Risk Assessment and Decision-Support Tools in Food Safety

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Overview

- Drivers Behind Increased Use of Tools
- Examples of Tools
  - JEMRA applications
  - iRisk
  - Impacts of Delays in Outbreak Detection
  - Public Health Preparedness
- A Glimpse into the Future
Drivers toward Increased Use of Modelling across Public Health Fields

- Reference to a ‘risk-based’ rationale for decision-making is increasingly common worldwide
- Increased attention to roles and accountability
  - Seeking more transparency from expert bodies
- More recent
  - World Trade Organization
  - Enabling Legislation of many Agencies
  - Reorganization of Inspectorates
  - ISO 31000: Risk Management Standard
Procedural Rationale for Formal Tool Development

- Management of Overwhelming Complexity
  - Multi-hazard, Multi-pathway, Multi-agent
  - Multi-outcome, complex event sequences

- Maintaining Focus on Avoiding Rare, But Major or Catastrophic Events

- Common Interdisciplinary Language

- Links to the Appropriate Toolboxes:
  - Decision Sciences
  - Risk and Reliability Sciences
Means-Based Rationale for Formal Tool Development

- Societal expectations for the application of information technology and knowledge are growing exponentially.

- The toolbox for rapid integration of data and knowledge from diverse sources is now a standard part of information technology.

- Web-based tools remove many technical barriers.
Outcome-based Rationale for Formal Tool Development

- Primarily, when there is a need to weigh exposure to risk against beneficial (desirable) activities or products

- Meeting the "Reasonable Person" test
  - "shall take reasonable steps to avoid…"
  - "shall ensure to a reasonable level of certainty…"
  - "safe in reasonably foreseeable conditions…"
  - "inspected at such frequencies as deemed necessary to ensure safe operation …"
Examples of Tools

- JEMRA applications
- iRisk
- Impacts of Delays in Outbreak Detection
- Outbreak Preparedness
JEMRA Applications

- *Cronobacter sakazakii* in powdered infant formula
- Microbiological Sampling Plan Analysis Tool
- Risk Management Tool for Control of Salmonella and Campylobacter in Poultry
Risks in Powdered Infant Formula

Risk Assessment Model for Enterobacter sakazakii in Powdered Infant Formula

Step 3: Define Preparation and Handling

Please define your preparation methods (1 required, 5 maximum). For each preparation method, you will need to define parameters for four stages: Preparation before cooling, cooling, warming, and feeding period.

Go to Preparation and Handling Guidance for detailed guidance on entering preparation methods.

Preparation Methods

<table>
<thead>
<tr>
<th>Method Name (Please use this table to add, remove and update methods)</th>
<th>Update Name</th>
<th>Remove</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current NICU Guidelines</td>
<td>update</td>
<td>remove</td>
</tr>
<tr>
<td>Proposed NICU Guidelines</td>
<td>update</td>
<td>remove</td>
</tr>
<tr>
<td>Add</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chicken Production Risk Management Tool

- A risk management simulation tool based on the Proposed Draft Guidelines for Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat
- Can describe the complete production-to-consumption process flow, using different process types
- Computes the residual risk between a baseline process flow and a process flow applying selected interventions
Chicken Production Risk Management Tool

Result Path 1 (Probability: 0.0100)

<table>
<thead>
<tr>
<th>IC</th>
<th>Initial Contamination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal (Mean: 6, Standard deviation: 1.2)</td>
</tr>
<tr>
<td></td>
<td>Starts at Step: First Step</td>
</tr>
<tr>
<td></td>
<td>Within Prevalence: 0.65</td>
</tr>
<tr>
<td></td>
<td>Between Prevalence: 0.6</td>
</tr>
</tbody>
</table>

| P0-1 | Manage chickens - No change                              |
|      | ** Prevalence only, concentration not modelled **       |

| INT-1 | Fly screens                                             |
|       | Fixed Value (Value: 0.7)                               |

Result Path 2 (Probability: 0.990)

<table>
<thead>
<tr>
<th>IC</th>
<th>Initial Contamination</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td></td>
<td>Between Prevalence: 0.6</td>
</tr>
</tbody>
</table>

| P0-1 | Manage chickens - No change                              |
|      | ** Prevalence only, concentration not modelled **       |

| INT-1 | Fly screens                                             |
|       | Fixed Value (Value: 0.7)                               |

Residual Risk

Residual risk of pathway after interventions: 0.17

Residual risk of pathway after interventions: 0.16

Weighted Residual Risk of all Paths: 0.16
Two main objectives:

- Rapid Comparative Risk Assessment
- Knowledge Management
iRisk

- Web-based risk assessment workspace
  - User Interface
  - Relational Database
  - Computational Tool
  - Report Generation
  - Library and Sharing Features
## Demonstration

### Risk Scenario

<table>
<thead>
<tr>
<th>Run</th>
<th>Scenario</th>
<th>Food</th>
<th>Hazard</th>
<th>Process Model</th>
<th>Consumption Model</th>
<th>Dose Response Model</th>
<th>DALY Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
<td>Afatoxin in jio, hypothetical process model</td>
<td>Peanut Butter</td>
<td>Afatoxin B1</td>
<td>Hypothetical model</td>
<td>Peanut Butter consumption by US population</td>
<td>Non-threshold linear for Afatoxin B1</td>
<td>Liver cancer</td>
</tr>
<tr>
<td>Edit</td>
<td>Ciguatoxin in Fish</td>
<td>Fish</td>
<td>Ciguatoxin</td>
<td>Ciguatoxin in Fish</td>
<td>Consumption of Fish</td>
<td>Exponential Dose Response for Ciguatoxin</td>
<td>Liver cancer</td>
</tr>
<tr>
<td>Edit</td>
<td>Salmonella in peanut butter, Ir specific for peanut butter</td>
<td>Peanut Butter</td>
<td>Salmonella</td>
<td>Salmonella in Peanut Butter, Post-occurring contamination</td>
<td>Peanut Butter consumption by US population</td>
<td>Dose response for Salmonella in peanut butter</td>
<td>Samonilosis in the general population (Olaniyan et al., 2011)</td>
</tr>
<tr>
<td>Edit</td>
<td>Salmonella in Peanut Butter, General Population</td>
<td>Peanut Butter</td>
<td>Salmonella</td>
<td>Salmonella in Peanut Butter, Post-occurring contamination</td>
<td>Peanut Butter consumption by US population</td>
<td>Beta Poisson for Salmonella</td>
<td>Samonilosis in the general population (Scallan et al., 2017)</td>
</tr>
</tbody>
</table>

Elements in orange are not complete.

- Override consumption model for acute chemical and microbial hazards
  (10,000,000 servings of 100g)
### Process Stages

**Process Model:** Listeria during production of Soft Cheese

**Initial Fixed Values:**
- **Prevalence:** Value: 0.0273

**Initial Concentration (Microbial):**
- **Triangular Distribution**
  - Minimum: -1
  - Mode: 0
  - Maximum: 1.57

**Unit Mass:** 5E6 (g)

**Reference/Rationale:**

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Stage Name</th>
<th>Process Type</th>
<th>Mass (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit 2</td>
<td>Combining Milk in Tanker</td>
<td>Pooling</td>
<td>22E6</td>
</tr>
<tr>
<td>Edit 3</td>
<td>Pasteurization</td>
<td>Decrease</td>
<td>No change</td>
</tr>
<tr>
<td>Edit 4</td>
<td>Post-pasteurization</td>
<td>Increase (addition)</td>
<td>No change</td>
</tr>
<tr>
<td>Edit 5</td>
<td>Draining</td>
<td>Evaporation/Dilution</td>
<td>Computed</td>
</tr>
<tr>
<td>Edit 6</td>
<td>Portioning</td>
<td>Partitioning</td>
<td>227</td>
</tr>
<tr>
<td>Edit 7</td>
<td>Ripening</td>
<td>Decrease</td>
<td>No change</td>
</tr>
<tr>
<td>Edit 8</td>
<td>Storage</td>
<td>Increase (growth)</td>
<td>No change</td>
</tr>
</tbody>
</table>
iRisk Sample output

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Final Conc</th>
<th>Final Prev</th>
<th>Mean Risk</th>
<th>Eating Occ</th>
<th>Total DALYs</th>
<th>Annual DALYs</th>
<th>DALYs per EO</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA1</td>
<td>0.86</td>
<td>4.90E-06</td>
<td>4.20E-07</td>
<td>1.70E+10</td>
<td>130</td>
<td>130</td>
<td>7.90E-09</td>
</tr>
<tr>
<td>SA2</td>
<td>0.86</td>
<td>0.000049</td>
<td>4.20E-06</td>
<td>1.70E+10</td>
<td>1300</td>
<td>1300</td>
<td>7.90E-08</td>
</tr>
<tr>
<td>SA3</td>
<td>0.86</td>
<td>0.00049</td>
<td>0.000042</td>
<td>1.70E+10</td>
<td>13000</td>
<td>13000</td>
<td>7.90E-07</td>
</tr>
</tbody>
</table>

Annual DALYs

![Graph showing DALYs for different scenarios](image-url)
Web-based Dissemination

Technical Development Environment

Computational Model (CM)

Technical Documentation

Web-Based Dissemination

Analytica™

PDF
Web-based Dissemination

- Administration and Security
- Supporting Information
- Context-Specific Help
- Exact Replicate of Technical Model
Modeling the Public Health System Response to a Terrorist Event
What is the tool for?

• Enables users to explore the role of components of the public health system in response to food contamination events

• Numerous components can be explored, and include:
  - Health system response components
    • e.g. likelihood to investigate causative agent, time it takes elucidate causative agent etc.
  - Protocols regarding public advisory issue
  - Impact of consumer compliance with advisory
  - Impact of speed of removal of contaminated product from the food chain
## Data Entry

### Bacillus Anthracis

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Most Likely</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likelihood of symptoms given ingestion</td>
<td>45</td>
<td>50</td>
<td>65</td>
</tr>
<tr>
<td>Likelihood seek treatment</td>
<td>80</td>
<td>92</td>
<td>97</td>
</tr>
<tr>
<td>Likelihood aetiology is investigated</td>
<td>80</td>
<td>85</td>
<td>90</td>
</tr>
<tr>
<td>Likelihood reported given cause</td>
<td>92</td>
<td>95</td>
<td>99</td>
</tr>
<tr>
<td>Delay to symptoms given ingestion</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Delay to seek treatment</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Delay to identification of causative agent</td>
<td>2</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Delay to report</td>
<td>0.5</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Number of confirmed cases till advisory issued</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of confirmed cases in 1 region before issue of advisory</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of days from advisory to complete removal of suspected source from market</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance of consumer with advisory</td>
<td>75</td>
<td>85</td>
<td>90</td>
</tr>
</tbody>
</table>
Product Type Selection

**Expected Total Number of People Exposed**
1000

**Rate of exposure per time step**
- **Shelf stable**
- **Frozen food**
- **Medium term shelf life**
- **Short Shelf Life**

**Expected Number of Exposures**

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NATIONAL CENTER FOR
FOOD PROTECTION AND DEFENSE
A Homeland Security Center of Excellence

PRIMARY PRODUCTION ➔ HARVEST ➔ TRANSPORTATION ➔ STORAGE ➔ PROCESSING ➔ DISTRIBUTION ➔ RETAIL/FOOD SERVICE ➔ CONSUMER
Simulation of Health Care System Preparedness for Outbreaks

- Five years
- $2+ billion
- How do we know if we are prepared?
- What are the best uses for future funding?
Examples of Policy Questions

- How does buying more equipment/supplies affect the number of patients who receive appropriate treatment?
- How do changes in triage and treatment protocols affect the number of patients who receive appropriate treatment?
- Does using exclusion criteria increase the number of patients who receive appropriate treatment?
Present State

♦ Tool Development Spans the Full Food Safety System
  ♦ Scientific Databases
  ♦ Single Food-Hazard Combination Tools
  ♦ Multiple Hazard, Single Food Tools
  ♦ Comparative Risk Assessment Tools
  ♦ Activity Specific Tools (sampling)
  ♦ Role of Public Health System in Food Safety

♦ Poorly integrated, lacks a master architect
Near Future State

- Tighter integration of data and information into public domain tools
  - Sampling of raw materials,
  - Predictive microbiology,
  - Role of indicator organisms,
  - Rapid risk assessment,
  - End product sampling,
  - Consumer behavior data
  - Consumption models
A Few Questions

♦ What would REACH for food safety look like?

♦ How many different ways are there to demonstrate that a food is safe?

♦ Which is easier:
  ♦ Demonstrating appropriate evidence of expenses from a trip taken two years ago
  ♦ Providing a report demonstrating the safety case for a food product that you are responsible for.
Future State

♦ Knowledge Management for Food Safety
  ♦ Tools to Support the Development and Management of a formal safety case for any commodity or food
  ♦ Goal: Not just safe but "Known to be Safe"
  ♦ "Epistemic audit"
Future State

- Systems-Level Characterization of the whole Food Safety System
  - Inspections,
  - Audits,
  - HACCP,
  - Contractual Requirements,
  - Communications