE product that supports growth

It appears that the incoming levels of *L. monocytogenes* in the contaminated RTE product for this baseline are relatively high and represent a higher overall loading than in the niche retail deli. In this case, pre-slicing of the contaminated RTE product actually makes the situation worse. Controlling the growth in the relatively highly contaminated RTE product is effective, because the model does not include growth at FCS or NFCS. Therefore, while a niche contaminates an associated site, growth does not occur at the site.

Baseline Condition: highly contaminated incoming RTE product that does not support growth

As with the previous scenario, a retail deli with a highly contaminated incoming RTE product is modeled. In this case, the product does not support growth. As before, the mean of the $\log_{10}$ concentration of *L. monocytogenes* in this incoming RTE product is greater than the one from other products (from -9.2 $\log_{10}$ cfu/g to -5 $\log_{10}$ cfu/g).

Sanitation scenarios are presented in Figure 34 and Figure 35; growth scenarios are shown in Figure 36 and Figure 37. The theoretical "no cross contamination" scenario (Transfers and Slicer to 0) in the deli is quite effective (61 % reduction). If cross contamination is completely prevented, the high bacteria concentrations in the contaminated RTE product cannot spread to other RTE products, notably to RTE products that support growth. For this situation, pre-slicing also reduces the predicted risk (34% reduction). As expected, the theoretical "no sanitation" scenario increases the predicted risk (24% increase). In our setting, the "Separate Slicer" scenario implies that deli meat products that support growth are sliced on a specific slicer, and all other products are sliced on the other slicer. In this baseline, this scenario leads to a higher number of potentially cross contaminated RTE products. As a consequence, separate slicers for deli meat that support growth (with or without separate cases) increase the predicted risk by 23% in this baseline. More specific settings could be tested in future runs of this model.

Growth inhibitors are still critically important. For an incoming contaminated RTE product that does not support growth, temperature control is significantly different from the baseline, although slightly. Controlling the case temperature to ≤5°C (41°F) results in an 8% reduction. Because the contaminated RTE product does not support growth at any temperature, temperature control affects only the other RTE products.

The risk comparisons between retail delis with multiple niches and retail delis with incoming contaminated non-growth RTE product are shown in Figure 38. The points are above the 1:1 reference line, indicating higher predicted risk for the incoming contaminated chubs baseline, compared with the baseline with multiple niches. "No cross contamination," "pre-slicing," and "no sanitation" scenarios lead to lower risks, relative to the niche retail deli. Separate slicers lead to relatively higher risks.

A comparison between the conditions with increased contamination in a growth versus non-growth RTE product is shown in Figure 39. Both incoming contaminated RTE products have the same mean *L. monocytogenes* levels (mean of the $\log_{10}$ concentration increased from -9.2 to -5 $\log_{10}$ cfu/g). The

non-growth RTE product actually has a higher sales level, but the predicted risks from the growth-permitting RTE product are always substantially higher. The 1:1 line cannot be shown, because of the difference in scale. Having "no cross contamination" while instituting effective temperature controls appears to reduce risk more for RTE product that supports growth than for RTE products that do not support growth. Growth, especially when the RTE product is heavily contaminated, is a major source of new bacteria within the retail environment. Temperature control to reduce or prevent growth reduces the predicted risk when the contaminated RTE product supports growth. Similarly preventing cross contamination from the growth chubs, particularly as growth increases the concentrations further, also reduces the risk well. On the other hand, pre-slicing RTE foods increases the predicted risk significantly more when foods support the growth of *L. monocytogenes*.

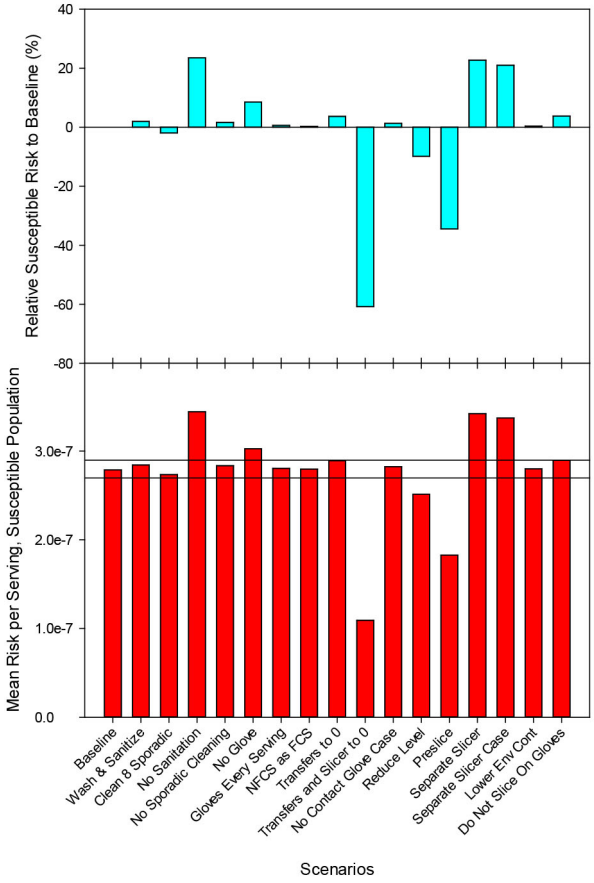


Figure 34: Effect of various sanitation scenarios on the mean risk per serving and relative risk in the susceptible population for retail delis with an incoming contaminated RTE product that does not support growth

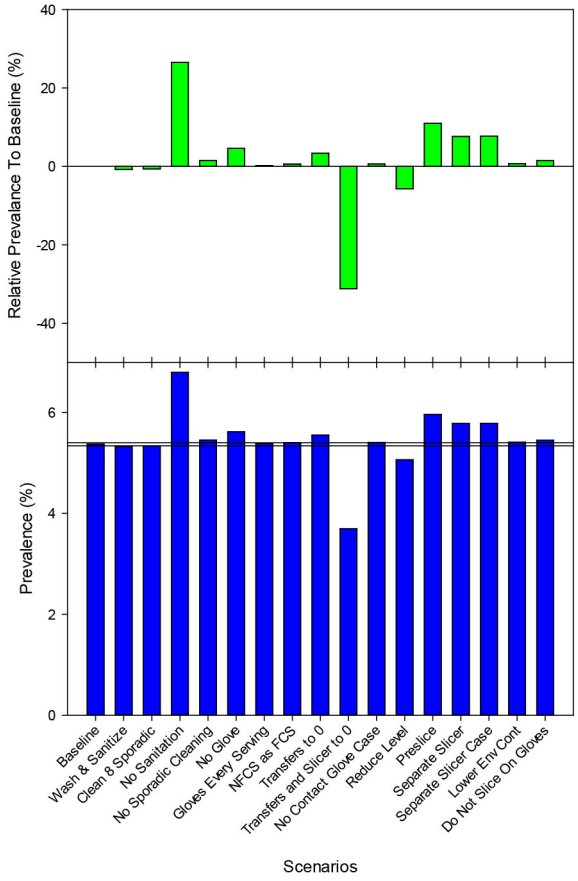


Figure 35: Effect of various sanitation scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products for retail delis with an incoming contaminated RTE product that does not support growth

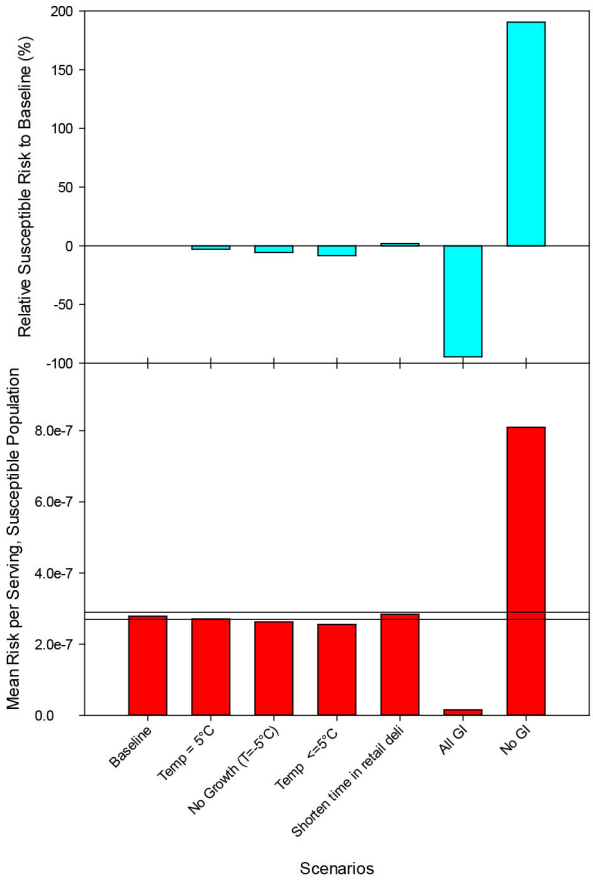


Figure 36: Effect of various growth scenarios on the mean risk per serving and relative risk in the susceptible population for retail delis with an incoming contaminated RTE product that does not support growth

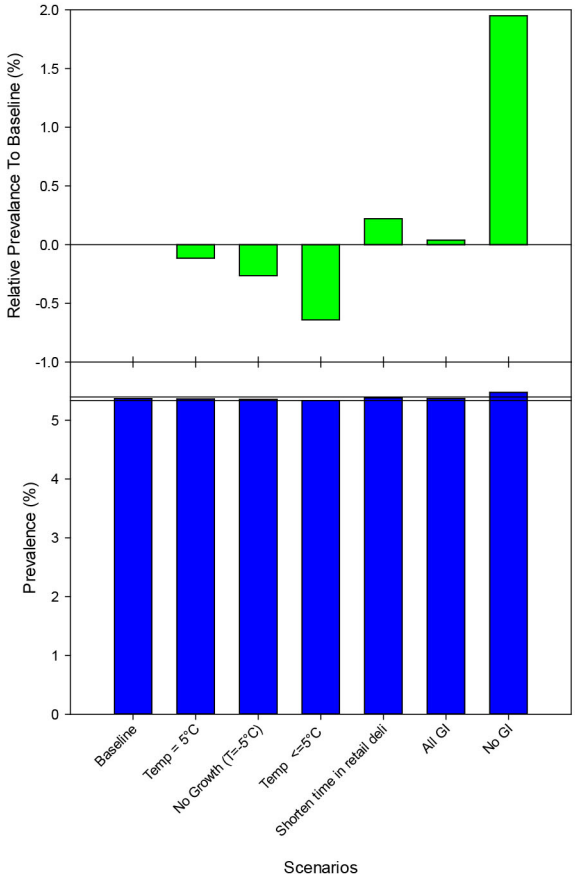


Figure 37: Effect of various growth scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products for retail delis with an incoming contaminated RTE product that does not support growth

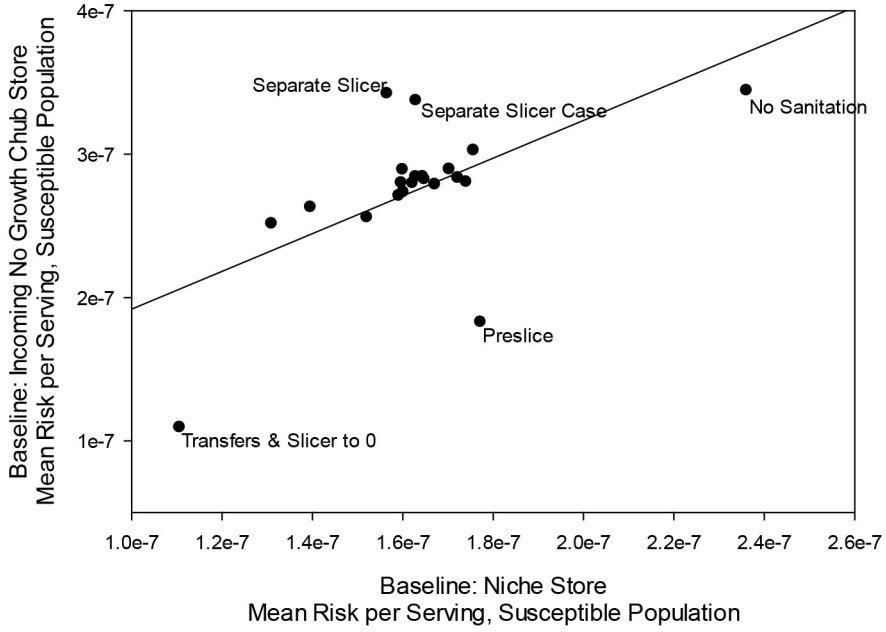


Figure 38: Risk comparison for niche retail deli versus a retail deli with incoming product that does not support growth

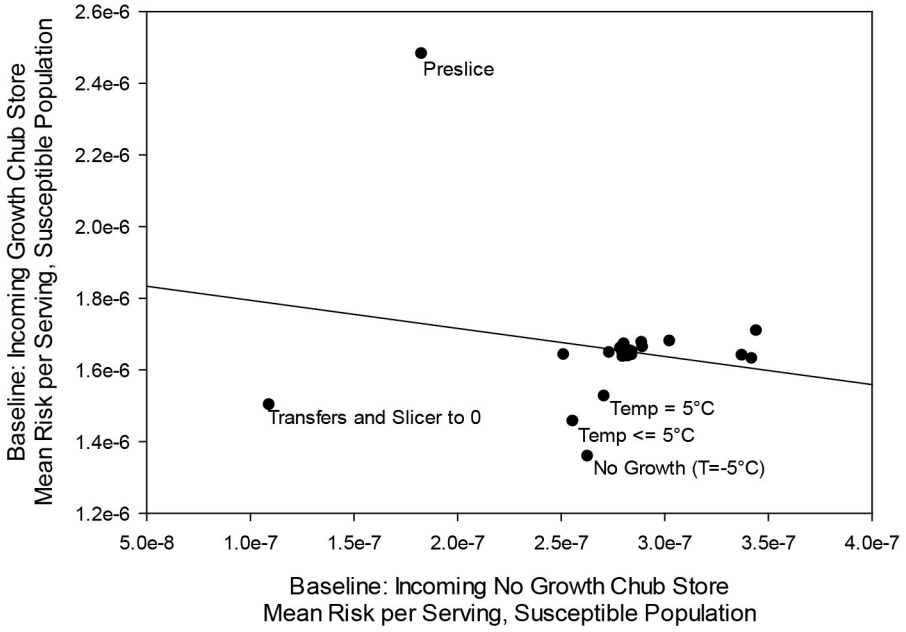


Figure 39: Risk comparison for niche retail deli versus retail deli with incoming RTE product that does not support growth versus one that does support growth

Baseline Condition: No niche, with required temperature control

The scenarios for a retail deli without any niches that maintains its deli case at ≤5°C (41°F) are shown in Figure 40 through Figure 43. As expected, the absolute magnitudes of the predicted risks are lower than in a baseline condition considering a retail deli without any niches. "No sanitation" and "pre-slicing" increase the predicted risk by 12% and 19%, respectively. Preventing all retail cross contamination and reducing the incoming *L. monocytogenes* level reduce the estimated risk by 19% and 22%, respectively. Growth inhibitors are still extremely effective.

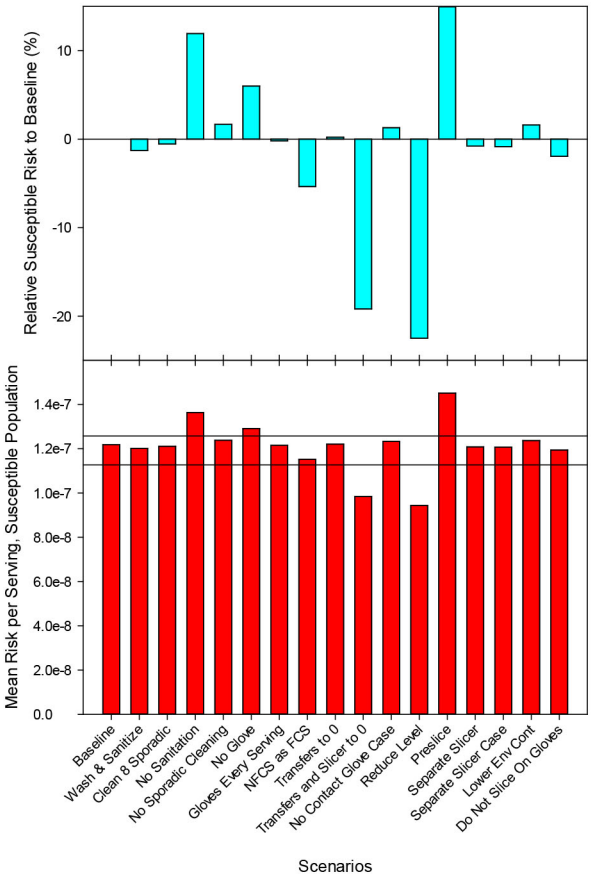


Figure 40. Effect of various sanitation scenarios on the mean risk per serving and relative risk in the susceptible population for retail deli with temperature control.

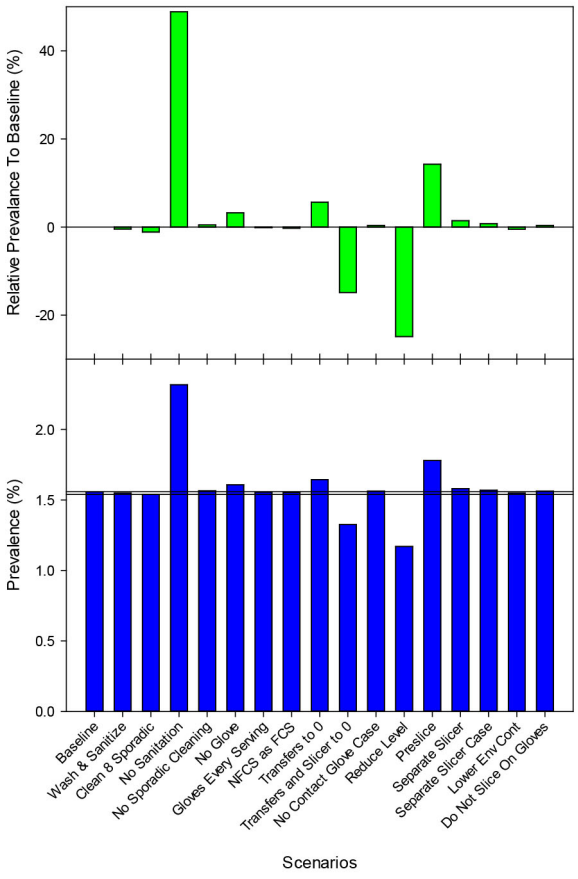


Figure 41. Effect of various sanitation scenarios on the prevalence and relative prevalence of *L. monocytogenes*-contaminated RTE products for retail deli with temperature control.

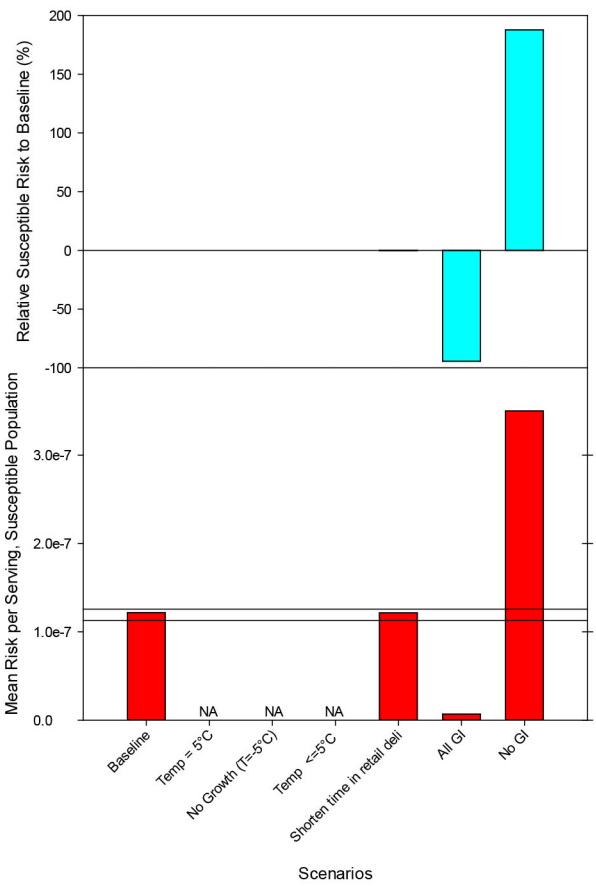


Figure 42. Effect of various growth scenarios on the mean risk per serving and relative risk in the susceptible population for retail deli with temperature control.

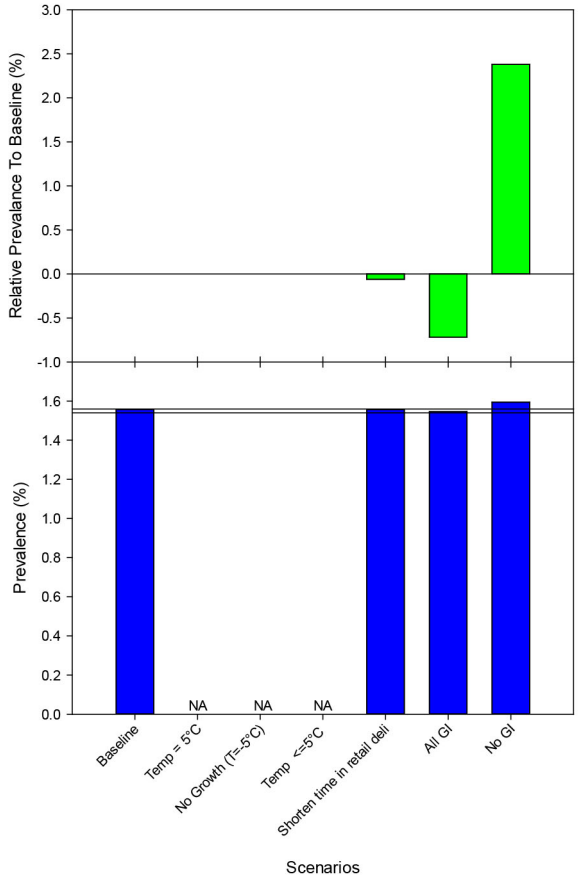


Figure 43. Effect of various growth scenarios on the prevalence and relative prevalence of *L. monocytogenes*-contaminated RTE products for retail deli with temperature control.

Baseline retail deli with multiple niches and temperature control

Results for retail delis with multiple niches, but with temperature control of the deli case at ≤5°C (41°F), are provided in Figure 44 to Figure 47. Lack of any sanitation increases the predicted risk by 50%; eliminating cross contamination and reducing incoming *L. monocytogenes* levels reduces the predicted risk by 30% and 16%, respectively. Growth inhibitors remain extremely effective.

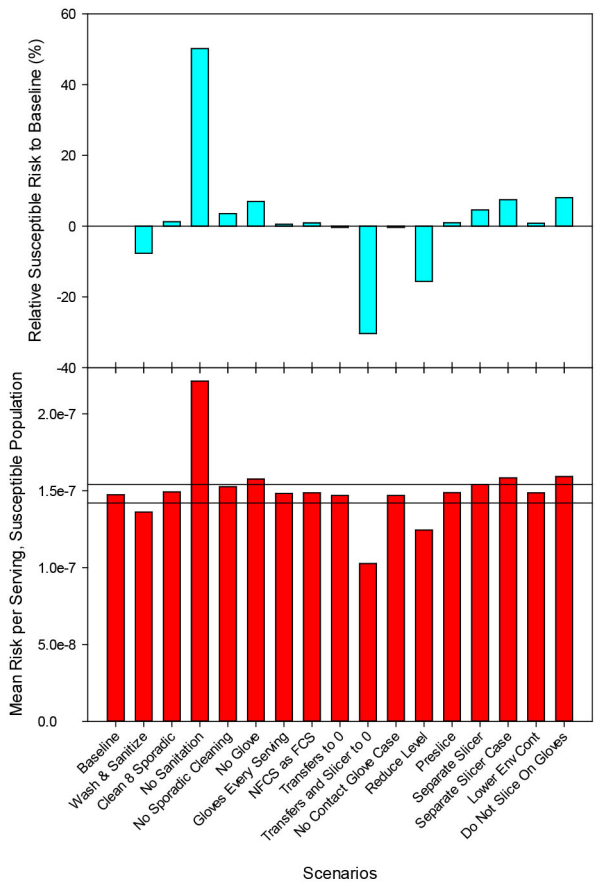


Figure 44. Effect of various sanitation scenarios on the mean risk per serving and relative risk in the susceptible population for retail deli with multiple niches and with temperature control

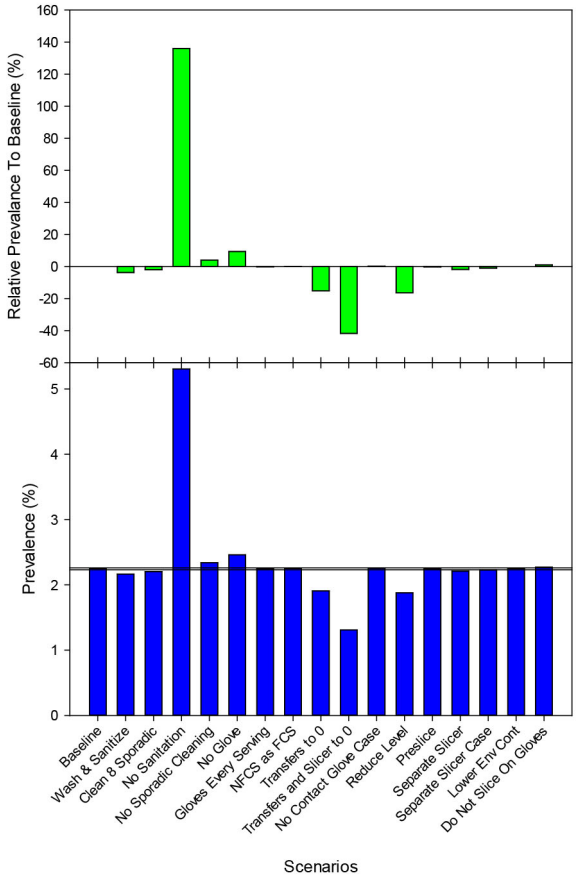


Figure 45. Effect of various sanitation scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products for retail deli with multiple niches and with temperature control

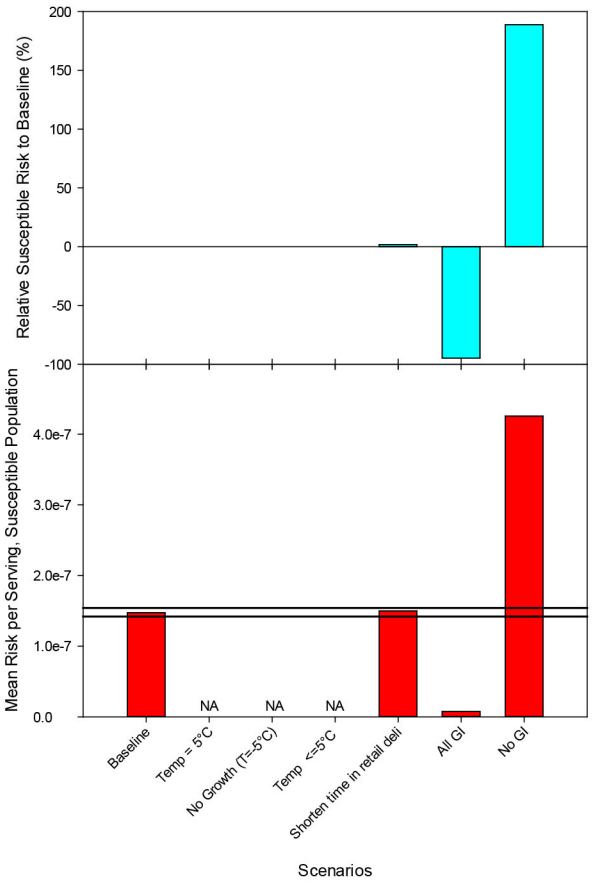


Figure 46. Effect of various growth scenarios on the mean risk per serving and relative risk in the susceptible population for retail deli with temperature control

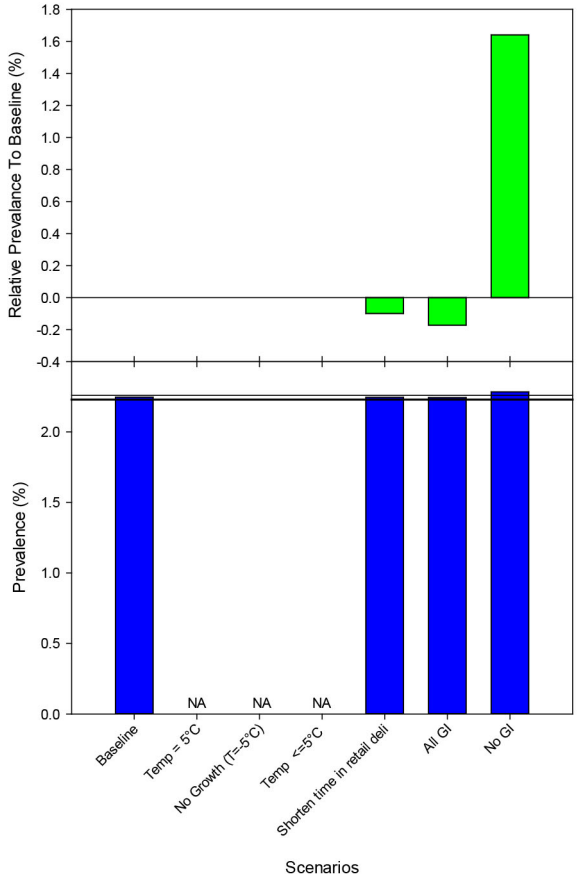


Figure 47. Effect of various growth scenarios on the prevalence and relative prevalence of *L. monocytogenes* contaminated RTE products for retail deli with temperature control

7.3. Responses to risk management questions

The relative risk associated with an alternative scenario, as compared with the risk calculated for a baseline condition, was evaluated within each baseline for the susceptible population. The scenarios were developed according to risk management questions provided in Section 3. Figure 48 through Figure 60 illustrates the results for the various alternative practices across baselines. Remember, the absolute values for the predicted risk change drastically for each baseline. With the exception of the growth inhibitor analysis, all the relative risks in the graphs are scaled the same, to make comparison between the predicted risks associated with different risk management scenarios more apparent. The baseline conditions and the scenarios are described in 7.1.1 and 7.2.2, respectively.

7.3.1 What would be the impact, on the prevalence of *L. monocytogenes* in RTE products sold in retail delis and on the corresponding mean risk of invasive listeriosis per serving, of practicing more frequent or more extensive cleaning procedures for food-contact surfaces and/or non-food-contact surfaces than is currently specified in the 2009 FDA Food Code 2009?

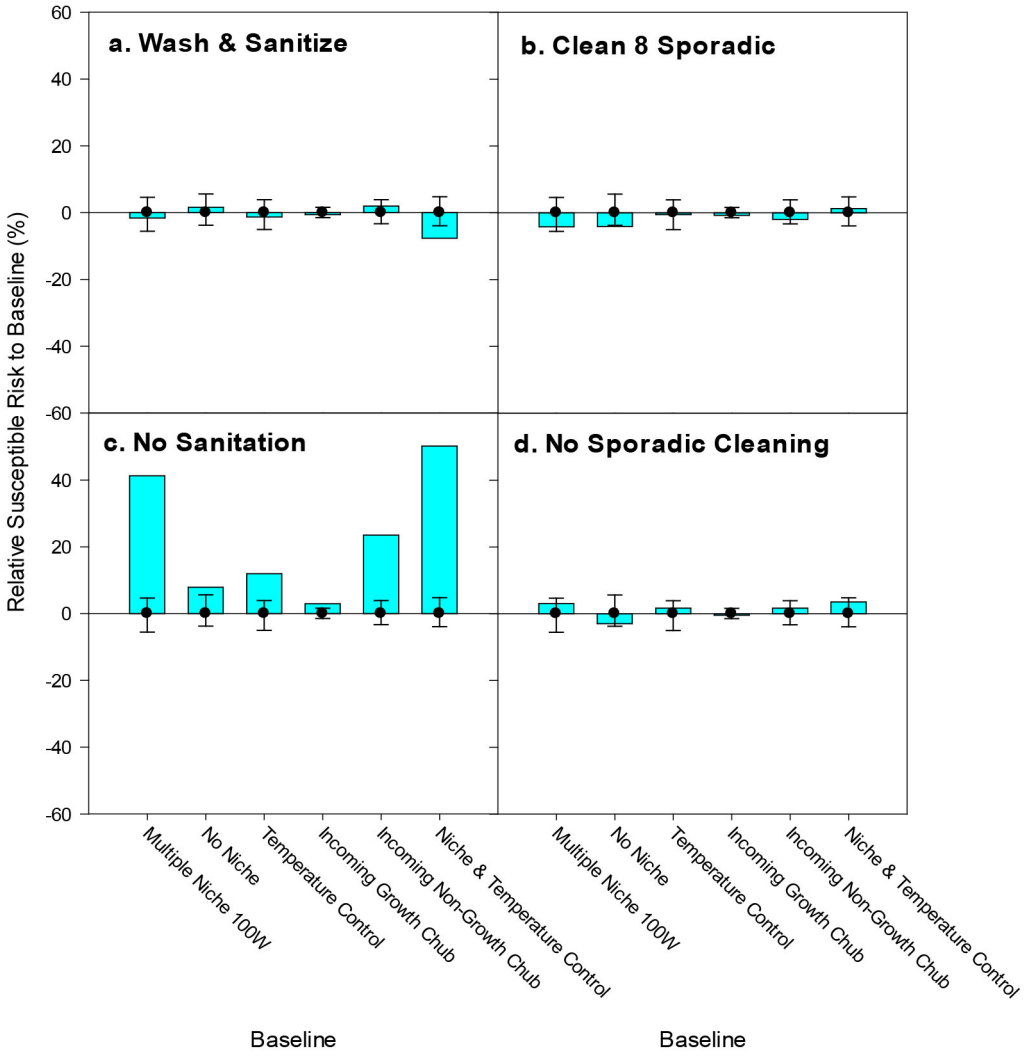


Figure 48: Relative risk comparison for sanitation options

Wash & Sanitize: increase the effectiveness of cleaning from simply washing to washing and sanitizing [i.e., from an average $\log_{10}$ reduction issued from a Pert(-1.5, -0.5, 0) to a Pert(-8, -6, -1.5)]; **Clean 8 Sporadic**: increase the number of sites sporadically cleaned from 4 to 8; **No Sanitation**: do not conduct any wiping, washing, or sanitizing; **No Sporadic Cleaning**: only clean FCS to the minimum required by the 2009 FDA Food Code, but do not conduct the additional sporadic cleanings (as was observed by Lubran et al. [28]).

The relative risks for changes in sanitation are shown in Figure 48. Figure 48c clearly indicates that failing to clean and sanitize all surfaces results in a significant increase in the predicted risk of listeriosis. Nevertheless, it seems that modifying any of the single sanitation-related practices individually [i.e., cleaning more effectively (Figure 48a), increasing the number of sporadic cleaning sites (Figure 48b), or not conducting any sporadic cleaning (Figure 48d)] had little impact on the relative risk in each retail deli condition studied. Specific scenarios for the cleaning frequency and disinfection of the slicer could be developed in future versions of this model.

7.3.2 What is the impact of increasing the use of single-service gloves in the retail environment?

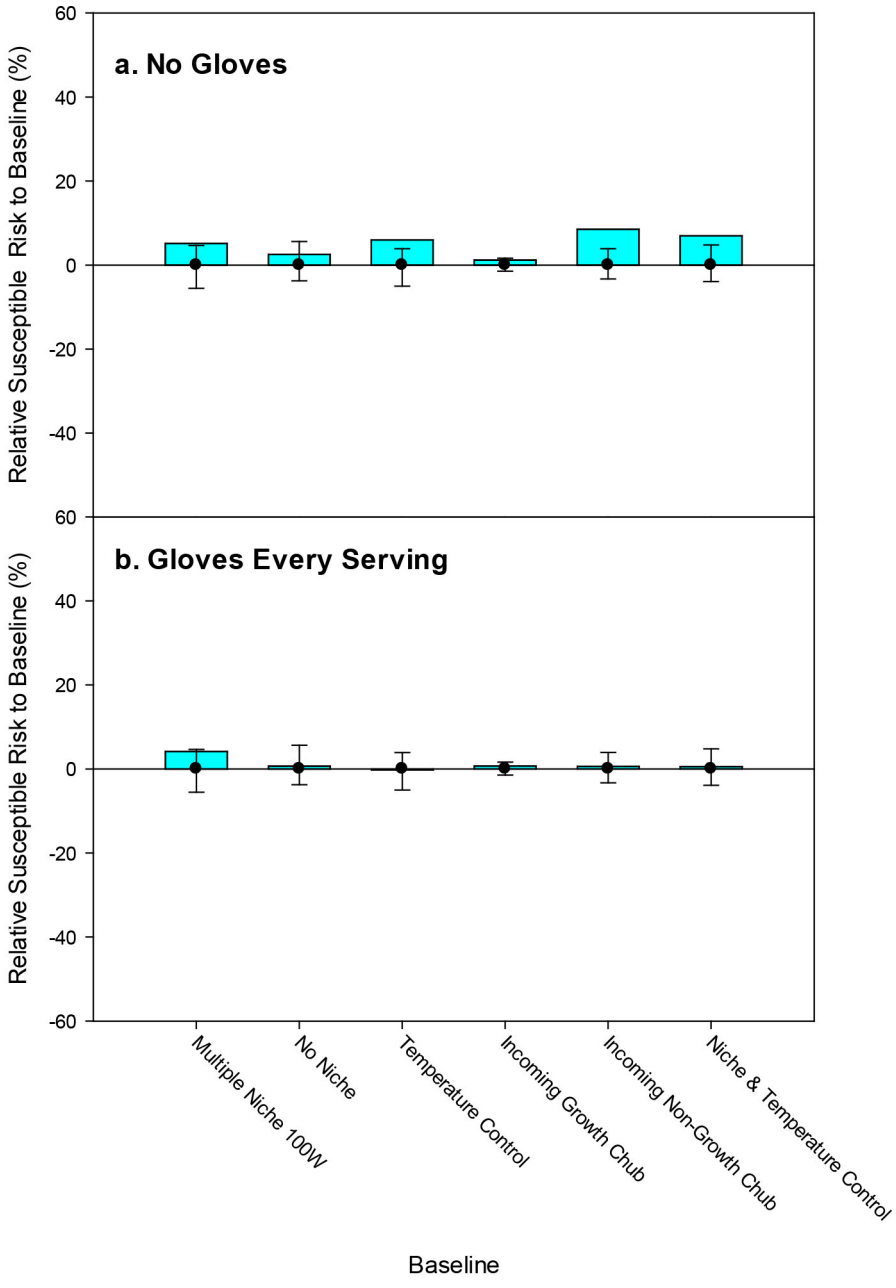


Figure 49: Relative risk comparison for glove use

No Glove: do not use gloves when serving customers; **Gloves Every Serving**: change gloves for every serving.

The lack of glove use consistently increases the predicted risk across all retail deli types (Figure 49a), often at statistically significant levels. Thus, glove use is recommended to aid in *L. monocytogenes*

control and would be expected to be critical for other foodborne pathogens, such as norovirus or *Shigella* [123]. Changing gloves for every serving did not result in a significant change (Figure 49b), but recall that gloves already are changed for approximately 65% of servings in baselines.

7.3.3 What if scale touch pads, refrigerator and deli case handles and other frequently touched non-food-contact surfaces were considered food-contact surfaces and were therefore required to be cleaned and sanitized at a minimum frequency?

These items were required to be cleaned and sanitized every four hours and, as a result, could then be touched by gloved hands without requiring a decontamination action afterwards.

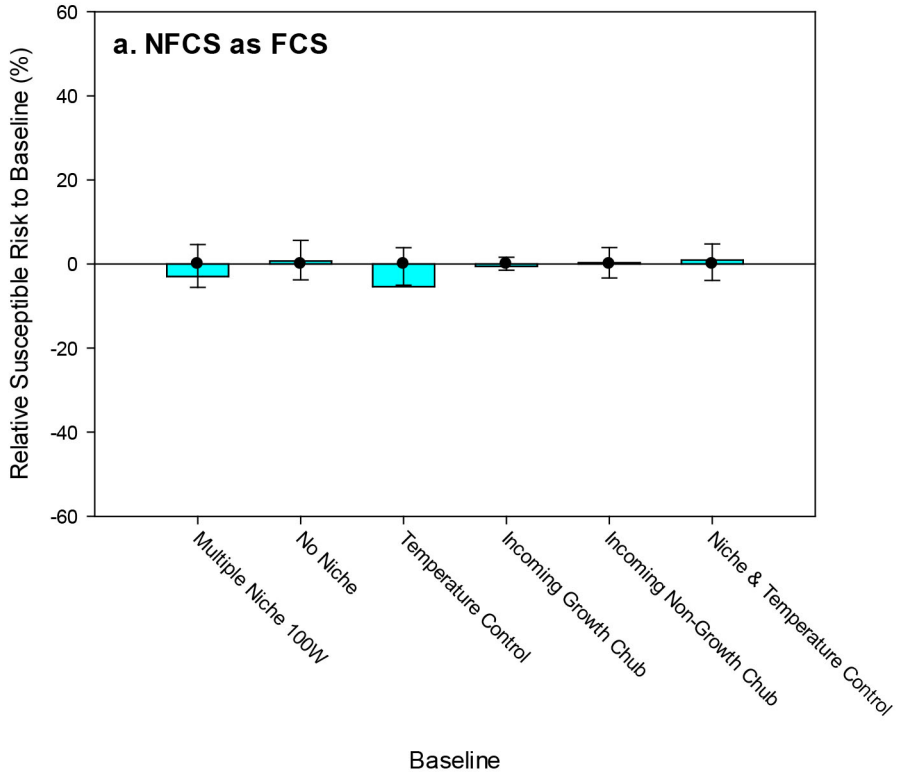


Figure 50: Relative risk comparison for treating NFCS as FCS

NFCS as FCS: treat NFCS as if they were FCS that must be cleaned every 4 hours, according to the FDA Food Code.

Treating NFCS as FCS for cleaning purposes had little impact on the predicted risk. The only retail deli type where the risk reduction was statistically significant was for a retail deli without any niches that

implemented temperature control. In this case, in which *L. monocytogenes* levels are low and growth is limited, the additional cleaning might be beneficial, relative to the baseline low risk.

7.3.4 What if practices were in place so that no cross contamination occurred in delis?

No additional *L. monocytogenes* added to incoming RTE product.

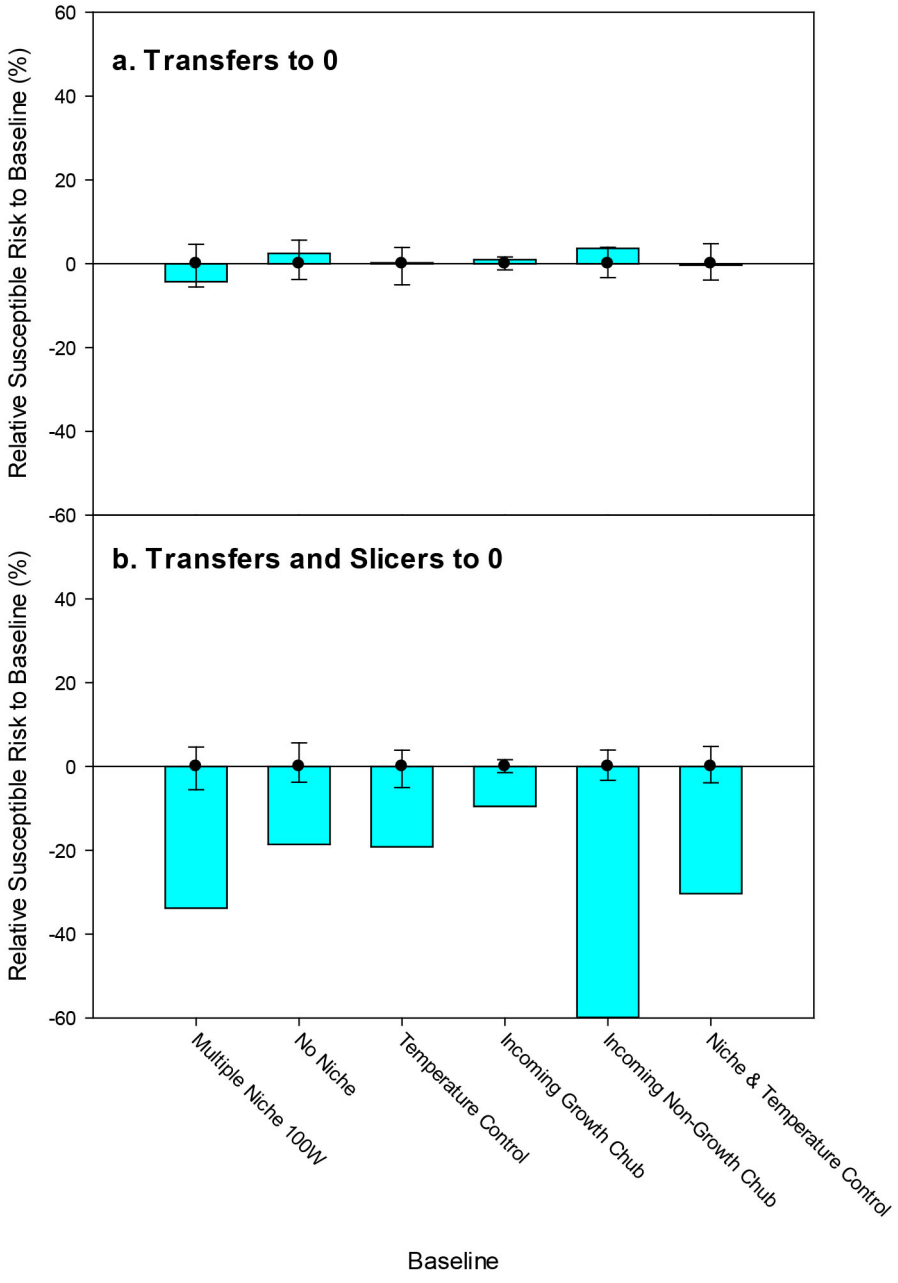


Figure 51: Relative risk comparison for transfer coefficients

Transfers to 0: set cross contamination transfer coefficients to 0 (i.e., no cross contamination occurs). This setting does not affect the slicer, (i.e., cross contamination can still occur from one sale to the next through the slicer). See the next scenario; **Transfers and Slicer to 0**: set cross contamination transfer coefficients to 0 (i.e., no cross contamination occurs, for all sites, including the slicer).

Setting the transfer coefficients to 0 prevents cross contamination for all sites except the slicer. This approach had no significant impact on the relative risk (Figure 51a). Including the slicer in the sites, however, greatly reduced the predicted risk (Figure 51b) across all retail deli types evaluated. This highlights the importance of the slicer in cross contamination. The importance of the slicer in potential cross contamination has been demonstrated experimentally [see for example 23, 37, 54, 58, 124]. Our results confirm that this element may be of major importance when all cross contamination events are considered in a deli department setting.

7.3.5 What if display cases were not touched with gloved or bare hands?

Use tissues or automatic door to open/shut display case to reduce cross contamination.

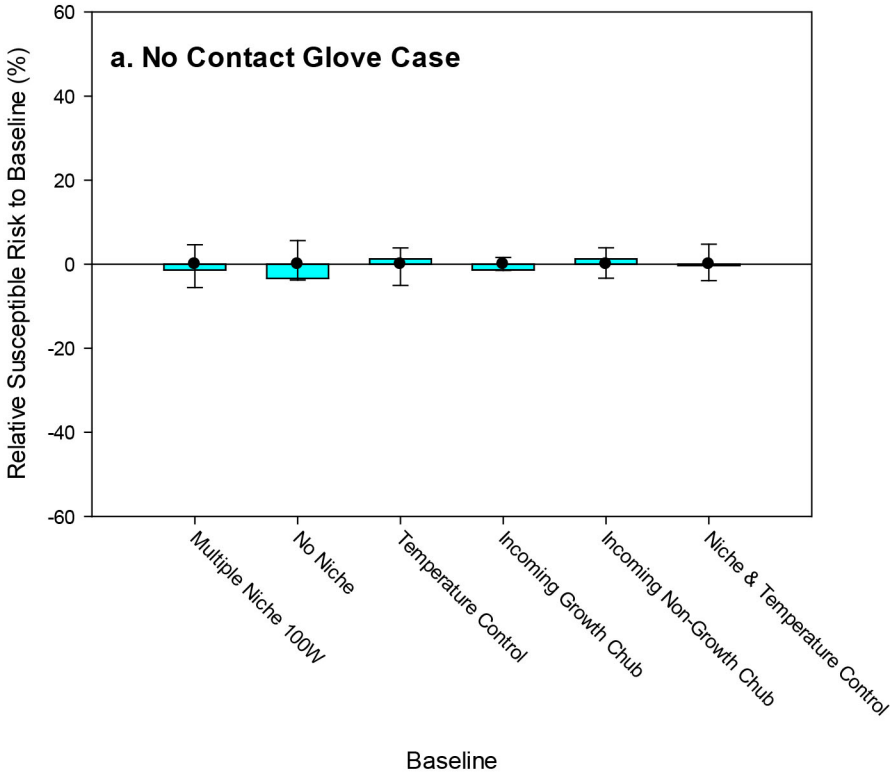


Figure 52: Relative risk comparison for contact between gloves and case handle

No-Contact Glove Case: glove/hands are not used to open the deli case (e.g., if a floor switch is used.)

Preventing contact between the case handle and hand/gloves had no significant impact in any of the baselines studied. Actually, this scenario is a subset of the scenario **Transfers to 0** [cross contamination transfer coefficients to 0 (i.e., no cross contamination occurs)], with one transfer set to 0. This result confirms that, within a baseline, no single cross contamination event has a major impact on the predicted risk, with the exception of the cross contamination within the slicer.

7.3.6 What would be the impact if the level/frequency of *L. monocytogenes* contamination were reduced in RTE foods coming into the retail deli?

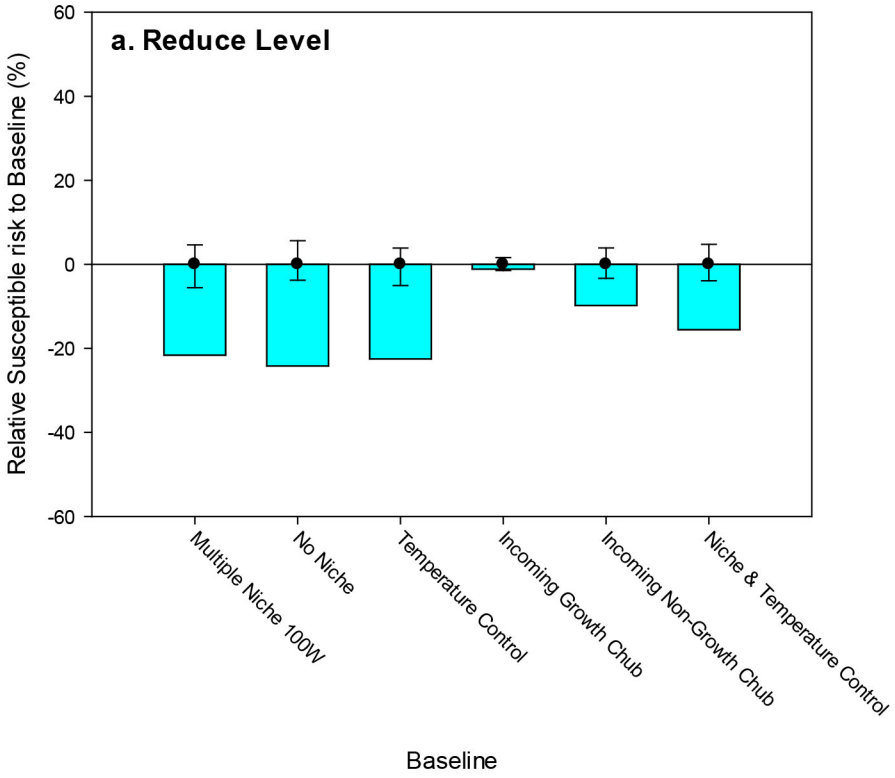


Figure 53: Relative risk comparison for reducing incoming level

Reduce Level: lower the mean incoming *L. monocytogenes* concentration on all RTE products from a mean of the $\log_{10}$ of -9.2 to a mean of the $\log_{10}$ of -9.5. This leads to an average prevalence for a 2,270 g chub of 2.35% *vs*. 2.97% in the baseline (Section 6.5.2).

Reducing the incoming *L. monocytogenes* concentration significantly reduced the predicted risk. Incoming *L. monocytogenes* represents one of the major routes through which the bacteria can come in contact with FCS and cross contaminate in this model. Even in situations in which *L. monocytogenes* from the environment are regularly introduced into the deli department, the level of bacteria in incoming RTE product does have an impact on the final relative risk of listeriosis from the consumption of RTE products from the deli department.

7.3.7 What would be the impact of "pre-slicing" all RTE products *vs*. "slicing to order"?

Following the hypothesis that less cross contamination occurs in the morning prior to other cross contamination events:

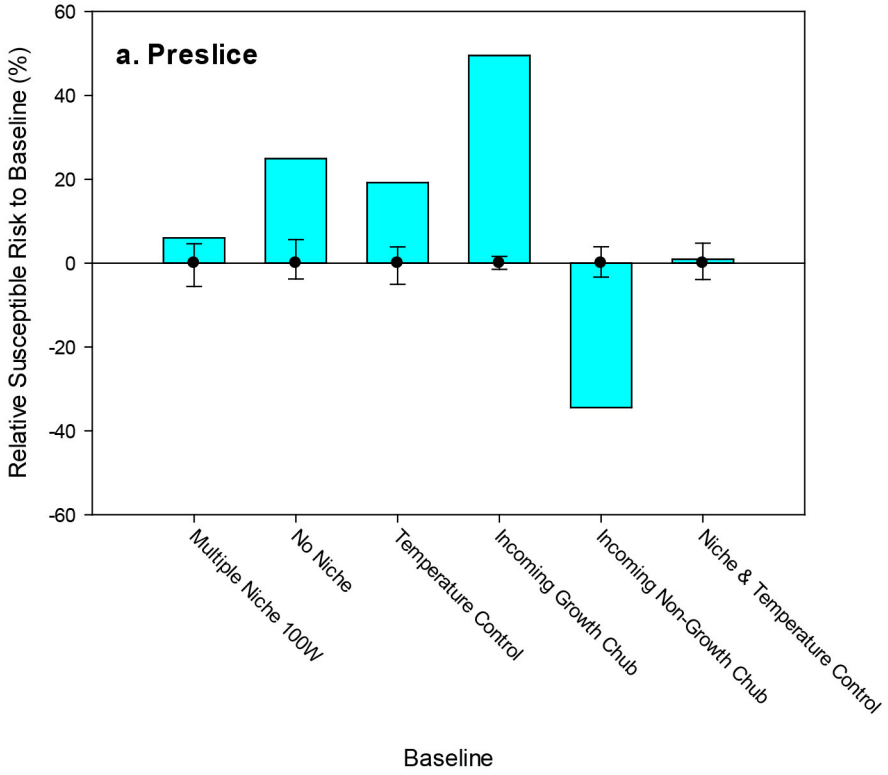


Figure 54: Relative risk comparison for pre-slicing

Pre-slice: pre-slice all chubs of RTE product in the morning after cleaning. For each RTE product, a quantity of food equal to the median of the daily sales is pre-sliced every morning. When a consumer orders a RTE product, the food worker serves the pre-sliced RTE product, until all the pre-sliced quantity is sold. If needed, additional RTE product is sliced to order. At the end of the day, the remaining pre-sliced RTE product is discarded.

Pre-slicing generally increased the predicted risk, often substantially and especially if a contaminated growth-supporting chub was present. Based on a deeper study of the model outputs (analysis per serving on a short run, rather than overall statistics - results not shown), it was determined that this is due to a relatively important contamination of the slicer during the pre-slicing process, following one single contaminated chub. A high number of RTE product servings are then cross contaminated, leading to a

higher predicted risk. A retail deli with an incoming contaminated non-growth chub was the only baseline situation in which pre-slicing led to a significantly lower predicted risk. In this situation, pre-slicing leads to a distribution of the bacteria to the same category of (non-growth) RTE products, rather than to various (growth and non-growth) RTE product if sliced throughout the day. This limits the contamination of the RTE product that supports the growth, and thus the predicted risk.

7.3.8 What would be the potential public health impact of using separate slicers and/or separate counters for RTE products that permit growth of *L. monocytogenes* and for RTE products that do not?

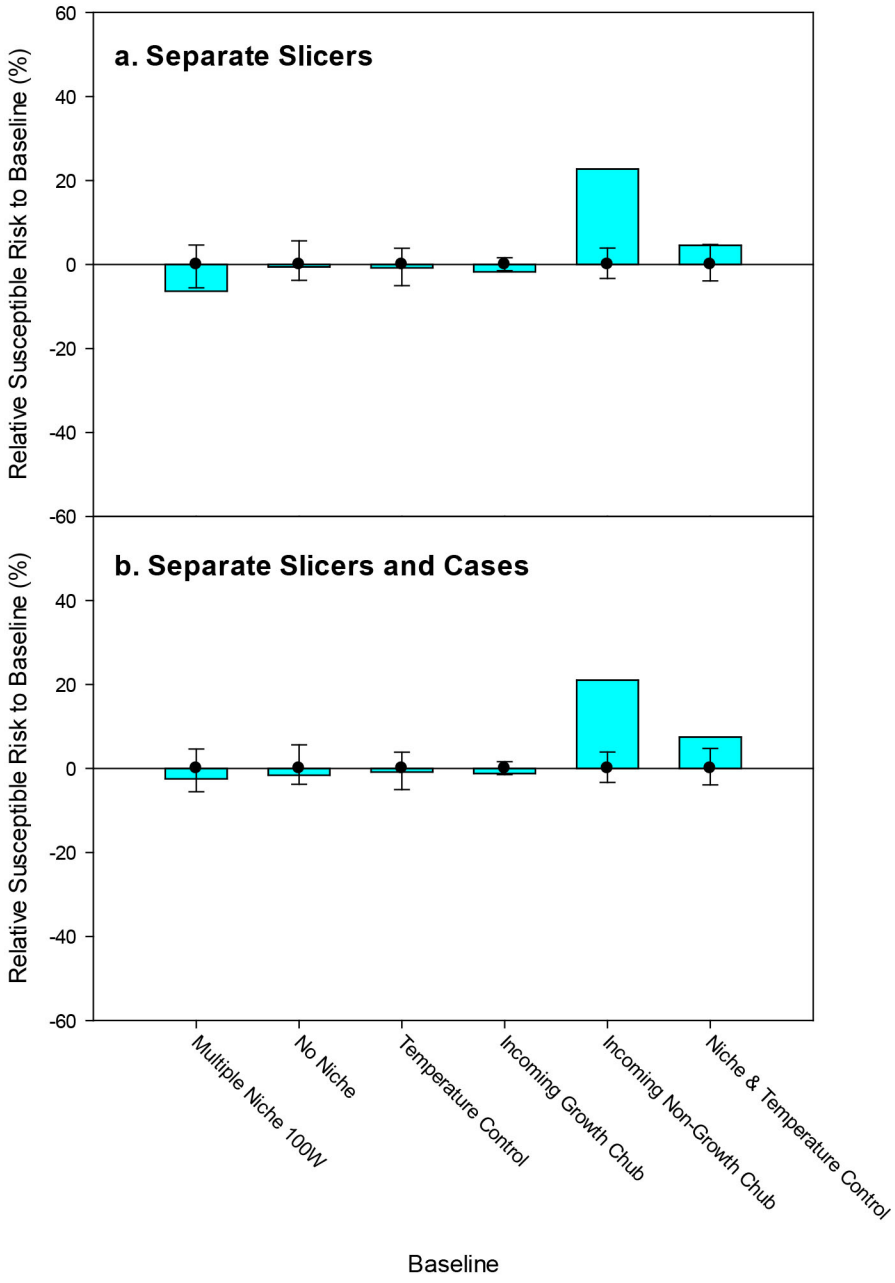


Figure 55: Relative risk comparison for separate slicers and cases

Separate Slicer: use a separate slicer for RTE products that support growth versus those that do not; **Separate Slicer Case**: use a separate slicer and a separate case for RTE products that support growth versus those that do not.

Figure 55 shows that there was minimal impact on the predicted risk relative to the baseline associated with establishing one slicer for RTE product that supports growth of *L. monocytogenes* and another for RTE product that does not support growth of *L. monocytogenes*. The exception was the condition in which a contaminated chub did not support the growth of *L. monocytogenes*. Similar impacts on the calculated relative risk were observed when separate slicers were used and the different RTE products were put into separate deli cases. This may be related to the fact that in the baseline matrix of contacts (Section 6.5.1), it was assumed that in larger retail deli with two slicers, one slicer is used only for deli cheese and that the other slicer is used for deli meat and deli cheese. In the separate slicer scenario, since one slicer would be used exclusively for high-growth product, the slicer for the contaminated cheese would be used for more products, and, as a consequence, the contaminated cheese would incidentally contaminate more products than in the baseline, including some additional "low-growth" product. The resulting risk would be higher. Other matrices of contact could be tested in the future.

7.3.9 What if food workers do not slice RTE products directly onto their gloved hands?

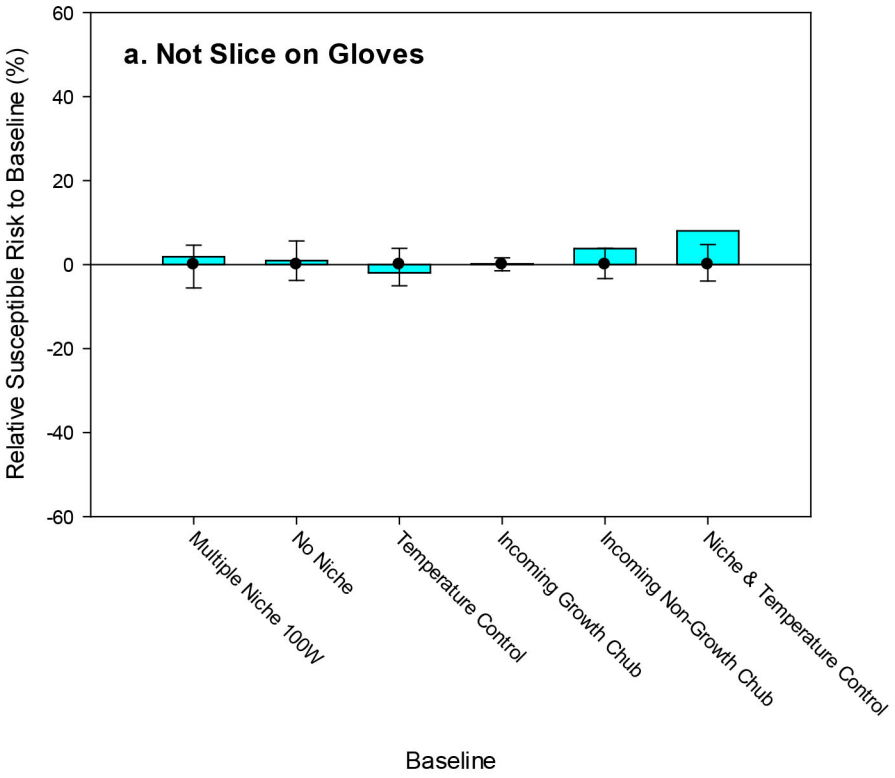


Figure 56: Relative risk comparison for not slicing onto gloves

Do Not Slice Onto Gloves: the food worker collects the sliced RTE product directly onto a deli tissue rather than slicing it directly onto a gloved hand, which represents the baseline condition.

Figure 56 suggests that slicing RTE product onto deli paper, rather than onto gloves, had little impact on the relative risk predicted by the model. Slicing onto gloves was a behavior observed during the observational study [28]. The model suggests that eliminating this practice would not play a major role, compared with some of the other mitigations directed at preventing cross contamination.

7.3.10 What is the impact of *L. monocytogenes* growth in retail delis?

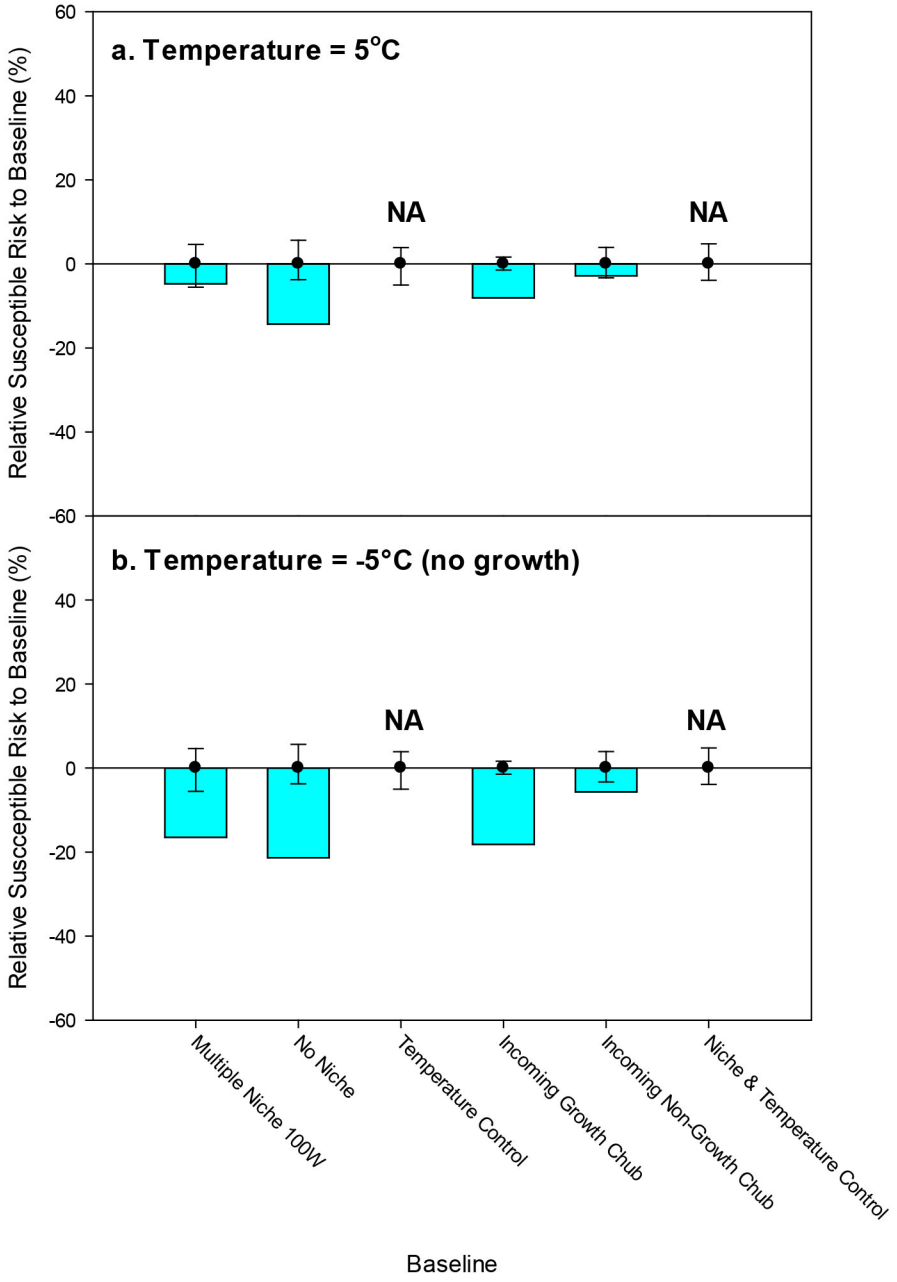


Figure 57: Relative risk comparison for fixed temperature control

Baseline: All RTE product in cases maintained at the actual temperatures observed in Ecosure dataset [19];

Temp = 5°C: Retail deli; all RTE products in cases consistently maintained at a temperature of 5°C (41°F); **No Growth (T = -5°C)**: Retail deli; all RTE products in case consistently maintained at a temperature of -5°C (23°F) (no potential *L. monocytogenes* growth).

Improving temperature controls in display cases to limit growth resulted in a lower predicted relative risk across all retail deli types. Baseline retail delis that included temperature control as part of the baseline are not shown. Note that the Temp = 5ºC (41°F) alternative represents an increase in the temperature for some of the RTE products, compared with the baseline. By reducing temperature of display cases to 5ºC, the overall predicted risk was still reduced. The "no growth" scenario (i.e., deli case temperature set to -5ºC) results in a 20% reduction in predicted risk. This further demonstrates the importance of controlling the growth of *L. monocytogenes* in RTE products, as suggested in previous risk assessments [3, 59].

7.3.11 What would be the potential public health impact of complete compliance to the cold holding requirements for certain RTE foods in deli cases [hold at 41°F (5°C) or less]?

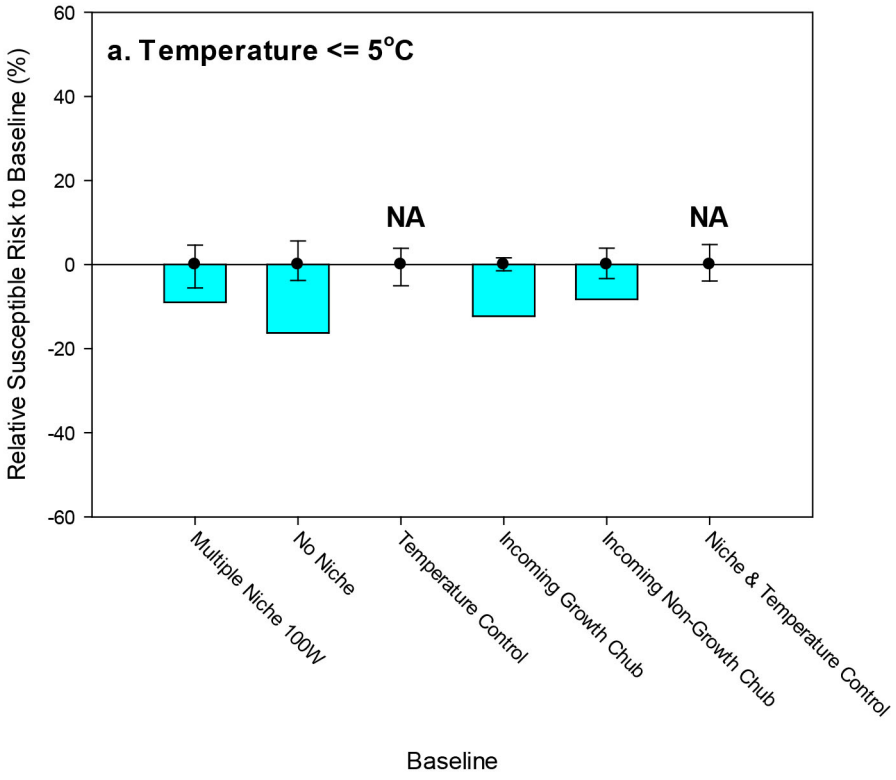


Figure 58: Relative risk comparison for temperature control

Temp <= 5°: Use the case temperature distribution as observed [19], but remove any temperatures greater than 5°C (41°F). This implies that all retail delis exceeding the FDA Food Code recommendation come into compliance.

Unlike the previous analysis, in which all retail deli cases were set to a fixed temperature, this analysis uses the existing temperature distribution, but removes those that exceed 5ºC. The model was used to study the effect that full compliance with the 2009 FDA Food Code [27] temperature requirements would have on the predicted risk, as compared with what Ecosure data suggest is typical practice. An approximate 10-15% reduction in predicted risk was achieved. The effect was greatest in a retail deli without any niches. The model predictions suggest that a reduction of the risk of listeriosis could be achieved by better compliance with recommended RTE product storage temperatures in the deli environment. FDA's 2008 Retail Risk Factor Study revealed that, in delis, the failure to control RTE product holding temperatures and times was the risk factor with the highest "Out of Compliance" percentage. For example, in 60% of the 98 retail delis studied by FDA in 2008, at least one observation was made in which food requiring temperature control was not held at 41ºF or below, as specified in the FDA Food Code [18].

7.3.12 What would be the potential public health impact of shortening the time a RTE product can be used in retail deli departments?

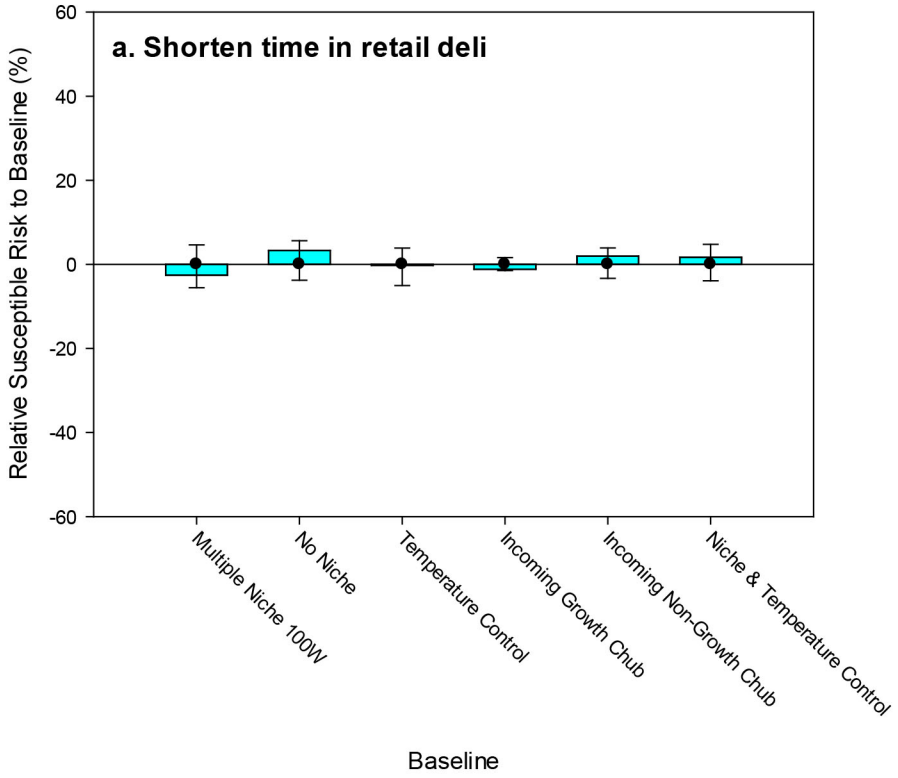


Figure 59: Relative risk comparison for shortening the time a RTE product can be used in a retail deli department

Shorten the time a RTE product can be used: shorten the length of time RTE product can be held in the retail deli before being sold or disposed, from 7 to 4 days.

Figure 59 suggests that shortening, from 7 days to 4 days, the maximum time a refrigerated RTE product that supports growth of *L. monocytogenes* is allowed to remain on hand in the retail deli after opening or preparation has little effect on the predicted risk. Under the current model, the time from when the chub is opened until it is completely sold is generally shorter than the 7-day FDA Food Code requirement. Note that the model does not currently simulate refrigerated storage prior to the chub/deli salad bulk being opened.

7.3.13 What would be the potential public health impact if all or none of the RTE products (e.g., deli meat, deli salads, and cheese) coming into the retail deli were formulated with growth inhibitors?

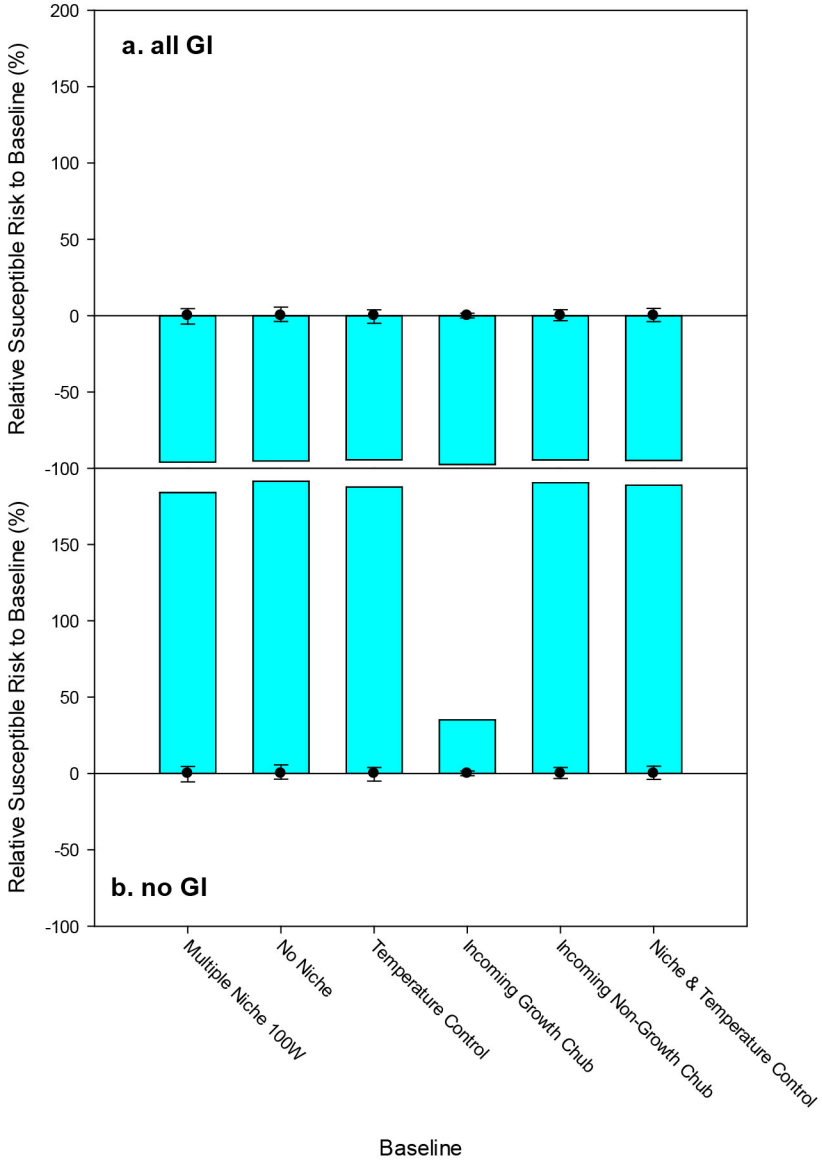


Figure 60: Relative risk comparison for growth inhibitor use

All GI: all RTE products sold that support growth are considered to have growth inhibitors; **No GI:** none of the RTE products that support growth are considered to have growth inhibitors.

Of all the scenarios tested, increasing or decreasing the percentage of RTE meat and poultry products and deli salads that contain *L. monocytogenes* growth inhibitors consistently had the greatest impact on the relative risk of listeriosis predicted by the model. Note that the risk scale (y axis) is different for Figure 60

than for the other figures. Using growth inhibitors in deli meats and deli salads almost completely mitigated the risk of listeriosis – by almost 100% reduction for all risk assessment model baselines considered in this analysis. Growth inhibitors continue to prevent growth even after the RTE product leaves the retail deli. If all RTE meat and poultry products and deli salads contain no growth inhibitors, then the risk assessment model predicts an almost doubled risk of listeriosis from these products over most baseline conditions. The percentage increase in relative risk was more modest for the baseline condition that considers a highly contaminated growth-supporting deli meat chub. Actually, this more modest percentage only reflects the greatest absolute risk of listeriosis for this baseline condition.
These results confirm the overwhelming importance of the growth of *L. monocytogenes* during retail and home storage, compared with other parameters in *L. monocytogenes* risk assessments, as has been consistently observed [3, 59].

7.4. Verification

Given the over-parameterization in the risk assessment model, a formal calibration (e.g., minimizing some objective function) or a validation is currently not possible. Nevertheless, some checks and controls were done with regard to the available literature and through studies specifically developed to inform the current risk assessment model.

7.4.1 Mass balance

Mass Balance, Transfer Matrix

Figure 61 depicts the sources of incoming and outgoing *L. monocytogenes* for the retail deli system. *L. monocytogenes* enter the retail deli through *i*) contaminated incoming raw RTE products; *ii*) niches (as currently written, the risk assessment model does differentiate the source of *L. monocytogenes* from a niche in the retail deli versus those resulting from contaminated incoming RTE product); or *iii*) the growth of *L. monocytogenes* on RTE product. *L. monocytogenes* are either on outgoing RTE product sold to consumers, eliminated through wiping, washing and disinfection of retail deli surfaces, or disposed of in the trash (e.g., on used gloves or expired RTE product).

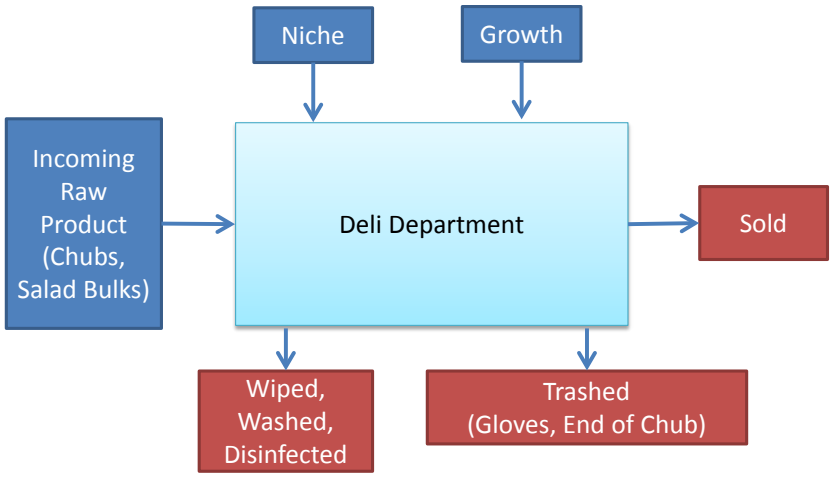


Figure 61. Incoming and outgoing bacteria in the *L. monocytogenes* in retail model

At any time, the sum of the *L. monocytogenes* entered in the system was equal to the sum of *L. monocytogenes* currently in the system plus the sum of *L. monocytogenes* that went out of the system. The checking of this mass balance additionally afforded a cross-check of proper functioning of this risk assessment model. The mass balance was controlled in all scenarios described in this report.

7.4.2 Surveys of *L. monocytogenes* in RTE foods

While validation is preferable, survey data were used to help establish parameters within the model. Two large datasets are available that describe the distribution of *L. monocytogenes* concentrations in RTE products. The first is a study by the National Food Processors Association [14] and the second is derived from a National Alliance for Food Safety and Security (NAFSS) study [16] [6]. Figure 62 illustrates the upper predicted tail of the cumulative distribution function for the incoming deli products and the deli products leaving the retail deli with niches and those without any niches (baselines). Superimposed are the NAFSS points for deli meat, the only food groups studied. It appears that the different retail deli baselines capture this critical portion of the distribution.

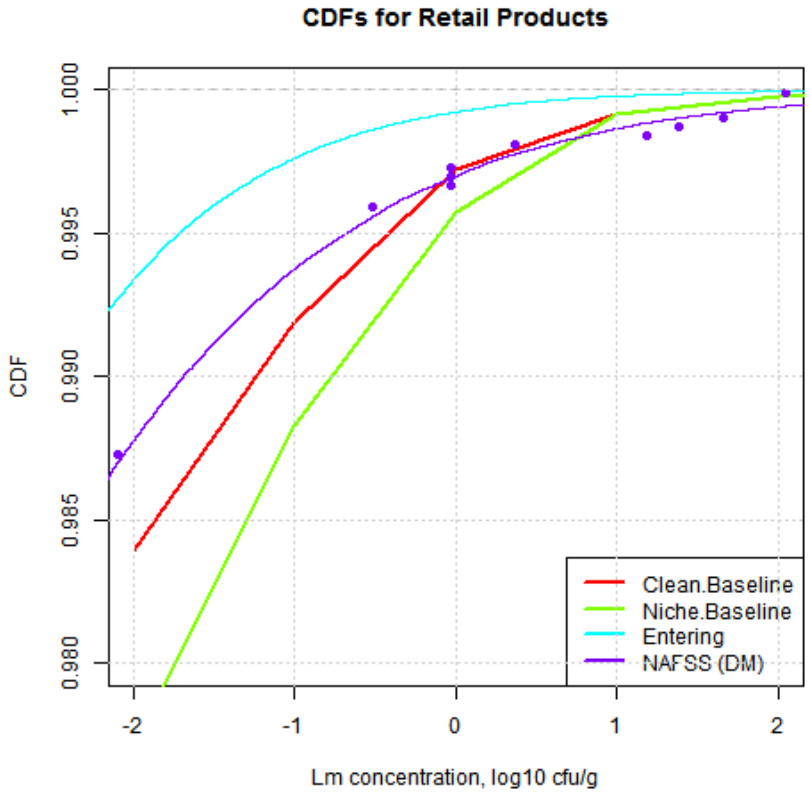


Figure 62: Comparison of predicted model distributions with observed retail deli observations

While this comparison should not be considered as a complete validation, because various pathways could lead to these results, this graph indicates that the model results are not inconsistent with observed data.

7.4.3 Virginia Tech mock deli

A mock retail deli study [29] was conducted, in which known sites were contaminated using an abiotic surrogate (GloGerm™); the mock retail deli was operated for a fixed period; and the resulting contaminated location recorded. Photographs under UV light were evaluated by a trained sensory panel, to estimate levels of surrogate contamination. As a manipulative study, the research directly links contaminated sites to resulting contaminated locations. Early results from this research were used to identify missing transfer events within the cross contamination model. Results are shown in Figure 63, with the color intensity and size of the circle indicating the amount of GloGerm™ transfer from an initially contaminated site to another site in the deli. In general, initial glove and initial slicer blade

contamination spread the surrogate across the most sites. This study serves as a validation of the conceptual model shown in Figure 4 and mass transfers illustrated in Figure 63.

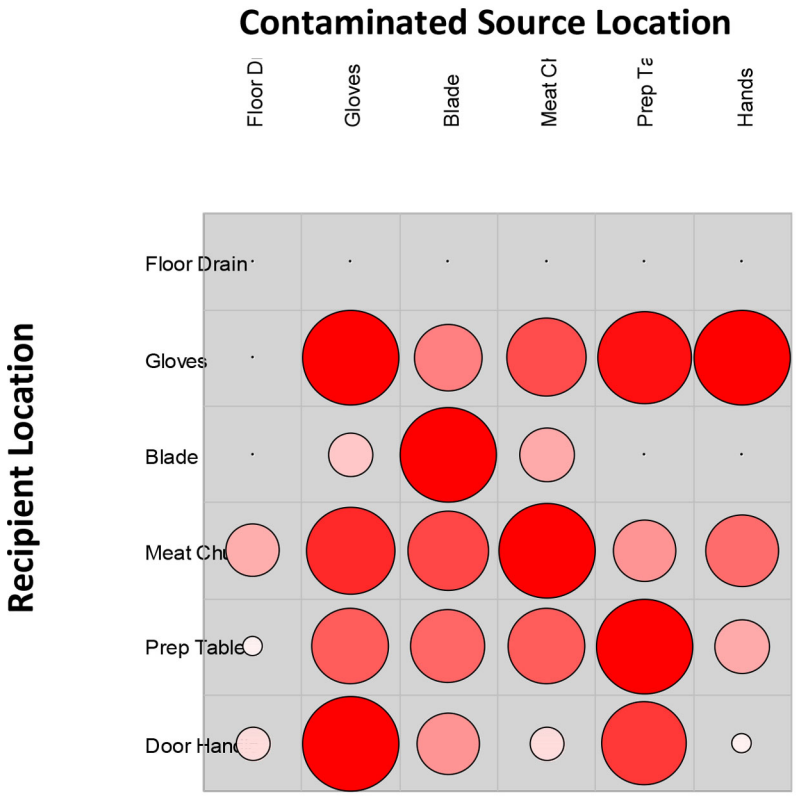


Figure 63: Mock retail deli results [29]. Size and color intensity indicate amount of surrogate transferred from source to recipient location.

7.4.4 Cornell University expert elicitation

Hoelzer et al. [31] published an expert elicitation study on *L. monocytogenes* transfer within retail delis. Table 17 presents the major conclusions and compares these to the conceptual cross contamination model. The first four columns are adapted from the authors' paper. The "Median Result" represents the percentage of experts who believe that the given transfer can occur. The "Percent Very Confident Experts" indicates a self-reported degree of confidence in their answers. The final column added for this report represents whether a given transfer can occur within the model.

Table 17: Comparison of expert elicitation to cross contamination model structure

L. monocytogenes transfer		Median Result (%) (Source [31])	**Percent "very confident" experts** (Source [31])	**Included in Model?**
Source	**Recipient**			
Slicer blade	RTE product[a]	86	89	Yes
Slicer blade	RTE product[b]	48	22	Yes
Slicer blade	Hands	23	39	Yes
Slicer blade guard	Hands	22	35	Yes, but slicer treated as one location.
Cutting board	RTE product	75	56	Yes, if cutting board treated as FCS.
Cutting board	Hands	47	39	No
Scale touchpad	Hands	55	59	Yes, but scale treated as one location.
Scale weigh table	RTE product	15	43	Yes, but scale treated as one location.
Deli case handle	Hands	53	90	Yes
Deli case	RTE product	86	58	No
Deli preparation sink[c]	RTE product	48	41	Yes
Deli preparation sink[d]	RTE product	5	47	No
Walk-in cooler door handle	Hands	63	47	No, walk in cooler not included as a site.
Walk-in cooler floor	FCS	4	47	No, walk in cooler not included as a site.
Knife rack	FCS	41	22	Yes, indirectly (utensils, e.g., knives, can contact RTE product and hands).
Central floor drain	FCS	5	15	No

[a]Transfer to first slice sliced on contaminated slicer; [b]Transfer to 10th slice sliced on contaminated slicer; [c]chub set down in sink during unwrapping; [d]chub not set down in sink during unwrapping.

The model thus includes all the perceived major routes of transfer. The major exceptions are the lack of a walk-in cooler site within the model and the lack of transfer from case to RTE product. The risk assessment model includes and assumes that the RTE product chubs are always wrapped when returned to the retail deli, thus limiting contact.

8. Summary of Risk Assessment Results

This QRA provides information on the predicted risk of listeriosis associated with the consumption of RTE foods prepared and sold in the deli of a retail food store and examines how the predicted risk may be impacted by different practices in a retail deli (e.g., sanitation, temperature control, and worker behavior).

8.1. Predictions of Absolute Risk

The predicted risk of listeriosis per serving of RTE food (hereafter referred to as "absolute risk"[37]) was evaluated for two U.S. populations: 1) the "susceptible population" (e.g., older adults, fetuses, newborns, and those who have immune-compromising conditions, as defined by FAO/WHO [59]); and 2) the remaining U.S. population (i.e., referred to as the "general population" in this QRA). Table 18 shows the predicted absolute risk to the two populations and six different baseline conditions that may characterize a retail deli and the RTE food it serves at different times over the course of operations. The baseline conditions are:

1) a retail deli with multiple niches or environmental transfers that regularly release *L. monocytogenes* to food-contact surfaces;
2) a retail deli with no niches or environmental *L. monocytogenes* transfer;
3) a retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product contaminated at levels higher than other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs. -9.2 $\log_{10}$ cfu/g) and with the incoming contaminated RTE product supporting growth;
4) a retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product contaminated at levels higher than other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs. -9.2 $\log_{10}$ cfu/g) and with the incoming contaminated RTE product not supporting growth;
5) a retail deli with multiple niches and compliant with the 2009 FDA Food Code guidance for temperature control (≤41°F); and,
6) a retail deli without any niches and with compliant temperature control (≤41°F).

[37] When interpreting the results, it is important to keep in mind that the specific values used in the QRA to characterize the baseline conditions are merely representative of a range of values that could possibly occur. For example, not all retail deli niches will transfer a mean of 100 cfu on a weekly frequency, as modeled in the "Multiple Niche 100W" baseline. Also, not all incoming contaminated product will have a mean $\log_{10}$ contamination of -5 $\log_{10}$ cfu/g, as the incoming product baselines are modeled. The range of values used in the models for various scenarios are evaluated through the sensitivity analysis discussed in Section 7.2.1.

In general, across all six baseline conditions, the predicted absolute risk for the susceptible population is much higher, compared with the predicted risk for the general population (Table 18). This result is expected, because of the differences in the dose-response relationships for these two populations (see Section 6.4.4). For any given dose of ingested *L. monocytogenes*, individuals from the susceptible population are predicted to have a higher probability of illness, compared with the general population. The predicted absolute risk to consumers in the general population ranges from 1.5×10^{-9} to 37.3×10^{-9} per serving and for susceptible consumers ranges from 1.2×10^{-7} to 16.6×10^{-7} (a ~45-fold higher risk under all baseline conditions examined in this QRA).

Table 18: Predicted absolute risk of invasive listeriosis per serving of ready-to-eat food sliced or prepared and sold at retail delis

U.S. Populations Evaluated[1]	Baseline Retail Deli Conditions[2]					
	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control	Niche & Temp. Control
Susceptible population	1.7×10^{-7}	1.4×10^{-7}	$16.6\times10^{-7*}$	$2.8\times10^{-7**}$	1.2×10^{-7}	1.5×10^{-7}
General population	3.8×10^{-9}	3.1×10^{-9}	37.3×10^{-9}	6.3×10^{-9}	2.7×10^{-9}	3.3×10^{-9}

Note: Detailed discussion of QRA model mathematics, assumptions, and data are provided earlier in this technical report.

[1]The U.S. population was divided in two subpopulations for the purpose of this risk assessment: the susceptible population (e.g., older adults, fetuses, newborns, and those who have immune-compromising conditions, according to FAO/WHO [59] definition) and the remaining population (referred to as the "general population").

[2]Description of the baseline conditions: **Multiple Niche 100W** = a retail deli with multiple niches that releases *L. monocytogenes* to food-contact surfaces at a rate of 100 cfu on an average weekly frequency; **No Niche** = a retail deli with no niches or environmental *L. monocytogenes* transfer; **Incoming Growth Chub** = A retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product that is contaminated at levels higher than those of other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs -9.2 $\log_{10}$ cfu/g) and that does support growth of *L. monocytogenes*; **Incoming Non-growth Chub** = A retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product that is contaminated at levels higher than those of other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs -9.2 $\log_{10}$ cfu/g) and does not support the growth of *L. monocytogenes*; **Niche & Temperature Control** = a retail deli with multiple niches and compliant with the 2009 FDA Food Code guidance for temperature control (≤41°F): **Temperature Control** = a retail deli without any niches and with compliant temperature control.

* The corresponding risk was 2.9×10^{-7} when the servings directly from the incoming highly contaminated product were removed from the calculation of the risk (see Section 7.2.1).

** The corresponding risk was 2.3×10^{-7} when the servings directly from the incoming highly contaminated product were removed from the calculation of the risk (see Section 7.2.1).

8.2. Evaluation of the Impact of Differences in Baseline Conditions

Comparisons among the six baselines provide insight about the extent to which some retail conditions impact the predicted risk of listeriosis. Two example comparisons follow, to illustrate the impact of retail conditions on the predicted absolute risk estimates shown in Table 18.

Temperature Control:

A comparison of retail delis that do not have niches or environmental transfer of *L. monocytogenes* ("No Niche" column) with those that also ensure storage temperatures maintained at ≤41°F ("Temp. Control" column) results in a reduction in the predicted absolute risk (from 1.4×10^{-7} to 1.2×10^{-7} for the susceptible population). A similar reduction (i.e., from 1.7×10^{-7} to 1.5×10^{-7} for the susceptible population) was predicted for retail delis with niches ("Multiple Niche 100W" column), when compared with those with niches that also maintain strict temperature control ("Niche & Temp. Control" column). The importance of the temperature control within a baseline condition is further illustrated in the Scenario Analysis section below.

L. monocytogenes *on Incoming RTE Products:*

A comparison of retail delis that do not have niches or environmental transfer of *L. monocytogenes* ("No Niche" column) with similar retail delis that also have more highly contaminated incoming RTE products (whether or not they support growth) provides information on the increased predicted risk from (a) the highly contaminated incoming product and; (b) those products subsequently cross contaminated in the deli.

When the incoming highly contaminated RTE product is one that does not support growth of *L. monocytogenes*, the predicted absolute risk increases from 1.4×10^{-7} to 2.8×10^{-7} for the susceptible population (compare "No Niche" with "Incoming Non-growth Chub"; Table 18). When the highly contaminated incoming RTE product is one that supports growth of *L. monocytogenes,* the predicted absolute risk increases to 16.6×10^{-7} for the susceptible population (compare "No Niche" with "Incoming Growth Chub"). The predicted absolute risk of product from stores that have a highly contaminated incoming RTE product that supports growth of *L. monocytogenes* is six times higher than the risk from stores that have a highly contaminated incoming RTE product that does not support growth of *L. monocytogenes* (16.6×10^{-7} vs. 2.8×10^{-7}).

However, when the servings directly associated with the incoming highly contaminated RTE product are removed from the calculation of the risk, the increase in the predicted absolute risk is only the risk associated with retail cross contamination. When the highly contaminated incoming RTE product is one that does not support growth of *L. monocytogenes*, the predicted absolute risk increases from 1.4×10^{-7} ("No niche"; Table 18) to 2.3×10^{-7} (Table 18 footnote and Section 7.2.1). This is almost the same increase in predicted absolute risk as when all RTE servings are included in the risk calculation (i.e., 2.8×10^{-7}). Most of the increase in the predicted absolute risk of products from these stores results from

cross contamination. This result, in addition to the ones evaluating cross contamination (see Scenario Analysis section below), illustrates the importance of retail cross contamination for RTE products that do not support growth of *L. monocytogenes*.

When the servings directly associated with the incoming highly contaminated product are removed from the calculation of the risk for the highly contaminated incoming RTE product that supports growth of *L. monocytogenes*, the predicted absolute risk increases from 1.4×10^{-7} ("No niche"; Table 18) to 2.9×10^{-7} for the susceptible population (Table 18 footnote and Section 7.2.1). The slightly higher predicted absolute risk for highly contaminated incoming RTE products that support growth (2.9×10^{-7} vs. 2.3×10^{-7}) is due to growth of *L. monocytogenes* on the products while in the retail delis, allowing for additional *L. monocytogenes* to cross contaminate other RTE foods. Most notable, however, is that the majority of the predicted absolute risk results directly from product contaminated during processing and growth of *L. monocytogenes* on these products during retail and home storage (i.e., 16.6×10^{-7} vs. 2.9×10^{-7} when only cross contaminated servings are considered). This result, in addition to the ones evaluating the impact of growth inhibitors (see "Scenario analysis" section below), illustrates the overwhelming importance of the growth of *L. monocytogenes* during retail and home storage for RTE products that support its growth.

Overall, the baseline conditions indicate that 1) retail delis without niches and retail delis that control temperature lead to lower predicted risk of listeriosis, and 2) retail delis with incoming RTE products that are highly contaminated with *L. monocytogenes*, notably if the product supports growth, and retail delis with niches lead to higher predicted risk of listeriosis.

8.3. Scenario Analysis

For each of the six baseline retail conditions (listed above), this QRA was used to evaluate the public health impact of 22 different "what if" scenarios (i.e., changes in sanitary practices, worker behaviors, product formulation, cross contamination, and product storage temperature and duration). In total, this QRA provides 126 summary public health findings related to retail practices (Table 19).

In Table 19, each column represents one of six different baseline conditions that may be present in retail delis. Each row shows the percentage change in the risk per serving for the susceptible population relative to the baseline condition for each "what if" scenario (hereafter referred to as "relative risk"). The scenarios are organized according to what they evaluate; i.e., changes in: 1) sanitation, 2) worker behavior, 3) use of growth inhibitors, 4) cross contamination, and 5) storage temperature control. In this

table, positive values represent an increase, while negative values represent a decrease in the predicted relative risk per serving. [Note: Table 19 provides a summary of the results for each scenario, relative to the baseline for only the susceptible population. While the predicted absolute risks were different between the susceptible populations and general population, the predicted relative change in risk is similar for both populations].

The relative effectiveness of a scenario applied to a specific baseline condition can be assessed by reading down the columns in Table 19. The effectiveness of a change in practice across different operating conditions can be assessed by reading across each row in Table 19, keeping in mind the magnitude of the predicted risk for that scenario (shown in Table 18). Some scenarios predict that the mitigation would not be very effective in reducing the predicted risk on a per-serving basis (e.g., no contact between the glove and the case), while others (e.g., pre-slicing) can either be slightly beneficial or highly detrimental, depending on retail deli baseline conditions.

Sanitation-Related Scenarios

Sanitation practices were a key driver in reducing the predicted risk of listeriosis. When sanitation activities were not modeled ("No Sanitation"), the predicted increase in risk could be as much as 50.2% (i.e., under retail deli conditions in which there were niches of *L. monocytogenes* and lack of temperature control to prevent growth; see "Niche & Temp. Control" column). The smallest predicted increase in risk from omitting sanitation was 2.9% ("Incoming Growth Chub" column); in this scenario, the impact of sanitation was overwhelmed by the additional bacteria from the incoming product and the potential growth of *L. monocytogenes* while the product was in the retail deli. While no individual changes in sanitation practices appear to substantively reduce the relative risk of listeriosis per serving of RTE food sliced or prepared in retail delis for all baselines, the substantive increase in risk (up to 50%) when sanitation is omitted is an indicator of the importance of sanitation at retail.

Worker Behavior-Related Scenarios

The impact of QRA simulated changes to worker behavior on the change in predicted relative risk varied, depending on the baseline retail deli condition. For example, if the retail deli had multiple niches ("Multiple Niche 100W), using separate slicers reduced the predicted relative risk by 6.3%. If workers did not use gloves, the predicted relative risk increased (5.1 to 8.5 %). In other cases, the public health benefits of some interventions appear to have been overwhelmed by other factors. For example the benefit

of pre-slicing product in the morning, after cleaning, was offset when incoming RTE products that support the growth of *L. monocytogenes* were highly contaminated.

Growth Inhibitor-Related Scenarios

Of all the scenarios tested, growth-inhibitor usage had the greatest impact on the predicted relative risk. The use of growth inhibitors in all products almost completely eliminated the predicted relative risk (reductions ranged from 94.4 to 97.5%). This level of predicted relative risk reduction (approximately 95%) is a significant finding, given that a 100% reduction would indicate no risk. In practice, however, not all products are amenable to incorporating growth inhibitors; therefore these results represent upper bounds in potential effectiveness.

The baseline scenarios consider that products in the retail deli are a mixture of products that include growth inhibitors and products that do not. In a comparison scenario in which no products in the retail deli contained growth inhibitors ("No GI"), the predicted risk nearly doubled to between 184.1 and 191.5%, compared with the baselines. The only apparent exception is in the "Incoming Growth Chub" baseline, where the estimated relative increase in risk was only 35.1%. This relatively low value is somewhat misleading, because, as mentioned above (see Table 18), the predicted absolute risk for this baseline was already almost 10 times higher than for other baselines.

These findings illustrate the importance of the growth of *L. monocytogenes* during retail and home storage for RTE products that support its growth.

Cross-Contamination-Related Scenarios

Table 19 shows that controlling cross contamination in retail delis is important in mitigating the risk of listeriosis. In the QRA scenarios in which cross contamination did not occur in the retail deli (i.e., the transfer coefficient for all sites and slicer were set to 0; see "Transfers and Slicer to 0" column), the predicted relative risk reduction was significant (ranging from 9.5% and 60.8%). However, when *L. monocytogenes* transfers from the slicer were not eliminated ("Transfers to 0" scenario), there was no significant reduction in the predicted relative risk. This highlights the importance of the slicer in retail delis as a primary source of cross contamination.

In addition to examining the relative risk values in Table 19, examining the absolute risk estimates reported in Section 7.2 of this report provides further insight regarding the role cross contamination plays in the risk from RTE products prepared in retail delis. The absolute risk for a "No Niche" baseline when

cross contamination is eliminated (i.e., "Transfer and Slicer to 0") is 1.1×10^{-7} (see Figure 24). The absolute risk increases to 1.4×10^{-7} when there is cross contamination (see Table 18, "No Niche"). When an "Incoming Non-growth Chub" is introduced to a "No Niche" retail deli where there is no cross contamination, the risk remains essentially the same as the "No Niche, Transfer and Slicer to 0" scenario (1.1×10^{-7}; Figure 34), indicating that if there is no cross contamination at retail, then the introduction of highly contaminated incoming RTE that does not support growth of *L. monocytogenes* does not result in any substantive increase in risk. However, when cross contamination does occur in these situations, the predicted absolute risk significantly increases (to 2.8×10^{-7}; Table 18). This QRA illustrates that any increase in *L. monocytogenes* on incoming RTE product (even those that do not support its growth) increases the predicted risk of listeriosis on a per-serving basis as a result of cross contamination.

It is of interest that Table 19 also showed that reducing the mean incoming *L. monocytogenes* levels in all RTE foods by a factor of 2 (0.3 $\log_{10}$ units) significantly reduced the predicted relative risk (between 1.1 and 24.2%; see "Reduce Level" scenario). This finding suggests that a continued effort to prevent even low levels of *L. monocytogenes* contamination during processing prevents illnesses from these products and other RTE foods.

Scenarios Related to Storage Temperature and Duration Control

Controlling the deli case temperature significantly reduced the predicted risk. For the scenario in which the RTE foods were held at the recommended temperature ("Temp ≤5°C"), the predicted reduction in risk was roughly the same as the reduction associated with holding RTE foods at temperatures that completely prevents growth of *L. monocytogenes* ("No Growth, T=-5°C"). This is an important finding, because maintaining products in the deli display at a temperature recommended by the FDA Food Code prevents almost all additional risk linked to the bacterial growth in retail. These findings highlight the importance of temperature control at retail.

Table 19: Predicted percent change in risk of invasive listeriosis per serving of ready-to-eat food sliced or prepared and sold at retail delis for the susceptible population according to various scenarios, as estimated by the "*L. monocytogenes* in retail delicatessens" risk assessment model.

(percent change in the risk relative to the respective baseline condition) [1]

Scenario	Baseline Conditions[2]					
	Multiple Niche 100W	**No Niche**	**Incoming Growth Chub**	**Incoming Non-growth Chub**	**Temp. Control**	**Niche & Temp. Control**
Sanitation Related Scenarios:						
Wash & Sanitize: Increase the effectiveness of cleaning from simply washing to washing and sanitizing.	-1.6	1.7	-0.6	2.0	-1.3	**-7.6***
Clean 8 Sporadic: Double the number of sites cleaned from 4 to 8.	-4.2	**-4.1***	-0.7	-1.9	-0.5	1.3
No Sanitation: No wiping, washing, or sanitizing.	**41.3***	**7.9***	**2.9***	**23.5***	**11.9***	**50.2***
No Sporadic Cleaning: Clean as required by the 2009 FDA Food Code, but no additional sporadic cleanings.	3.0	-3.0	-0.4	1.7	1.7	3.5
NFCS As FCS: Workers clean deli NFCSs at same rate as FCS.	-3.0	0.7	-0.6	0.3	**-5.4***	0.9
Worker Behavior Related Scenarios:						
No Glove: Workers do not use gloves when serving customers.	**5.1***	2.5	1.2	**8.5***	**6.0***	**7.0***
Gloves Every Serving: Workers change gloves before every sale.	4.1	0.7	0.7	0.6	-0.2	0.6
No Contact Glove Case: Workers do not use their hands to open the deli case (e.g. if a floor switch is used).	-1.4	-3.4	-1.3	1.3	1.3	-0.3
Pre-slice: Workers pre-slice RTE products in the morning, after cleaning	**6.0***	**24.9***	**49.5***	**-34.4***	**19.2***	1.0
Separate Slicer: Workers use a separate slicer for RTE products that support growth of *L. monocytogenes*.	**-6.3***	-0.6	**-1.7***	**22.7***	-0.8	4.6
Do Not Slice Onto Gloves: Workers collect the slices of RTE products on tissue paper rather than on his/her gloved hand.	1.9	1.0	0.2	3.8	-1.9	**8.0***
Growth Inhibitor Related Scenarios:						
All GI: Reformulate all RTE products sold at the retail deli that would otherwise support *L. monocytogenes* growth to include growth inhibitors.	**-96.0***	**-95.2***	**-97.5***	**-94.5***	**-94.4***	**-94.8***
No GI: Reformulate all RTE products that support *L. monocytogenes* growth that are sold at the retail deli to not include GI to restrict *L. monocytogenes* growth.	**184.1***	**191.5***	**35.1***	**190.5***	**187.7***	**188.9***

Scenario	Baseline Conditions[2]					
	Multiple Niche 100W	**No Niche**	**Incoming Growth Chub**	**Incoming Non-growth Chub**	**Temp. Control**	**Niche & Temp. Control**
Cross Contamination Related Scenarios:						
Transfers to 0: Cross contamination results only from the deli slicer.	-4.3	2.5	1.0	3.7	0.2	-0.3
Transfers and Slicer to 0: No cross contamination in the retail deli.	**-33.8***	**-18.6***	**-9.5***	**-60.8***	**-19.2***	**-30.4***
Reduce Level: Mean incoming *L. monocytogenes* $\log_{10}$ concentration in all RTE products lowered from -9.2 to -9.5 $\log_{10}$ cfu/g.	**-21.6***	**-24.2***	-1.1	**-9.8***	**-22.5***	**-15.6***
Separate Slicer Case: Workers use a separate slicer and a separate deli case for RTE products that support the growth of *L. monocytogenes*.	-2.5	-1.6	-1.2	**21.0***	-0.9	**7.5***
Lower Env Cont: Reduce transfer of *L. monocytogenes* among RTE products, FCSs, and NFCs (i.e., reduce transfer coefficients by 50%).	-4.5	**-4.4***	-1.4	0.4	1.6	0.9
Storage Temperature and Duration Control Related Scenarios:						
Temp = 5°C: Set the retail deli case temperature to 5°C (41°F) (i.e., in compliance with the 2009 FDA Food Code) for all delis, instead of using the deli case temperatures reported by Ecosure.	-4.8	**-14.3***	**-8.1***	-2.8	NA	NA
No Growth (T=-5°C): At this temperature, no *L. monocytogenes* growth will occur.	**-16.5***	**-21.3***	**-18.2***	**-5.7***	NA	NA
Temp ≤ 5°C: Use only the retail deli case temperatures observed in the Ecosure dataset at or below 5°C (41°F).	**-9.0***	**-16.3***	**-12.3***	**-8.2***	NA	NA
Shorten Time in Retail Delis: Reduce the length of time RTE products are held before they are sold or disposed from 7 to 4 days.	-2.5	3.3	-1.2	2.0	-0.2	1.7

Readers should refer to the body of the document for further details on the assumptions, model, data, baselines, and scenarios. See Table 18 for the predicted absolute risk of the baseline conditions.

* bold: Outside the 95% confidence interval for the median.

NFCS = non-food-contact surface; FCS = food-contact surface; Temp. = Temperature; NA= not applicable to this scenario; Chub refers to bulk product (deli meat or cheese) before it is sliced.

[1]The US population was split in two subpopulations for the purposes of this risk assessment: the susceptible population (e.g., older adults, fetuses, newborns, and people with immune-compromising conditions, according to FAO/WHO 2004 definition) and the remaining population. The results for the susceptible population only are presented, because this population comprises 80-98% of the public health burden for listeriosis

[2]Description of the baseline conditions: **Multiple Niche 100W** = a retail deli with multiple niches that releases *L. monocytogenes* to food-contact surfaces at a rate of 100 cfu on an average weekly frequency; **No Niche** = a retail deli with no niches or environmental *L. monocytogenes* transfer; **Incoming Growth Chub** = A retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product that is contaminated at levels higher than those of other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs -9.2 $\log_{10}$ cfu/g) and that does support the growth of *L. monocytogenes*; **Incoming Non-growth Chub** = A retail deli with no niche or environmental *L. monocytogenes* transfer, with one incoming RTE product that is contaminated at levels higher than those of other products in the deli (mean of the $\log_{10}$: -5 $\log_{10}$ cfu/g vs -9.2 $\log_{10}$ cfu/g) and does not support the growth of *L. monocytogenes*; **Niche & Temperature Control** = a retail deli with multiple niches and compliant with the 2009 FDA Food Code guidance for temperature control (≤41°F): **Temperature Control** = a retail deli without any niches and with compliant temperature control.

9. Conclusions

This QRA represents the first large-scale effort to model *L. monocytogenes* cross contamination at retail. The risk assessment model contributes to our understanding of *L. monocytogenes* transmission, survival, and growth in the retail environment and was used to evaluate how retail practices may impact the predicted risk of listeriosis. The approach used was to evaluate the public health effect of various changes in practices under six different baseline conditions that may characterize a retail deli and the RTE food it serves.

The key findings from this assessment of listeriosis risk associated with RTE foods prepared and served in retail deli operations include:

- **Control Growth**. Employing practices that prevent bacterial growth dramatically reduced the predicted risk of listeriosis, as observed in other *L. monocytogenes* risk assessments. The use of growth inhibitors for suitable products prevents growth of *L. monocytogenes* in RTE foods both at retail and during consumer home storage. In this risk assessment, use of growth inhibitors led to an overall dramatic reduction in the predicted risk of listeriosis (ca. 95%, see table). The strict control of temperature during refrigerated storage in retail delis did reduce the predicted risk. The impact of this control is nevertheless lower as it reduces growth only during this specific storage (5-20% reduction according to the baseline and the scenario) (see "Temperature Control" baseline and growth inhibitor scenarios).
- **Control Cross Contamination**. Cross contamination of *L. monocytogenes* in the retail environment dramatically increases the predicted risk of listeriosis. Cross contamination during the routine operation of the retail deli is not amenable to a simple solution (cf. "Transfers and Slicer to 0" scenarios).
- **Control Contamination at Its Source**. Increasing the concentration and transfers of *L. monocytogenes* from incoming products, the environment, or niches directly increases the predicted risk of illness. Increasing *L. monocytogenes* concentration in incoming product increased the predicted risk of listeriosis whether or not the contaminated RTE product itself supported growth. The increase in predicted risk was greater when the equivalent contamination occurred on product that supported the growth of *L. monocytogenes* (cf. predicted risks for "Incoming Growth Chub" baseline and "Incoming Non-growth Chub" baseline, as well as "Reduce Level" scenarios).

- **Continue Sanitation.** Sanitation practices that eliminate *L. monocytogenes* from deli FCS results in a reduction in the predicted risk of illness. Cleaning and sanitizing FCS reduced the predicted *L. monocytogenes* levels in the deli area (see "No Sanitation" scenario). Wearing gloves while serving customers reduces the estimated risk of listeriosis.
- **Identify Key Routes of Contamination**. The slicer is a primary source of *L. monocytogenes* cross contamination to deli meats and cheeses. Control of *L. monocytogenes* cross contamination at this point during retail preparation reduced the predicted risk of listeriosis (see "Transfers to 0" versus "Transfers and Slicer to 0" scenarios).

In summary, this risk assessment improves our understanding of *L. monocytogenes* in the retail deli and is intended to encourage improvements to retail food safety practices and mitigation strategies to further control *L. monocytogenes* in RTE foods. The "what if" scenarios modeled in this risk assessment provide insight on how cross contamination, sanitary practices, and temperature control impact the predicted risk of listeriosis. This risk assessment is based on an extensive amount of information gathered through partnerships with academia and input from stakeholders. Additional data would be useful, to refine and improve the predictions made by this "Virtual Deli" model and to further explore how more specific retail practices and conditions (e.g., equipment design) impact the risk of listeriosis.

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Appendix 1: The Secondary Growth Model

The Mejlholm and Dalgaard model [75] is a predictive microbiology secondary model. It predicts the change in the primary model parameters according to a change in the growth environment. This model uses the gamma concept [65]. The model used here is limited to T, pH, a_w, nitrites, LAC, and DAC and their interaction. It is written:

$$\mu = \mu_{ref} \cdot \gamma_T(T) \cdot \gamma_{pH}(pH) \cdot \gamma_{a_w}(a_w) \cdot \gamma_{nit}(nit) \cdot \gamma_{LAC}(LAC) \cdot \gamma_{DAC}(DAC) \cdot \xi_{\text{int}}(T, pH, a_w, nit, LAC, DAC)$$

where

- $\mu_{ref} = 0.419\ \text{h}^{-1}$ is equal to μ_{opt} at a reference temperature (T_{ref}) of 25°C in the RTE product;
- $\gamma_T(T) = \begin{cases} \left(\frac{T+2.83}{T_{ref}+2.83}\right)^2 & if\ T > -2.83°C \\ 0 & if\ T \le -2.83°C \end{cases}$ with T, the temperature in degrees Celsius.

  Note that this model for temperature is equivalent to a Ratkowsky [68] model, as used in [3], with T_{min}, the minimal temperature of growth for *Listeria* equals to -2.83°C (26.91°F);
- $\gamma_{a_w}(a_w) = \begin{cases} \frac{(a_w - 0.923)}{(1-0.923)} & if\ a_w > 0.923 \\ 0 & if\ a_w \le 0.923 \end{cases}$ with a_w , the water activity of the RTE product;
- $\gamma_{pH}(pH) = \begin{cases} 1 - 10^{(4.97-pH)} & if\ pH > 4.97 \\ 0 & if\ pH \le 4.97 \end{cases}$ with pH, the pH of the RTE product;
- $\gamma_{nit}(nit) = \begin{cases} \left(\frac{350-nit}{350}\right)^2 & if\ nit < 350\ ppm \\ 0 & if\ nit \ge 350\ ppm \end{cases}$ with *nit* the concentration of nitrites (ppm);
- $\gamma_{LAC}([LAC_U]) = \begin{cases} \left(1 - \frac{[LAC_U]}{3.79}\right) & if\ [LAC_U] < 3.79\ mM \\ 0 & f\ [LAC_U] \ge 3.79\ mM \end{cases}$ with $[LAC_U]$, the concentration (mM) of undissociated lactic acid.
- $\gamma_{DAC}([DAC_U]) = \begin{cases} \left(1 - \sqrt{\frac{[DAC_U]}{4.80}}\right) & if\ [DAC_U] < 4.80\ mM \\ 0 & if\ [DAC_U] \ge 4.80\ mM \end{cases}$ with $[DAC_U]$, the concentration (mM) of undissociated diacetate.

The value of [LAC_U] from the concentration of growth inhibitors in the RTE product is evaluated in two steps: First, the total lactic acid concentration (LAC_{tot}, %) is evaluated from the concentration in sodium lactate (NaL, %), the concentration in potassium lactate (KL, %), and the concentration in lactic acid (LAC, %) using their respective molecular weight, as:

$$LAC_{tot} = 90.08 \times \left(\frac{NaL}{112.1} + \frac{KL}{128.2} + \frac{LAC}{90.08} \right).$$

Then, the concentration in undissociated lactic acid (mM) is evaluated from the total concentration of lactic acid using the Henderson-Hasselbach equation:

$$pH = pK_a + \log_{10} \frac{[A-]}{[A_U]}$$

leading to

$$[LAC_U] = \frac{LAC_{tot} \times \frac{10000}{90.08}}{1 + 10^{pH-3.86}};$$

The pKa dependence on temperature was found to be negligible for lactic acid [125] and assumed so for diacetate. Similarly, the total diacetate concentration (DAC_{tot}, %) is evaluated from the concentration in sodium lactate (NaDAC, %) and the concentration in diacetate (DAC, %) using their respective molecular weight, as:

$$DAC_{tot} = 119.1 \times \left(\frac{NaDAC}{142.09} + \frac{DAC}{119.1} \right).$$

The concentration in undissociated diacetate (mM) is evaluated from the total concentration of diacetate using:

$$[DAC_U] = \frac{DAC_{tot} \times \frac{10000}{119.1}}{1 + 10^{pH-4.76}};$$

As for the interaction term, Mejlholm and Dalgaard [75] use the Le Marc [71] approach, i.e.:

$$\xi(T, a_w, pH, nit, [LAC_U], [DAC_U]) = \begin{cases} 1 & if\ \psi \le 0.5 \\ 2(1-\psi) & if\ 0.5 < \psi < 1 \\ 0 & if\ \psi \ge 1 \end{cases}$$

where

$$\psi = \sum_i \left(\frac{\varphi(i)}{2 \prod_{j \ne i} (1 - \varphi(j))} \right) = 0.5 \times \left(\frac{\sum_i \varphi(i)(1-\varphi(i))}{\prod_i (1-\varphi(i))} \right)$$

with

$$\varphi(T) = \left(1 - \frac{T + 2.83}{T_{ref} + 2.83}\right)^2,$$

$$\varphi(a_w) = \left(1 - \sqrt{\frac{a_w - 0.923}{1 - 0.923}}\right)^2,$$

$$\varphi(pH) = \left(1 - \sqrt{1 - 10^{(4.97 - pH)}}\right)^2,$$

$$\varphi(nit) = \left(1 - \frac{350 - nit}{350}\right)^2 \text{ and}$$

$$\varphi([LAC_u];[DAC_U]) = \left(1 - \left(1 - \sqrt{\frac{[LAC_U]}{3.79}}\right) \cdot \left(1 - \sqrt{\frac{[DAC_U]}{4.80}}\right)\right)^2.$$

The growth model was slightly adapted to fit the structure of the present model. Nevertheless, these adaptations were made with no change in the mathematical model.

Simplification of the model

We first simplify the final evaluation of ξ. We have:

$$\xi = \begin{cases} 0 & 2(1-\psi) \le 0 \\ 2(1-\psi) & 0 < 2(1-\psi) < 1 \\ 1 & 2(1-\psi) \ge 1 \end{cases}.$$

Define $\chi = 2(1 - \psi)$. We have:

$$\chi = 2 - \frac{\sum_i \varphi_i (1 - \varphi_i)}{\prod_i (1 - \varphi_i)}$$

Then we can rewrite ξ simply as:

$$\xi = \begin{cases} 0 & \chi \le 0 \\ \chi & 0 < \chi < 1 \\ 1 & \chi \ge 1 \end{cases}$$

Mathematical derivation when only one parameter is varying

A given RTE product has a set of chemical characteristics (pH, a_w, [LAC]tot, [DAC]tot, nit). We will consider those characteristics as constant throughout the process, from entry in the deli to consumption.

Only one parameter is considered: temperature T. The following procedure will help us evaluate the growth of the RTE product while the temperature varies in the process.

The gamma concept with interaction is written, for $i \in \{T, pH, a_w, nit, [LAC]_{tot}, [DAC]_{tot}\}$:

$$\mu = \mu_{opt} \times \prod_i \gamma_i(x_i) \times \xi = \left(\mu_{opt} \times \prod_{i \neq T} \gamma_i(x_i) \right) \times \gamma_T(T) \times \xi \, .$$

$\left(\mu_{opt} \times \prod_{i \neq T} \gamma_i(x_i) \right)$ is characteristic of the RTE product. In our particular process, it is a constant.

We have:

$$\chi = 2 - \frac{\sum_i \varphi_i(1-\varphi_i)}{\prod_i (1-\varphi_i)} = 2 - \frac{\sum_{i \neq T} \varphi_i(1-\varphi_i) + \varphi_T(1-\varphi_T)}{\prod_{i \neq T} (1-\varphi_i) \times (1-\varphi_T)}, \text{ then}$$

$$\chi = 2 - \frac{\sum_{i \neq T} \varphi_i(1-\varphi_i)}{\prod_{i \neq T} (1-\varphi_i) \times (1-\varphi_T)} - \frac{\varphi_T}{\prod_{i \neq T} (1-\varphi_i)}$$

Define $\chi_{i \neq T}$ the factor χ for all parameters but T. We have:

$$\chi_{i \neq T} = 2 - \frac{\sum_{i \neq T} \varphi_i(1-\varphi_i)}{\prod_{i \neq T} (1-\varphi_i)}$$

Then:

$$\chi = 2 - \frac{(2 - \chi_{i \neq T})}{(1-\varphi_T)} - \frac{\varphi_T}{\prod_{i \neq T} (1-\varphi_i)}$$

Then, $\xi = \chi$ if $0 < \chi < 1$; $\xi = 1$ if $\chi > 1$ and $\xi = 0$ if $\chi < 0$.

Note, moreover, that at $T = T_{\text{ref}}$, $\gamma_T = 1$, $\varphi_T = 0$. We can thus define our parameters at $T = T_{\text{ref}}$ since $\gamma_{Tref} = \gamma_{i \neq T}$, $\chi_{Tref} = \chi_{i \neq T}$.

In practice

For a given RTE product with a different set of parameters (pH, aw, [LAC], [DAC]) and a μ_{ref}. Assume that only the temperature changes. The following process may be used to evaluate the growth at a temperature T.

For a given RTE product, at $T = T_{ref}$

1. Evaluate and store $\gamma_{T_{ref}} = \prod_i \gamma_i$. If $\gamma_{Tref} = 0 \Rightarrow$ No growth $\forall T$

2. Evaluate and store $A_{T_{ref}} = \prod_i (1-\varphi_i)$

3. Evaluate and store $\chi_{T_{ref}} = 2 - \frac{\sum_i \varphi_i (1-\varphi_i)}{A_{T_{ref}}}$. If $\chi_{Tref} \le 0 \Rightarrow$ No growth $\forall T$

For a given temperature T If $T \le T_{min} \Rightarrow$ No growth for T

4. Evaluate $\gamma_T = \left(\frac{T - T_{\min}}{T_{ref} - T_{\min}} \right)^2 = \left(\frac{T + 2.83}{27.83} \right)^2$

5. Evaluate $\varphi_T = \left(1 - \left(\frac{T + 2.83}{27.83} \right) \right)^2 = \left(1 - \sqrt{\gamma_T} \right)$

6. Evaluate $\chi = 2 - \frac{2 - \chi_{T_{ref}}}{1 - \varphi_T} - \frac{\varphi_T}{A_{T_{ref}}}$ If $\chi \le 0 \Rightarrow$ No growth for T

7. If if $\chi \ge 1$, set $\xi = 1$; else $\xi = \chi$

8. Evaluate $\mu = \left(\mu_{ref} \times \gamma_{T_{ref}} \right) \times \gamma_T \times \xi$

Appendix 2: Consumption Data

The objective was to derive a distribution for serving sizes for "Deli meat," "Deli Cheese," and "Deli Salad." Consumption data were extracted from the 1999-2006 National Health and Nutrition Examination Survey (NHANES, a USDA / DHHS survey) results, using the FARE™ Program (Food Analysis and Residue Evaluation Program, v. 8.63) developed by Exponent®. Briefly, the nutritional assessment component of the NHANES includes a 24-hour dietary recall interview for participants of all ages. Dietary recall interviews are conducted, in person, by trained dietary interviewers fluent in Spanish and English. Each dietary interview room contains a standard set of measuring guides. These tools are used to help the respondent report the volume and dimensions of the food items consumed. They are not intended to represent any one particular food, but rather are designed to help respondents estimate portion sizes. This set of measuring guides is designed specifically for use in the current NHANES setting with a target population of non-institutionalized U.S. civilians.

Method

All analyses were performed using the following options:

- Database: NHANES, combined 1999-2006 data, using only the first day of intake data;
- Uses statistical weights, does not divide intake by body weight;
- Intake timing by specific meal and snack period. For meal and snack period, brunch and lunch were combined, as well as supper and dinner. All snacks were gathered daily as a single eating occasion;
- The population was the standard U.S. population (all season, region, age, sex, and ethnicity), the pregnant 13+ population and the senior (55+) population.

Deli Meat

An analysis by ingredient ("RAC", Raw Agricultural Commodities) was used, because part of this deli meat is used within complex food, such as sandwiches. First, the software extracted from the NHANES database all recorded eating occasions of any of the foods-as-eaten items listed, considered as including a "Deli Meat" as ingredient (Table 20). The list is an update of the 2003 FDA/FSIS risk assessment list (provided in [3], appendix 5, p.419). Then, the "Meat" part of these food items was extracted using recipe translation files included with the FARE™ program.

Table 20: Food items considered as including "Deli Meat"

CODE	Description
22301000	Ham, fresh, cooked, NS as to fat eaten
22301110	Ham, fresh, cooked, lean and fat eaten
22301120	Ham, fresh, cooked, lean only eaten
22311000	Ham, smoked or cured, cooked, NS as to fat eaten
22311010	Ham, smoked or cured, cooked, lean and fat eaten
22311020	Ham, smoked or cured, cooked, lean only eaten
22311200	Ham, smoked or cured, low sodium, cooked, NS as to fat eaten
22311210	Ham, smoked or cured, low sodium, cooked, lean and fat eaten
22311220	Ham, smoked or cured, low sodium, cooked, lean only eaten
22311450	Ham, prosciutto
23322100	Deer bologna
24201500	Turkey, light or dark meat, smoked, cooked, NS as to skin eaten
24201510	Turkey, light or dark meat, smoked, cooked, skin eaten
24201520	Turkey, light or dark meat, smoked, cooked, skin not eaten
25220010	Cold cut, NFS
25220390	Bologna, beef, lowfat
25220400	Bologna, pork and beef
25220410	Bologna, NFS
25220420	Bologna, Lebanon
25220430	Bologna, beef
25220440	Bologna, turkey
25220450	Bologna ring, smoked
25220460	Bologna, pork
25220470	Bologna, beef, lower sodium
25220480	Bologna, chicken, beef, and pork
25220490	Bologna, with cheese
25220500	Bologna, beef and pork, lowfat
25220710	Chorizos
25221210	Mortadella
25221250	Pepperoni
25221480	Mettwurst
25221500	Salami, NFS
25221510	Salami, soft, cooked
25221520	Salami, dry or hard
25221530	Salami, beef
25221710	Souse
25221810	Thuringer
25230110	Luncheon meat, NFS
25230210	Ham, sliced, prepackaged or deli, luncheon meat
25230220	Ham, sliced, low salt, prepackaged or deli, luncheon meat
25230230	Ham, sliced, extra lean, prepackaged or deli, luncheon meat
25230310	Chicken or turkey loaf, prepackaged or deli, luncheon meat
25230410	Ham loaf, luncheon meat
25230430	Ham and cheese loaf
25230450	Honey loaf
25230510	Ham, luncheon meat, chopped, minced, pressed, spiced, not canned
25230520	Ham, luncheon meat, chopped, minced, pressed, spiced, lowfat, not canned
25230560	Liverwurst
25230610	Luncheon loaf (olive, pickle, or pimiento)
25230710	Sandwich loaf, luncheon meat
25230790	Turkey ham, sliced, extra lean, prepackaged or deli, luncheon meat
25230800	Turkey ham

CODE	Description
25230810	Veal loaf
25230820	Turkey pastrami
25230840	Turkey salami
25230900	Turkey or chicken breast, prepackaged or deli, luncheon meat
25230905	Turkey or chicken breast, low salt, prepackaged or deli, luncheon meat
25231110	Beef, sliced, prepackaged or deli, luncheon meat
25231150	Corned beef, pressed
27500050	Sandwich, NFS
27500100	Meat sandwich, NFS
27500200	Wrap sandwich, filled with meat, poultry, or fish, vegetables, and cheese
27500300	Wrap sandwich, filled with meat, poultry, or fish, and vegetables
27510910	Corned beef sandwich
27510950	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread
27511010	Pastrami sandwich
27513010	Roast beef sandwich
27513020	Roast beef sandwich, with gravy
27513030	Roast beef sandwich dipped in egg, fried, with gravy and spread
27513040	Roast beef submarine sandwich, with lettuce, tomato and spread
27513050	Roast beef sandwich with cheese
27513060	Roast beef sandwich with bacon and cheese sauce
27513070	Roast beef submarine sandwich, on roll, au jus
27520110	Bacon sandwich, with spread
27520120	Bacon and cheese sandwich, with spread
27520130	Bacon, chicken, and tomato club sandwich, with lettuce and spread
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread
27520140	Bacon and egg sandwich
27520150	Bacon, lettuce, and tomato sandwich with spread
27520160	Bacon, chicken, and tomato club sandwich, on multigrain roll with lettuce and spread
27520165	Bacon, chicken fillet (breaded, fried), and tomato club with lettuce and spread
27520166	Bacon, chicken fillet (breaded, fried), and tomato club sandwich with cheese, lettuce and spread
27520170	Bacon on biscuit
27520250	Ham on biscuit
27520300	Ham sandwich, with spread
27520310	Ham sandwich with lettuce and spread
27520320	Ham and cheese sandwich, with lettuce and spread
27520330	Ham and egg sandwich
27520350	Ham and cheese sandwich, with spread, grilled
27520360	Ham and cheese sandwich, on bun, with lettuce and spread
27520370	Hot ham and cheese sandwich, on bun
27520380	Ham and cheese on English muffin
27520390	Ham and cheese submarine sandwich, with lettuce, tomato and spread
27520410	Cuban sandwich, (Sandwich cubano), with spread
27520540	Ham and tomato club sandwich, with lettuce and spread
27540110	Chicken sandwich, with spread
27540130	Chicken barbecue sandwich
27540290	Chicken submarine sandwich, with lettuce, tomato, and spread
27540310	Turkey sandwich, with spread
27540330	Turkey sandwich, with gravy
27540350	Turkey submarine sandwich, with cheese, lettuce, tomato and spread
27541000	Turkey, ham, and roast beef club sandwich, with lettuce, tomato and spread
27560000	Luncheon meat sandwich, NFS, with spread
27560110	Bologna sandwich, with spread
27560120	Bologna and cheese sandwich, with spread
27560510	Salami sandwich, with spread

CODE	Description
27560910	Cold cut submarine sandwich, with cheese, lettuce, tomato, and spread

Deli Cheese

For deli cheese, an analysis using the same option of the FARE™ program was performed on the food items shown in Table 21. The analysis was based on Dun & Bradstreet (DNB) ingredients (USDA Nutrient Databank Identifier).

Table 21: Food items considered as including "Deli Cheese"

NDB Code	Description
1004	Cheese, blue
1005	Cheese, brick
1009	Cheese, cheddar
1011	Cheese, Colby
1018	Cheese, Edam
1020	Cheese, Fontina
1022	Cheese, Gouda
1023	Cheese, Gruyère
1024	Cheese, Limburger
1025	Cheese, Monterey
1030	Cheese, Muenster
1035	Cheese, provolone
1040	Cheese, Swiss
1042	Cheese, pasteurized process, American, with di sodium phosphate
1043	Cheese, pasteurized process, pimento
1044	Cheese, pasteurized process, Swiss, with di sodium phosphate
1046	Cheese food, pasteurized process, American, without di sodium phosphate

Deli Salad

The list of foods-as-eaten used to identify deli salad is an update (Table 22) of the one provided for the 2003 FDA/FSIS risk assessment (see [3] appendix 5, p. 429).

Table 22: Food items considered as "Deli Salad".

Code	Description
25240000	Meat spread or potted meat, NFS
25240110	Chicken salad spread
25240220	Ham salad spread
25240310	Roast beef spread
25240320	Corned beef spread
27416250	Beef salad
27420020	Ham or pork salad
27446200	Chicken or turkey salad
27446205	Chicken or turkey salad with nuts and/or fruits

Code	Description
27446220	Chicken or turkey salad with egg
27446300	Chicken or turkey garden salad (chicken and/or turkey, tomato and/or carrots, other vegetables), no dressing
27446310	Chicken or turkey garden salad (chicken and/or turkey, other vegetables excluding tomato and carrots), no dressing
27446315	Chicken or turkey garden salad with bacon (chicken and/or turkey, bacon, cheese, lettuce and/or greens, tomato and/or carrots, other vegetables), no dressing
27446320	Chicken or turkey (breaded, fried) garden salad with bacon (chicken and/or turkey, bacon, cheese, lettuce and/or greens, tomato and/or carrots, other vegetables), no dressing
27446350	Oriental chicken or turkey garden salad (chicken and/or turkey, lettuce, fruit, nuts), no dressing
27446355	Oriental chicken or turkey garden salad with crispy noodles (chicken and/or turkey, lettuce, fruit, nuts, crispy noodles), no dressing
27446360	Chicken or turkey caesar garden salad (chicken and/or turkey, lettuce, tomato, cheese), no dressing
27446362	Chicken or turkey (breaded, fried) caesar garden salad (chicken and/or turkey, lettuce, tomatoes, cheese), no dressing
27450010	Crab salad
27450020	Lobster salad
27450030	Salmon salad
27450060	Tuna salad
27450070	Shrimp salad
27450080	Seafood salad
27450090	Tuna salad with cheese
27450100	Tuna salad with egg
27450110	Shrimp garden salad (shrimp, lettuce, eggs, tomato and/or carrots, other vegetables), no dressing
27450120	Shrimp garden salad (shrimp, lettuce, eggs, vegetables excluding tomato and carrots), no dressing
27450130	Crab salad made with imitation crab
27450180	Seafood garden salad with seafood, lettuce, vegetables excluding tomato and carrots, no dressing
27450190	Seafood garden salad with seafood, lettuce, tomato and/or carrots, other vegetables, no dressing
27450200	Seafood garden salad with seafood, lettuce, eggs, vegetables excluding tomato and carrots, no dressing
27450210	Seafood garden salad with seafood, lettuce, eggs, tomato and/or carrots, other vegetables, no dressing
27460490	Julienne salad (meat, cheese, eggs, vegetables), no dressing
27460510	Antipasto with ham, fish, cheese, vegetables
27520340	Ham salad sandwich
27540120	Chicken salad or chicken spread sandwich
27540320	Turkey salad or turkey spread sandwich
27550710	Tuna salad sandwich, with lettuce
27550720	Tuna salad sandwich
27550750	Tuna salad submarine sandwich, with lettuce and tomato
32103000	Egg salad
32203010	Egg salad sandwich
41203020	Kidney bean salad
41205070	Hummus
58101930	Taco or tostada salad with beef, beans and cheese, fried flour tortilla
58101940	Taco or tostada salad, meatless, with cheese, fried flour tortilla
58148110	Macaroni or pasta salad
58148120	Macaroni or pasta salad with egg

Code	Description
58148130	Macaroni or pasta salad with tuna
58148140	Macaroni or pasta salad with crab meat
58148150	Macaroni or pasta salad with shrimp
58148160	Macaroni or pasta salad with tuna and egg
58148170	Macaroni or pasta salad with chicken
58148180	Macaroni or pasta salad with cheese
58148500	Pasta or macaroni salad with oil and vinegar-type dressing
58148550	Pasta or macaroni salad with meat
71601010	Potato salad with egg
71602010	Potato salad, German style
71603010	Potato salad
72116140	Caesar salad (with romaine)
73101010	Carrots, raw
73101110	Carrots, raw, salad
73101210	Carrots, raw, salad with apples
74506000	Tomato and cucumber salad made with tomato, cucumber, oil, and vinegar
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing
75141000	Cabbage salad or coleslaw, with dressing
75141100	Cabbage salad or coleslaw with apples and/or raisins, with dressing
75141200	Cabbage salad or coleslaw with pineapple, with dressing
75142500	Cucumber salad with creamy dressing
75142550	Cucumber salad made with cucumber, oil, and vinegar
75142600	Cucumber salad made with cucumber and vinegar
75143000	Lettuce, salad with assorted vegetables including tomatoes and/or carrots, no dressing
75143050	Lettuce, salad with assorted vegetables excluding tomatoes and carrots, no dressing
75143100	Lettuce, salad with avocado, tomato, and/or carrots, with or without other vegetables, no dressing
75143200	Lettuce, salad with cheese, tomato and/or carrots, with or without other vegetables, no dressing
75143300	Lettuce, salad with egg, tomato, and/or carrots, with or without other vegetables, no dressing
75143350	Lettuce salad with egg, cheese, tomato, and/or carrots, with or without other vegetables, no dressing
75144100	Lettuce, wilted, with bacon dressing
75145000	Seven-layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise, cheese, eggs, and/or bacon)
75146000	Greek Salad
75147000	Spinach salad, no dressing
75148000	Cobb salad with dressing
75201030	Artichoke salad in oil
75302080	Bean salad, yellow and/or green string beans
75416500	Pea salad
75416600	Pea salad with cheese

Results

The FARE™ program provides bins of grams per eating occasion and corresponding weighted occurrences for breakfast, lunch, dinner, and snack as well as a Total. As an example, 537,349 (weighted) eating occasions of (0.35-0.70)g of deli cheese are recorded in the 1999-2006 NHANES data base.

g			Occurrences per defined eating occasion (1000):	
per eating occ			SNACKS	Total
0	to	0.3	123313	222637
0.3502069	to	0.7004138	211539	**537349**
0.700414	to	1.050621	214141	787902
1.050621	to	1.400828	163497	763834
1.400828	to	1.751034	185311	744600
1.751034	to	2.101241	100822	908607
2.101241	to	2.451448	337827	1246231
2.451448	to	2.801655	34015	643428
2.801655	to	3.151862	136648	579838
3.151862	to	3.502069	72437	536624
…				

The cumulative distribution of the serving size per eating occasion for deli meat, deli cheese, and deli salad for the total, the pregnant, and the senior populations are provided in Figure 64, Figure 65, and Figure 66.

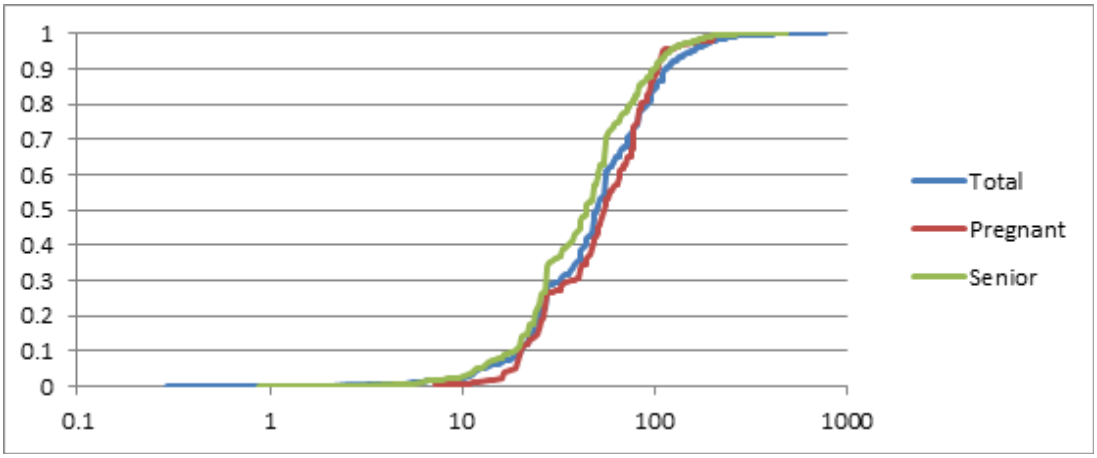

Figure 64: Empirical cumulative density function of the serving size per eating occasion (unit: g/EO) for deli-meat for the total population, pregnant women, and seniors (55+): data NHANES 1999-2006.

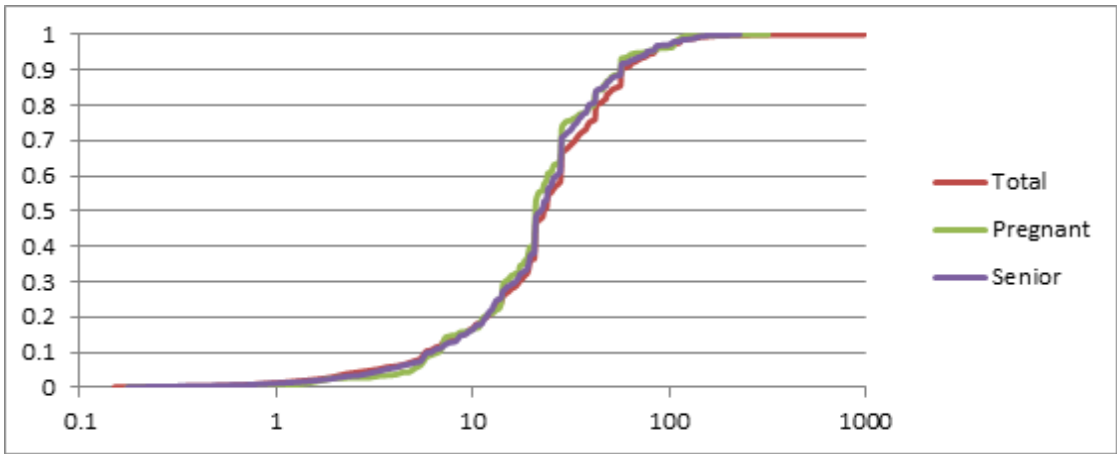

Figure 65: Empirical cumulative density function of the serving size per eating occasion (unit: g/EO) for deli-cheese for the total population, pregnant women, and seniors (55+): data NHANES 1999-2006

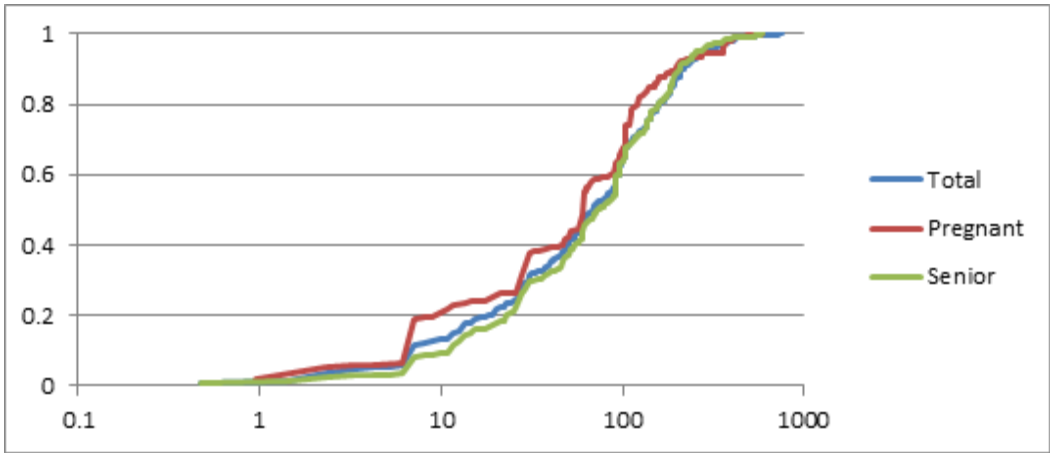

Figure 66: Empirical cumulative density function of the serving size per eating occasion (unit: g/EO) for deli-salad for the total population, pregnant women, and seniors (55+): data NHANES 1999-2006

Simulation

To provide simulated serving sizes within this "interagency *L. monocytogenes* in retail risk assessment" model, we used the following algorithm:

- from the FARE results, one bin is randomly sampled proportionally to its number of occurrence;
- then, a serving size is randomly sampled uniformly within the bounds of this bin;
- the value is rounded to the upper gram.

The resulting empirical cumulative distributions and their relative statistics for the overall population are provided in Figure 11 of this document.