The Role of Testing in an Enterprise Risk-Based Food Safety Program

Martin Wiedmann
Department of Food Science, Cornell University, Ithaca, NY
E-mail: mw16@cornell.edu
Phone: 607-254-2838
Outline

• Hazard, risk, public health risk, enterprise risk: intro and case studies
• How to use testing data to assess enterprise risks: from back of the envelope calculations to models
Hazard versus risk

- **Hazard:** Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent.
  - **Examples:** *Listeria monocytogenes*; Presence of *Listeria monocytogenes* in the loading dock area
- **Risk:** The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent.
  - **Examples:** Consumption of a single serving of a food with $10^9$ *Listeria monocytogenes* represents a 1:14,000 likelihood of causing neonatal death
Public Health Risk Metrics

• Risks of foodborne illness, risk of severe disease due to foodborne illness, QALY, DALYs
• Can be expressed on a per serving basis
  • A food serving with 1 million *L. monocytogenes* has a 1 in 10 million chance of causing neonatal listeriosis if consumed by a pregnant women
### USDA-FDA Listeria risk assessment

Table IV-12. Dose-Response with Variable *Listeria monocytogenes* Strain Virulence for Three Age-Based Subpopulations

<table>
<thead>
<tr>
<th>Dose (cfu/serving)</th>
<th>Intermediate-Age</th>
<th>Neonatal(^b)</th>
<th>Elderly</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.5x10^-16 (1.2x10^-14, 1.9x10^-12)</td>
<td>1.6x10^-13 (1.2x10^-9, 4.0x10^-11)</td>
<td>4.0x10^-15 (6.3x10^-12, 1.8x10^-12)</td>
</tr>
<tr>
<td>10^3</td>
<td>1.2x10^-13 (5.4x10^-12, 6.8x10^-11)</td>
<td>1.3x10^-10 (4.3x10^-7, 1.7x10^-8)</td>
<td>3.6x10^-12 (2.2x10^-9, 7.2x10^-10)</td>
</tr>
<tr>
<td>10^6</td>
<td>1.0x10^-10 (1.9x10^-8, 3.5x10^-8)</td>
<td>1.3x10^-7 (1.2x10^-5, 8.6x10^-6)</td>
<td>3.1x10^-9 (5.7x10^-6, 3.3x10^-7)</td>
</tr>
<tr>
<td>10^9</td>
<td>1.2x10^-2 (6.0x10^-2, 1.9x10^-5)</td>
<td>1.4x10^-4 (1.6x10^-3, 5.1x10^-4)</td>
<td>3.4x10^-6 (1.3x10^-4, 1.9x10^-4)</td>
</tr>
<tr>
<td>10^10</td>
<td>1.3x10^-6 (2.5x10^-5, 1.5x10^-6) (^c)</td>
<td>1.5x10^-3 (3.3x10^-3, 2.7x10^-2)</td>
<td>3.9x10^-5 (6.0x10^-2, 1.7x10^-3)</td>
</tr>
<tr>
<td>10^12</td>
<td>1.9x10^-4 (4.9x10^-5, 9.2x10^-3)</td>
<td>7.4x10^-2 (7.8x10^-4, 2.2x10^-1)</td>
<td>4.9x10^-3 (9.8x10^-6, 4.8x10^-2)</td>
</tr>
</tbody>
</table>

\(^a\) The 5\(^{th}\) and 95\(^{th}\) percentiles from the uncertainty are in parenthesis.

\(^b\) An adjustment to account for total perinatal deaths (prenatal and neonatal) is in the risk characterization section.

\(^c\) The median mortality rate per serving of 1.3x10^-6 for the intermediate-age subpopulation at the 10^10 cfu/serving dose level, corresponds to 1 death in approximately 769,231 servings (1/1.3x10^-6).

*Listeria monocytogenes* Risk Assessment 110
Public Health Risk Metrics

- Risks of foodborne illness, risk of severe disease due to foodborne illness, QALY, DALYs
- Can be expressed on a per serving basis
  - Food serving with 1 million *L. monocytogenes* has a 1 in 10 million chance of causing neonatal listeriosis if consumed by a pregnant woman
- Can be expressed on population basis
  - Ready-to-Eat deli meats are estimated to be responsible for 1,600 listeriosis cases per year in the US
  - Ready-to-Eat deli meats are estimated to be responsible for 5.5 listeriosis cases per million population
<table>
<thead>
<tr>
<th>Food product</th>
<th>Hazard</th>
<th>Region</th>
<th>Risk per serving</th>
<th>Risk per person per year</th>
<th>Cases per year</th>
<th>Cases/million population</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deli meat</td>
<td>L. monocytogenes</td>
<td>USA</td>
<td>$7.7 \cdot 10^{-8}$</td>
<td>$5.5 \cdot 10^{-6}$</td>
<td>1599</td>
<td>5.5</td>
<td>[23]</td>
</tr>
<tr>
<td>Unpasteurised milk</td>
<td>L. monocytogenes</td>
<td>USA</td>
<td>$7.1 \cdot 10^{-9}$</td>
<td>$1.1 \cdot 10^{-8}$</td>
<td>3.1</td>
<td>0.011</td>
<td>[23]</td>
</tr>
<tr>
<td>Smoked seafood</td>
<td>L. monocytogenes</td>
<td>USA</td>
<td>$6.27 \cdot 10^{-9}$</td>
<td>$4.5 \cdot 10^{-9}$</td>
<td>1.3</td>
<td>0.0045</td>
<td>[23]</td>
</tr>
<tr>
<td>Pasteurised milk</td>
<td>L. monocytogenes</td>
<td>USA</td>
<td>$1.0 \cdot 10^{-9}$</td>
<td>$3.1 \cdot 10^{-7}$</td>
<td>90.8</td>
<td>0.31</td>
<td>[23]</td>
</tr>
<tr>
<td>Vegetables</td>
<td>L. monocytogenes</td>
<td>USA</td>
<td>$2.8 \cdot 10^{-12}$</td>
<td>$6.9 \cdot 10^{-10}$</td>
<td>0.2</td>
<td>0.00069</td>
<td>[23]</td>
</tr>
<tr>
<td>Hard Cheese</td>
<td>L. monocytogenes</td>
<td>USA</td>
<td>$4.5 \cdot 10^{-15}$</td>
<td>$1.4 \cdot 10^{-13}$</td>
<td>&lt;0.1</td>
<td>&lt;0.00035</td>
<td>[23]</td>
</tr>
<tr>
<td>Fermented meats</td>
<td>L. monocytogenes</td>
<td>Worldwide</td>
<td>$2.5 \cdot 10^{-12}$</td>
<td>$6.6 \cdot 10^{-8}$</td>
<td>514.8</td>
<td>0.000096</td>
<td>[24]</td>
</tr>
<tr>
<td>Beef</td>
<td>L. monocytogenes</td>
<td>Brazil</td>
<td>$8.1 \cdot 10^{-6}$</td>
<td>$1.2 \cdot 10^{-6}$</td>
<td>252</td>
<td>0.0000012</td>
<td>[25]</td>
</tr>
<tr>
<td>Beef</td>
<td>Salmonella</td>
<td>Brazil</td>
<td>$4.7 \cdot 10^{-3}$</td>
<td>$8.6 \cdot 10^{-4}$</td>
<td>179,496</td>
<td>0.00086</td>
<td>[25]</td>
</tr>
<tr>
<td>Leafy green vegetable</td>
<td>Salmonella</td>
<td>The Netherlands</td>
<td>$6.83 \cdot 10^{-6}$</td>
<td>$1.1 \cdot 10^{-5}$</td>
<td>187</td>
<td>10.82</td>
<td>[26]</td>
</tr>
<tr>
<td>salad</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oysters</td>
<td>Vibrio</td>
<td>USA</td>
<td>$4.5 \cdot 10^{-4}$  to $8.1 \cdot 10^{-3}$</td>
<td>$9.7 \cdot 10^{-6}$</td>
<td>2826</td>
<td>8.6</td>
<td>[27]</td>
</tr>
<tr>
<td>Oysters</td>
<td>Vibrio</td>
<td>Taiwan</td>
<td>$8.56 \cdot 10^{-5}$</td>
<td>$2.8 \cdot 10^{-6}$</td>
<td>67</td>
<td>2.8</td>
<td>[28]</td>
</tr>
<tr>
<td>Shrimps</td>
<td>Vibrio</td>
<td>Malaysia</td>
<td>$4.80 \cdot 10^{-6}$</td>
<td>$3.9 \cdot 10^{-6}$</td>
<td>123</td>
<td>12</td>
<td>[29]</td>
</tr>
</tbody>
</table>

**Notes:**

- On the basis of a population of 290 million.
- On the basis of a population of 7.8 billion.
- On the basis of a population of 209.5 million.
- On the basis of a population of 17.28 million.
- On the basis of a population of 23.57 million.
- On the basis of a population of 31.53 million.
Public Health Risk Metrics

- Risks of foodborne illness, risk of severe disease due to foodborne illness
  - Can be expressed on a per serving basis
  - Can be expressed on population basis
    - Ready-to-Eat deli meats are estimated to be responsible for 1,600 listeriosis cases per year in the US
  - Can be expressed on a per company basis
    - Company X produces 10% of deli meat in the US  -> company X is estimated to be responsible for 160 listeriosis cases per year in the US??
    - But company X is better than the average? How much?
Enterprise Food Safety Risk Metrics

• Financial risk due to food safety issues
• Risk of recall or likelihood of recall happening in a given year
  • Multiply by cost of average recall
  • Risk of a recall is 1 in 10 years (how do I know that?); average cost of recall is $20 million = 2 million/year
• Risk of an outbreak linked to a company
  • Facility X causes 4 listeriosis cases/year
  • As 1 of 2 listeriosis cases are estimated to be reported, this means 2 reported listeriosis cases/year
    • All are the same subtype (by WGS) → over 3 - 4 years most likely an outbreak linked to a company
    • All are different subtypes → most likely not recognized as an outbreak
Enterprise Risks - conclusions

• This sounds hard
• And impossible to come up with a good quantitative estimate of enterprise risk
• At best this is gonna be a bunch of hand waving and guessing
• Can’t we just have a dashboard that says % of environmental Listeria positives in each of our facilities
Outline

• Hazard, risk, public health risk, enterprise risk: intro and case studies
• How to use testing data to assess enterprise risks: from back of the envelope calculations to models
Classical food safety testing

- Presence of foodborne pathogens in (“qualitative testing”)
  - Raw material
  - Environment
  - Finished product
- Quantitative pathogen testing
- Qualitative and quantitative testing for indictor organisms

Mainly provides information on hazard presence/absence or likelihood of hazard occurrence
We got us a hazard – but what’s the risk?
The back of the envelope approach

- Given information
  - Our current sampling program finds *L. monocytogenes* in 3% of environmental samples
  - 50% of *L. monocytogenes* we find are closely related by subtyping
  - Chance of a visit by a regulatory agency where they collect 100 samples (“swab-a-thon”) is 20% (1 in 5 years)

- “back of the envelope” enterprise risk assessment
  - Swab-a-thon has a 95% likelihood of a positive sample
  - Likelihood of follow-up investigation by a regulatory agency that find another positive that has the same subtype is about 47%
  - Estimated 9% risk of a recall in a given year (0.2 * 0.95 * 0.47 = 0.089)
  - Per industry studies, the average cost of a recall is estimated to be $10 million, with a 9% chance our company could have a recall in a given year, this could be seen as representing an annualized financial risk of $900,000.
The back of the envelope approach – part 2

• Using this as a starting point, one can then estimate the risk reduction that can be achieved by an infrastructure improvement (e.g., reducing the frequency of positives from 3% to 1% or reducing the frequency of a persistent strain from 50% to 10%.
  • New risk of a recall in a given year is 0.5% (0.2 * 0.54 * 0.05 = 0.005) as compared to 8% before
  • $50,000 versus $900,000 financial exposure
How does one decide on the acceptable risk

• This is a decision for the risk manager(s)
  • For public health there tends to be some guidance, e.g., *De minimis* risk: agreement in the EU on individual fatality risk of $10^{-6}$/year (1 in 1 million) for the general population
  • For firms, this is a leadership decision
    • Seems to often be made by gut feeling rather than numbers
    • Different companies will have different risk tolerances, e.g., based on value of brand, desired brand reputation, etc.
• Need to consider both costs and benefits
  • With small risks, the cost/impact of further reducing the risks can outweigh the benefits

How to move past “back of the envelope calculations”

• Use modelling-based approaches that are fed by testing as well as other data
  • Weather data, temperature data, etc.

• Classical public heath-based risk assessment models need to be modified to assess enterprise risk
  • Recall or outbreak risk (in addition or in stead of public health risk)

• Modelling tools include
  • Classical risk models
  • GIS models
  • Agent-based models
Running head: Assessment of recall risk for \( Lm \) on cold-smoked salmon

Manuscript type: Research Paper

Title: Development of a modeling tool to assess and reduce the recall risk for cold-smoked salmon due to \( Listeria monocytogenes \) contamination

Authors: Ruixi Chen, Renato H. Orsi, Veronica Guariglia-Oropeza, and Martin Wiedmann*

Department of Food Science, Cornell University, Ithaca, NY 14853
Recall risk assuming a lot with 4% Lm prevalence is sampled with n=60 (baseline) and impact of various interventions on re-call risk
Validation of a Previously Developed Geospatial Model That Predicts the Prevalence of *Listeria monocytogenes* in New York State Produce Fields

Daniel Weller,¹ Suvash Shiwakoti,² Peter Bergholz,² Yrjo Grohn,³ Martin Wiedmann,¹ Laura K. Strawn⁴
Validation of a Previously Developed Spatial Model for Predicting the Prevalence of Listeria monocytogenes in Corn Fields

Daniel Weller, a Suvash Shiakoti, b Peter Bergholz, b Yrjo Gro
EnABLE: An agent-based model to understand Listeria dynamics in food processing facilities

Using agent-based modeling to compare corrective actions for Listeria contamination in produce packinghouses

Cecil Barnett-Neefs, Genevieve Sullivan, Claire Zoellner, Martin Wiedmann, Renata Ivanek
Using agent-based modeling to compare corrective actions for *Listeria* contamination in produce packinghouses

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Fig 6. Comparison of corrective action efficacy against baseline conditions in Facility B. Efficacy was calculated...
Take home messages

• While “risk-based food safety decision making” has so far focused on public health risks, it is time to better assess and quantify food safety enterprise risks
  • May challenge the old approach of “Food safety is non competitive”
• The tools are here - from back of the envelope to increasingly sophisticated risk models
  • Need to invest into the appropriate modelling tools
• As food safety professionals, we need to do a better job to communicate food safety associated enterprise risks internally (e.g., to the company leadership)
  • We also need to train students to better understand risk and risk-based decision making