

Interagency Risk Assessment for *L. monocytogenes* in Retail Delis

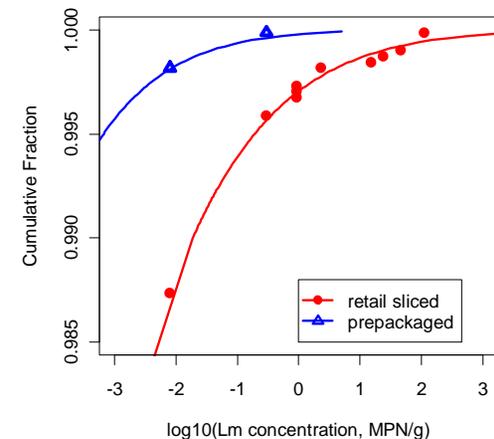
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2013 IRAC/NCAC-SRA/ORACA Risk Analysis Workshop: Advancing Analysis
Washington, DC – USDA South Building – June 18, 2013

Focus on Retail Food Safety

- *L. monocytogenes* (Lm): 2nd-3rd cause of foodborne-disease related death in the US
 - ❖ 1450 hospitalizations, 255 deaths per year (Scallan et al. 2011)
- Deli meat: 1st ready-to-eat (RTE) food vehicle of Lm
 - ❖ ca. 1,600 cases per year (FDA/FSIS, 2003)
- Lm prevalence and Lm levels are higher for in-store packaged than for manufacturer-packaged RTE food
 - ❖ Gombas et al., 2003 , NAFSS, 2008
- ca. 80% of all listeriosis cases attributed to deli meat are from deli meat sliced and packaged at retail
 - ❖ Endrikat et al., 2010, Pradhan et al. 2010
- **Hypothesis:** at retail
 - ❖ Additional cross-contaminations?
 - ❖ Temperature abuses?



Interagency Retail *Lm* Risk Assessment

- Objective: Ascertain the impact on public health of current practices and potential interventions that reduce or prevent *Listeria monocytogenes* contamination in ready-to-eat food sliced, prepared and/or packaged in retail facilities



What's So Special About This Project?

▶ Partnership

- USDA/FSIS & FDA/CFSAN

▶ Collaboration

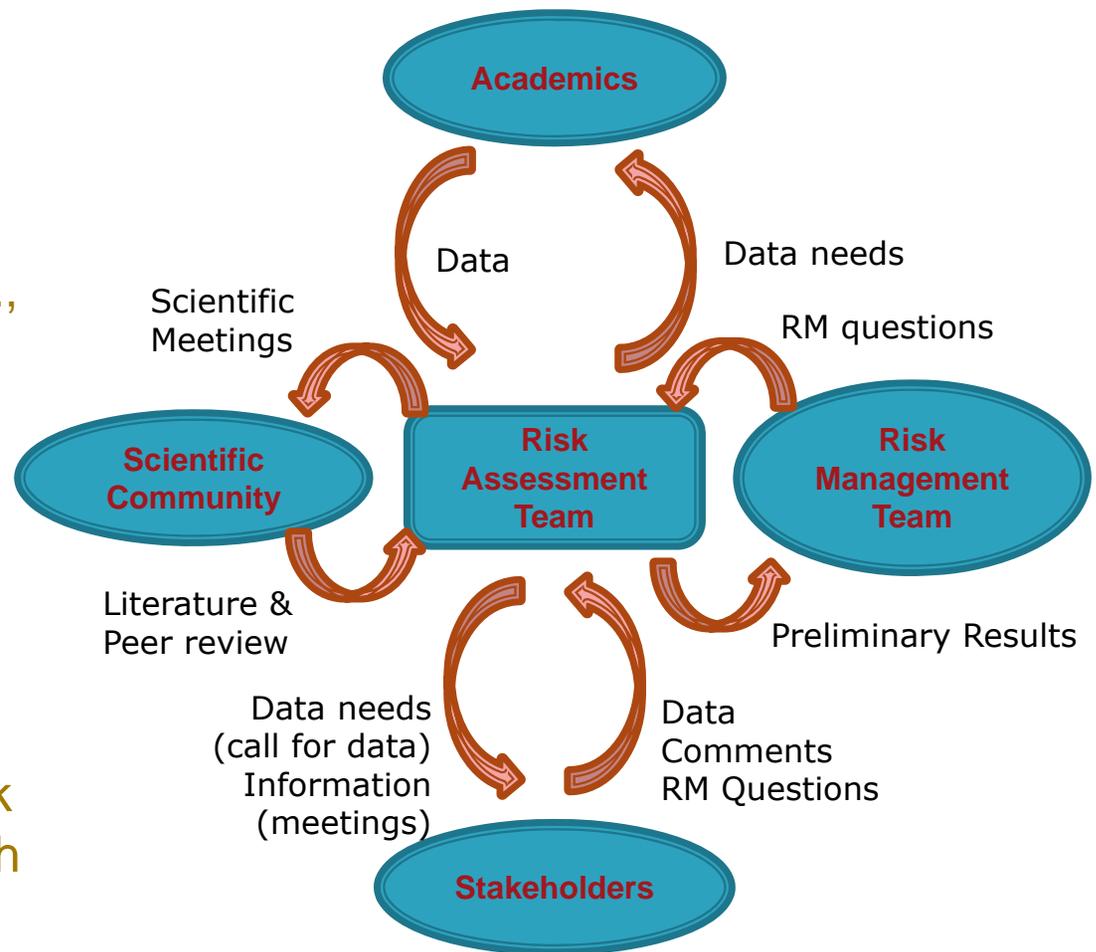
- Univ. of Maryland, Cornell Univ., VA Tech

▶ Engagement

- Stakeholders early and throughout; > 56 meetings

▶ Innovation

- 1st QMRA to quantitatively link retail practices to public health outcomes



Risk Management Questions

- “What is the exposure to *Listeria monocytogenes* from consuming ready-to-foods prepared in retail facilities?”
- “What are the key processes that increase ready-to-foods contamination at retailers?”
- “How much is the relative risk per serving reduced according to specific risk management options?”

Risk Management Questions

Further refined; a list of proposed 'what if' scenarios to evaluate:

- ❖ Sanitation
 - ❖ Worker behavior
 - ❖ Growth inhibition
 - ❖ Cross contamination
 - ❖ Storage temperature & duration
-
- Examples
 - ❖ What is the public health impact of temperature abuse in deli cases?
 - ❖ What would be the impact of separated slicers/counters for growth versus non-growth products?
 - ❖ What is the impact of the use of gloves in the retail environment?

Outline

- **Design**
- Data Sources
- Implementation
- Modeling Approach
- Key Findings

Design: The Retail Deli Area



Food workers
Behavior → Events



Food
Meat
Cheese
Salad



Sites

Slicers

Cases

Food Contact Surfaces

Non Food Contact Surfaces

Utensils

...



Niches

Slicers

Cases

...



Example Serve Customer Event



Example: Serve Customer Event

Wipe Slicer

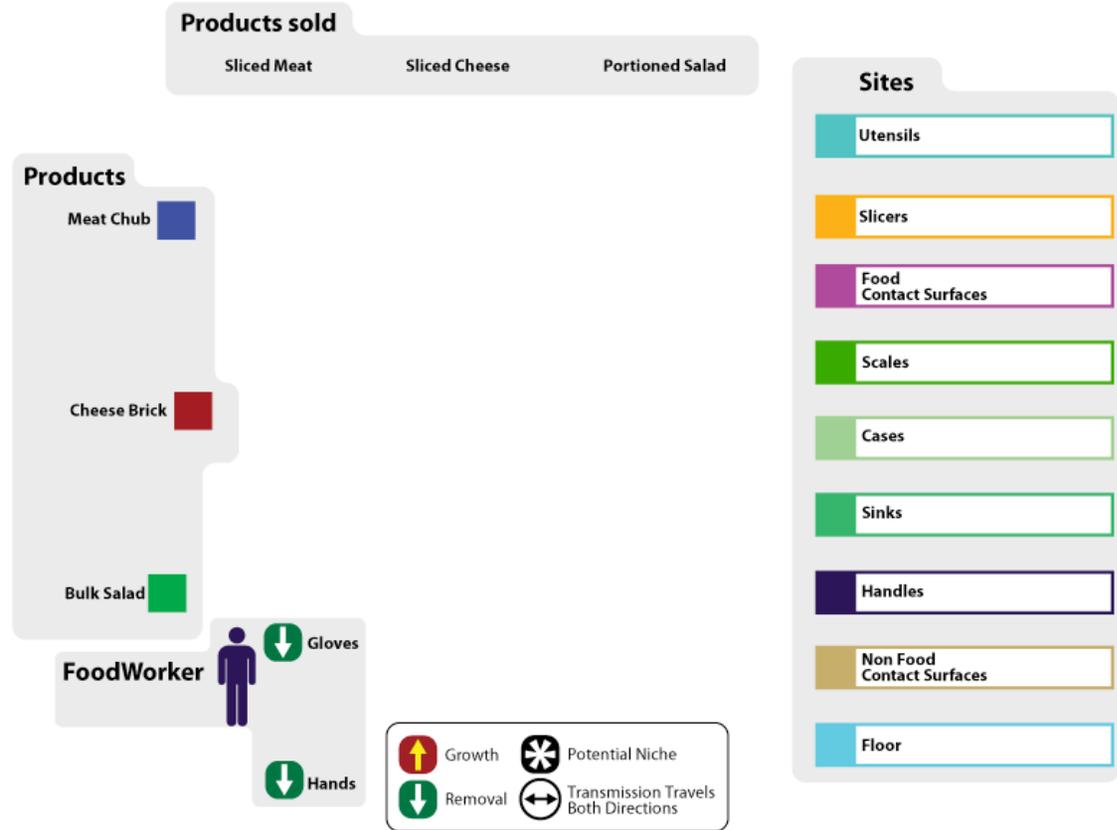


Removes some bacteria from the slicer (if any)

Example: Serve Customer Event

Wipe Slicer

Wash hands & change gloves



Removes some bacteria from hands (if any).
No bacteria on the gloves

Example: Serve Customer Event

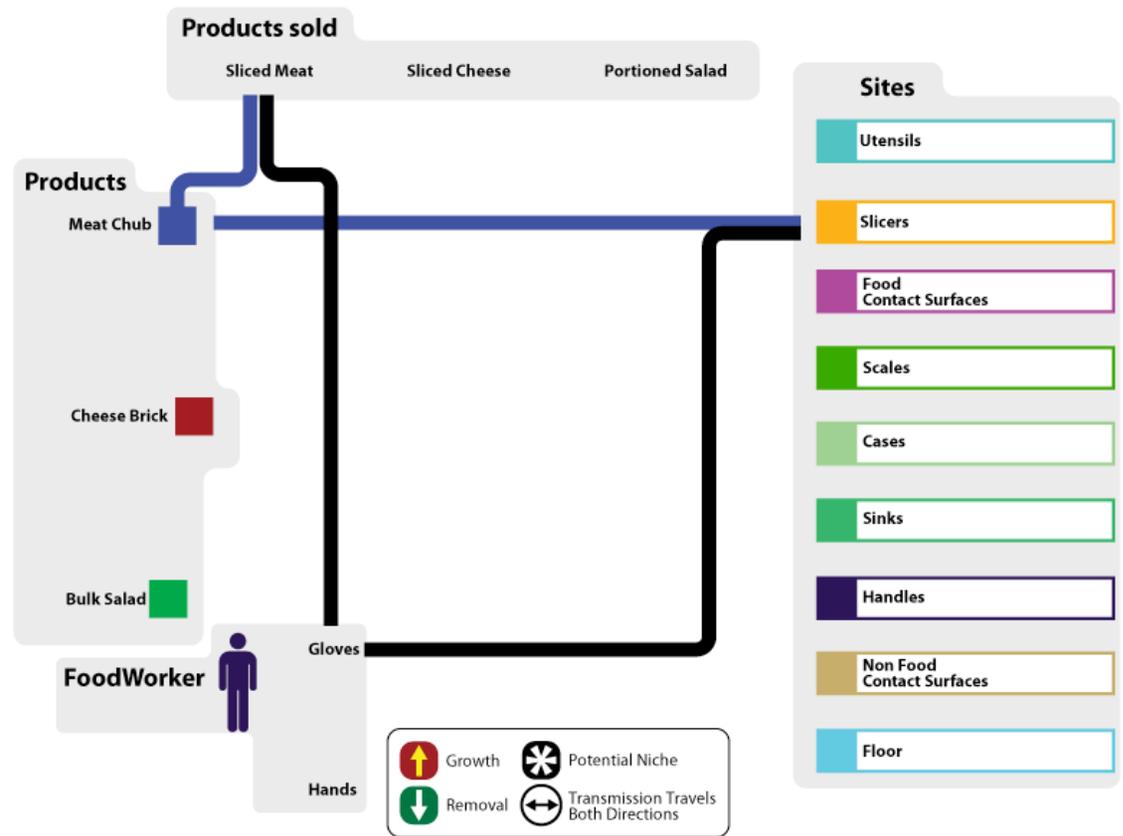
- Wipe Slicer
- Wash hands & change gloves
- Open case, remove chub, close case



Potential cross contamination
between gloves and case

Example: Serve Customer Event

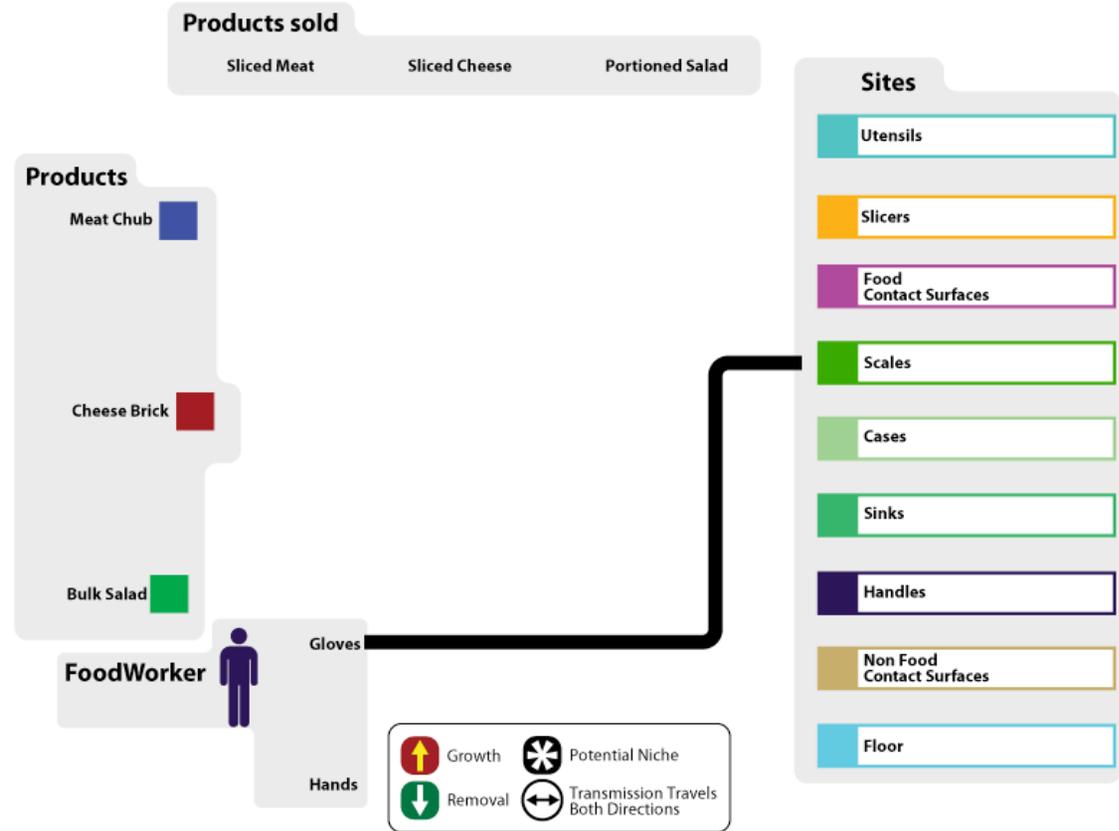
- Wipe Slicer
- Wash hands & change gloves
- Open case, remove chub, close case
- Slice on gloves



Potential cross contamination among gloves, slicer, chub and potential contamination of the product sold

Example: Serve Customer Event

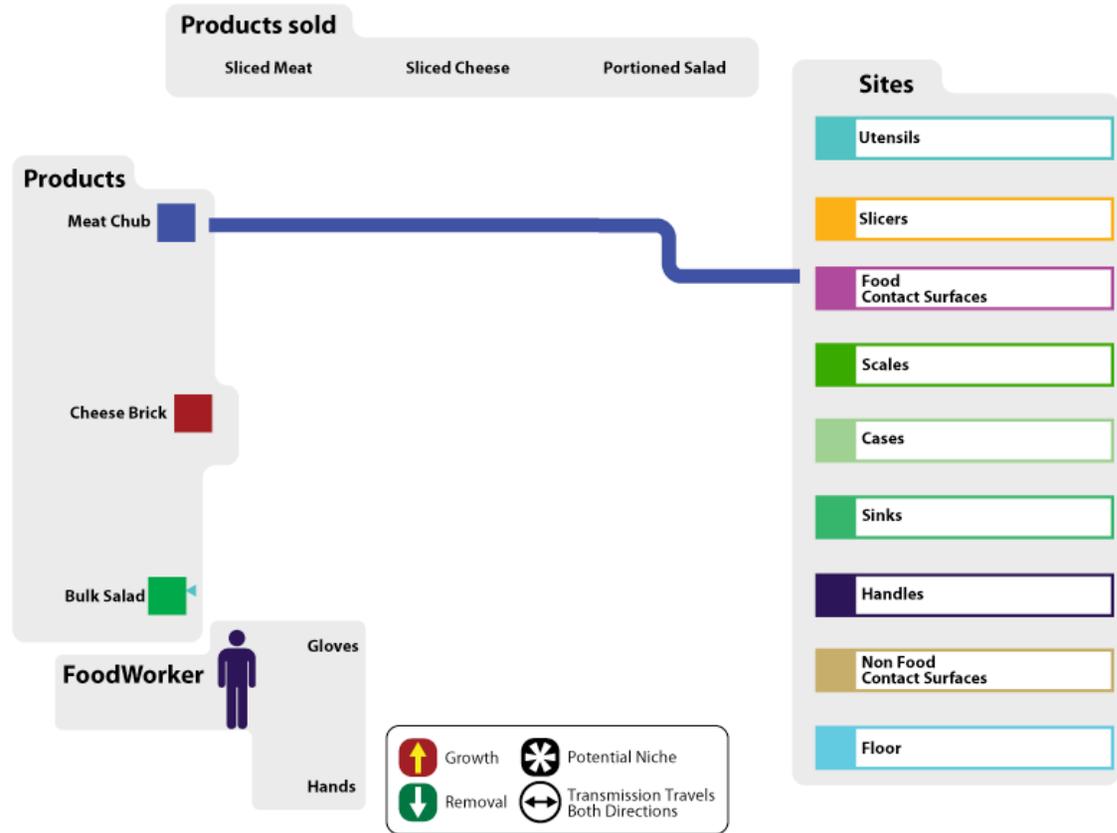
- Wipe Slicer
- Wash hands & change gloves
- Open case, remove chub, close case
- Slice on gloves
- Touch scale



Potential cross contamination
between gloves and scale

Example: Serve Customer Event

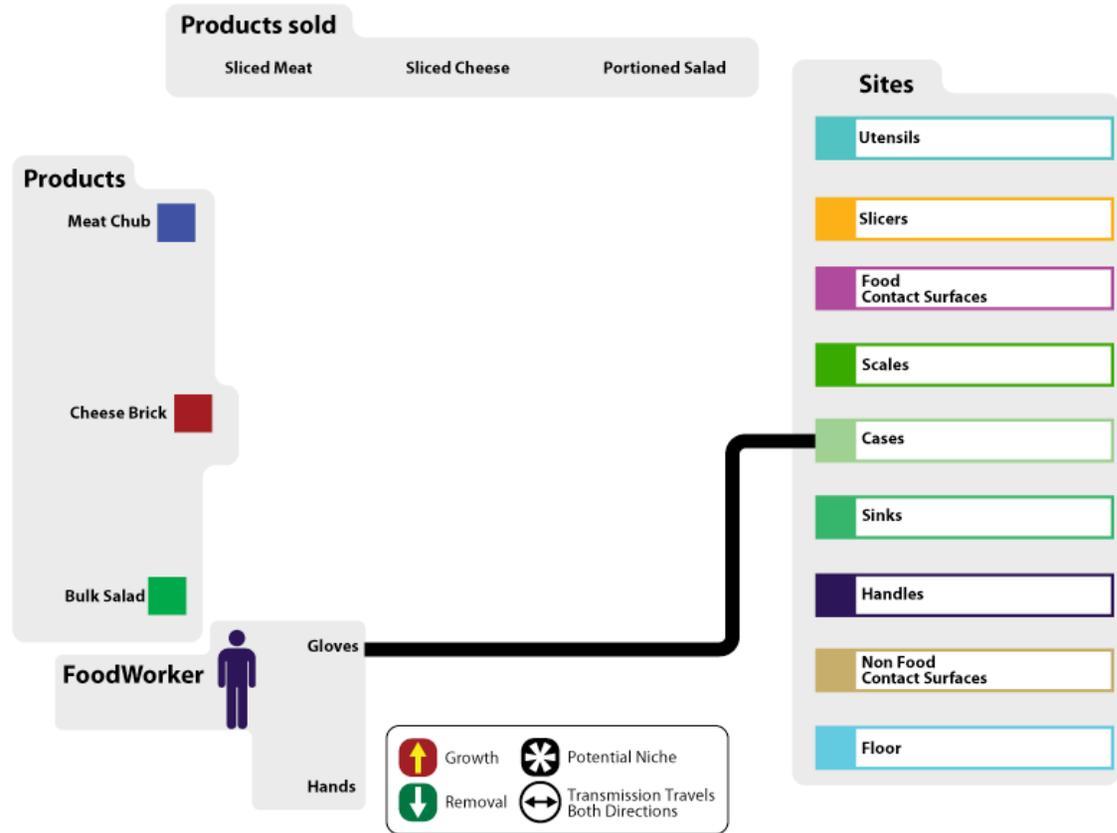
- Wipe Slicer
- Wash hands & change gloves
- Open case, remove chub, close case
- Slice on gloves
- Touch scale
- Rewrap chub



Potential cross contamination between the chub and the food contact surface

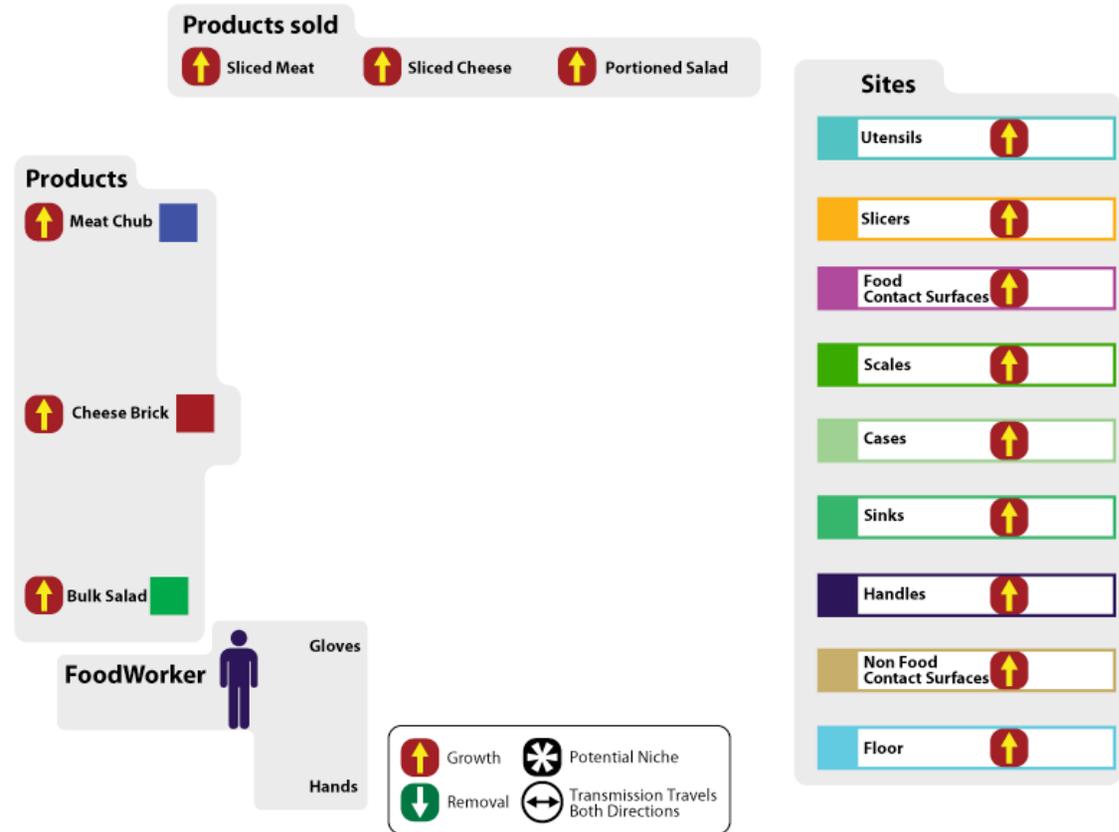
Example: Serve Customer Event

- Wipe Slicer
- Wash hands & change gloves
- Open case, remove chub, close case
- Slice on gloves
- Touch scale
- Rewrap chub
- Open case, replace chub, close case

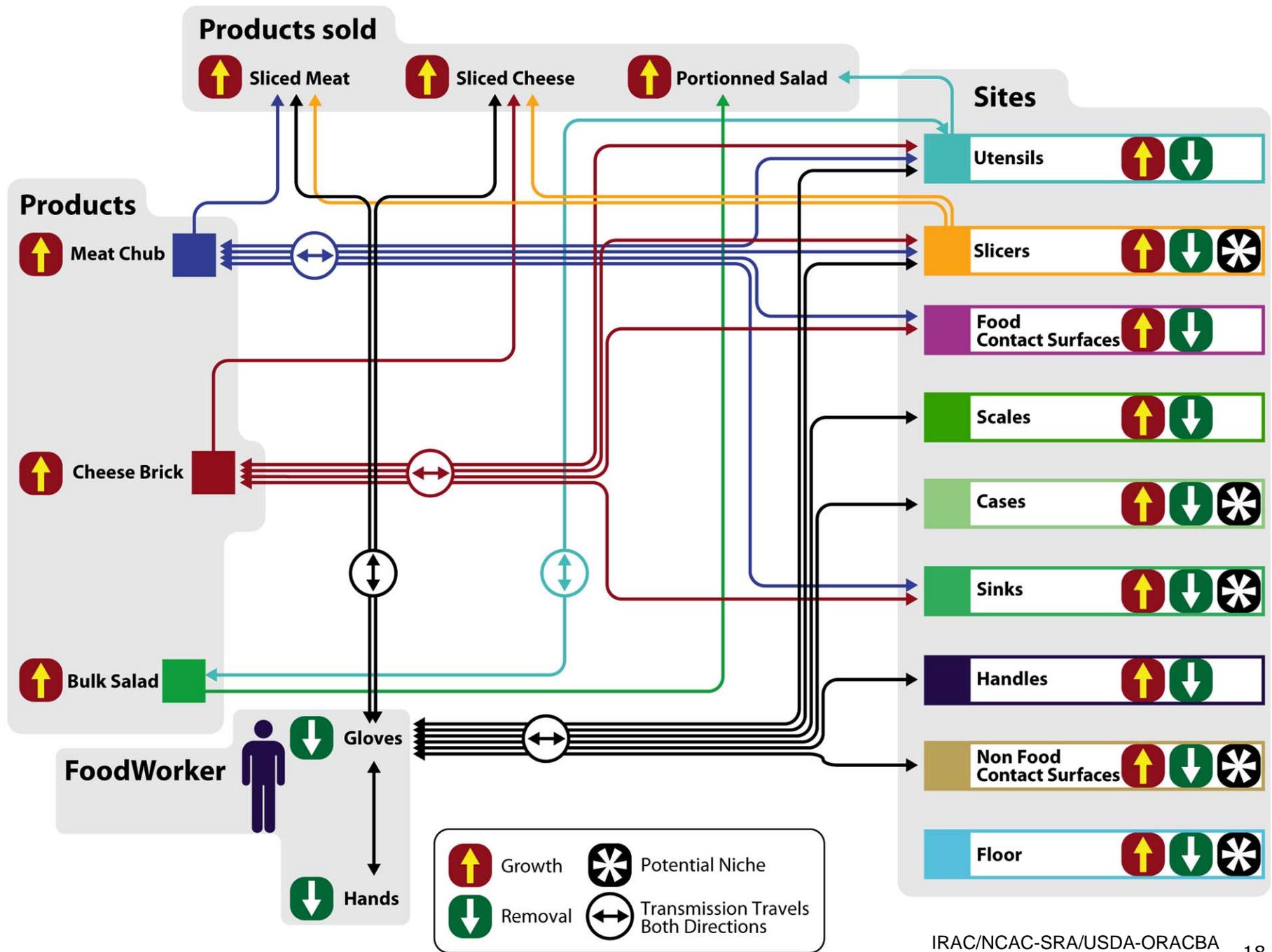


Potential cross contamination
between the gloves and the case

Example: Non Deli Time Event

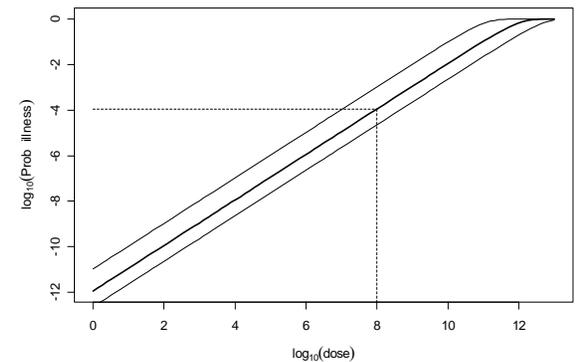
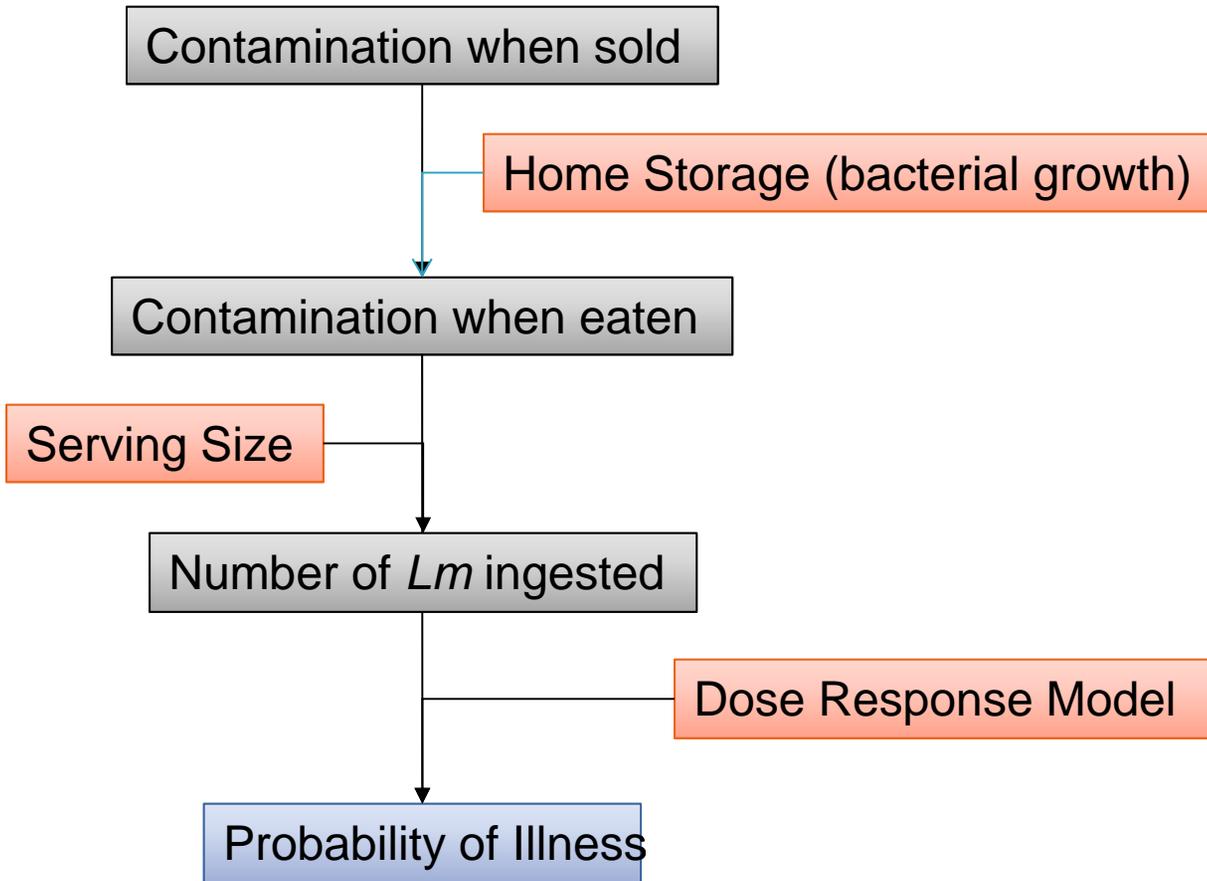


Bacterial growth on products



June 18, 2013

From Retail to Risk



(FAO/WHO, 2004)

Outline

- **Design**
- **Data Sources**
- Implementation
- Modeling Approach
- Key Findings

Data Sources

- **Food worker behavior**
 - *Lubran MB, et al. (2010) J Food Protection, 73 (10):1849-57*
- **Transfer coefficients and Slicer**
 - *Hoelzer K, et al. (2012) International J of Food Microbiology, 157:267-77*
- **Risk mapping**
 - *Hoelzer K, et al. (2012) Risk analysis, 32(7): 1139-56*
- **Persistent strains in deli departments**
 - *Oliver R. et al. (Cornell Univ./Purdue Univ.) (expected Summer 2013)*
- **Potential transfer during specific events**
 - *Maitland J, et al. (2013) J Food Protection, 76 (2): 272-82*
- **Growth model**
 - *Mejholm and Dalgaard, 2009 J Food Prot, 72(10), 2132-2143*
- **Temperature in deli case**
 - Ecosure 2007 (www.FoodRisk.org)
- **Time/ temperature during transport and at home**
 - Ecosure 2007 (www.FoodRisk.org)
- **Consumption data**
 - NHANES study, WWEIA data, 1999-2006
- **Dose response model**
 - FAO/WHO 2004

Funded studies

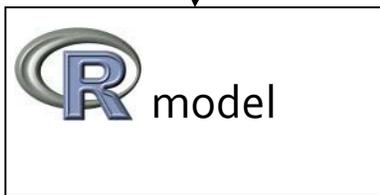
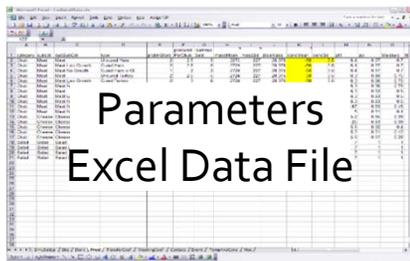
Literature sources

Outline

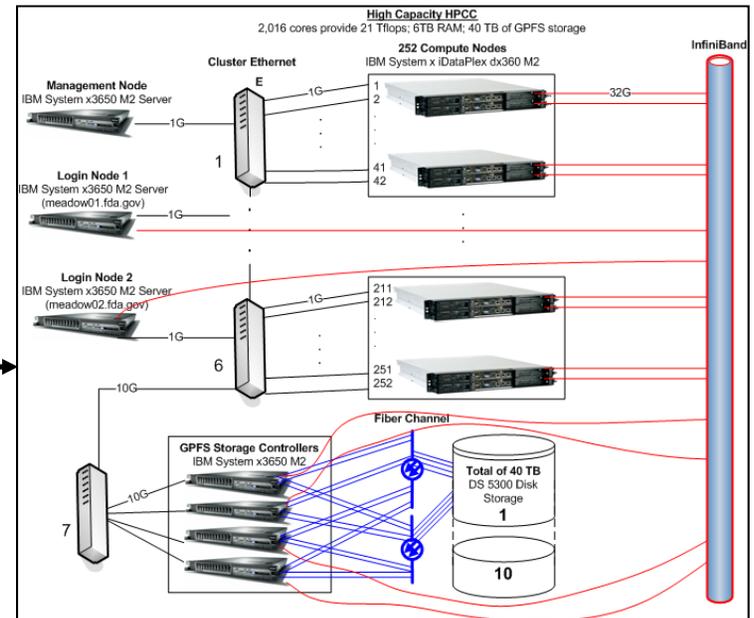
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A Technical Challenge

- Discrete Event model + Few bacteria in the system = Slow convergence
- Each simulation: 100 Stores; 1,000,000 Servings
- Currently: 22 Scenarios tested, for 6 Baseline Conditions



Parallel computing



“Blue Meadow” cluster
2,016 cores, 21 TFlops

Available through the Office of Science and Engineering Research Laboratories,
CDRH - FDA

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- **Implementation**
- **Modeling Approach**
- **Key Findings**

Modeling Approach

- We evaluated a range of retail delicatessens conditions

- Approach
 - ❖ Define some *baseline conditions*
 - Baseline #1: regular environmental contaminations occur in the stores
 - Baseline #2: no environmental contamination occurs in stores
 - ...
 - ❖ Evaluate various *scenarios* **within** these *baseline conditions*

Step 1: Definition of Baseline Conditions

#1: “Multiple Niche 100W” baseline condition

Stores with regular *L. monocytogenes* transfer from the environment and/or niches

Incoming *L. monocytogenes* : from incoming products and from the environment/niche

#2: “No Niche” baseline condition

Stores without transfer from the environment and/or niche

Incoming *L. monocytogenes* : from incoming products

#3: “Incoming Growth Chub” baseline condition

Stores with highly contaminated incoming product type that supports growth

#4: “Incoming Non-Growth Chub” baseline condition

Stores with highly contaminated incoming product type that does not support growth

#5: “Temperature Control” baseline condition

Stores without transfer from the environment and/or niche and with compliant temperature control ($\leq 41^{\circ}\text{F}$)

#6: “Niche & Temperature Control” baseline condition

Stores with regular *L. monocytogenes* transfer from the environment and/or niches and with compliant temperature control ($\leq 41^{\circ}\text{F}$)

Step 2: Evaluation of the impact of various mitigation strategies in these contexts

- **Within each of the 6 Baseline conditions**
 - ❖ **22 Scenarios**

- Answer the question (example):
 - ❖ **Given that there is a niche in a retail deli**, what are the best mitigation strategies?
and not
 - ❖ What is the probability that there is a niche in the store?

Approach to Risk Management Questions

- Separate slicers / counters for growth versus non growth products?
 - ❖ Model more than one slicer. Select slicer to use each time customer is served based on product type.
- What is the impact of the use of “gloves” in the retail environment?
 - ❖ Set probability of wearing gloves to 100%
- Consider frequently touched non-food contact surfaces (e.g. case handles, scale touch pads) as food contact surfaces (i.e., required to be cleaned and sanitized every four hours)?
 - ❖ Change site classification to FCS

➤ Flexibility of the Discrete Event Model

“What-If” Scenarios

- **Sanitation Related Scenarios**

- ❖ Some NFCS cleaned FCS, Increase the effectiveness of cleaning, No sanitation, ...

- **Worker Behavior Related Scenarios**

- ❖ No glove, No contact glove-case, Preslice products in the morning, Do not slice product on gloves

- **Growth Inhibitor Related Scenarios**

- ❖ All products with GI, No product with GI

- **Cross contamination Related Scenarios**

- ❖ Separate slicers, No cross contamination

- **Storage Temperature and Duration Related Scenarios**

- ❖ Temperature in compliance with FDA food code, Temperature set so that no growth can occur

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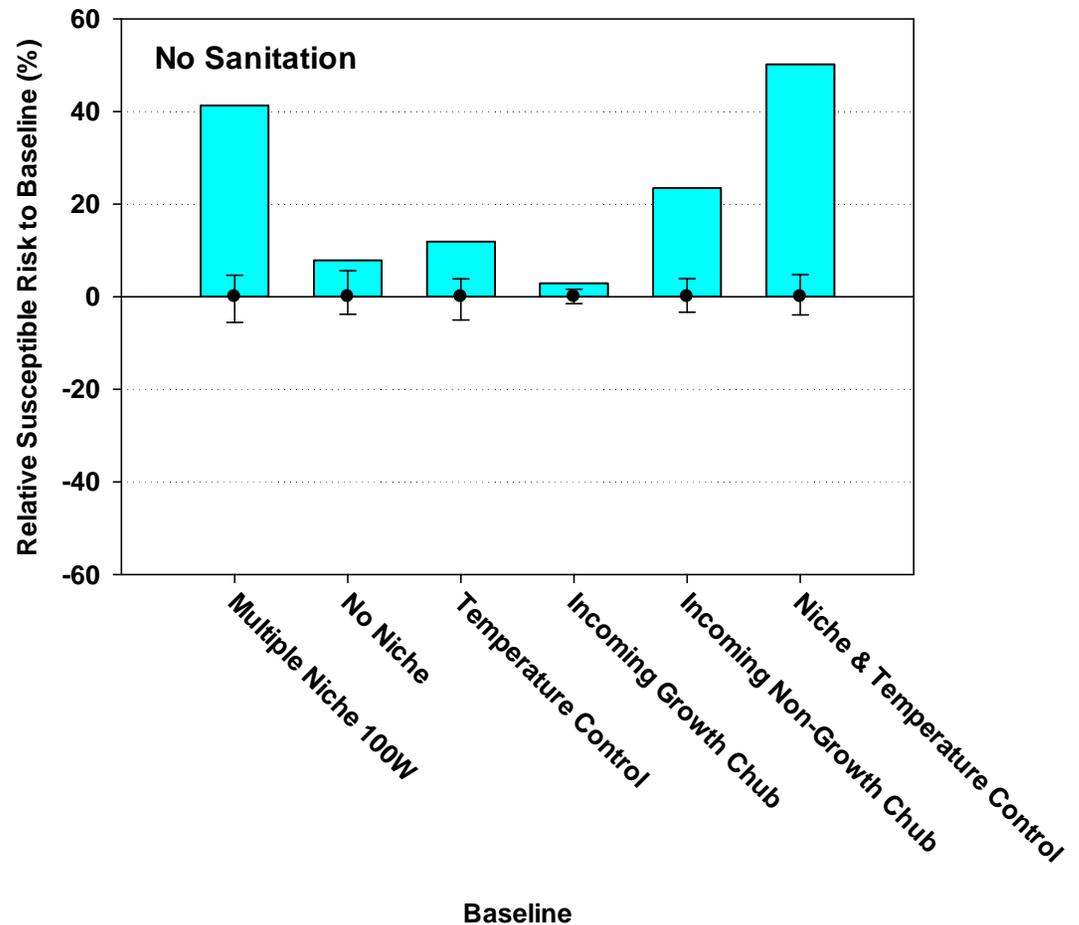
This is a “Virtual Deli” model.

What can we learn from the model about the retail deli environment?

	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 NFCSs at same rate as FCSs	-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 On 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*
Cross Contamination Related Scenarios:						
Transfers to 0: 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*	-60.8*	-19.2*	-30.4*
Reduce Level: Mean incoming L. monocytogenes 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 NFCSs (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

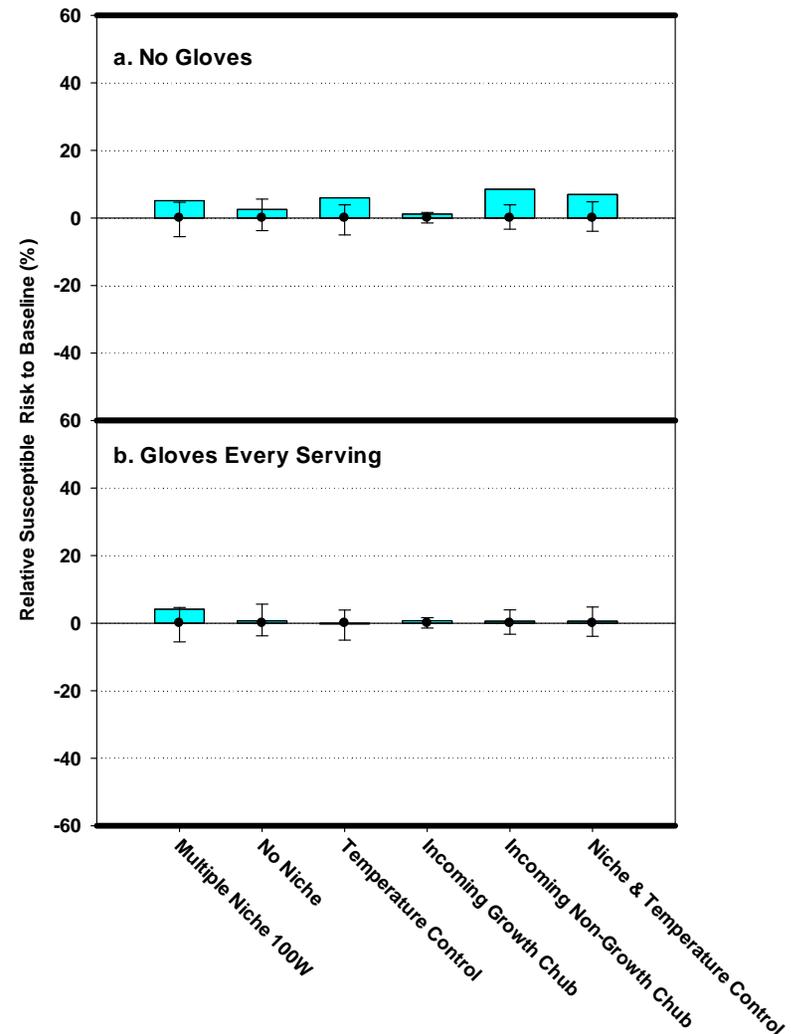
Risk Management Question: Sanitation

- Observed sanitation practices critical in reducing risk.
 - ❖ Stopping sanitation increased risk across all baselines.
- Additional sanitation (more effective cleaning, more frequent cleaning, ...) generally not significant.



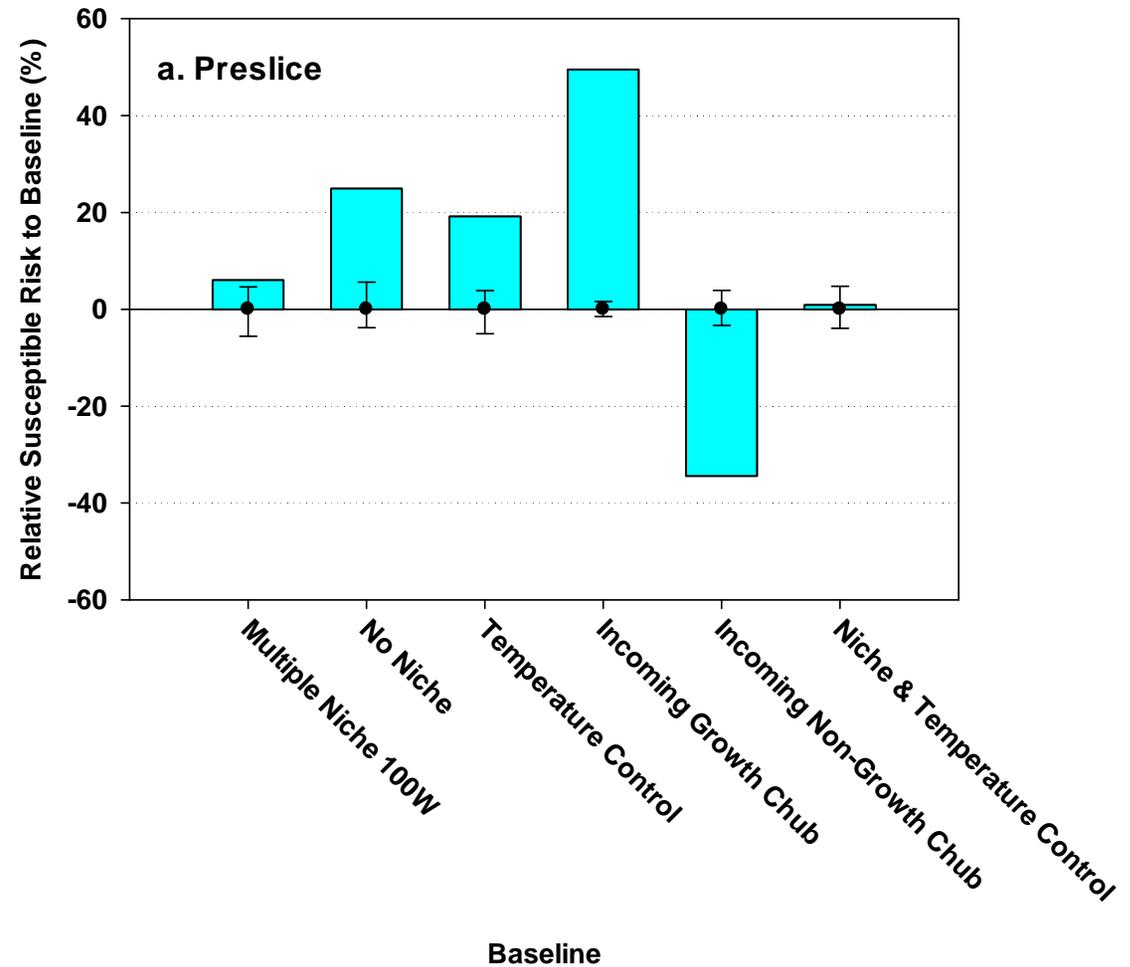
Risk Management Question: Worker behavior, glove use

- Glove changes observed ~65% of customers.
- Never using gloves increased risk in 4 of 6 baselines.
- Changing gloves for every customer led to no significant risk reduction.



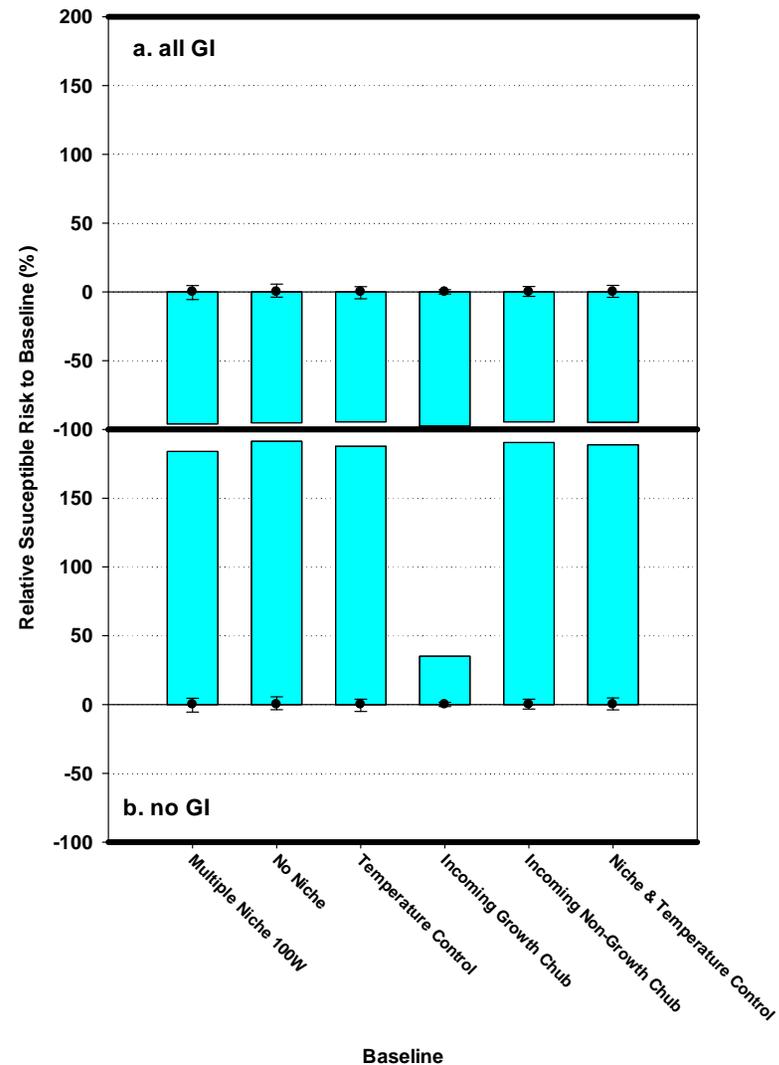
Risk Management Question: Worker behavior

- Changes to worker behavior sometimes depended on the type of baseline store.



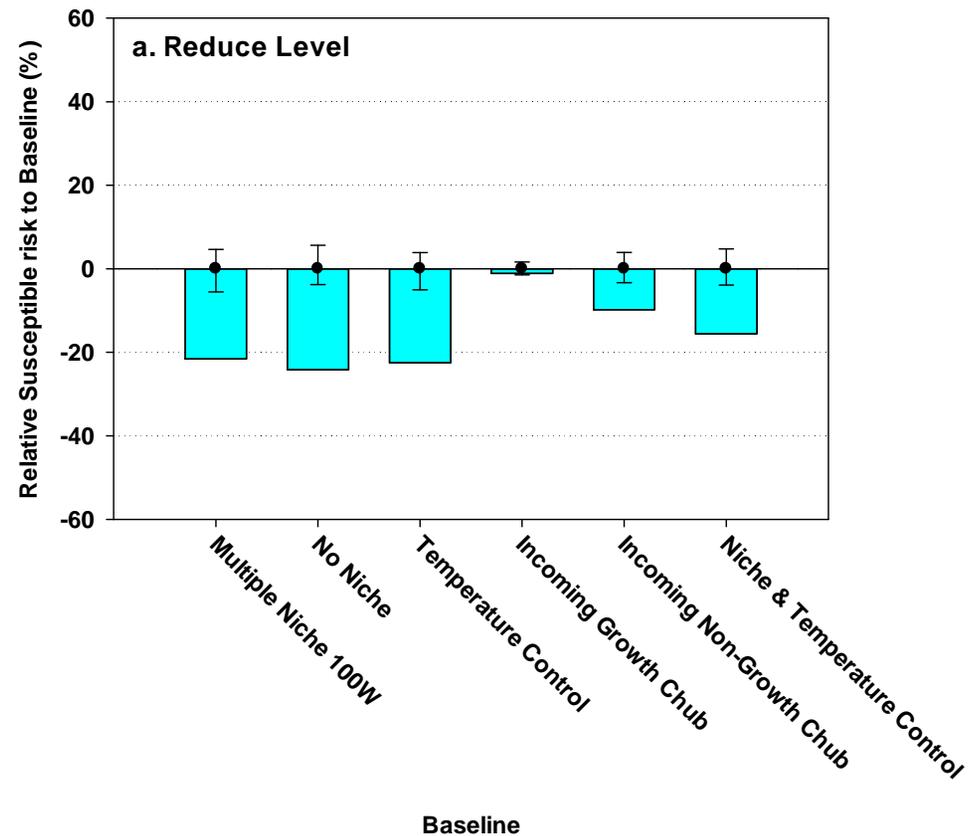
Risk Management Question: Growth Inhibitors

- Growth inhibitors prevented growth both at retail and at home.
- Broad growth inhibitor use led to dramatic reduction in risk.



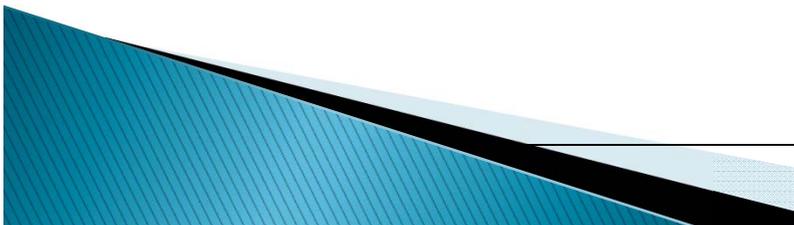
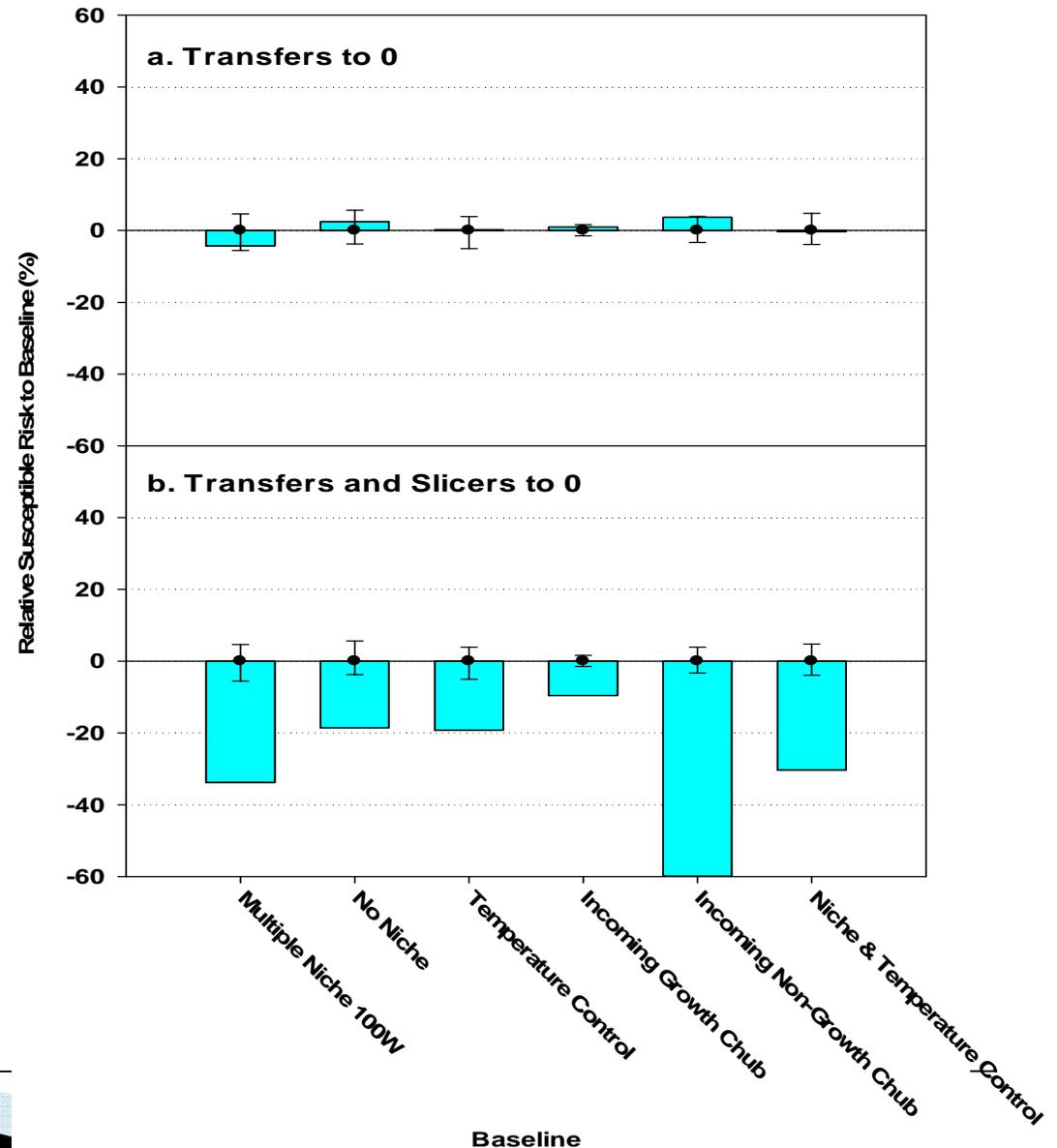
Risk Management Question: Cross contamination, incoming levels

- Reducing incoming mean concentrations by factor of 2 reduced risk across all baselines except incoming growth chub.



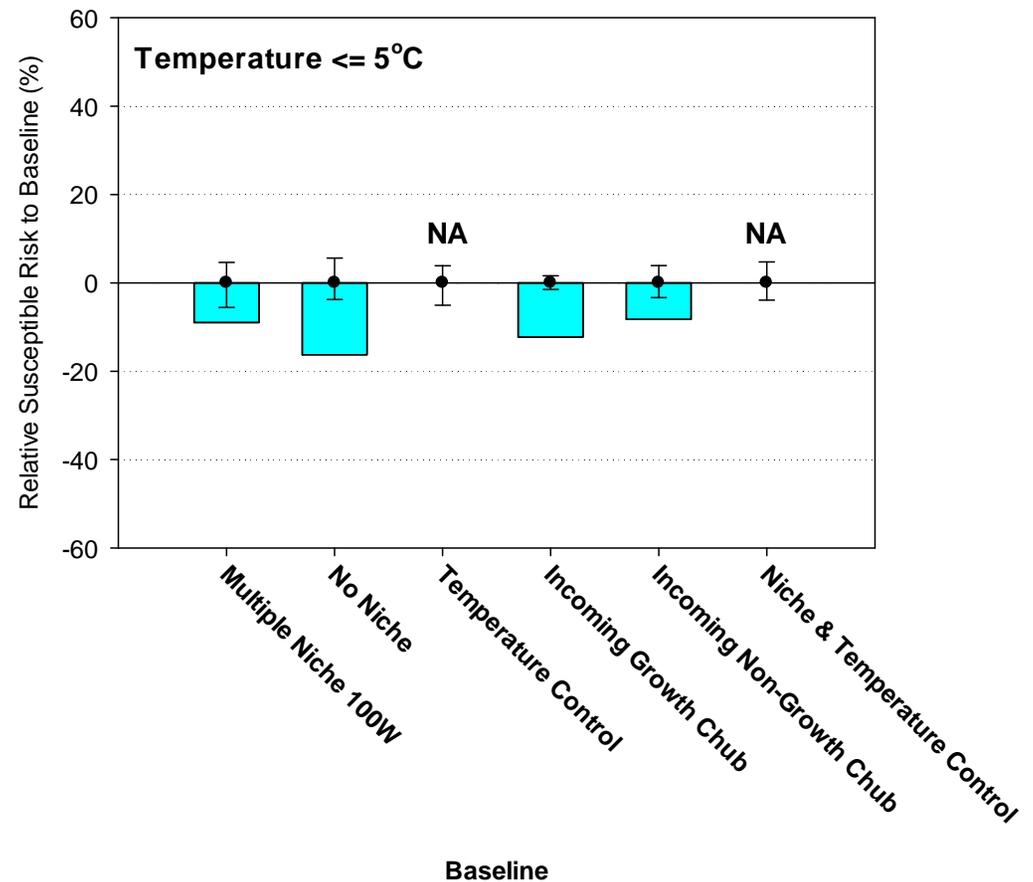
Risk Management Question: Cross contamination

- Eliminating cross contamination reduced risk across all baselines, especially incoming non growth chub
- Slicer is primary nexus for cross contamination.



Risk Management Question: Temperature

- If retail delis simply followed the FDA recommended temperature versus current observed practice, an 8-16% reduction could be achieved.
- Reduces in-store growth



Key Findings

- ▶ To reduce predicted risks of listeriosis to consumers
 - Prevent Lm entering deli department
 - from incoming growth supporting product
 - from incoming non growth supporting product
 - from environment / niches
 - Increase growth inhibitor use (prevent growth at retail/home)
 - Improve temperature control (deli case <41°F)
 - Maintain adequate sanitation & glove use
 - Pre-slicing increases the risk of listeriosis

No single intervention will eliminate listeriosis risk from food sold at retail delis. Instead, there are a host of steps that deli operators and suppliers can take to reduce the risk.

Draft Interagency Risk Assessment—*Listeria monocytogenes* in Retail Delicatessens (May 2013)

Model, Report and Interpretive Summary available at:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments>

Public meeting agenda and presentations available at:
<http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/past-meetings/05-22-2013/agenda-05-22-2013>

Seeking public comment (Docket FSIS-2013-0019) by July 12, 2013:
<http://www.fsis.usda.gov/wps/portal/frame-redirect?url=http://www.fsis.usda.gov/OPPDE/rdad/FRPublics/2013-0019.htm>

