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 …”

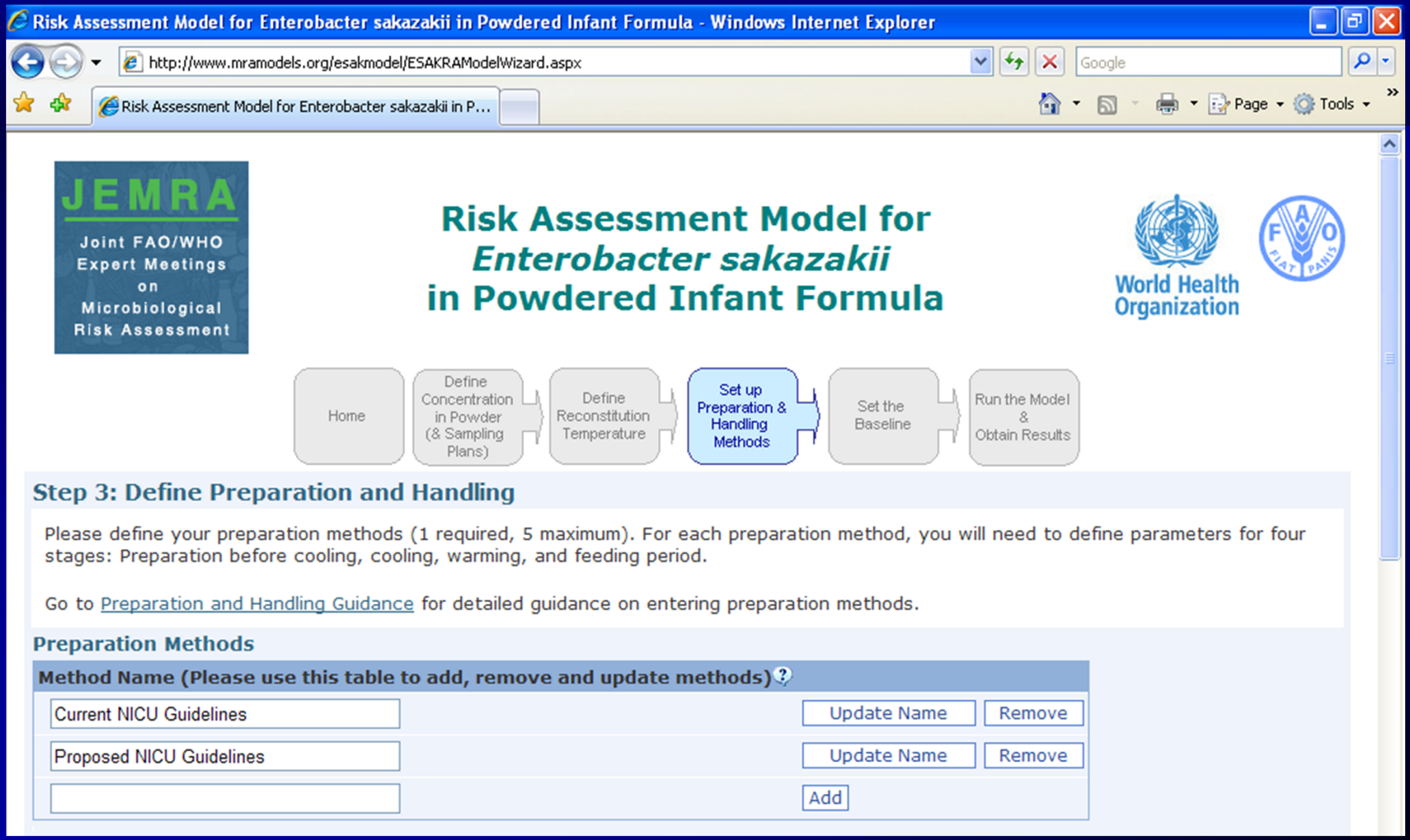
Examples of Tools

- 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

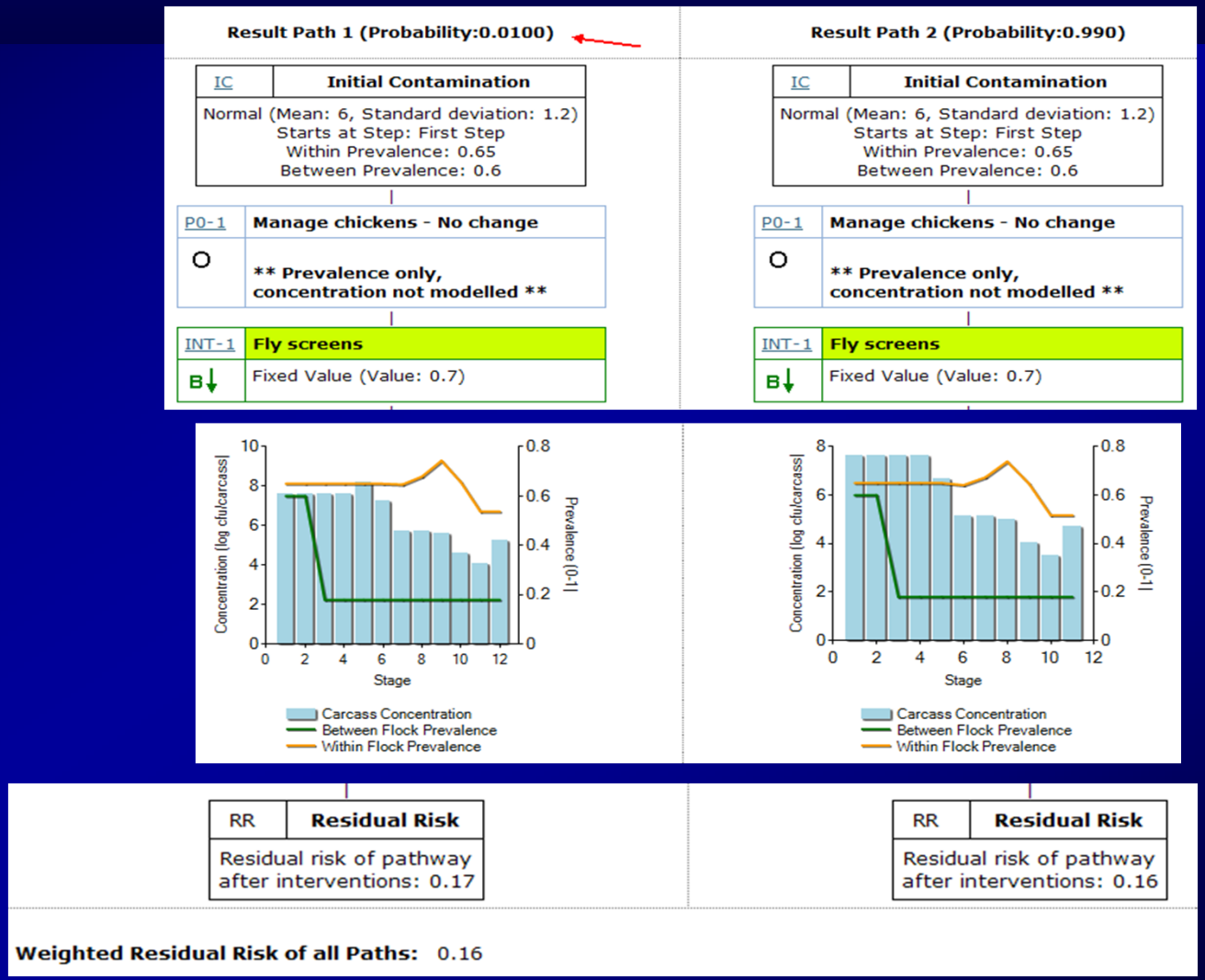
Risks in Powdered Infant Formula



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



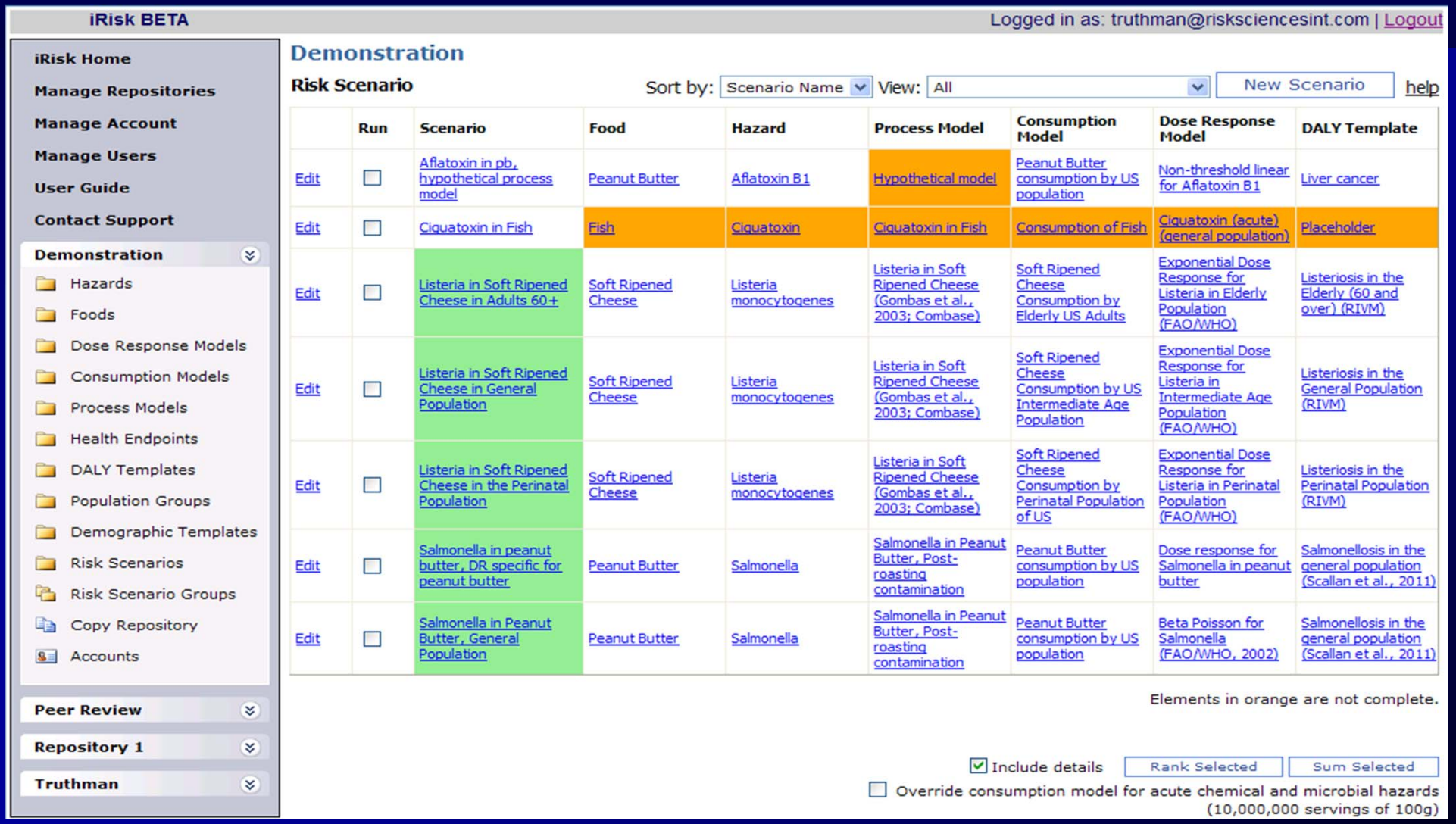
iRisk

- 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

iRisk


iRisk BETA
Logged in as: truthman@risksciencesint.com | Logout
iRisk Home
Manage Repositories
Manage Account
Manage Users
User Guide
Contact Support
Demonstration
Hazards
Foods
Dose Response Models
Consumption Models
Process Models
Health Endpoints
DALY Templates
Population Groups
Demographic Templates
Risk Scenarios
Risk Scenario Groups
Copy Repository
Accounts
Peer Review
Repository 1
Truthman
Demonstration
Risk Scenario
Sort by: Scenario Name
View: All
New Scenario
help
Run
Scenario
Food
Hazard
Process Model
Consumption Model
Dose Response Model
DALY Template
Edit
Aflatoxin in pb, hypothetical process model
Peanut Butter
Aflatoxin B1
Hypothetical model
Peanut Butter consumption by US population
Non-threshold linear for Aflatoxin B1
Liver cancer
Edit
Ciguatoxin in Fish
Fish
Ciguatoxin
Ciguatoxin in Fish
Consumption of Fish
Ciguatoxin (acute) (general population)
Placeholder
Edit
Listeria in Soft Ripened Cheese in Adults 60+
Soft Ripened Cheese
Listeria monocytogenes
Listeria in Soft Ripened Cheese (Gombas et al., 2003; Combase)
Soft Ripened Cheese Consumption by Elderly US Adults
Exponential Dose Response for Listeria in Elderly Population (FAO/WHO)
Listeriosis in the Elderly (60 and over) (RIVM)
Edit
Listeria in Soft Ripened Cheese in General Population
Soft Ripened Cheese
Listeria monocytogenes
Listeria in Soft Ripened Cheese (Gombas et al., 2003; Combase)
Soft Ripened Cheese Consumption by US Intermediate Age Population
Exponential Dose Response for Listeria in Intermediate Age Population (FAO/WHO)
Listeriosis in the General Population (RIVM)
Edit
Listeria in Soft Ripened Cheese in the Perinatal Population
Soft Ripened Cheese
Listeria monocytogenes
Listeria in Soft Ripened Cheese (Gombas et al., 2003; Combase)
Soft Ripened Cheese Consumption by Perinatal Population of US
Exponential Dose Response for Listeria in Perinatal Population (FAO/WHO)
Listeriosis in the Perinatal Population (RIVM)
Edit
Salmonella in peanut butter, DR specific for peanut butter
Peanut Butter
Salmonella
Salmonella in Peanut Butter, Post-roasting contamination
Peanut Butter consumption by US population
Dose response for Salmonella in peanut butter
Salmonellosis in the general population (Scallan et al., 2011)
Edit
Salmonella in Peanut Butter, General Population
Peanut Butter
Salmonella
Salmonella in Peanut Butter, Post-roasting contamination
Peanut Butter consumption by US population
Beta Poisson for Salmonella (FAO/WHO, 2002)
Salmonellosis in the general population (Scallan et al., 2011)
Elements in orange are not complete.
Include details
Rank Selected
Sum Selected
Override consumption model for acute chemical and microbial hazards (10,000,000 servings of 100g)

iRisk

Process Model: Listeria during production of Soft Cheese

Process Stages

Initial Prevalence: Fixed 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:

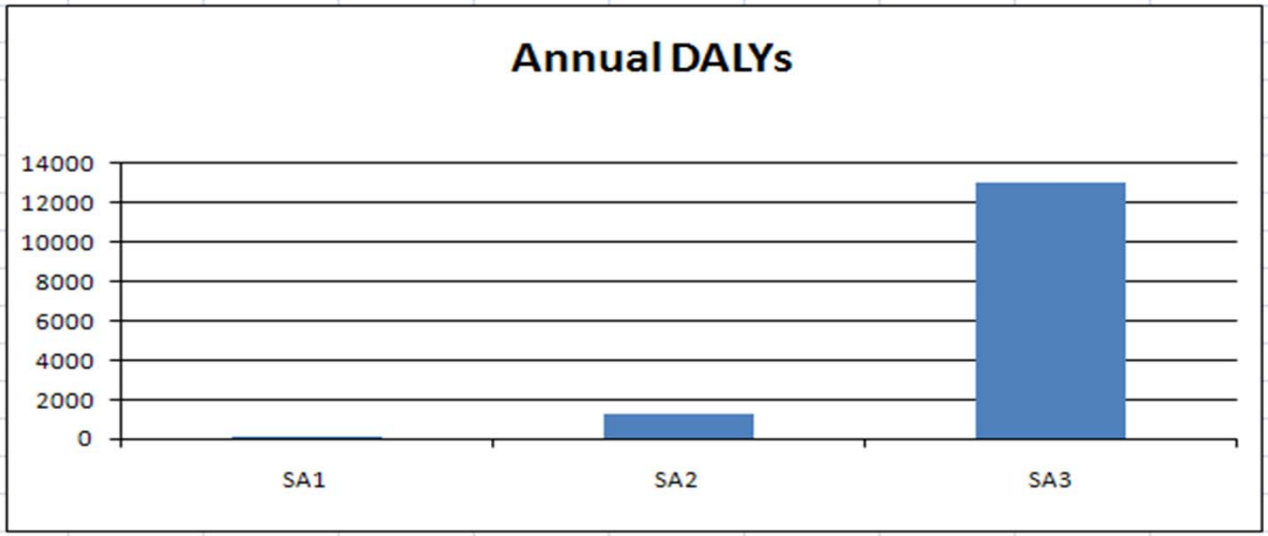
Process Stages

New Stage

	Sequence	Stage Name	Process Type	Mass(g)		
Edit	2	Combining Milk in Tanker	Pooling	22E6	↑	↓
Edit	3	Pasteurization	Decrease	No change	↑	↓
Edit	4	Post-pasteurization Contamination	Increase (addition)	No change	↑	↓
Edit	5	Draining	Evaporation/Dilution	Computed	↑	↓
Edit	6	Portioning	Partitioning	227	↑	↓
Edit	7	Ripening	Decrease	No change	↑	↓
Edit	8	Storage	Increase (growth)	No change	↑	↓

iRisk Sample output

	A	B	C	D	E	F	G	H	I	J
1	**Sensivity Analysis Report for Salmonella in Peanut Butter, General Population**									
2										
3	SA1	with Process Model - Initial Conditions: Initial Prevalence: Fixed Value (Value:5.5E-6)								
4	SA2	with Process Model - Initial Conditions: Initial Prevalence: Fixed Value (Value:5.5E-5)								
5	SA3	with Process Model - Initial Conditions: Initial Prevalence: Fixed Value (Value:5.5E-4)								
6										
7	**Scenario**	**Final Conc**	**Final Prev**	**Mean Risk**	**Eating Occ**	**Total DALY**	**Annual DA**	**DALYs per EO**		
8	SA1	0.86	4.90E-06	4.20E-07	1.70E+10	130	130	7.90E-09		
9	SA2	0.86	0.000049	4.20E-06	1.70E+10	1300	1300	7.90E-08		
10	SA3	0.86	0.00049	0.000042	1.70E+10	13000	13000	7.90E-07		
11										
12										



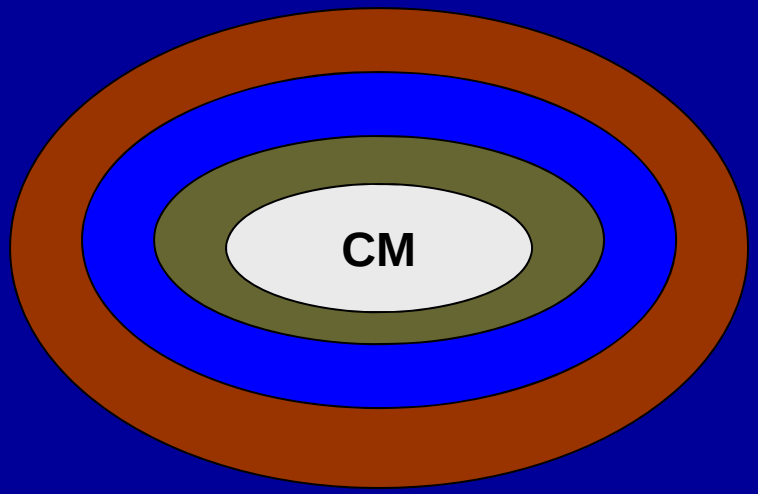
Web-based Dissemination

Technical Development Environment

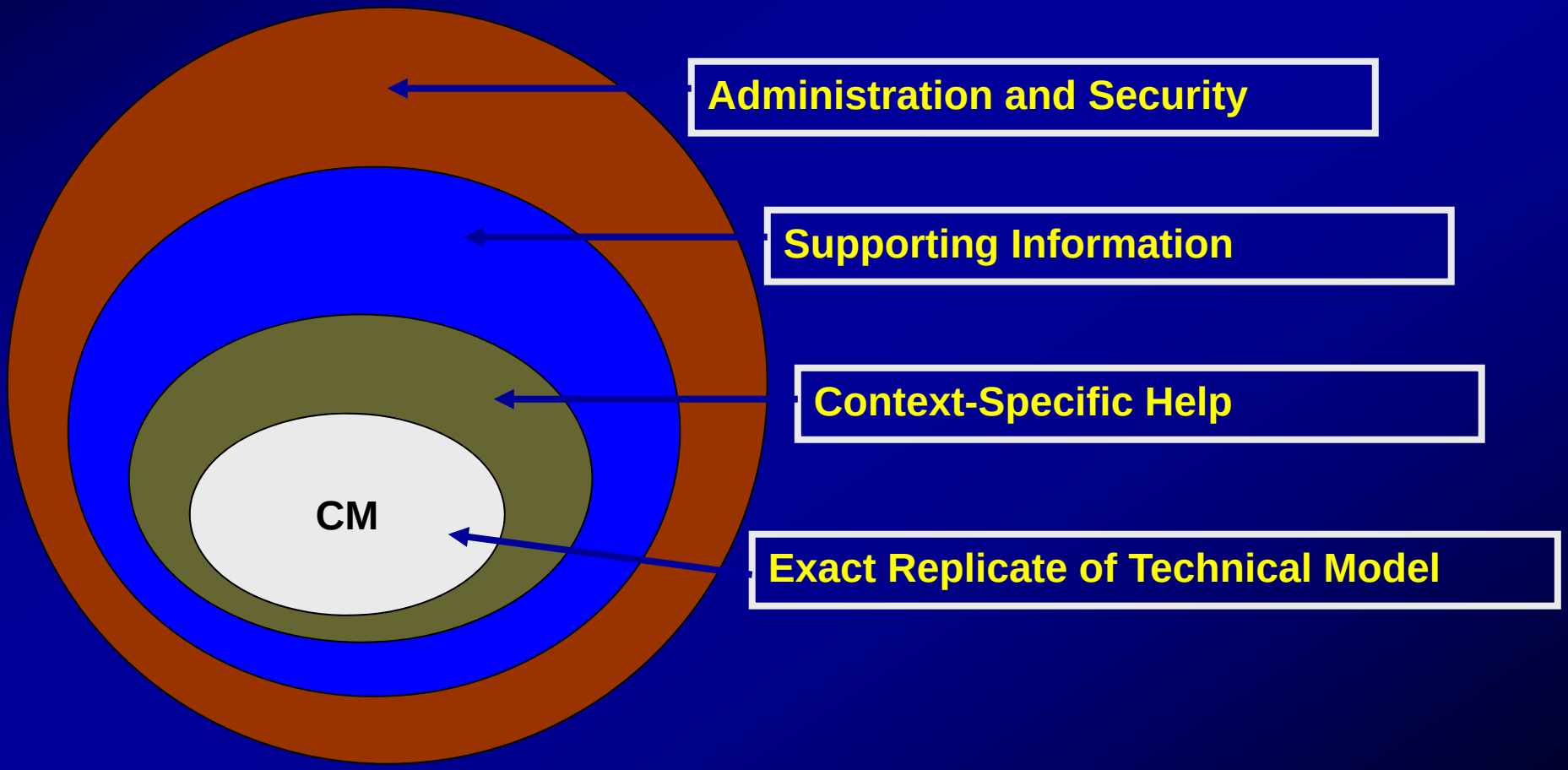
Computational Model (CM) — **Analytica™**

Technical Documentation — **PDF**

Web-Based Dissemination



Web-based Dissemination



Modeling the Public Health System Response to a Terrorist Event

NATIONAL CENTER FOR
FOOD PROTECTION AND DEFENSE
A HOMELAND SECURITY CENTER OF EXCELLENCE

Contamination Incident

Consumption Of food

Consequences of Exposure

Response of Health Care Provider

Unreported Cases / exposures

Impact

Advisory Issue

Confirmed Cases

PHS Investigation

PRIMARY PRODUCTION ➤ HARVEST ➤ TRANSPORTATION ➤ STORAGE ➤ PROCESSING ➤ DISTRIBUTION ➤ RETAIL/FOOD SERVICE ➤ CONSUMER

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

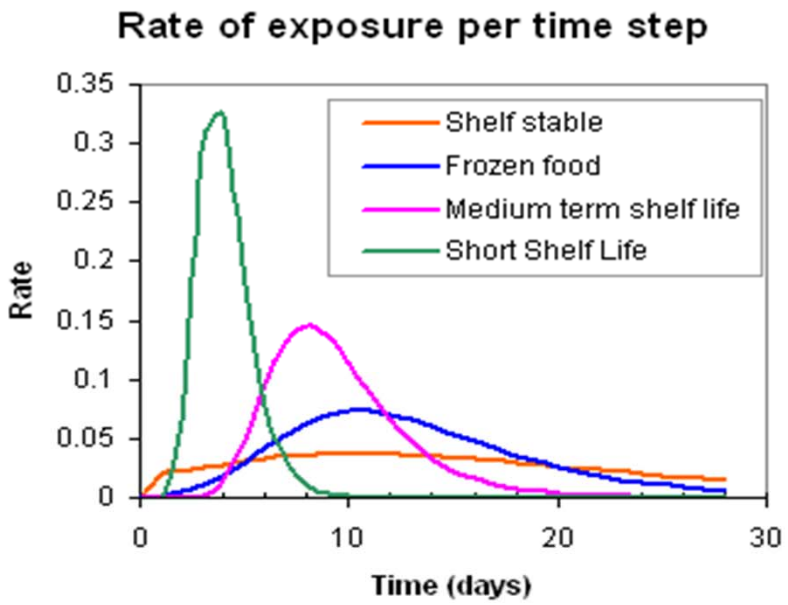
Data Entry

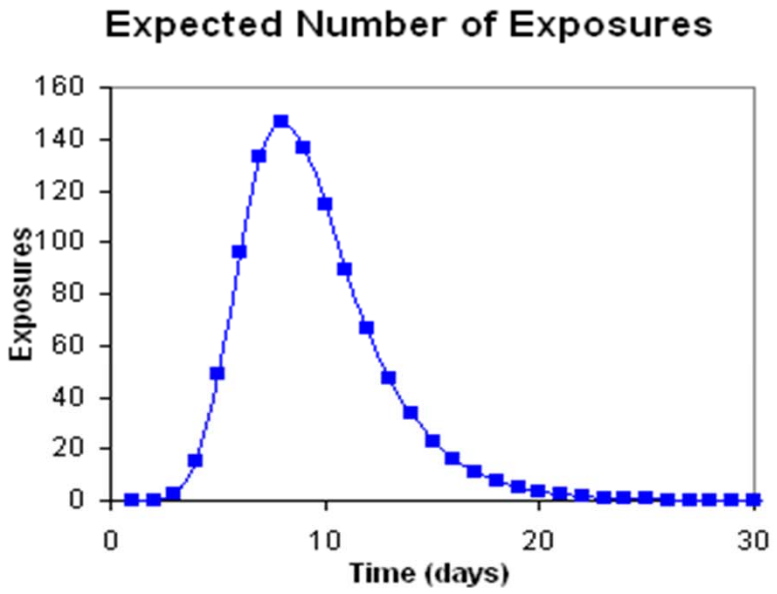
Bacillus Anthracis			
	Minimum	Most Likely	Max
Likelihood of symptoms given ingestion	45	50	65
Likelihood seek treatment	80	92	97
Likelihood aetiology is investigated	80	85	90
Likelihood reported given cause	92	95	99
Delay to symptoms given ingestion	2	3	4
Delay to seek treatment	1	2	3
Delay to identification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

Product Type Selection

Medium term shelf life

Expected Total Number of People Exposed
1000



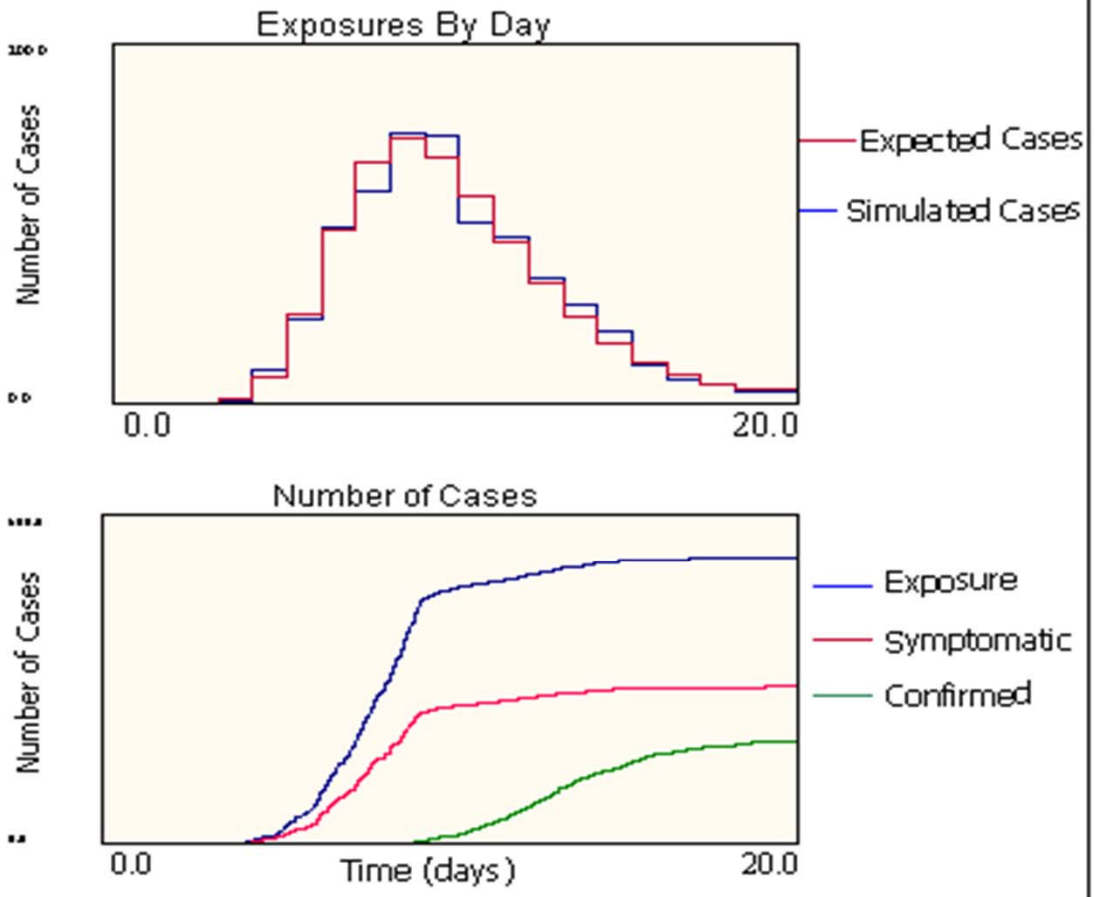


NATIONAL CENTER FOR
FOOD PROTECTION AND DEFENSE
A HOMELAND SECURITY CENTER OF EXCELLENCE

Example Results

July 8, 2007 08:08:28

Exposure Occurence and Reporting



Pathway of Exposures

Total number of exposures	517
Number averted by advisory	470
Number symptomatic	282
Number asymptomatic	235
Number don't seek treatment	58
Number not investigated	34
Number of confirmed cases	190

Advisory Issued

Day Issued: 9

Day of Last Exposure: 19

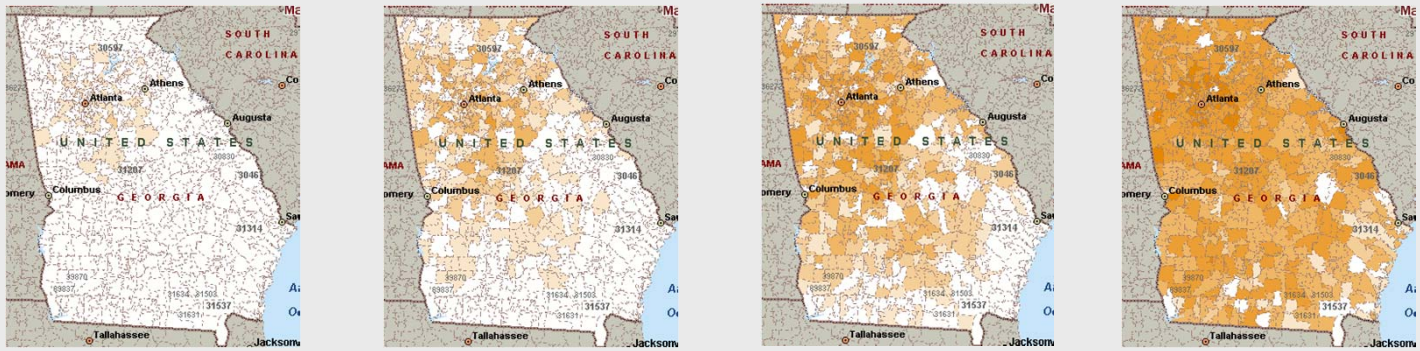
Day Incident Over: 24

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?



time (cases by location)

location of patient

number seeking care

resources

time

Treated

Downgraded Treatment

try another hospital

Untreated

try overflow centre

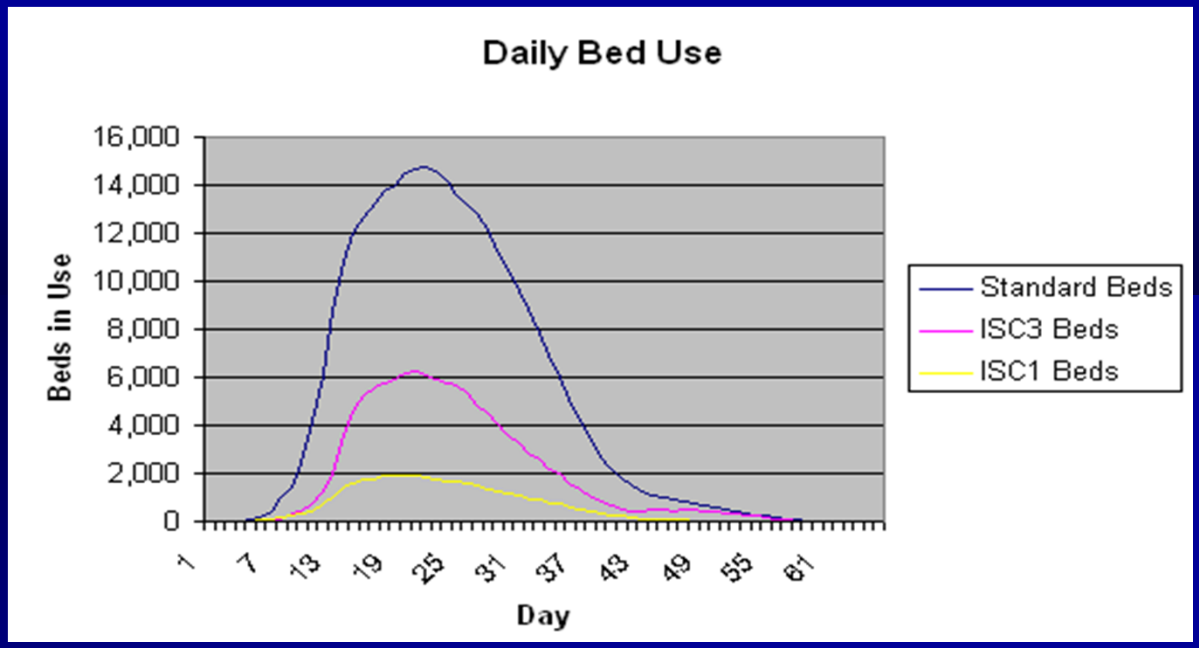
number seeking care

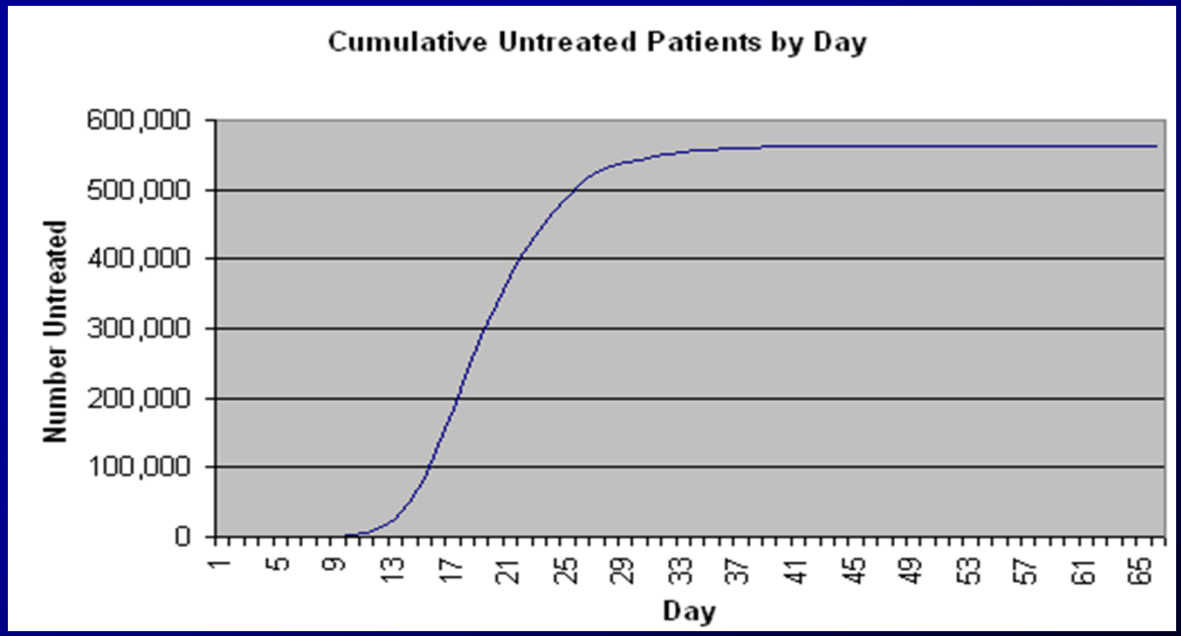
resources

time

Treated

Downgraded Treatment


Daily Bed Use
Beds in Use
16,000
14,000
12,000
10,000
8,000
6,000
4,000
2,000
0
1
7
13
19
25
31
37
43
49
55
61
Day
Standard Beds
ISC3 Beds
ISC1 Beds


Cumulative Untreated Patients by Day
Number Untreated
600,000
500,000
400,000
300,000
200,000
100,000
0
1
5
9
13
17
21
25
29
33
37
41
45
49
53
57
61
65
Day

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