Risk Assessment and Decision-Support Tools in Food Safety

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JIFSAN Advisory Council Annual Symposium
April 27, 2010
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></td>
<td></td>
</tr>
<tr>
<td>Proposed NICU Guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Add</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)

Initial Contamination
Normal (Mean: 6, Standard deviation: 1.2)
Starts at Step: First Step
Within Prevalence: 0.65
Between Prevalence: 0.6

PO-1
Manage chickens - No change

** Prevalence only, concentration not modelled **

INT-1
Fly screens

B↓ Fixed Value (Value: 0.7)

---

Result Path 2 (Probability: 0.990)

Initial Contamination
Normal (Mean: 6, Standard deviation: 1.2)
Starts at Step: First Step
Within Prevalence: 0.65
Between Prevalence: 0.6

PO-1
Manage chickens - No change

** Prevalence only, concentration not modelled **

INT-1
Fly screens

B↓ Fixed Value (Value: 0.7)

---

Concentration (log counts)

Carcass Concentration
Between Flock Prevalence
Within Flock Prevalence

Stage
Residual Risk
Residual risk of pathway after interventions: 0.17

RR
Residual Risk
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
<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>Aflatoxin in peanut butter, hypothetical process model</td>
<td>Peanut Butter</td>
<td>Aflatoxin B1</td>
<td>Hypothetical model</td>
<td>Peanut Butter consumption by US population</td>
<td>Non-threshold linear for Aflatoxin 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>Ciguatoxin (acute) (general population)</td>
<td>Placeholder</td>
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<tr>
<td>Edit</td>
<td>Salmonella in peanut butter, DR specific for peanut butter</td>
<td>Peanut Butter</td>
<td>Salmonella</td>
<td>Salmonella in Peanut Butter, Post-roasting contamination</td>
<td>Peanut Butter consumption by US population</td>
<td>Dose response for Salmonella in peanut butter</td>
<td>Salmonellosis in the general population (Scallan et al., 2011)</td>
</tr>
</tbody>
</table>
# Process Model: Listeria during production of Soft Cheese

## Process Stages

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Stage Name</th>
<th>Process Type</th>
<th>Mass (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
<td>2 Combining Milk in Tanker</td>
<td>Pooling</td>
<td>2.2E6</td>
</tr>
<tr>
<td>Edit</td>
<td>3 Pasteurization</td>
<td>Decrease</td>
<td>No change</td>
</tr>
<tr>
<td>Edit</td>
<td>4 Post-pasteurization Contamination</td>
<td>Increase (addition)</td>
<td>No change</td>
</tr>
<tr>
<td>Edit</td>
<td>5 Draining</td>
<td>Evaporation/Dilution</td>
<td>Computed</td>
</tr>
<tr>
<td>Edit</td>
<td>6 Portioning</td>
<td>Partitioning</td>
<td>227</td>
</tr>
<tr>
<td>Edit</td>
<td>7 Ripening</td>
<td>Decrease</td>
<td>No change</td>
</tr>
<tr>
<td>Edit</td>
<td>8 Storage</td>
<td>Increase (growth)</td>
<td>No change</td>
</tr>
</tbody>
</table>

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

**Initial Concentration (Microbial: log cfu/g or log pfu/g; Chemical: g/g):**
- Triangular
- Minimum: -1
- Mode: 0
- Maximum: 1.57

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

**Reference/Rationale:**

---

**New Stage**
iRisk Sample output

Sensitivity Analysis Report for Salmonella in Peanut Butter, General Population

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Final Conc</th>
<th>Final Prev</th>
<th>Mean Risk Eating Occ</th>
<th>Total DALY Annual 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>170E+10</td>
</tr>
<tr>
<td></td>
<td>130</td>
<td>130</td>
<td>7.90E-09</td>
<td></td>
</tr>
<tr>
<td>SA2</td>
<td>0.86</td>
<td>0.000049</td>
<td>4.20E-06</td>
<td>170E+10</td>
</tr>
<tr>
<td></td>
<td>1300</td>
<td>1300</td>
<td>7.90E-08</td>
<td></td>
</tr>
<tr>
<td>SA3</td>
<td>0.86</td>
<td>0.000049</td>
<td>0.000042</td>
<td>1.70E+10</td>
</tr>
<tr>
<td></td>
<td>13000</td>
<td>13000</td>
<td>7.90E-07</td>
<td></td>
</tr>
</tbody>
</table>

Annual DALYs
Web-based Dissemination

Technical Development Environment

Computational Model (CM)
Technical Documentation

Analytica™
PDF

Web-Based Dissemination
Web-based Dissemination

- Administration and Security
- Supporting Information
- Context-Specific Help
- Exact Replicate of Technical Model

CM
Modeling the Public Health System Response to a Terrorist Event
Contamination Incident

Consumption of food

Consequences of exposure

Response of Health Care Provider

Impact

Advisory Issue

Confirmed Cases

PHS Investigation

Unreported Cases / exposures
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>Parameter</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

Rate of exposure per time step

- Orange: Shelf stable
- Blue: Frozen food
- Pink: Medium term shelf life
- Green: Short Shelf Life

Expected Number of Exposures

Expected Total Number of People Exposed: 1000
Example Results

July 8, 2007 08:08:28

Exposure Occurrence and Reporting

Pathway of Exposures

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of exposures</td>
<td>517</td>
</tr>
<tr>
<td>Number averted by advisory</td>
<td>470</td>
</tr>
<tr>
<td>Number symptomatic</td>
<td>282</td>
</tr>
<tr>
<td>Number asymptomatic</td>
<td>233</td>
</tr>
<tr>
<td>Number don’t seek treatment</td>
<td>58</td>
</tr>
<tr>
<td>Number not investigated</td>
<td>34</td>
</tr>
<tr>
<td>Number of confirmed cases</td>
<td>190</td>
</tr>
</tbody>
</table>

Exposures By Day

<table>
<thead>
<tr>
<th>Time (days)</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>3</td>
<td>40</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

Day Issued: 9
Day of Last Exposure: 19
Day Incident Over: 24
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