# Draft Interagency Risk Assessment – Listeria monocytogenes in Retail Delicatessens

# **Interpretative Summary**

The Interagency Retail *Listeria monocytogenes*Risk Assessment Workgroup



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## **Interpretative 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 changes to common or recommended practices. This quantitative risk assessment (QRA) 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 President's Food Safety Working Group identified this risk assessment as a priority. It provides information useful to those responsible for implementing policies, programs and practices that target the prevention of listeriosis in the population.

#### **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 Centers for Disease Control and Prevention (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).

To reduce listeriosis, it is important to identify (1) which RTE foods pose the greatest risk and (2) which changes in practices improve the safety of these RTE products. Risk assessment is a tool that has been used to accomplish these goals successfully by prioritizing RTE foods according to risk and linking food safety research to changes in practices that will impact public health outcomes.

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

levels as well as survival and proliferation of the organism. *L. monocytogenes* can contaminate foods via cross contamination from one product to another or through contamination from the environment, or both. To understand *L. monocytogenes* transmission, survival, and growth in the retail environment better and to evaluate how retail practices may impact public health, an interagency risk assessment was developed jointly by the U.S. Department of Agriculture, Food Safety and Inspection Services (FSIS) and the Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition.

#### **Overview of Risk Assessment**

The QRA simulates the retail deli environment and evaluates how various sanitary and food handling practices may influence the risk of listeriosis associated with consuming RTE foods that are sliced, prepared or packaged in retail grocery delis. In other words, the risk assessment evaluates the extent to which retail practices may increase or decrease the relative exposure to *L. monocytogenes* in RTE foods, and the subsequent public health risk of listeriosis from these RTE foods (e.g., deli meats, cheeses, or deli salads sliced, prepared, or packaged in grocery delis). The model also evaluates which intervention or mitigation strategies confer the largest potential reduction of the risk of listeriosis.

The risk assessment is designed to evaluate RTE foods that are:

- sliced, prepared and/or packaged in the retail deli environment and consumed in the home (e.g., sliced deli meats, sliced cheeses, and deli-type salads); and
- sold in a range of retail types such as the delicatessen departments of major and large grocery chains, supermarket facilities and other groceries (i.e., multipurpose, independent, small or local facilities).

The QRA is unique in its ability to quantitatively link activities within a retail deli directly to predicted public health outcomes. Model inputs include:

- the work routines of deli workers (i.e., the frequency and sequence of actions to serve customers, as well as the cleaning and sanitation practices in the deli);
- L. monocytogenes concentrations in incoming product (e.g., prevalence and levels in food);
- the potential environmental contamination of food contact sites and potential cross contaminations among those sites (e.g., transfer of *L. monocytogenes* from the slicer to food); and
- the probability that a specific dose will result in listeriosis (e.g., dose-response modeling).

The QRA quantitatively predicts listeriosis risk associated with activities in the retail deli operation and as such, it can be thought of as a "Virtual Deli." The model simulates the *L. monocytogenes* concentration

and prevalence in products sold to customers, predicts changes in concentrations during consumer home storage, and finally estimates the risk of listeriosis from consumption of these products in the home. The model also allows an evaluation of the impact of changes to the retail deli operation or practices. The population was divided into two subpopulations for purpose of this QRA: (1) a population with increased susceptibility (including neonates, older adults, and the immunocompromised); and (2) the remaining population. Specific risk management questions provided by federal partners and stakeholders were used to guide the simulation scenarios conducted with this risk assessment model.

#### Key Activities in the Development of this Risk Assessment

Many activities have been conducted or supported to improve transparency and ensure stakeholder engagement in the process of developing the risk assessment. These activities assisted in our efforts to obtain the data needed to develop the risk assessment model and to ensure scientific and technical credibility of the interagency risk assessment. Below is a summary of the key activities that are completed, ongoing, and planned to further these goals:

- o **Fall 2008**: FSIS and FDA began collaborating on development of the Interagency Retail *L. monocytogenes* Risk Assessment.
- o **June 2009**: A public meeting was held to bring stakeholders into the development of this risk assessment early in the process, provide them with insights regarding data needs, and garner input from them. Input was subsequently provided by Center for Science in the Public Interest (CSPI), the Grocery Manufacturers of America (GMA), the American Meat Institute (AMI), and academic institutions.
- June 2009 Present: FSIS and FDA coordinated with several universities and CDC to conduct research and surveys to gather specific additional data for this risk assessment.
- Winter 2010: The mathematics and the structure of the cross contamination model were reviewed by experts selected through a rigorous process managed by a third party and nongovernmental entity to ensure an independent review. The draft interagency risk assessment was refined in response to these peer review comments.
- o Fall 2010 Present: Outreach to industry and consumer groups was conducted to keep stakeholders informed on the status of the risk assessment and obtain input on how to improve the retail cross contamination model. Among those who have been involved in the outreach

conducted are the Joint Institute of Food Safety and Applied Nutrition (JIFSAN), Food Marketing Institute (FMI), AMI, CSPI, GMA, Safe Food Coalition (SFC), and Association of Food and Drug Officials (AFDO). Technical presentations about the novel mathematical modeling approach to characterize cross contamination in a deli environment also have been made at several scientific meetings.

 September 2012 – Present. Finalized the draft risk assessment report to prepare for web posting for public input.

### **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 at retail delis?
- 3. How much is the relative risk per serving reduced according to specific risk management options?

The above risk management questions are very broad in nature and were further refined to a list of risk mitigations 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?

#### **Risk Assessment Model**

The interagency risk assessment workgroup developed an innovative quantitative retail-to-table risk assessment model that included a dynamic cross contamination capability ("stochastic discrete event model," Figure ).

#### This QRA:

- considers *L. monocytogenes* entering the retail deli area from either contaminated incoming products or from environmental/niche contamination;
- considers a variety of RTE foods (e.g., different types of cheeses, deli meats, and deli salads) entering the retail deli;
- simulates transmission of *L. monocytogenes* among multiple pathways (e.g., product-to-slicers, gloves-to-display cases, utensils-to-gloves, *etc.*);
- incorporates employee behaviors that contribute to the spread or inactivation of *L. monocytogenes* (e.g., cleaning and sanitizing); and
- includes potential bacterial growth (e.g., temperature/time, product pH, water activity, presence of growth inhibitors, *etc.*).

#### **Risk Assessment Data**

FSIS and FDA coordinated with CDC and several universities to gather additional data for this risk assessment. In parallel, partnerships were established with stakeholders to fill the major data gaps identified in a request for scientific data and information for this project (i.e., Federal Register Notice, Vol 74, No 12, January 21, 2009. 3617-3619). Research commissioned to fill data needs of this risk assessment includes:

#### • Employee Behavior Data

- o **University of Maryland/JIFSAN** completed a multi-state study (DC-metro area) of retail deli practices for handling RTE foods, sanitation, and other practices at retail.
- CDC/Environmental Health Specialists Network (EHS-Net) leads an Office of Management and Budget approved national study to gather retail food handling and preparation information for RTE foods prepared and sliced at retail. FSIS is working with CDC and State partners to gathering behavior data based on observations of employees in 300 delicatessens across 5 states (i.e., California, Minnesota, New York, Rhode Island, and Tennessee) and New York City. This data will be used to further refine future versions of this risk assessment.

#### • Transmission Studies

Virginia Tech/Mock Deli – A mock deli was set up and used to study the dynamics of
 L. monocytogenes by measuring transfer during events and actions as RTE deli

- products are prepared, sliced, and/or packaged in retail facilities using an abiotic surrogate. The mock deli was used to film a training video for the CDC/EHS-Net study.
- Interagency *L. monocytogenes* in Retail Risk Assessment Workgroup Completed a meta-analysis that synthesized the available scientific evidence to derive probability distributions and mathematical models of bacterial transfers between environmental surfaces and foods, including those during slicing of food and bacterial removal during cleaning and sanitizing data.

#### Contamination in the Retail Environment

- o Cornell University
  - ➤ Completed a risk mapping of *L. monocytogenes* in a retail environment through elicitation of expert opinion, to validate where *L. monocytogenes* occurs in a retail facility.
  - A longitudinal study to collect data on the prevalence, level and subtype of L. monocytogenes in 30 retail deli environments of 3 grocery chains in Indiana, New York, and North Carolina was completed. This data was incorporated into this risk assessment.
- Purdue University, in partnership with the AMIF and FMI, is currently conducting an
  extension of the Cornell University study to examine the impact of retail interventions.
  These data will be considered in future versions of this risk assessment.

#### **Risk Assessment Results**

This QRA evaluated the public health effect of various mitigations under six different baseline conditions that may characterize a retail deli and the RTE food it serves at different times over the course of operations. These six baseline conditions are<sup>1</sup>:

- A retail deli with multiple niches that releases L. monocytogenes to food contact surfaces. This
  approach would also represent retail delis where general environmental contamination of nonfood contact surfaces is transferred to surfaces that may be in contact with food (denoted
  Multiple Niche 100W);
- A retail deli with no niches or environmental *L. monocytogenes* transfer (denoted **No niche**);

<sup>&</sup>lt;sup>1</sup> Refer to the main body of the report for assumptions, models and data.

- A retail deli with no niche and with an incoming RTE product more highly contaminated with *L. monocytogenes* than current average FSIS inspected plant data indicate. Two situations are examined:
  - The incoming contaminated RTE product supports growth (denoted **Incoming Growth Chub**);
  - The incoming contaminated RTE product does not support growth. (denoted **Incoming Non-growth Chub**);
- A retail deli compliant with the 2009 FDA Food Code guidance to maintain deli cases at ≤41°F (≤5°C). Two situations are examined:
  - A retail deli with multiple niches and compliant temperature control (denoted Niche & Temperature Control)
  - A retail deli without any niches and with compliant temperature control (denoted Temperature Control).

Note that, 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. A range of values for niche characteristics and levels of contamination of incoming products are evaluated by a sensitivity analysis (see detail in the body of the report).

Table provides a summary of the results for each baseline and the tested "what if" scenarios. Each column represents one of six different conditions that may be present in a retail deli. The baseline predicted risk per serving for the susceptible population is shown in the first row. Each subsequent row shows the percentage change relative to the baseline as a result of running each of the "what if" scenario mitigations independently. The scenarios are organized by those that evaluate sanitation, worker behavior, growth inhibitors, cross contamination, and storage control. Positive values represent an increase in predicted risk per serving, while negative values represent a decreased predicted risk per serving.

The effectiveness of a single mitigation across different operating conditions can be assessed by looking across a row (i.e. by evaluating the change due to a proposed scenario for each of the retail delis conditions), keeping in mind the order of magnitude of the absolute value of the predicted risk for that scenario. For example, lowering the level of *L. monocytogenes* on RTE foods from the manufacturer always leads to a reduced predicted risk; no sanitation leads to an increased predicted risk. Some model scenarios show that some mitigations are not very effective (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

deli retail condition. Overall the model 'what if' scenario results indicate that (1) retail delis without niches and retail delis that control temperature lead to lower predicted risks; and (2) retail delis with incoming RTE products that are highly contaminated with *L. monocytogenes*, notably if this product supports growth, or retail delis with niches lead to higher predicted risks.

#### **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, leading 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) (cf. "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 the deli area food contact surfaces results 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 (*cf.* "No

Sanitation" scenario). Wearing gloves while serving customers reduces the estimated risk of listeriosis.

• Identify Key Routes of Contamination. The slicer (for deli meats and cheeses) and the salad utensils (for deli salads) are sources of *L. monocytogenes* cross contamination to RTE foods. Control of *L. monocytogenes* cross contamination at these points during retail preparation and handling of RTE foods reduced the predicted risk of listeriosis (*cf.* "Transfers to 0" versus "Transfers and Slicer to 0" scenarios).

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 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 the "Virtual Deli" model. Additional data would be useful to further explore how more specific retail practices and conditions (e.g., equipment design) impact the risk of listeriosis.

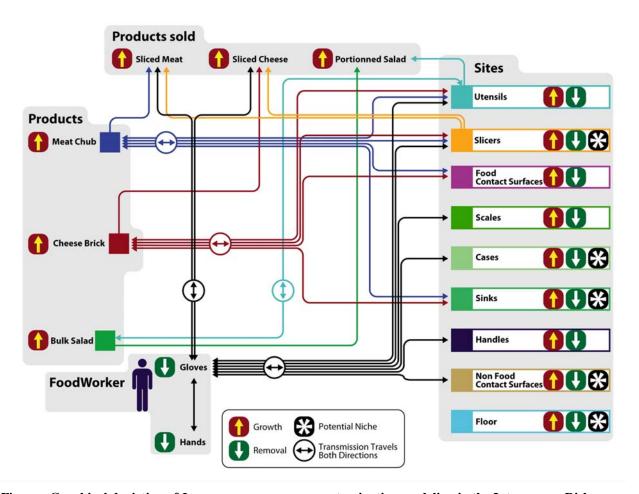


Figure: Graphical depiction of *L. monocytogenes* cross contamination modeling in the Interagency Risk Assessment - *L. monocytogenes* in Retail Delicatessens.

The food worker is depicted on the lower left. Food 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 of RTE foods. Each of these specific products has associated growth rates, and probability of being sold. Each product is also tracked for age. Sites within each retail deli are shown on the right. Vertical arrows at a site indicate the possibility of growth (up arrow) or removal by cleaning (down arrow). In practice, only growth for products was actually used for model scenarios. Asterisks at a site indicate the possibility of a niche. Arrows between sites, workers, and products indicate the potential cross contamination routes. RTE servings (i.e., products sold) leaving the retail deli are depicted in the upper left.

Table: Predicted risk of invasive listeriosis for the susceptible population.

Parameter	Baseline Conditions <sup>1</sup>								
	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control	Niche & Temp. Control			
Predicted risk per serving, susceptible population <sup>2</sup>	1.7×10 <sup>-7</sup>	1.4×10 <sup>-7</sup>	16.6×10 <sup>-7</sup>	2.8×10 <sup>-7</sup>	1.2×10 <sup>-7</sup>	1.5×10 <sup>-7</sup>			
Sanitation Related Scenarios:	Percent Change Relative to Baseline								
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 <sup>*</sup>			
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*			
<b>No Sporadic Cleaning</b> : 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 FCSs	-3.0	0.7	-0.6	0.3	-5.4 <sup>*</sup>	0.9			
Worker Behavior Related Scenarios:	Percent Change Relative to Baseline								
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			
<b>No Contact Glove Case</b> : 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			
<b>Pre-slice</b> : Workers pre-slice RTE products in the morning, after cleaning	6.0*	24.9*	49.5*	-34.4*	19.2*	1.0			
<b>Separate Slicer</b> : Workers use a separate slicer for RTE products that support growth of <i>L. monocytogenes</i>	-6.3*	-0.6	-1.7*	22.7*	-0.8	4.6			
<b>Do Not Slice On Gloves</b> : 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	Percent Change Relative to Baseline								
<b>All GI:</b> Reformulate all RTE products sold at the retail deli that would otherwise support <i>L. monocytogenes</i> growth to include growth inhibitors	-96.0*	-95.2*	-97.5*	-94.5 <sup>*</sup>	-94.4*	-94.8*			
<b>No GI:</b> Reformulate all RTE products that support <i>L. monocytogenes</i> growth that are sold at the retail deli to not include GI to restrict <i>L. monocytogenes</i> growth	184.1*	191.5*	35.1*	190.5*	187.7*	188.9*			

	Baseline Conditions <sup>1</sup>								
Parameter	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control	Niche & Temp. Control			
Cross Contamination Related Scenarios:	Percent Change Relative to Baseline								
<b>Transfers to 0</b> : Cross contamination would only result 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 <sup>*</sup>	-60.8*	-19.2*	-30.4*			
<b>Reduce Level</b> : Mean incoming <i>L. monocytogenes</i> concentration in all RTE products lowered from -9.2 to -9.5 log <sub>10</sub> cfu/g	-21.6 <sup>*</sup>	-24.2*	-1.1	-9.8 <sup>*</sup>	-22.5*	-15.6*			
<b>Separate Slicer Case</b> : Workers use a separate slicer <u>and</u> a separate delicase for RTE products that support the growth of <i>L. monocytogenes</i> .	-2.5	-1.6	-1.2	21.0*	-0.9	7.5*			
<b>Lower Env Cont</b> : Reduce transfer of <i>L. monocytogenes</i> 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	Percent Change Relative to Baseline								
<b>Temp = 5°C</b> : 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			
<b>No Growth (T=-5°C):</b> At this temperature, no <i>L. monocytogenes</i> growth will occur	-16.5*	-21.3 <sup>*</sup>	-18.2*	-5.7 <sup>*</sup>	NA	NA			
<b>Temp</b> $\leq$ <b>5</b> °C: Use only the retail deli case temperatures observed in the Ecosure dataset at or below 5°C (41°F).	-9.0 <sup>*</sup>	-16.3 <sup>*</sup>	-12.3*	-8.2 <sup>*</sup>	NA	NA			
<b>Shorten Time in Retail Delis</b> : 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 and for additional results.

<sup>\*</sup> bold: Outside the 95% confidence interval for the median. Columns: Baseline situations; first line: predicted risk of invasive listeriosis per serving according to the baseline condition; other lines: predicted percent change in this risk relative to the respective baseline condition. 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.

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 and with an incoming RTE product more highly contaminated with *L. monocytogenes* than current average FSIS inspected plant data indicate and the incoming contaminated RTE product supports growth. Incoming Non-growth Chub = a retail deli with no niche and with an incoming RTE product more highly contaminated with *L. monocytogenes* than current average FSIS inspected plant data indicate and the incoming contaminated RTE product does not support growth; Niche & Temperature Control = a retail deli with multiple niches and compliant with the 2009 FDA Food Code guidance to maintain deli cases at ≤41°F (≤5°C): Temperature Control = a retail deli without any niches and with compliant temperature control.

<sup>&</sup>lt;sup>2</sup> The results for the susceptible population only are presented as this population comprises 80-90% of the public health burden for listeriosis.