UNDERSTANDING RESIDUAL RISK

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Reach out if you want to collaborate!

More info on grants and pubs at:
https://mjs.fshn.illinois.edu/

Thanks to my lab, & their support people
Take Home Messages

Residual Risk is that which remains at the end of a good food safety system. This can be very low, but never zero.

Residual Risk is best managed thru preventative controls. Product testing can be a tool for continuous improvement, and to verify lack of major failures.

Acknowledging residual risk is important for managing it. Can allow for better (safer, more secure) food systems than perusing impossible zero risk.
Residual Risk
Residual Risk

- Residual risk is that which remains at the end of a good food safety system
  - Meaning production with good agricultural and manufacturing practices
  - Appropriate transport, retail, and consumer behavior

- Residual risk is never zero
  - But can be low

- Why?
  - CDC Numerator: 1 in 6 Americans, or 76 million have a foodborne disease each year
  - Denominator: 3+ meal * 365 day = \textbf{1000+ meals/year/person}
    334 million American (2023 Census predic.)
    \textbf{334+ billion meals}
  - 76 million / 334+ billion = \textbf{1 illness in 4,400+ meals overall}; complex foods

Is this high? Low? Compared to products?
Ways to Look at Risk

Unpasteurized v. Pasteurized Milk
~7X more risk per serving
~30X fewer cases per year
Concepts: (lack of) preventative controls, residual hazard levels, different consumption, different residual risk
Table 8.4 Suggested sampling plans for combinations of degrees of health concern and conditions of use (i.e., the 15 “cases”)

| Degree of concern relative to utility and health hazard | Conditions in which food is expected to be handled and consumed after sampling in the usual course of events
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditions reduce degree of concern</td>
</tr>
<tr>
<td>Conditions cause no change in concern</td>
</tr>
<tr>
<td>Conditions may increase concern</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Utility: general contamination, reduced shelf-life, incipient spoilage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase shelf-life</td>
</tr>
<tr>
<td>Case 1</td>
</tr>
<tr>
<td>3-class n = 5, c = 3</td>
</tr>
<tr>
<td>Reduce shelf-life</td>
</tr>
<tr>
<td>Case 2, Case 3</td>
</tr>
<tr>
<td>3-class n = 5, c = 2</td>
</tr>
<tr>
<td>3-class n = 5, c = 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Indicator: Low, indirect hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce hazard</td>
</tr>
<tr>
<td>Case 4</td>
</tr>
<tr>
<td>3-class n = 5, c = 3</td>
</tr>
<tr>
<td>No change</td>
</tr>
<tr>
<td>Case 5</td>
</tr>
<tr>
<td>3-class n = 5, c = 2</td>
</tr>
<tr>
<td>3-class n = 5, c = 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderate hazard: direct, limited spread</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 7</td>
</tr>
<tr>
<td>3-class n = 5, c = 2</td>
</tr>
<tr>
<td>No change</td>
</tr>
<tr>
<td>Case 8</td>
</tr>
<tr>
<td>3-class n = 5, c = 1</td>
</tr>
<tr>
<td>3-class n = 10, c = 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Serious hazard: incapacitating but not usually life threatening, sequelae are rare, moderate duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 10</td>
</tr>
<tr>
<td>2-class n = 5, c = 0</td>
</tr>
<tr>
<td>Case 11</td>
</tr>
<tr>
<td>2-class n = 10, c = 0</td>
</tr>
<tr>
<td>Case 12</td>
</tr>
<tr>
<td>2-class n = 20, c = 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severe hazard: for (a) the general population or (b) restricted populations, causing life threatening or substantial chronic sequelae or illness of long duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 13</td>
</tr>
<tr>
<td>2-class n = 15, c = 0</td>
</tr>
<tr>
<td>Case 14</td>
</tr>
<tr>
<td>2-class n = 30, c = 0</td>
</tr>
<tr>
<td>Case 15</td>
</tr>
<tr>
<td>2-class n = 60, c = 0</td>
</tr>
</tbody>
</table>

Limited Power at Moderate Contamination

Table 1

<table>
<thead>
<tr>
<th>Assumed level of contamination</th>
<th>Sampling plan description</th>
<th>Number of samples</th>
<th>Sample size (g)</th>
<th>Probability of acceptance (%)</th>
<th>Probability of rejection of lot (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CFU/kg</td>
<td>60 individual samples</td>
<td>25 g</td>
<td>6.40</td>
<td>93.60</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduced size and number</td>
<td>10 g</td>
<td>82.76</td>
<td>17.24</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 individual samples</td>
<td>1 g</td>
<td>99.04</td>
<td>0.96</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 CFU/16 kg</td>
<td>60 individual samples</td>
<td>25 g</td>
<td>74.89</td>
<td>25.11</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduced size and number</td>
<td>10 g</td>
<td>98.08</td>
<td>1.92</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 individual samples</td>
<td>1 g</td>
<td>99.90</td>
<td>0.10</td>
<td></td>
</tr>
</tbody>
</table>

More stringent sampling plans would generally be used for sensitive foods destined for susceptible populations.
Thought Experiment - Chocolate

Limits of Traditional Sampling

- **Assumptions**
  - 1 cell / 10,000 bars of 100 g
  - 100,000 bars / d
  - Sample 5 bars / d

- **Implications**
  - Probability detect
    - Single unit = 0.01%
    - Single day = 0.05%
    - **1 positive per 5.5 years**
    - Low risk?
  - Illness
    - 1 cell = 1 case / 400 servings
    - 10 bars with cell / d
    - ~9 illness per year
    - Low risk?

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Large Scale Production

- **Assumptions, 3 mths production**
  - 90 million bars (9x10⁷)
  - 9 billion grams (9x10⁹)
  - 360 million servings (3.6x10⁸)
  - Great prevention and intervention
    - Yet, 1 harborage site
    - 0.0000033 CFU/g residual contamination
    - Virtually impossible to detect by sampling

- **Implications**
  - ~30,000 servings contaminated
  - ~74 illness
  - Modern genomics and epi might identify this link
    - Caveat: 30-fold under-reporting, ≤2 reported
Key points

- The residual risk that remains (High? Low?) is influenced by
  - Inactivation is never absolute
  - Limitations to traditional sampling schemes
  - The era of molecular epidemiology
  - Large scale food production
In ‘Class’ Exercise: With our calculator

Change our assumptions

- ↑↓ Incoming Load
- ↑↓ Process Control
- ↑↓ Testing
- Track differences in outputs like
  - Frequency of positive test
  - Risk of reported illness

If BOLD: Model your interest

- What is a lot?
- What contamination?
- What process reduction?
- What testing?

https://go.illinois.edu/ResidualRisk
Preventative Controls and Product Testing
Three Problems Our Lab Works On

Pathogens – Leafy Greens

C.D.C. Issues E. Coli Warning on Romaine Lettuce Ahead of Thanksgiving
At least 23 people have been hospitalized after being infected by E. coli linked to the Salinas, Calif., growing region.

Salmonella – Powders

Lactalis’s Salmonella-Contaminated Baby Formula: What Parents Should Know

Share Tables – Norovirus, Spoilage
Three Problems Our Lab Works On

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Norovirus, Spoilage

Share Tables – WORLD-CLASS PROGRAMS
Scope of the Problem

Immediate issue

- Many negative samples
- Still outbreaks
- What is the value of pre-harvest sampling?
How Powerful are Sampling Plans for Which Hazards?

Current produce best practices do not reliably detect contamination

- Point-source contamination in one-acre plot
- Systematic (area) contamination in one-acre plot

- Acceptance probability with single fecal contamination
- Simple random sampling of composites of 60-1,200 individual 3 g samples.

More, smaller, randomized samples are needed for powerful sampling.

- Acceptance probability with low-level background to high-level contamination
- Same sampling
Interventions Matter

What is the marginal role of sampling?

Questions
Sampling relative to interventions?
Where should we sample?

Quantify cells in the system

Baseline system with No-Interventions
Effective interventions such as Washing and Prewash

This change is a 3.4 log difference (Effect of all interventions)

Pre-processing | Process Stage | Post-processing

Small sampling effects

Effect of all interventions
Where to sample?

Most effective sampling plans, for specific processing systems

Finished product sampling is powerful if No-Interventions

When a good system is in place, Sampling pre-processing will always be more effective
Product Testing and Preventative Control

From Produce Work

- Increasing preventative controls reduces residual risk
- Testing before preventative controls more powerful
  - And can help identify new or unknown pathways for failure
Three Problems Our Lab Works On

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Salmonella – Powders

[Lactalis’s Salmonella-Contaminated Baby Formula: What Parents Should Know]

Baby formula recalled by Lactalis as a precaution in Anglet, France, because of potential salmonella contamination. Photo: Fracois Mori/Associated Press

Share Tables – Norovirus, Spoilage

[Cold Zone]

Missi Blue is recalling more than 7,100 pounds of salad products, the United States Department of Agriculture said. Photo: D. Ann Healy/Space Race Press – Getty Images
Our Conceptual Model

- **Hazard** – Explicit location defined in simulation
  - **Allows for defining different contamination scenarios**, known food safety risks
- **Samples** – Represented as points in 2D space
  - **Each sample can have a probability of contamination** when CFU/g << 1
- Can compare **grab sampling to autosampling**

**Hazards and Sampling Mapped to a 2D box**

- Production Rate [ton/h]
- Instantaneous 1-75+ g samples
- Production time [h]
Benchmarking CODEX and more Intensive plans

Recalled Batch: Detected
High-prevalence, low-level

Reference (non-recalled) Batch: Non-Detected
Low-prevalence, low-level

All plans detect hazard at recall levels

Plans do not reliably detect hazard at non-recall levels

Work under 1st revision for Journal Food Protection
More, Smaller, Samples are Better (recalled batch)

Stratification helps at low sample number.

At 30+ grabs, sampling reliably detects contamination.

Sampling every 1kg can is unnecessary.
Product Testing and Preventative Control

From Produce Work
- Increasing preventative controls reduces residual risk
- Testing before preventative controls more powerful
  - And can help identify new or unknown pathways for failure

Powders Work
- Testing only powerful on a recalled batch (a failure), not a non-recalled batch (representing residual risk)
- Implication
  - What are other ways to manage residual risk?
Residual Risk and Food Safety Management
Three Problems Our Lab Works On

- **Pathogens – Leafy Greens**
- **Salmonella – Powders**
- **Share Tables – Norovirus, Spoilage**
Example of Residual Risk Impacting Food System Progress

Can ‘Share Tables’ get hungry kids otherwise wasted food?

- Pair up and discuss the main concern for each group
  - Advocate – School Nutrition Professional, Food Waste Reducer
  - Critic – Health Inspector
  - Unsure – Cafeteria Worker, Parent, Child

- Why?
  - Can you see how each person has a valid position?
  - What happens to the discussion in a hazard mindset versus a risk mindset?
Shifting The Discussion

Hazard - Stuck
- Advocate – Kids eat every day, no problem. Why not share?
- Critic – Sharing is risky, NO
- Health inspector wins, nothing is done

Risk - Progress
- We already accept risks in cafeterias (kids gotta eat), and schools more generally
- Given that:
  - Does sharing meaningfully increase risks compared to no sharing?
    o With respect to benefits?
  - Can these risks be managed?
Our modeling solution – QMRA (Norovirus – Apples)

**Process Model**
- Simulate students selecting **apples**, then choosing to consume, share, or discard

**Risk Model**
- Simulate **cross-contamination of norovirus** in school cafeterias
  - Source being contaminated students
- Evaluate the effect of share tables on the final **illness prevalence** among students
Share tables modestly increase food safety risks

- **Share tables:**
  - Increased relative illness prevalence by **6.8%**, from **1.5%** to **1.6%**

- **Question**
  - How can we **manage** the risk added by share tables?

**Scenario:**

<table>
<thead>
<tr>
<th>#</th>
<th>Scenario:</th>
<th>Sick Students Mean [95% variability Interval]</th>
<th>Illness prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Traditional Cafeteria</td>
<td>1.49% [0.52%-2.68%]</td>
<td>100.0%</td>
</tr>
<tr>
<td>2</td>
<td>Cafeteria + Share Table</td>
<td>1.59% [0.67%-2.75%]</td>
<td>106.8%</td>
</tr>
</tbody>
</table>

**Explanation:**

- **Share tables:**
  - Increased relative illness prevalence by **6.8%**, from **1.5%** to **1.6%**

- **Question:**
  - How can we **manage** the risk added by share tables?
### Added risk can be managed

#### What-if scenario takeaways:

- Set healthy environment with handwashing or hand sanitizer
- One-way share table allows for apples to be washed and items inspected prior to being consumed
- One-way share tables can mitigate most of the risk for Norovirus

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<tbody>
<tr>
<td>1</td>
<td>Baseline Traditional Cafeteria</td>
<td>1.49% [0.52%-2.68%]</td>
<td>100.0%</td>
</tr>
<tr>
<td>2</td>
<td>Baseline Share Table</td>
<td>1.59% [0.67%-2.75%]</td>
<td>106.8%</td>
</tr>
<tr>
<td>11</td>
<td>Hand washing Station</td>
<td>0.65% [0.14%-1.40%]</td>
<td>43.6%</td>
</tr>
<tr>
<td>12</td>
<td>Hand Sanitizer Station</td>
<td>0.62% [0.00%-1.89%]</td>
<td>41.9%</td>
</tr>
</tbody>
</table>

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</tr>
<tr>
<td>7</td>
<td>One-way share table</td>
<td>1.50% [0.52%-2.69%]</td>
<td>100.6%</td>
</tr>
</tbody>
</table>
What about milk?
Milks will rarely be in the system long enough to exceed the quality threshold

- 99.8% of milks are consumed within the first two days they are serviced
- Only 4/450,806 (0.0009%) spoil
Meaning...

Incoming microbial quality is the main driver of milk spoilage

- High-quality milks do not spoil in the fridge nor with repeated sharing over 5 days
- Low-quality milks may spoil after 4 days in the fridge, and after 3 days of repeated sharing

Spoilage is mostly caused by overnight storage of milk in the fridge, not the ST

- Improving overnight storage temperature likely more helpful than improving ST temperature

Most milks are consumed before they are spoiled

- Essentially all (99.8%) milks are consumed by the second time they are serviced
- Only milks of incoming low-quality that are shared more than once, end up spoiled
- This is very unlikely

So, share tables can have low risk compared to benefits
What other opportunities can you see?
Take Home Messages

Residual Risk is that which remains at the end of a good food safety system. This can be very low, but never zero.

Residual Risk is best managed thru preventative controls. Product testing can be a tool for continuous improvement, and to verify lack of major failures.

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Share Table Work

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- Single Kernel Work