

Interagency Risk Assessment:

***Listeria monocytogenes* in Retail Delicatessens**

Interpretive Summary

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Risk Assessment Workgroup**

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Interpretive Summary

This document summarizes a quantitative, scientific assessment of (1) the risk of listeriosis posed by consumption of ready-to-eat (RTE) foods commonly prepared and sold in delicatessens in retail food stores and (2) how that risk may be impacted by changes in practice. The risk assessment 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 Food Safety and Inspection Service (USDA/FSIS), in consultation with the DHHS Centers for Disease Control and Prevention (CDC). Members of the food industry, academic institutions, and consumer-advocacy groups provided input, and many activities were included to ensure transparency and stakeholder engagement in the development of the risk assessment.

The President’s Food Safety Working Group identified this risk assessment as a priority. The risk assessment provides information useful to those responsible for making decisions about policies, programs, and practices intended to prevent listeriosis cases. A full report on the risk assessment (the “technical report”) and its results are available on the FDA¹ and FSIS² Web sites.

FSIS and FDA coordinated with CDC and several universities to fill major gaps in data that were needed to conduct the risk assessment and were identified in a request for scientific data and information (Federal Register Notice, Vol. 74, No. 12, January 21, 2009; 3617-3619). A history of the risk assessment’s development and a list of partners who provided additional data are provided in Table 2 and Table 3, respectively.

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. 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* species or *Escherichia coli* O157:H7).

¹ <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment>

² <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments>

To reduce listeriosis, it is important to identify (1) which RTE foods pose the greatest risk and (2) which changes in practice improve the safety of those RTE products. Previous risk assessments have prioritized RTE foods according to the risk of listeriosis. Risk assessments also are useful tools for linking food-safety research to changes in practice that will improve public health outcomes, as reflected in this quantitative risk assessment (QRA).

The QRA model mathematically simulates the retail delicatessen (deli) environment and, as such, can be thought of as a “virtual deli.” It is unique in its ability to quantitatively link activities in a retail deli to predicted public health outcomes. It evaluates the extent to which deli practices may increase or decrease exposure to *L. monocytogenes* from consumption of deli RTE foods, as well as the subsequent public health risk, and predicts which intervention or mitigation strategies have the largest impact on the risk.

Risk-Management Questions

To initiate the QRA, FDA and FSIS risk managers initially charged risk assessors with answering the following questions.

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?

These questions are very broad in nature and were refined as a list of more specific questions, which then were evaluated through scenario analyses in this QRA. Specific risk-management questions from federal partners and stakeholders helped guide the development of the (“what if”) scenarios evaluated within the QRA. Examples include:

- What impact does improved compliance with the cold-holding and storage-duration requirements 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 risk?
- What impact does using dedicated slicers for specific products have on the predicted risk?
- What impact does reducing the presence and level of *L. monocytogenes* on foods coming into the deli have on the predicted risk?

Model and Risk Assessment Design

To answer these and other questions, the Interagency Retail Risk Assessment Workgroup developed an innovative, retail-to-table model, which includes a dynamic cross-contamination modeling capability (Figure 1, Stochastic Discrete Event Model). Cross contamination is thought to be an important contributor to *L. monocytogenes* contamination of RTE foods in the deli, but, prior to this risk assessment, little was known about the transfer of the pathogen in this setting. *L. monocytogenes* can contaminate foods via cross contamination among products or from the environment, or both. Once contamination occurs, the bacterium can survive and grow in foods held at ambient and refrigeration temperatures. Adequate preventive controls must take into account not only contamination by the organism, but also its survival and proliferation.

The model was designed to evaluate RTE deli meats, cheeses, and salads that are (1) sliced, prepared, and/or packaged in the retail deli environment and consumed at home; and (2) sold in a range of retail types, such as the deli departments of major and large grocery chains, supermarket facilities, and other groceries (e.g., multipurpose, independent, small, or local facilities).

The model:

- considers *L. monocytogenes* entering the retail deli area from either contaminated incoming products or from the environment/niches;
- considers a variety of RTE foods (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
- considers factors that impact potential bacterial growth (e.g., temperature/time, product pH, water activity, presence of growth inhibitors, etc.).

Model inputs include deli-worker routines (e.g., cleaning and sanitation practices in the deli and frequency and sequence of actions taken to serve customers) and *L. monocytogenes* concentrations on incoming product (e.g., prevalence and levels in food).

In addition to simulating the impact of practices in the deli itself and the *L. monocytogenes* concentration and prevalence in products sold to customers, the model (1) predicts changes in concentrations during

storage in the consumer’s home and (2) estimates listeriosis risk from consumption of the products (e.g., dose-response modeling). Two populations are considered: (1) those with increased susceptibility (neonates, pregnant women, older adults, immunocompromised) and (2) the remaining population. The model allows an evaluation of the impact on that risk via simulated changes to the deli operation or practices.

The Six Baseline Scenarios

This QRA evaluated the public health effect of various retail practices 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 shown below.³

Scenario Name	Condition
Multiple Niche 100W	A retail deli with multiple <i>L. monocytogenes</i> niches in its environment that release the bacterium to food-contact surfaces. This also represents retail delis in which general environmental contamination of non-food-contact surfaces is transferred to surfaces that may be in contact with food. <i>L. monocytogenes</i> are released to food-contact surfaces at a rate of 100 colony forming units (cfu) on an average weekly (W) frequency.
No Niche	A retail deli with no niches or environmental <i>L. monocytogenes</i> transfer.
Incoming Growth Chub (incoming contaminated RTE product <u>supports growth</u>)	A retail deli without any niches, with one incoming RTE product whose <i>L. monocytogenes</i> contamination is greater than baselines (mean log ₁₀ concentration of -5 log ₁₀ cfu per gram vs. -9.2 log ₁₀ cfu per gram). Two situations are examined, as titles at left indicate (supports growth vs. does not support growth).
Incoming Non-Growth Chub (incoming contaminated RTE product <u>does not support growth</u>)	
Niche & Temperature Control (retail deli with <u>multiple niches</u> and compliant temperature control)	A retail deli compliant with the 2009 FDA Food Code guidance to maintain deli cases at ≤41°F (≤5°C). Two situations are examined, as the titles at left indicate (temperature control, with vs. without niches).
Temperature Control (retail deli <u>without niches</u> and with compliant temperature control)	

³ Refer to the technical report for assumptions, models, and data.

The QRA evaluated “what if” scenarios to these baseline conditions, to estimate the change in listeriosis risk that would occur with various changes in practices in the deli. Note that, in the absence of ad-hoc data, the specific values defining each baseline type are merely representative. A range of values for niche characteristics and levels of contamination of incoming products are evaluated by a sensitivity analysis (see details in the technical report).

Key Findings from the Risk Assessment Simulations

- **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 home storage by consumers. In this risk assessment, use of growth inhibitors led to an overall dramatic reduction in the predicted risk of listeriosis (ca. 95%, see Table 1). The strict control of temperature during refrigerated storage in retail delis also reduced the predicted risk. The impact of this control is, nevertheless, lower, as it reduced growth only during this specific storage (5-20% reduction according to the baseline and the scenario) (see “Temperature Control” baseline and growth inhibitor scenarios results in Table 1).
- **Control Cross Contamination.** Cross contamination of *L. monocytogenes* in the retail environment dramatically increased the predicted risk of listeriosis. Cross contamination during the routine operation of the retail deli is not amenable to a simple solution (see “Transfers and Slicer to 0” scenarios).
- **Control Contamination at its Source.** Increasing the concentration and transfer of *L. monocytogenes* from incoming products, the environment, or niches directly increased 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* (see 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 food-contact surfaces resulted 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 (see “No Sanitation” scenario). 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 for 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 (see “Transfers to 0” versus “Transfers and Slicer to 0” scenarios).

Detailed Results

Table 1, below, provides a summary of the results for each baseline and the “what if” scenarios tested in the QRA. Each column represents one of six different baseline conditions that may be present in a retail deli. The predicted risk per serving at baseline for the susceptible population is shown in the first row. Each subsequent row shows the percentage change, relative to baseline, that results from running each of the “what if” scenarios independently. The scenarios are organized according to those that evaluate sanitation, worker behavior, growth inhibitors, cross contamination, and storage control. Positive values represent an increase in predicted risk per serving; negative values represent a decrease in predicted risk per serving.

The effectiveness of a change in deli practices 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-deli 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 retail practices 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 retail-deli baseline 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 the product supports growth) and retail delis with niches lead to higher predicted risks.

In Conclusion

The “what if” scenarios modeled in the QRA provide insight as to how cross contamination, sanitary practices, and temperature control impact the predicted risk of listeriosis from consumption of RTE products sliced / prepared in retail deli departments. The results of the QRA improve our understanding of *L. monocytogenes* in the retail deli and encourage improvements to retail food-safety practices and mitigation strategies for controlling *L. monocytogenes* in retail deli RTE foods.

The QRA was based on an extensive amount of information gathered through partnerships with academia and input from stakeholders. Additional data would be useful for (1) refining and improving the predictions made by the “virtual deli” model and (2) exploring the impact of more specific retail practices and conditions (e.g., equipment design) on the risk of listeriosis.

Table 1: Predicted Risk of Invasive Listeriosis for the Susceptible Population

Parameter	Baseline Conditions ¹					
	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control	Niche & Temp. Control
Predicted risk per serving, susceptible population ²	1.7×10 ⁻⁷	1.4×10 ⁻⁷	16.6×10 ⁻⁷	2.8×10 ⁻⁷	1.2×10 ⁻⁷	1.5×10 ⁻⁷
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*
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 NFCS at same rate as FCS	-3.0	0.7	-0.6	0.3	-5.4*	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
No-Contact Glove Case: Workers do not use their hands to open the deli case (e.g., 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 <i>L. monocytogenes</i>	-6.3*	-0.6	-1.7*	22.7*	-0.8	4.6

Parameter	Baseline Conditions ¹					
	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control	Niche & Temp. Control
Do Not Slice On Gloves: Workers collect the slices of RTE products on tissue paper, rather than on their gloved hands	1.9	1.0	0.2	3.8	-1.9	8.0*
Growth-Inhibitor-Related Scenarios:	Percent Change Relative to Baseline					
All GI: Reformulate all RTE products sold at the retail deli that would otherwise support <i>L. monocytogenes</i> growth to <u>include</u> growth inhibitors	-96.0*	-95.2*	-97.5*	-94.5*	-94.4*	-94.8*
No GI: Reformulate all RTE products that support <i>L. monocytogenes</i> growth that are sold at the retail deli to <u>not</u> include growth inhibitors to restrict <i>L. monocytogenes</i> growth	184.1*	191.5*	35.1*	190.5*	187.7*	188.9*
Cross-Contamination-Related Scenarios:	Percent Change Relative to Baseline					
Transfers to 0: Cross contamination would result 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 <i>L. monocytogenes</i> 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 <u>and</u> a separate deli case for RTE products that support the growth of <i>L. monocytogenes</i> .	-2.5	-1.6	-1.2	21.0*	-0.9	7.5*
Lower Env Cont: 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

Parameter	Baseline Conditions ¹					
	Multiple Niche 100W	No Niche	Incoming Growth Chub	Incoming Non-growth Chub	Temp. Control	Niche & Temp. Control
Storage-Temperature and Duration-Control-Related Scenarios	Percent Change Relative to Baseline					
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 <i>L. monocytogenes</i> 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 of, from 7 days to 4 days	-2.5	3.3	-1.2	2.0	-0.2	1.7

Readers should refer to the technical report for further details on the assumptions, model, data, baselines, and scenarios and for additional results.

* **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.

¹Description 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 log₁₀: -5 log₁₀ cfu/g vs -9.2 log₁₀ 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 log₁₀: -5 log₁₀ cfu/g vs -9.2 log₁₀ 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.

²The US population was split in two subpopulations for the purposes of this risk assessment: the susceptible population (e.g., older adults, fetuses, newborns, pregnant women, 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.

Table 2. Key Activities, with Stakeholders, in the Development of the Risk Assessment

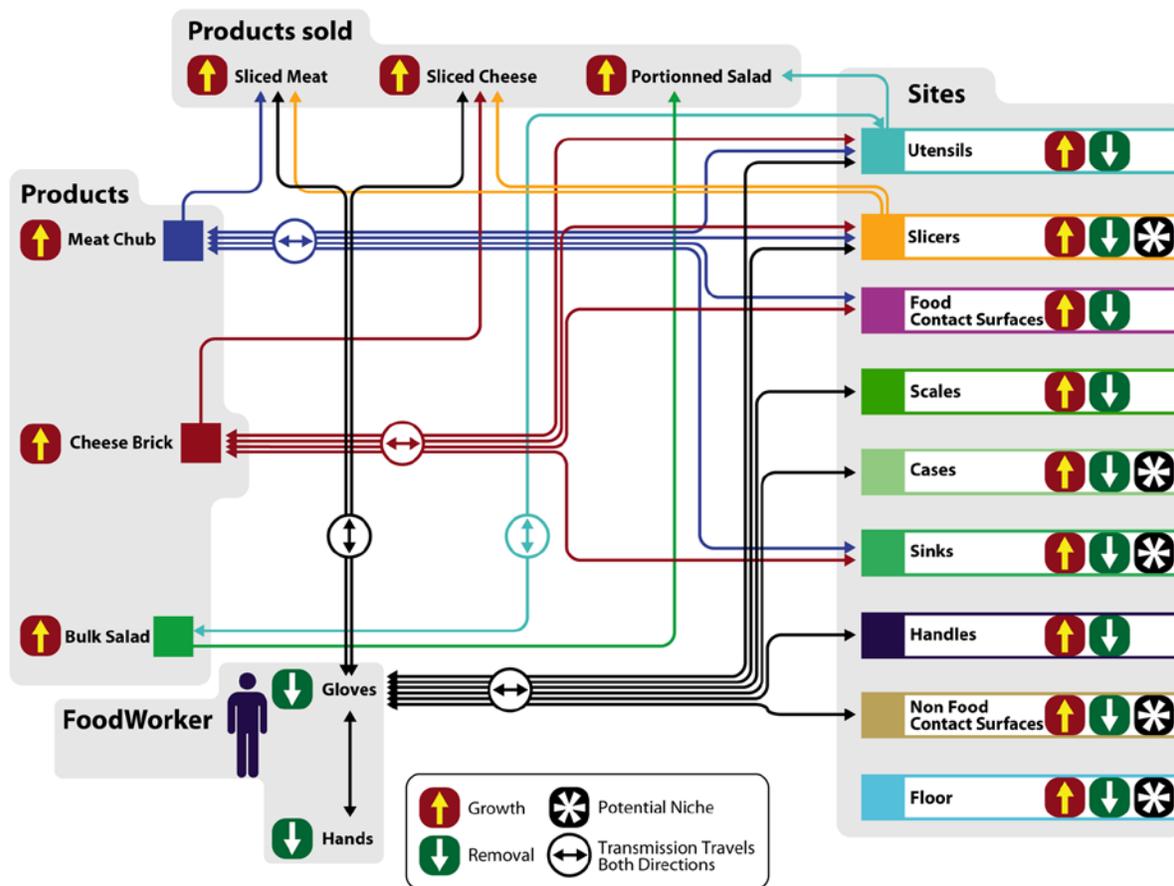
This summary includes key activities with stakeholders. These and other activities improved transparency and ensured stakeholder involvement in the development and scientific credibility of the QRA.

Timeline	Activity
Fall 2008	FSIS and FDA began collaborating on development of the risk assessment.
June 2009	A public meeting was held to bring stakeholders into the development of the risk assessment early in the process, provide them with insight regarding data needs, and garner their input. The Center for Science in the Public Interest, Food Marketing Institute (FMI), Grocery Manufacturers of America (GMA), American Meat Institute (AMI), and academic institutions subsequently provided input.
June 2009 – Present	FSIS and FDA coordinated with several universities and CDC to conduct research and surveys, to gather specific additional data.
Winter 2010	The mathematics and structure of the cross contamination model were reviewed by experts selected through a rigorous process managed by a third party and non-governmental entity, to ensure an independent review. The draft model was refined in response to these peer-review comments.
Fall 2010 – July 2013	Outreach to industry and consumer groups were conducted, to keep stakeholders informed about the status of the risk assessment and obtain input on how to improve the model. Among those who have been involved in the outreach conducted are the Joint Institute for Food Safety and Applied Nutrition, (JIFSAN), FMI, AMI, CSPI, GMA, Safe Food Coalition, and Association of Food and Drug Officials. The novel mathematical modeling approach to characterize cross contamination in a deli environment also has been presented at several scientific meetings.
Sept. 2012 – July 2013	The agencies posted the draft risk assessment report for public input, via a Federal Register notice.
July – Sept. 2013	The agencies prepared and published (1) replies to public comments and (2) the final risk assessment.

Table 3. Additional Data Provided for This Risk Assessment

Type of Data	Provider of Data: Activity Undertaken
Employee-behavior data	<p>University of Maryland/JIFSAN: completed a multistate study (DC-metro area) of retail deli practices for handling RTE foods, sanitation, and other practices at retail. This data was used in this QRA.</p>
	<p>CDC/Environmental Health Specialists Network (EHS-Net): led 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 worked with CDC and State partners to gather behavior data based on observations of employees in 300 delicatessens across 5 states (California, Minnesota, New York, Rhode Island, and Tennessee) and New York City. The data will be used to refine future versions of this QRA.</p>
Transmission studies	<p>Virginia Polytechnic Institute and State University (Virginia Tech): set up and used a mock deli to study the dynamics of <i>L. monocytogenes</i>. Transfer of an abiotic surrogate was measured during events and actions while RTE deli products were prepared, sliced, and/or packaged in retail facilities. This study served as a validation of this QRA. The mock deli also was used to film a training video for the above-mentioned CDC/EHS-Net study.</p>
	<p>The Interagency <i>L. monocytogenes</i> in Retail Risk Assessment Workgroup: Completed a meta-analysis to derive probability distributions and mathematical models of (1) bacterial transfers between environmental surfaces and foods; (2) bacterial transfers during slicing of food and; (3) bacterial removal during cleaning and sanitizing.</p>
Contamination in the retail environment	<p>Cornell University:</p> <ul style="list-style-type: none"> • Completed a risk mapping of <i>L. monocytogenes</i> in a retail environment through elicitation of expert opinion, to validate where <i>L. monocytogenes</i> occurs in a retail facility. • Conducted a longitudinal study to collect data on the prevalence, level, and subtype of <i>L. monocytogenes</i> in 30 retail deli environments of 3 grocery chains in Indiana, New York, and North Carolina. The data were incorporated into this QRA.
	<p>Purdue University, in partnership with the American Meat Institute Foundation and FMI: conducted an extension of the Cornell University study, to examine the impact of retail interventions. These data will be considered in future versions of this QRA.</p>

Figure 1. 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 *L. monocytogenes* 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, growth of *L. monocytogenes* in the environment was not considered.
- 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.