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

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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

	Median Mortality Rate per Serving[a]		
Dose (cfu/serving)	Intermediate-Age	Neonatal[b]	Elderly
1	$1.5x10^{-16}$ ($1.2x10^{-146}$, $1.9x10^{-13}$)	$1.6x10^{-13}$ ($1.2x10^{-99}$, $4.0x10^{-11}$)	$4.0x10^{-15}$ ($6.3x10^{-124}$, $1.8x10^{-12}$)
10^3	$1.2x10^{-13}$ ($5.4x10^{-92}$, $6.8x10^{-11}$)	$1.3x10^{-10}$ ($4.3x10^{-56}$, $1.7x10^{-8}$)	$3.6x10^{-12}$ ($2.2x10^{-74}$, $7.2x10^{-10}$)
10^6	$1.0x10^{-10}$ ($1.9x10^{-50}$, $3.5x10^{-8}$)	$1.3x10^{-7}$ ($1.2x10^{-25}$, $8.6x10^{-6}$)	$3.1x10^{-9}$ ($5.7x10^{-38}$, $3.3x10^{-7}$)
10^9	$1.2x10^{-7}$ ($6.0x10^{-22}$, $1.9x10^{-5}$)	$1.4x10^{-4}$ ($1.6x10^{-8}$, $5.1x10^{-3}$)	$3.4x10^{-6}$ ($1.3x10^{-14}$, $1.9x10^{-4}$)
10^{10}	$1.3x10^{-6}$ ($2.5x10^{-15}$, $1.5x10^{-4}$)[c]	$1.5x10^{-3}$ ($3.3x10^{-6}$, $2.7x10^{-2}$)	$3.9x10^{-5}$ ($6.0x10^{-10}$, $1.7x10^{-3}$)
10^{12}	$1.9x10^{-4}$ ($4.9x10^{-8}$, $9.2x10^{-3}$)	$7.4x10^{-2}$ ($7.8x10^{-4}$, $2.2x10^{-1}$)	$4.9x10^{-3}$ ($9.8x10^{-6}$, $4.8x10^{-2}$)

[a] The 5th and 95th 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

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- 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 women
- 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 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]
Vegetables	*L. monocytogenes*	USA[a]	$2.8{\cdot}10^{-12}$	$6.9{\cdot}10^{-10}$	0.2	0.00069	[23]
Hard Cheese	*L. monocytogenes*	USA[a]	$4.5{\cdot}10^{-15}$	$1.4{\cdot}10^{-13}$	<0.1	<0.00035	[23]
Fermented meats	*L. monocytogenes*	Worldwide[b]	$2.5{\cdot}10^{-12}$	$6.6{\cdot}10^{-8}$	514.8	0.000066	[24]
Beef	*L. monocytogenes*	Brazil[c]	$8.1{\cdot}10^{-6}$	$1.2{\cdot}10^{-6}$	252	0.0000012	[25]
Beef	*Salmonella*	Brazil[c]	$4.7{\cdot}10^{-3}$	$8.6{\cdot}10^{-4}$	179,496	0.00086	[25]
Leafy green vegetable salad	*Salmonella*	The Netherlands[d]	$6.83{\cdot}10^{-6}$	$1.1{\cdot}10^{-5}$	187	10.82	[26]
Oysters	*Vibrio*	USA[a]	$4.5{\cdot}10^{-4}$ to $8.1{\cdot}10^{-1}$	$9.7{\cdot}10^{-6}$	2826	8.6	[27]
Oysters	*Vibrio*	Taiwan[e]	$8.56{\cdot}10^{-5}$	$2.8{\cdot}10^{-6}$	67	2.8	[28]
Shrimps	*Vibrio*	Malaysia[f]	$4.80{\cdot}10^{-6}$	$3.9{\cdot}10^{-6}$	123	12	[29]

[a] On the basis of a population of 290 million.
[b] On the basis of a population of 7.8 billion.
[c] On the basis of a population of 209.5 million.
[d] On the basis of a population of 17.28 million.
[e] On the basis of a population of 23.57 million.
[f] 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

Duijm, N. J. (2009). *Acceptance criteria in Denmark and the E.U. environmental project report No. 1269*. Copenhagen: Danish Environmental Protection Agency, Ministry of the Environment.

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

TITLE PAGE

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*

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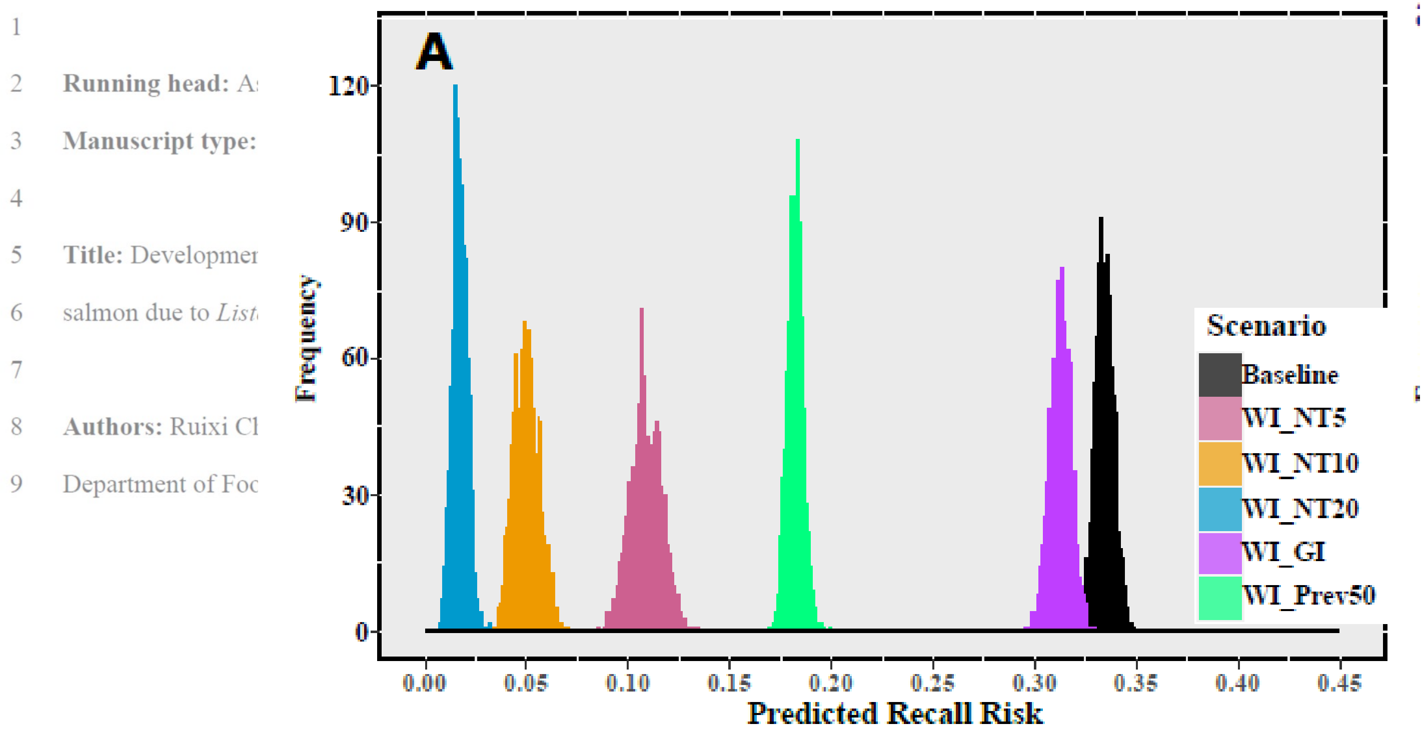

Recall risk assuming a lot with 4% Lm prevalence is sampled with n=60 (baseline) and impact of various interventions on re-call risk

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Validation of a Previously Developed Geospatial Model That Predicts the Prevalence of *Listeria monocytogenes* in New York State Produce Fields

Daniel Weller,[a] Suvash Shiwakoti,[b] Peter Bergholz,[b] Yrjo Grohn,[c] Martin Wiedmann,[a] Laura K. Strawn[d]

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Validation of a Previously Devel
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Fields

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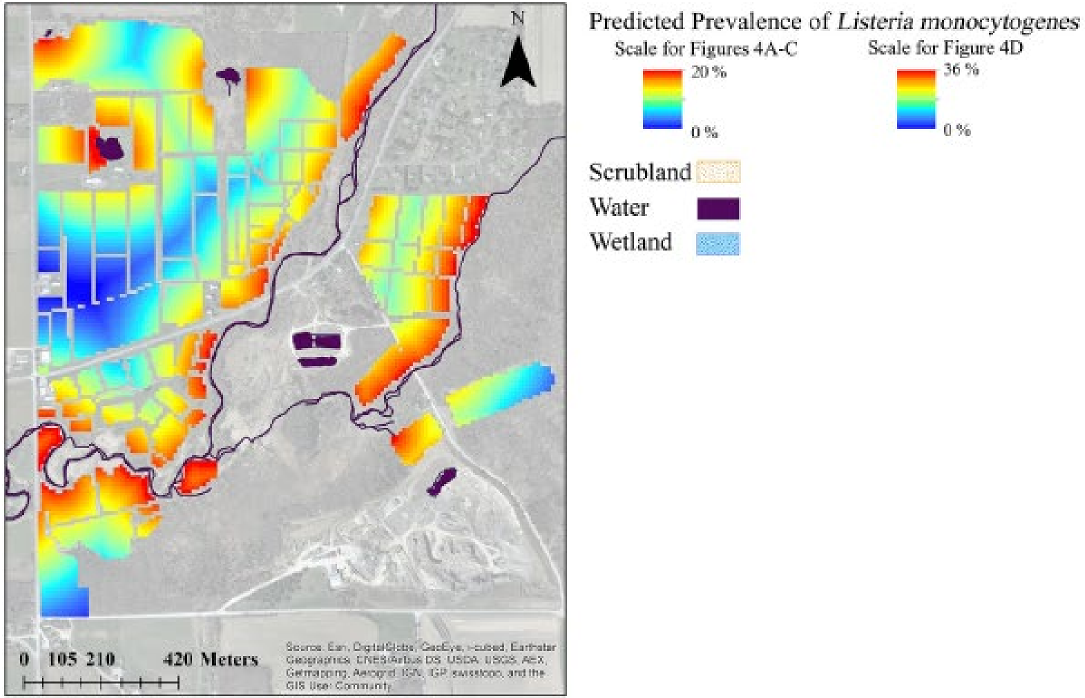

SCIENTIFIC REPORTS

OPEN

EnABLe: An agent-based model to understand *Listeria* dynamics in food processing facilities

Received: 22 August 2018

Claire Zoellner[1], Rachel Jennings[1], Martin Wiedmann[2] & Renata Ivanek[1]

PLOS ONE

RESEARCH ARTICLE

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

Cecil Barnett-Neefs[1]*, Genevieve Sullivan[1,2], Claire Zoellner[3], Martin Wiedmann[2], Renata Ivanek[1]

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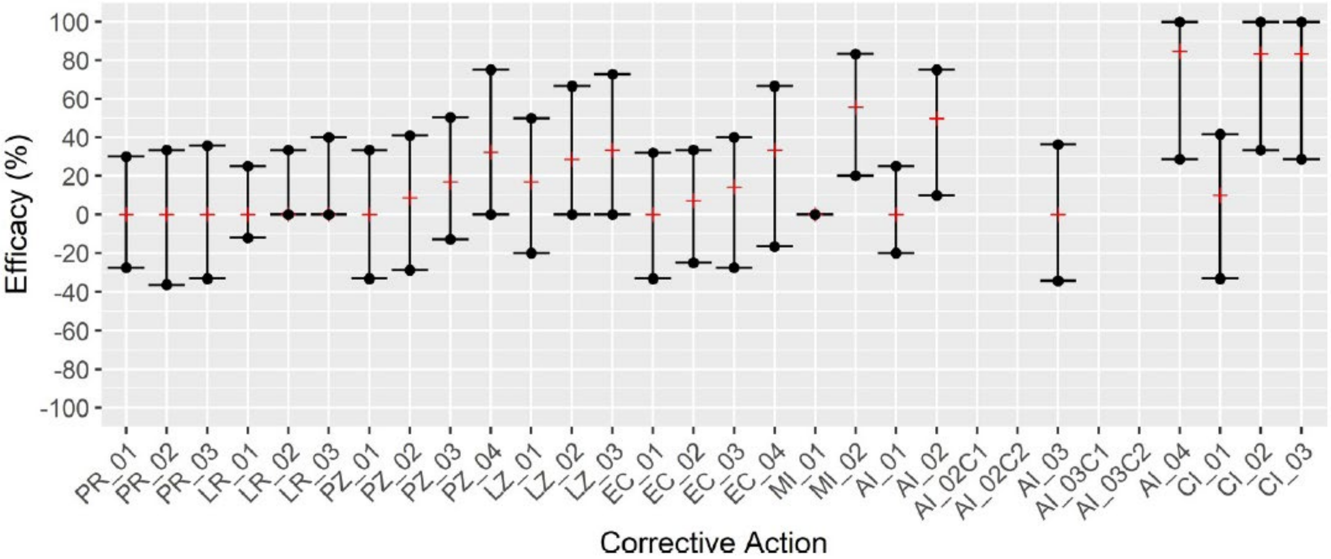

Fig 6. Comparison of corrective action efficacy against baseline conditions in Facility B. Efficacy was calculated

Take home messages

- While "risk-based food safety decision making" has so far focused on public heath 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