ILLINOIS
College of Agricultural, Consumer & Environmental Sciences

Thanks to my lab, & their support people

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/

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 = **1000+ meals/year/person**
    334 million American (2023 Census predic.)
    334+ billion meals
  - 76 million / 334+ billion = **1 illness in 4,400+ meals overall**; complex foods
    Is this high? Low? Compared to products?

Ways to Look at Risk

Available online at www.sciencedirect.com
ScienceDirect
Current Opinion in Food Science

All food processes have a residual risk, some are small, some very small and some are extremely small: zero risk does not exist

Marcel H Zwietering[1], Alberto Garre[1], Martin Wiedmann[2] and Robert L Buchanan[3,4]

Table 2

Examples of risk per serving of several diseases from RTE foods, risk per person per year, cases per year and cases per million population

Food product	Hazard	Region	Risk per serving	Risk per year per person	Cases per year	Cases/million population	Source
Deli meat	*L. monocytogenes*	USA[a]	$7.7 \cdot 10^{-8}$	$5.5 \cdot 10^{-6}$	1599	5.5	[23]
Unpasteurised milk	*L. monocytogenes*	USA[a]	$7.1 \cdot 10^{-9}$	$1.1 \cdot 10^{-8}$	3.1	0.011	[23]
Smoked seafood	*L. monocytogenes*	USA[a]	$6.27 \cdot 10^{-9}$	$4.5 \cdot 10^{-9}$	1.3	0.0045	[23]
Pasteurised milk	*L. monocytogenes*	USA[a]	$1.0 \cdot 10^{-9}$	$3.1 \cdot 10^{-7}$	90.8	0.31	[23]

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

Current Best Practices – ICMSF plans

Plan Descriptions

Available online at www.sciencedirect.com
ScienceDirect
Current Opinion in Food Science
ELSEVIER

All food processes have a residual risk, some are small, some very small and some are extremely small: zero risk does not exist

Marcel H Zwietering[1], Alberto Garre[1], Martin Wiedmann[2] and Robert L Buchanan[3,4]

Limited Power at Moderate Contamination

Table 8.4 Suggested sampling plans for combinations of degrees of health concern and conditions of use (i.e., the 15 "cases")

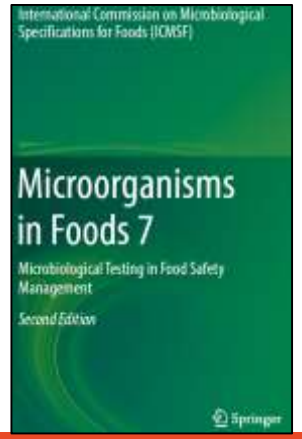
Degree of concern relative to utility and health hazard	Conditions in which food is expected to be handled and consumed after sampling in the usual course of events[a]		
	Conditions reduce degree of concern	Conditions cause no change in concern	Conditions may increase concern
Utility; general contamination, reduced shelf-life, incipient spoilage	Increase shelf-life Case 1 3-class n = 5, c = 3	No change Case 2 3-class n = 5, c = 2	Reduce shelf-life Case 3 3-class n = 5, c = 1
Indicator; Low, indirect hazard	Reduce hazard Case 4 3-class n = 5, c = 3	No change Case 5 3-class n = 5, c = 2	Increase hazard Case 6 3-class n = 5, c = 1
Moderate hazard; direct, limited spread	Case 7 3-class n = 5, c = 2	Case 8 3-class n = 5, c = 1	Case 9 3-class n = 10, c = 1
Serious hazard; incapacitating but not usually life threatening, sequelae are rare, moderate duration	Case 10 2-class n = 5, c = 0	Case 11 2-class n = 10, c = 0	Case 12 2-class n = 20, c = 0
Severe hazard; for (a) the general population or (b) restricted populations, causing life threatening or substantial chronic sequelae or illness of long duration	Case 13 2-class n = 15, c = 0	Case 14 2-class n = 30, c = 0	Case 15 2-class n = 60, c = 0

[a]More stringent sampling plans would generally be used for sensitive foods destined for susceptible populations

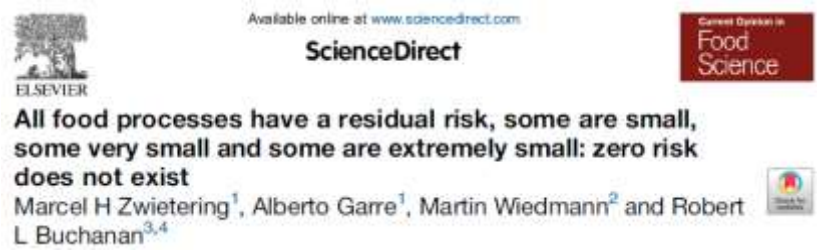
Table 1

Examples of different sampling plans acceptance/rejection characteristics as calculated by the ICMSF Sampling Software for 2-class enrichment samples [22] using a σ of 0.5

Assumed level of contamination	Sampling plan description	Number of samples	Sample size (g)	Probability of acceptance (%)	Probability of rejection of lot (%)
1 CFU/kg	Sixty individual 25-g samples	60 individual samples	25 g	6.40	93.60
	Reduced size and number	10 individual samples	10 g	82.76	17.24
	Small sampling size and number	5 individual samples	1 g	99.04	0.96
1 CFU/10 kg	Sixty individual samples	60 individual samples	25 g	74.89	25.11
	Reduced size and number	10 individual samples	10 g	98.08	1.92
	Small sampling size and number	5 individual samples	1 g	99.90	0.10



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?**

Large Scale Production

- Assumptions, 3 mths production
  - 90 million bars ($9x10^7$)
  - 9 billion grams ($9x10^9$)
  - 360 million servings ($3.6x10^8$)
  - 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

The New York Times

C.D.C. Issues E. Coli Warning on Romaine Lettuce Ahead of Thanksgiving

At least 28 people have been hospitalized after being infected by E. coli linked to the Salinas, Calif., growing region.

Missa Bay is recalling more than 75,000 pounds of salad products, the United States Department of Agriculture said.

Salmonella – Powders

The New York Times

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

Baby formula recalled by Lactalis at a drugstore in Anglet, France, because of potential salmonella contamination.

By Liz Alderman

Feb. 1, 2018

Share Tables – Norovirus, Spoilage

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PLAY THE CROSSWORD

C.D.C. Issues E. Coli Warning on Romaine Lettuce Ahead of Thanksgiving

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Missa Bay is recalling more than 75,000 pounds of salad products, the United States Department of Agriculture said. Frederic J. Brown/Agence France-Presse — Getty Images

***Salmonella* – Powders**

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Share Tables – Norovirus, Spoilage

Scope of the Problem

Immediate issue

- Many negative samples
- Still outbreaks
- What is the value of pre-harvest sampling?

Applied and Environmental Microbiology

FOOD MICROBIOLOGY

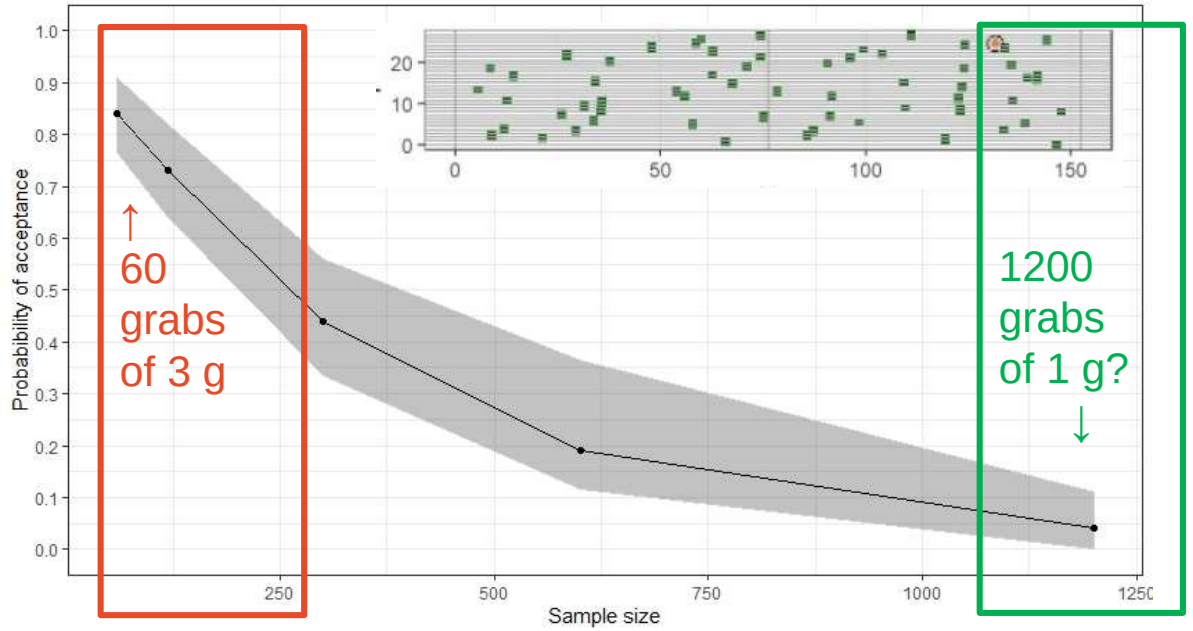
A Validated Preharvest Sampling Simulation Shows that Sampling Plans with a Larger Number of Randomly Located Samples Perform Better than Typical Sampling Plans in Detecting Representative Point-Source and Widespread Hazards in Leafy Green Fields

Jorge Quintanilla Portillo,[a] Xianbin Cheng,[a] Alexandra M. Belias,[b] Daniel L. Weller,[b,c] Martin Wiedmann,[b] Matthew J. Stasiewicz[a]

How Powerful are Sampling Plans for Which Hazards?

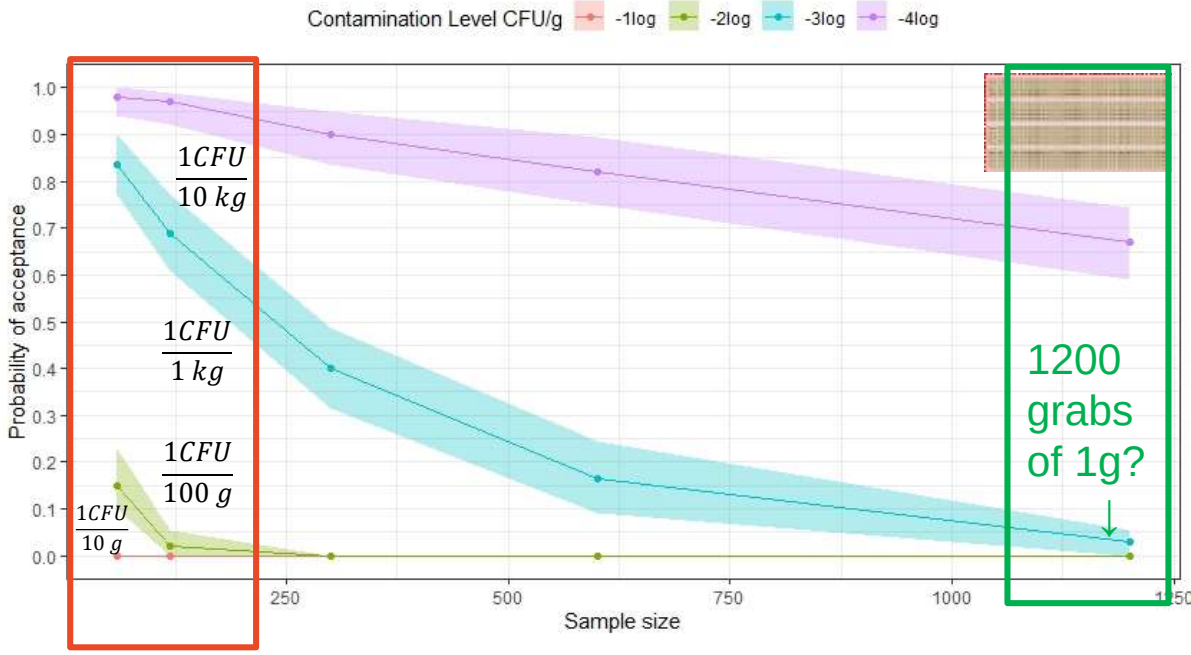
Current produce best practices do not reliably detect contamination

Point-source contamination in one-acre plot



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

Systematic (area) contamination in one-acre plot



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

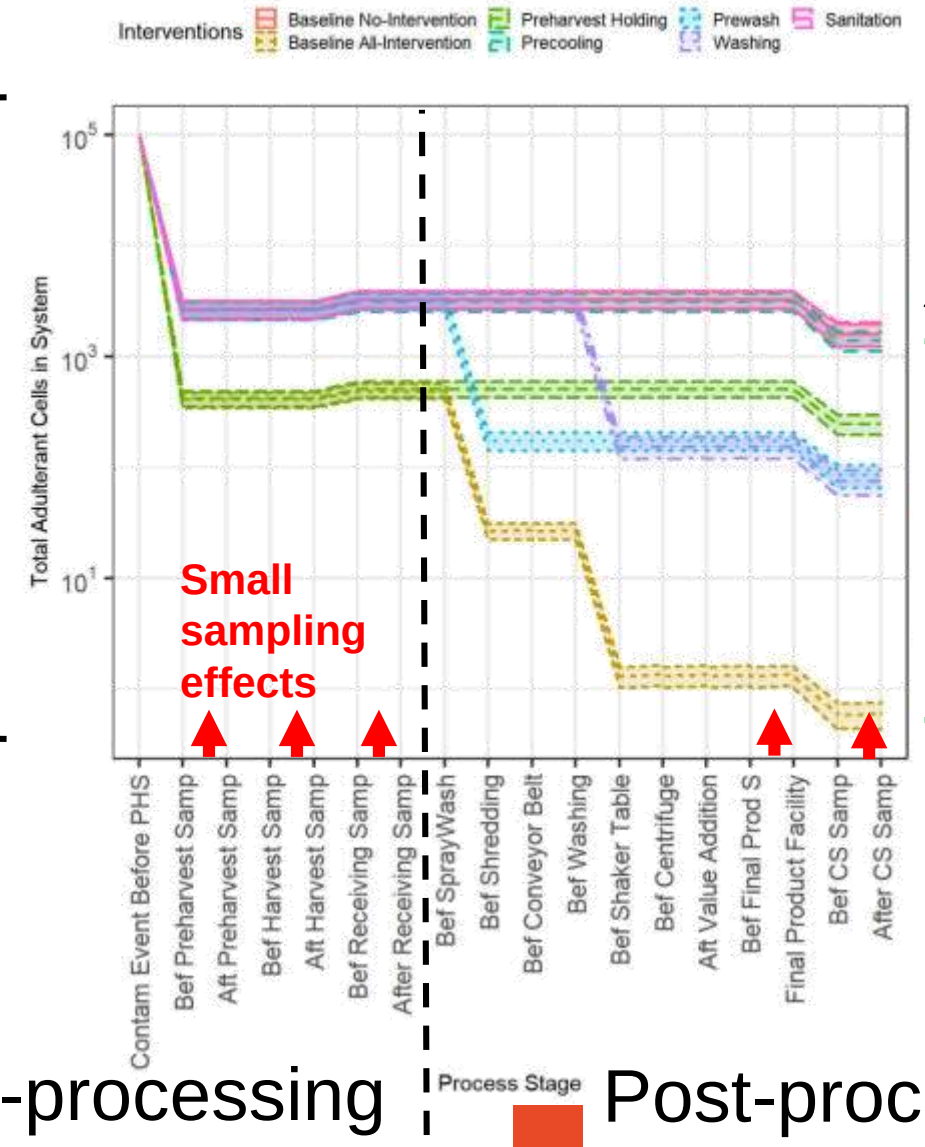
More, smaller, randomized samples are needed for powerful sampling

Interventions Matter
What is the marginal role of sampling?

Quantify cells in the system

Questions

Sampling relative to interventions? Where should we sample?



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

Post-processing

Applied and Environmental Microbiology

ENVIRONMENTAL MICROBIOLOGY

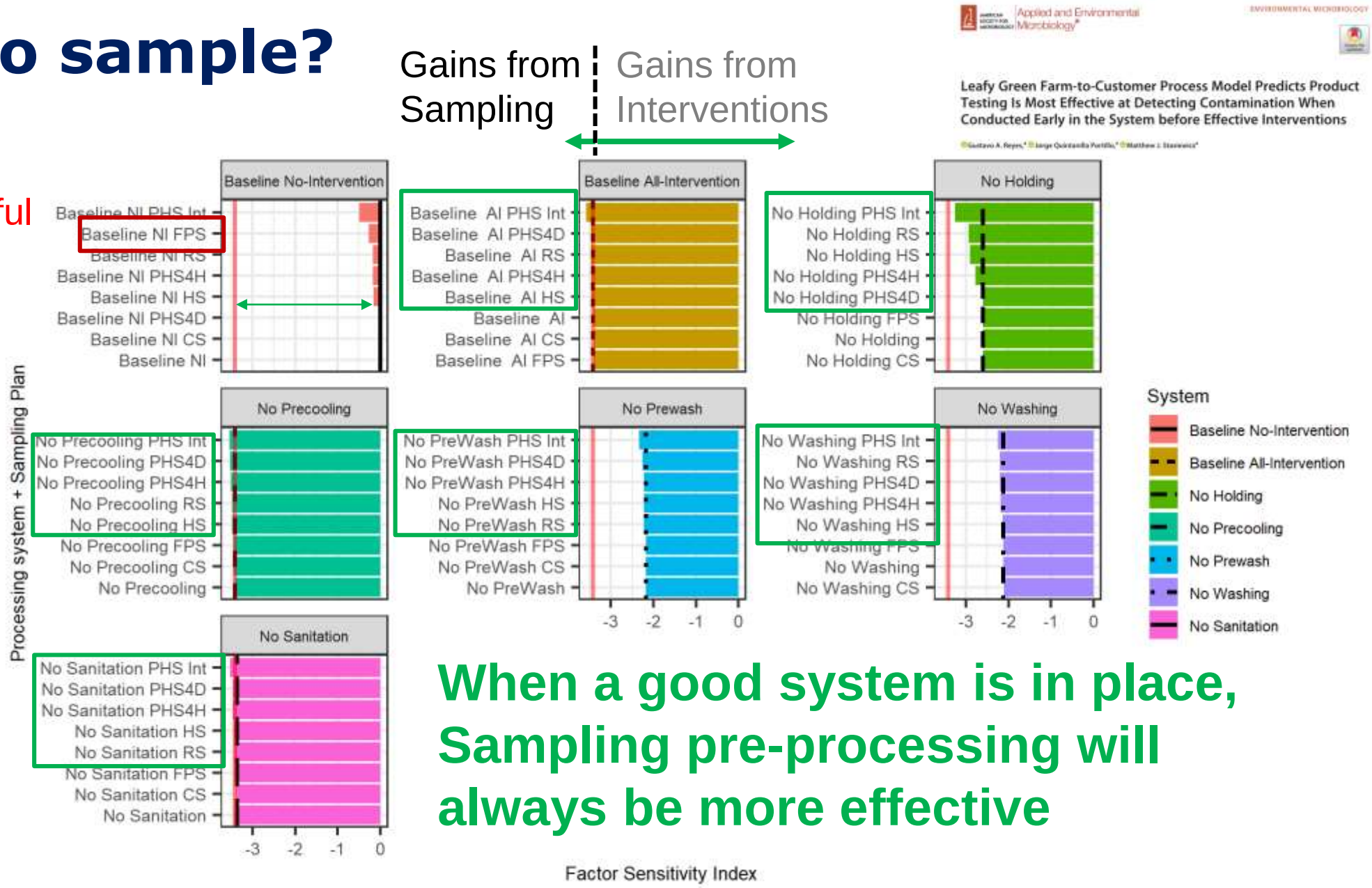
Leafy Green Farm-to-Customer Process Model Predicts Product Testing Is Most Effective at Detecting Contamination When Conducted Early in the System before Effective Interventions

Gustavo A. Reyes,[a] Jorge Quintanilla Portillo,[a] Matthew J. Stasiewicz[a]

Where to sample?

Finished product sampling is powerful If No-Interventions

Most effective sampling plans, for specific processing systems



Applied and Environmental Microbiology

Leafy Green Farm-to-Customer Process Model Predicts Product Testing Is Most Effective at Detecting Contamination When Conducted Early in the System before Effective 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

Pathogens –
Leafy Greens

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***Salmonella* –**
Powders

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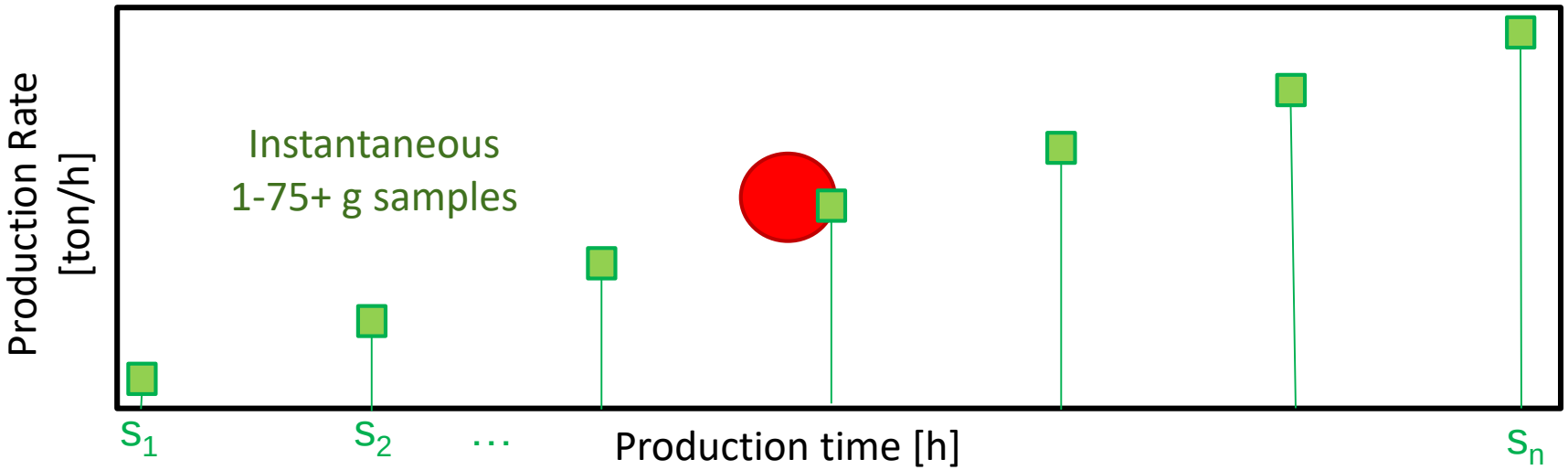
By Liz Alderman

Feb. 1, 2018

Share Tables –
Norovirus, Spoilage

Our Conceptual Model

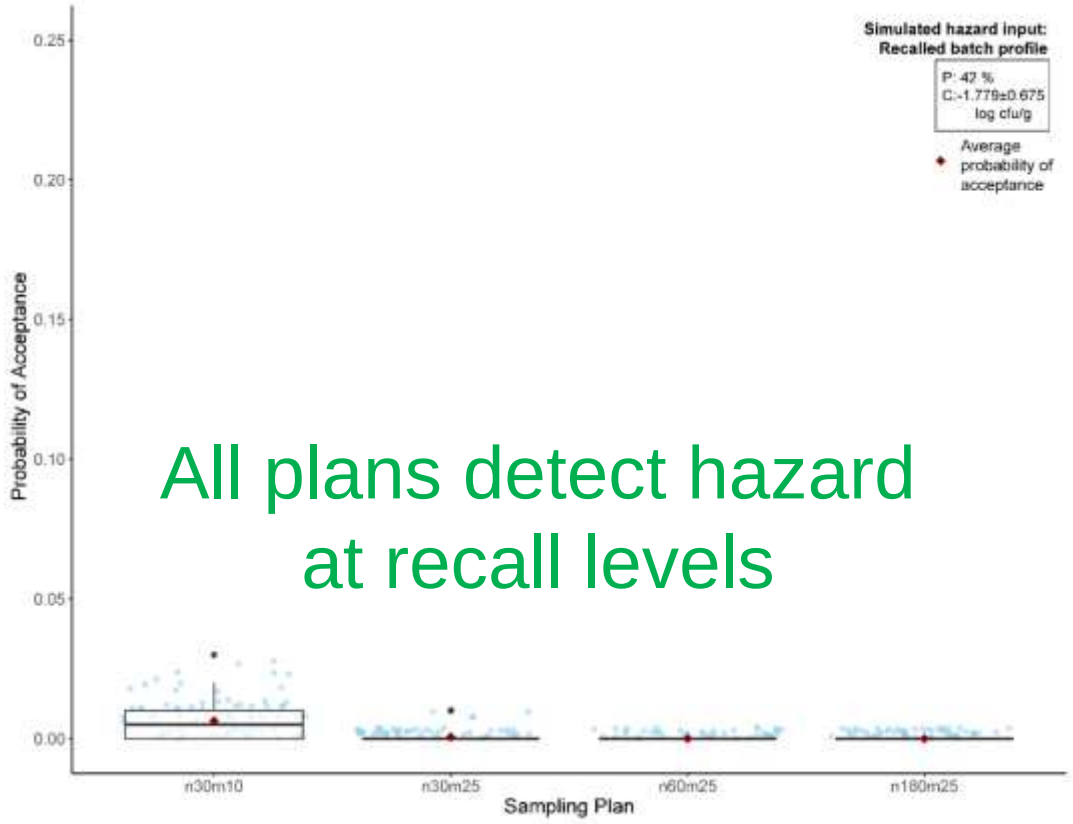
Hazards and Sampling Mapped to a 2D box



- 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**

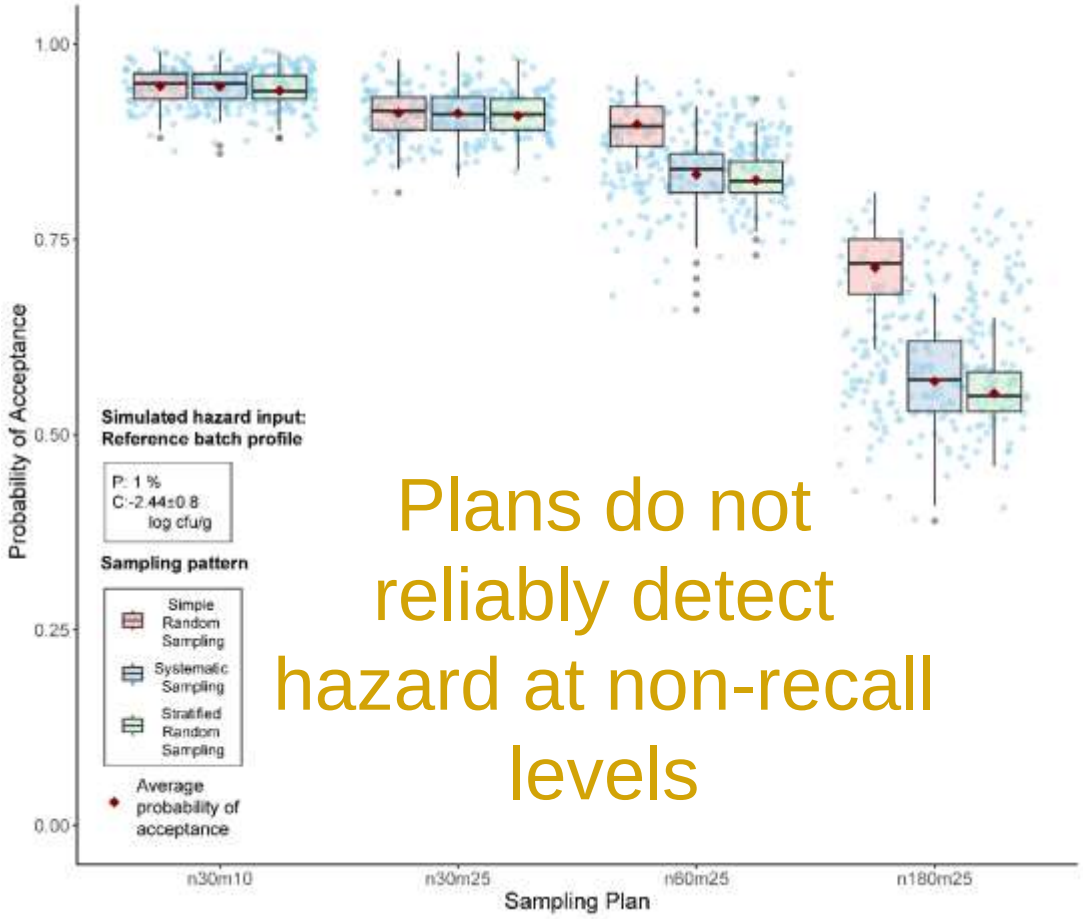
Benchmarking CODEX and more Intensive plans

Recalled Batch: Detected
High-prevalence, low- level



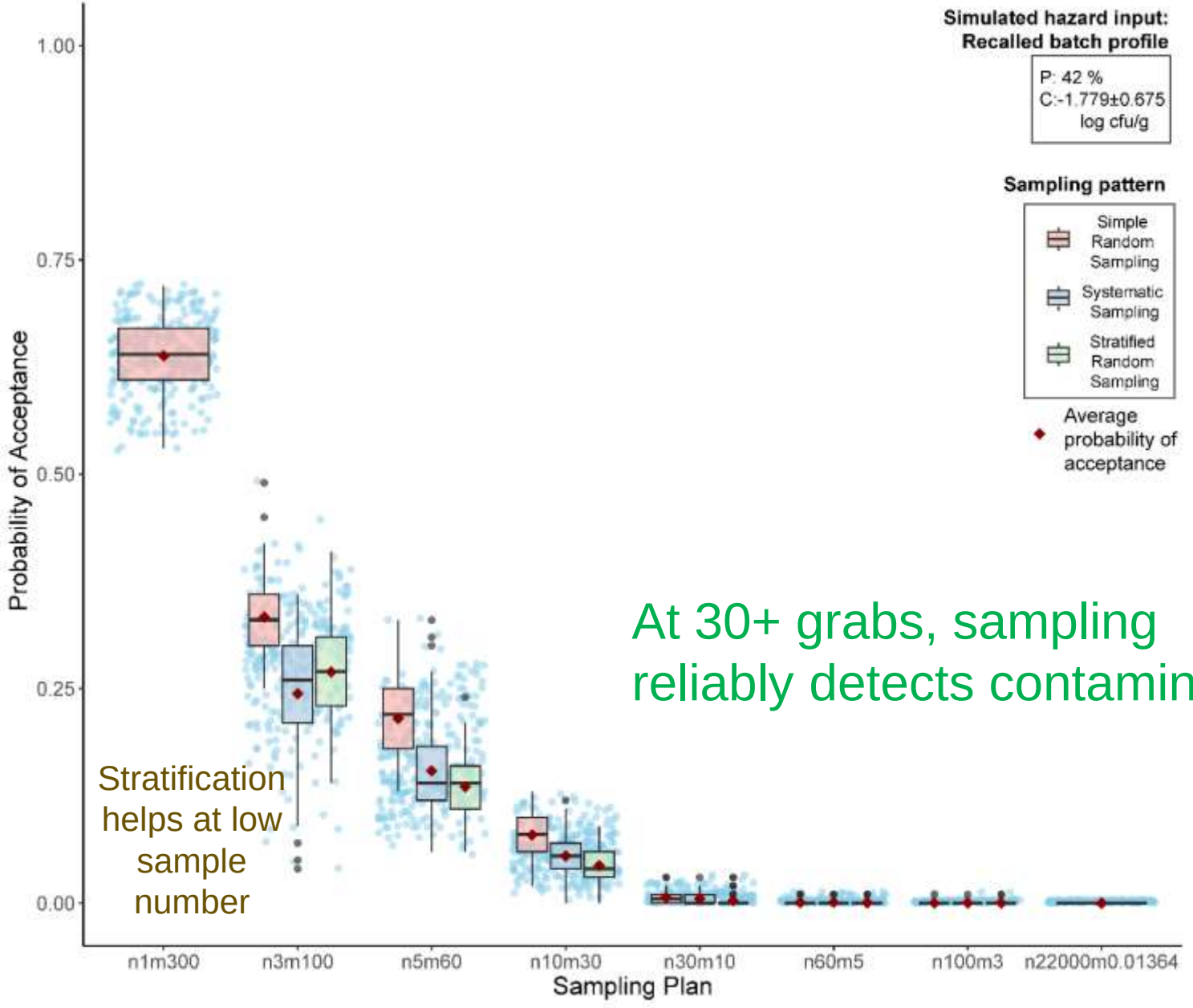
All plans detect hazard at recall levels

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



Plans do not reliably detect hazard at non-recall levels

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

The New York Times

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***Salmonella* – Powders**

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By Liz Alderman

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

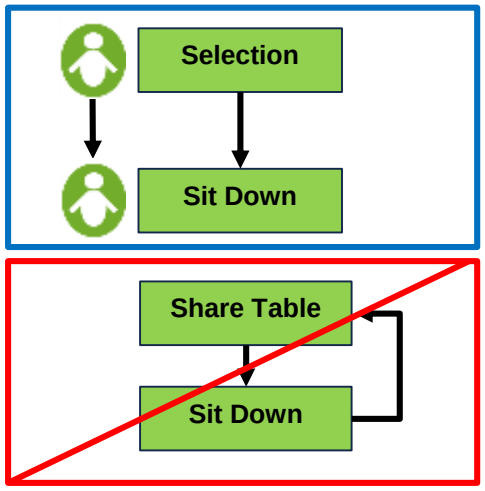
- We already accept risks in cafeterias (kids gotta eat), and schools more generally
- Given that:
  - Does sharing meaningfully increase risks compared to no sharing?
    - With respect to benefits?
  - Can these risks be managed?

Our modeling solution – QMRA (Norovirus – Apples)

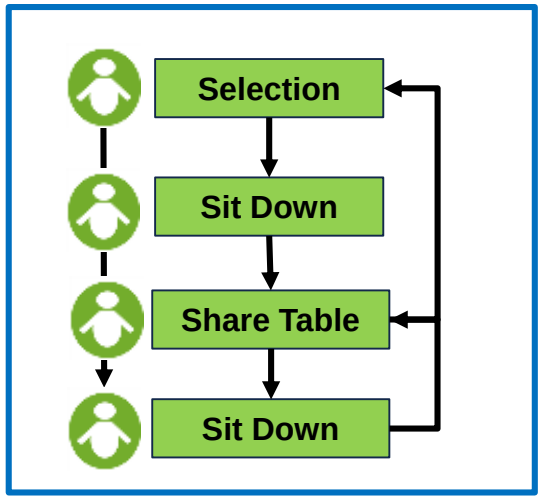
Process Model

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

Traditional Cafeteria

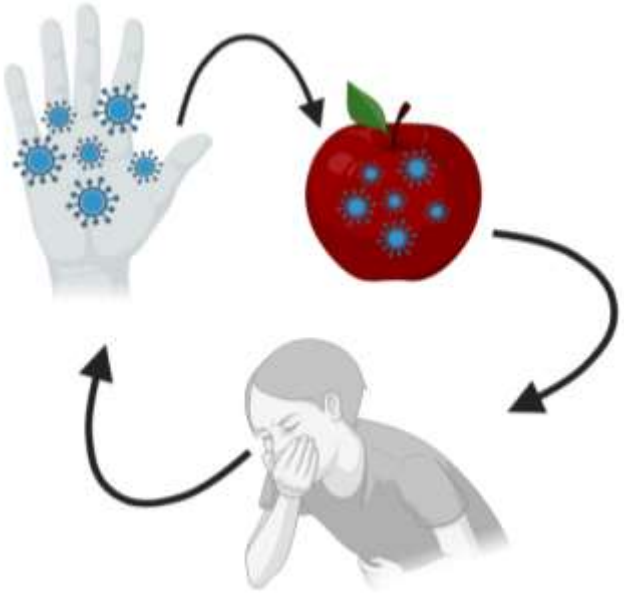


Share Table



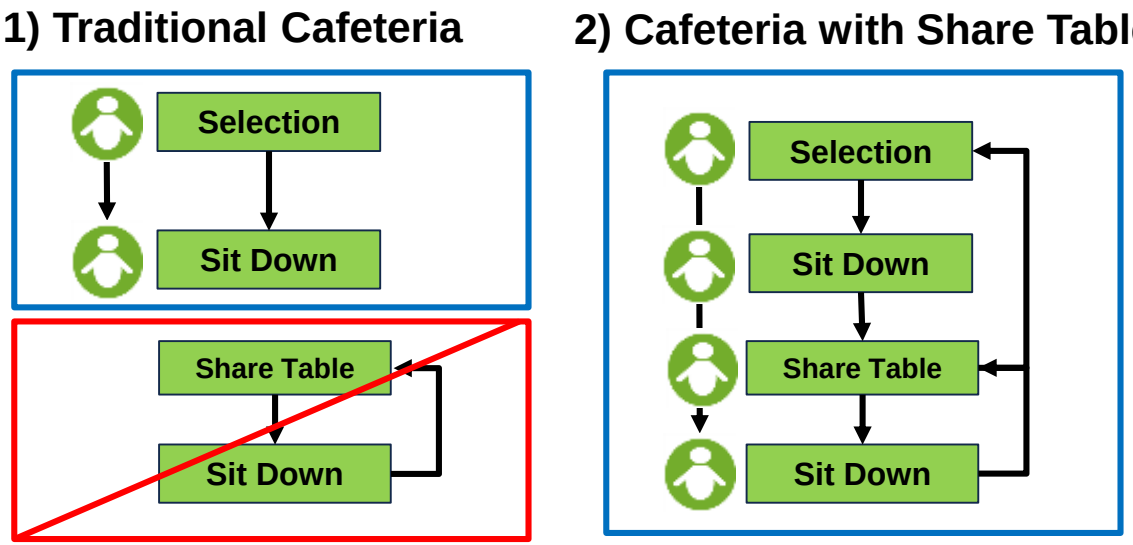
Risk Model

- 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?

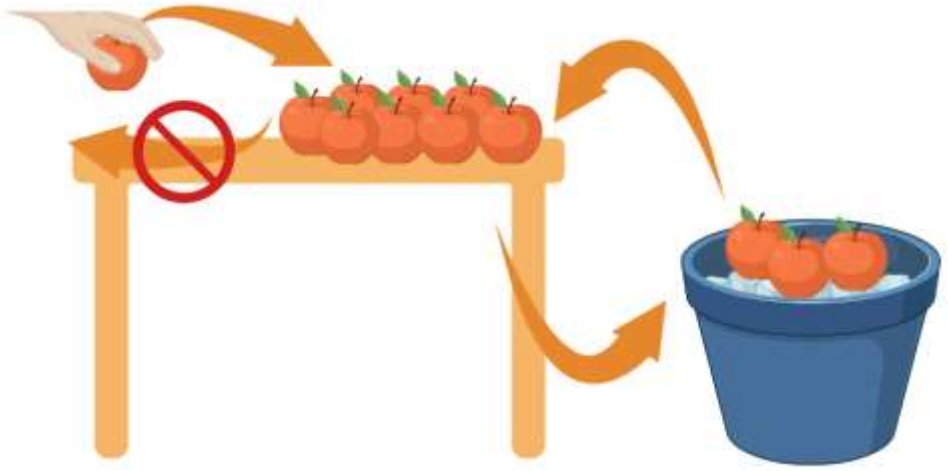


#	Scenario:	Sick Students Mean [95% variability Interval]	Illness prevalence
1	**Traditional Cafeteria**	1.49% [0.52%-2.68%]	**100.0%**
2	**Cafeteria + Share Table**	1.59% [0.67%-2.75%]	**106.8%**

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



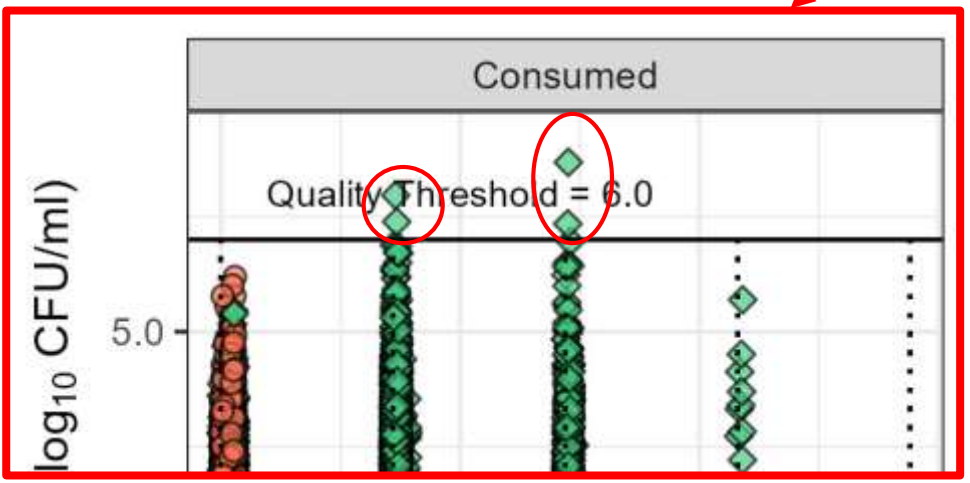
#	Scenario:	Sick Students Mean [95% variability Interval]	Illness prevalence
1	Baseline Traditional Cafeteria	1.49% [0.52%-2.68%]	**100.0%**
2	Baseline Share Table	1.59% [0.67%-2.75%]	**106.8%**
11	**Hand washing Station**	0.65% [0.14%-1.40%]	**43.6%**
12	**Hand Sanitizer Station**	0.62% [0.00%-1.89%]	**41.9%**

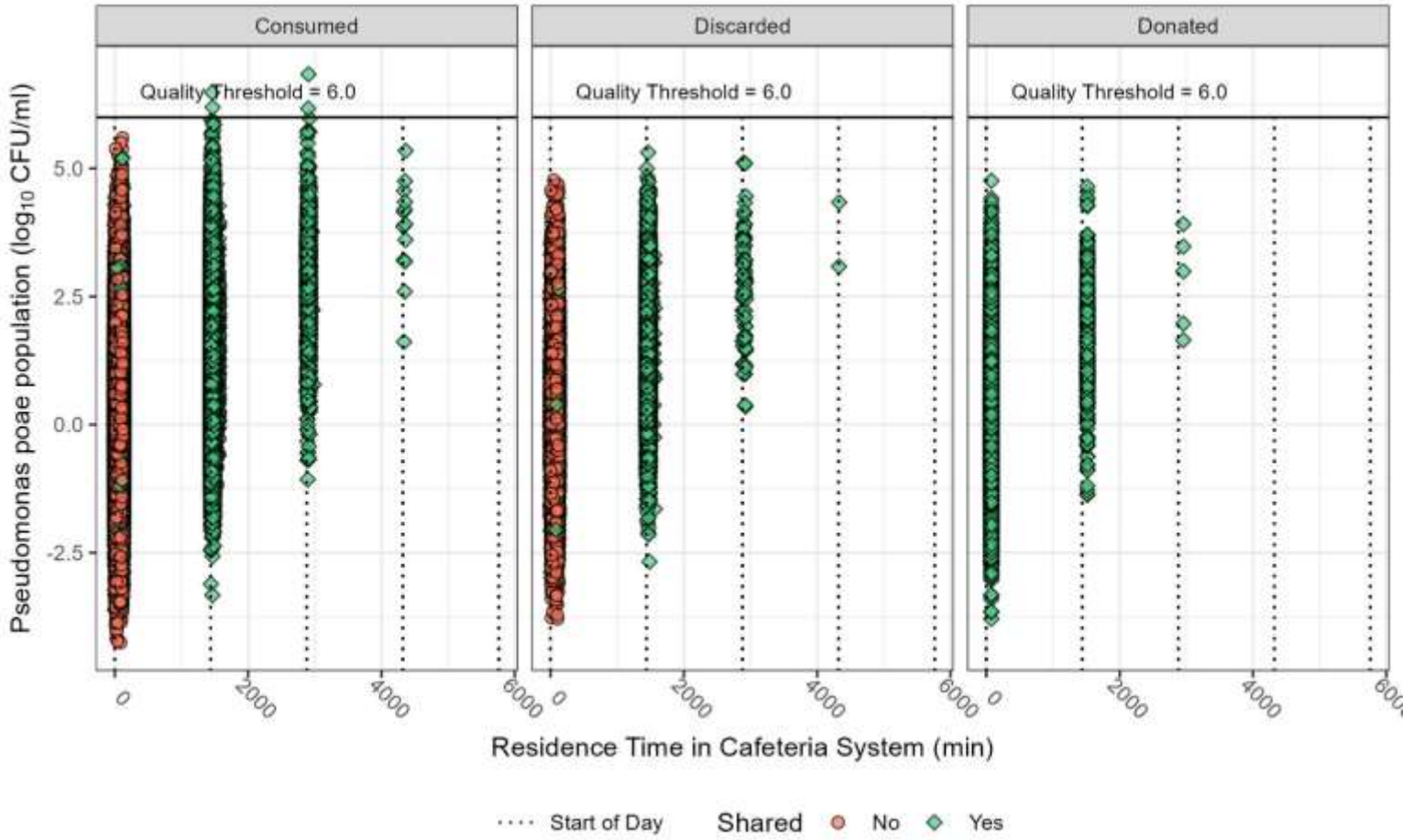
#	Scenario:	Sick Students Mean [95% variability Interval]	Illness prevalence
1	Baseline Traditional Cafeteria	1.49% [0.52%-2.68%]	**100.0%**
2	Baseline Share Table	1.59% [0.67%-2.75%]	**106.8%**
7	**One-way share table**	1.50% [0.52%-2.69%]	**100.6%**

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	Spoilage is mostly caused by overnight storage of milk in the fridge, not the ST	Most milks are consumed before they are spoiled
• 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	• Improving overnight storage temperature likely more helpful than improving ST temperature	• 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

Acknowledging residual risk is important for managing it

Can allow for better (safer, more secure) food systems than perusing impossible zero risk

Funding

CENTER for PRODUCE SAFETY

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ILSI North America

iafns

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- **Single Kernel Work**

FEED THE FUTURE INNOVATION LAB
Post-Harvest Loss Reduction

ADMI
Institute for the Prevention of Postharvest Loss
University of Illinois