Risk Ranking Framework
The IFT-FDA Cooperative Initiative

Presentation at JFSAN Workshop: Tools for Prioritizing Food Safety Concerns
By
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Topics

- Overview of IFT-FDA risk ranking prototype
  - Risk Criteria
  - Issues and considerations in ranking across microbes and chemical food risks
Overview: The Charge

• Develop a risk-ranking framework
• Facilitate the evaluation and ranking of microbiological agents, toxins, and chemicals

  – Quantitatively or semi-quantitatively comparing and determining potential health threats

  – Evaluating interventions or control points … to protect the food supply.
Overview: Participants

Frank F. Busta, PhD (U. Minnesota)
Sherri Dennis, PhD (FDA)
Joseph Hotchkiss, PhD (Cornell Univ.)
Lee-Ann Jaykus, PhD (NC State)
Jennifer McEntire, PhD (IFT)
Marianne Miliotis, PhD (FDA)
Rosie Newsome, PhD (IFT)
Greg Paoli, MAS (Decisionanalysis)
Barbara Petersen, PhD, MPH (Exponent)
Donald Schaffner, PhD (Rutgers Univ.)
Fred Shank, PhD (IFT)
Bruce Tompkin, PhD (ConAgra)
Nga Tran, DrPH, MPH (Exponent)
Mary Wagner, PhD (E & J Gallo Winery)
Overview: The Process

- Two years (2003-2005)
- Reviewed literature and other developments
- Developed risk ranking criteria modules and integration algorithm
- Developed, deliberated, implemented and peer reviewed a web-based prototype
Risk Ranking Framework Prototype

Please Select an Item

Home
- Hazards
  - Microbial
  - Chemical
- Foods
  - Animal Origin
  - Plant Origin
  - Complex Food
- Health Impacts
- pDALY Templates
- Risk Ranking
- Reports

Browser

Please note: this prototype was designed for Netscape. Although it should work, it will be much slower and enter data using Netscape.

Introduction

This prototype application demonstrates the concept of a risk ranking framework for food safety. It acts as both a data capture tool and as a risk-ranking tool for numerous food-hazard combinations.

Features: Each section typically demonstrates one feature and could be applied to all sections in a complete and comprehensive manner as described below in italics with a grey background.

Navigation

The tree view on the left side of the page provides a dynamic and interactive way to navigate through the different sections and features of the framework.
Risk Ranking Prototype Highlights

• Risk criteria
  – Exposure (prevalence and concentration, food intake)
  – Dose response
  – Risk characterization and public health impacts

• Module components
  – Expert insight, evidence databases
  – Hazard metrics/weights, decision logic, help files

• Module integration via algorithms and evidence hierarchy
Risk Criteria: Exposure

I) Primary Production
- Prevalence, concentration at departure from the farm gate

II) Processing
- Prevalence, concentration at the shipping dock (upon leaving the manufacturer)

III) Distribution
- Prevalence, concentration after distribution and storage

IV) Retail, Consumers
- Prevalence, concentration at time of consumption

Food Intake

A. Likelihood of hazard introduction?
B. How Controllable is the hazard?
C. Potential for abuse, mishandling
Prevalence and Levels

• Expert insights (microbe); Data/Evidence (chemical)
• Prevalence: yes/no (microbe); non-detects (chemical)
• Enumeration:
  – log units/g (microbes)
  – g/g scale (chemicals)
Food Intake

- US survey data (e.g. Continuing Survey of Food Intakes by Individuals (CSFII) 1996-98
- Exposed population and quantity of food consumed:
  - grams/eating occasion
  - grams/day
  - grams/kg body weight per day
Risk Criteria: Hazard Characterization or Dose Response

- Multiple Endpoints:
  - Chemical: cancer, non-cancer (acute and chronic)
  - Micro: infectious or toxigenic
- Multiple dose-response models
  - Toxigenic responses: exponential, step threshold, threshold linear, non-threshold linear and cancer
  - Infectious responses: Beta-Poisson, exponential, threshold linear, and non-threshold linear.
Criteria: Risk Characterization

- Monte Carlo simulation:
  - A range of doses combined with dose-response model(s)
  - Mean probability of illness

- Traditional chemical and micro approaches
  - Chemical: lifetime and annual risk, exposed population, annualized cases
  - Micro: risk per serving, annual contaminated servings, annualized cases
Risk Criteria: Public Health Impacts

- Risk estimates expressed as annual p-DALYs for both microbes and chemicals
  - Pseudo (p)-Disability Adjusted Life Years (DALY)
  - Alternatives to disease specific DALY
    DALY = disability adjusted life years = YLL + YLD
    YLL = years of life lost
    YLD = years lived with disability

- Mean to rank public health impacts across chemical and micro food risks
p-DALY

- Health impact is captured semi-quantitatively on 2 dimensions:
  - impact severity (mild, moderate, severe, and death) and
  - duration (short, medium, long)
  - 12 ways of describing a health impact.

- The p-DALY Template allows the impact of the hazard, whether cancer, infectious, or toxic, to be put on a relative scale.
<table>
<thead>
<tr>
<th>Health Impact</th>
<th>Duration (Years)</th>
<th>Severity</th>
<th>pDALY</th>
<th>Fraction of Cases</th>
<th>Adjusted pDALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate, Short-Term Impacts</td>
<td>0.0055</td>
<td>0.050000</td>
<td>0.000274</td>
<td>0.970400</td>
<td>0.0002659</td>
</tr>
<tr>
<td>Severe, Short-Term Impacts</td>
<td>20.000000</td>
<td>0.300000</td>
<td>6.000000</td>
<td>0.027900</td>
<td>0.1674000</td>
</tr>
<tr>
<td>Severe, Long-Term Impacts</td>
<td>20.000000</td>
<td>0.300000</td>
<td>6.000000</td>
<td>0.001000</td>
<td>0.0060000</td>
</tr>
<tr>
<td>Childhood Mortality</td>
<td>75.000000</td>
<td>1.000000</td>
<td>75.000000</td>
<td>0.000600</td>
<td>0.0450000</td>
</tr>
<tr>
<td>Elderly Mortality</td>
<td>10.000000</td>
<td>1.000000</td>
<td>10.000000</td>
<td>0.000600</td>
<td>0.0060000</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td></td>
<td></td>
<td><strong>1.000500</strong></td>
<td></td>
<td><strong>0.2246659</strong></td>
</tr>
</tbody>
</table>
Remaining Issues

- The IFT-FDA prototype can rank across chemical cancer and microbe risks, but not for non-cancer risks (below or above threshold)

  - What to do with MOE, HI or HQ?
  - Additional considerations are needed to include chemical non-cancer risks.

- The p-DALY

  - Expert judgment
  - Further evaluation is warranted.
Considerations

- What is the strength of the judgment that the agent causes adverse effects when ingested?
  - How to adjust for unequal weight of evidence?

- What is the likelihood that the hazard is present and at what level in a particular food?
  - What information is available to determine exposure/dose? Data, expert judgment?
  - What metric and potential impact on estimates used for ranking

- What information is available for dose (exposure) response?
  - What metric and potential impact on estimates used for ranking
Considerations – Public Health Impact

- Chemicals: multiple disease outcomes with different severity

- Microbes:
  - Often focus one main disease outcome, but more serious disease manifestations associated with a proportion of cases
  - Some instances, different syndromes by a single agent.

- Susceptible sub-population(s) (e.g. children, the elderly, and immunocompromised)