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

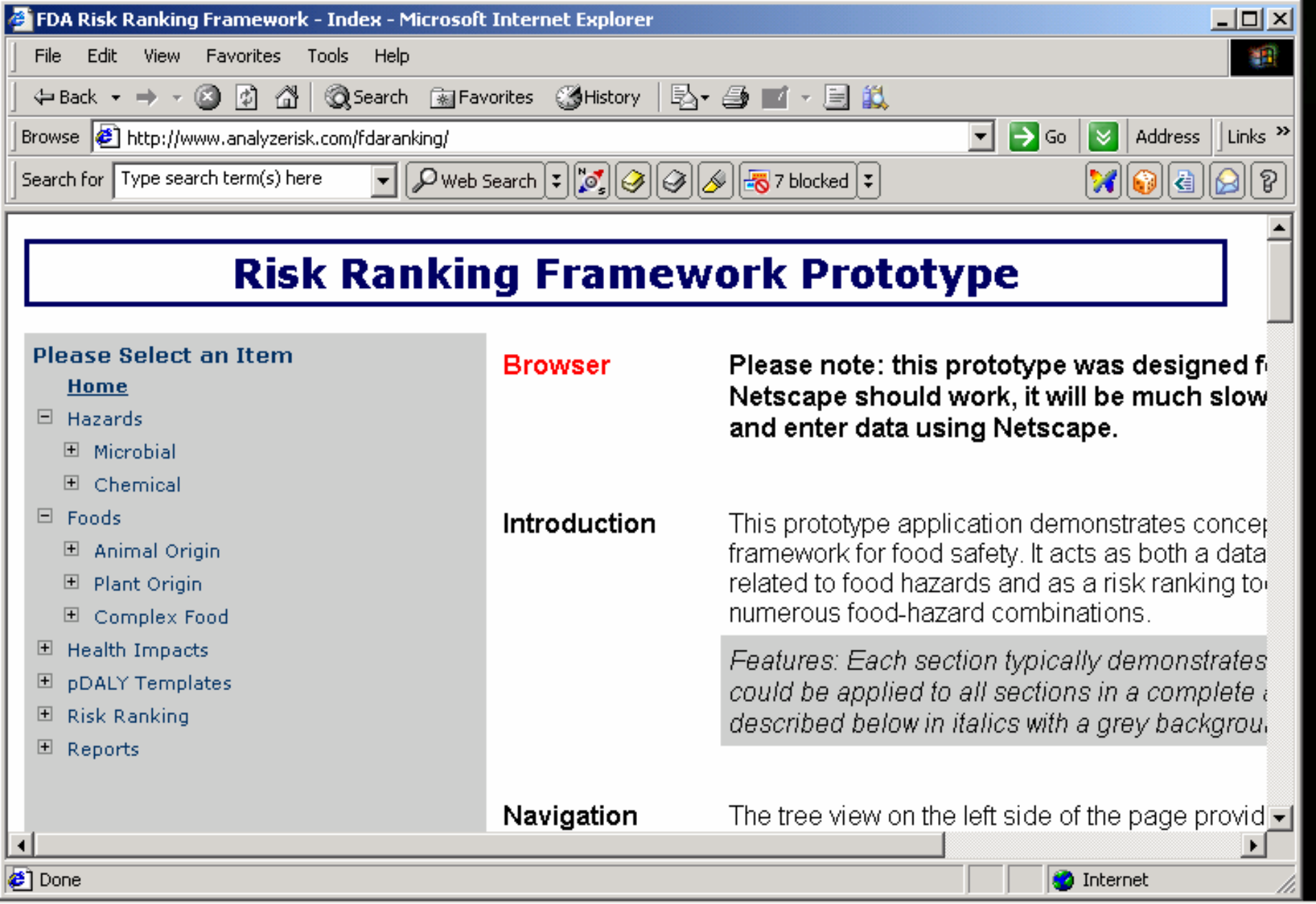
- Develop a risk-ranking framework
- Facilitate the evaluation and ranking of microbiological agents, toxins, and chemicals
  - Quantitatively or semi-quantitatively comparing and determining potential health threats
  - Evaluating interventions or control points … to protect the food supply.

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


FDA Risk Ranking Framework - Index - Microsoft Internet Explorer
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Risk Ranking Framework Prototype
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Hazards
Microbial
Chemical
Foods
Animal Origin
Plant Origin
Complex Food
Health Impacts
pDALY Templates
Risk Ranking
Reports
Browser
Please note: this prototype was designed f
Netscape should work, it will be much slow
and enter data using Netscape.
Introduction
This prototype application demonstrates concep
framework for food safety. It acts as both a data
related to food hazards and as a risk ranking to
numerous food-hazard combinations.
Features: Each section typically demonstrates
could be applied to all sections in a complete
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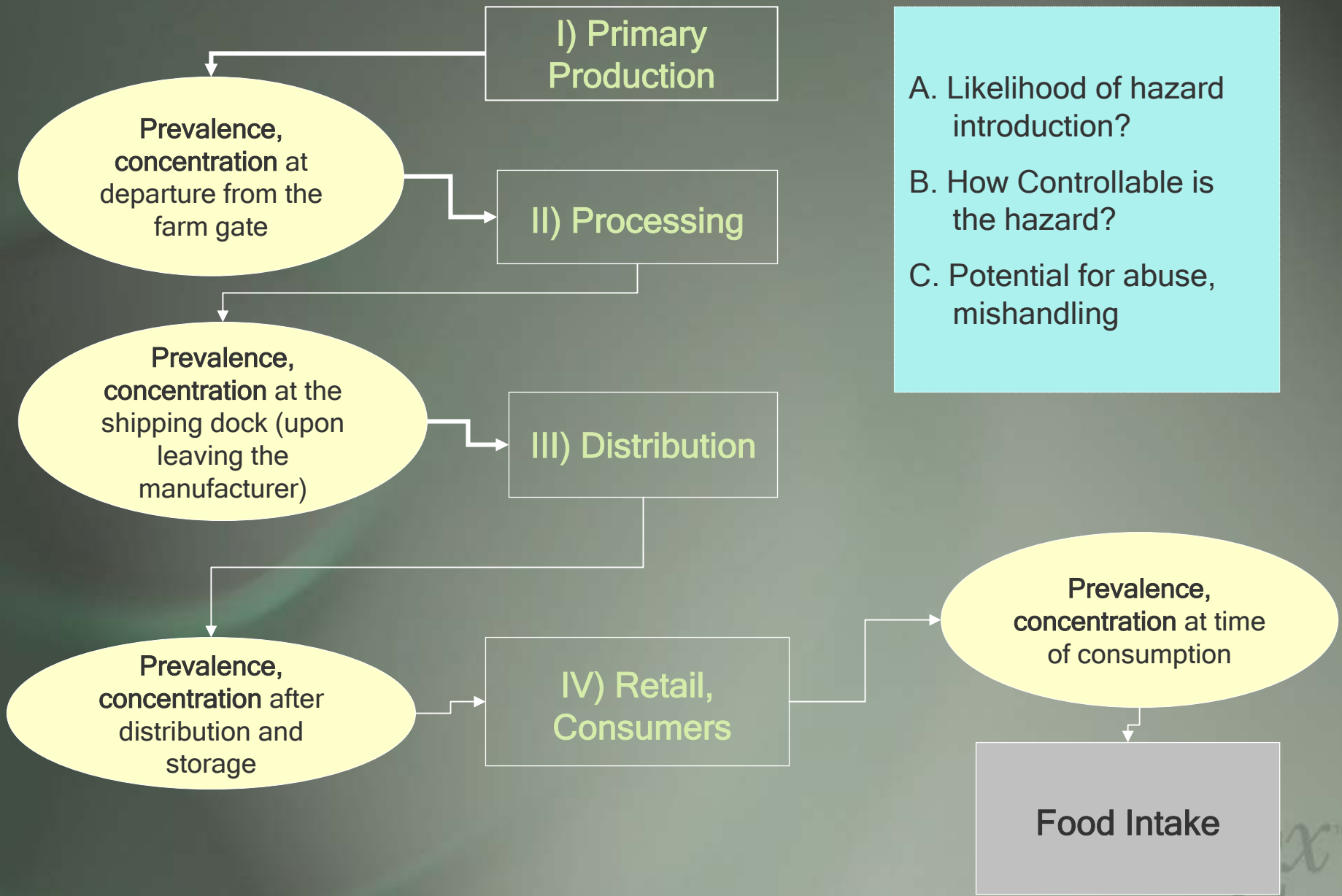
Risk Ranking Prototype Highlights

- 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



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

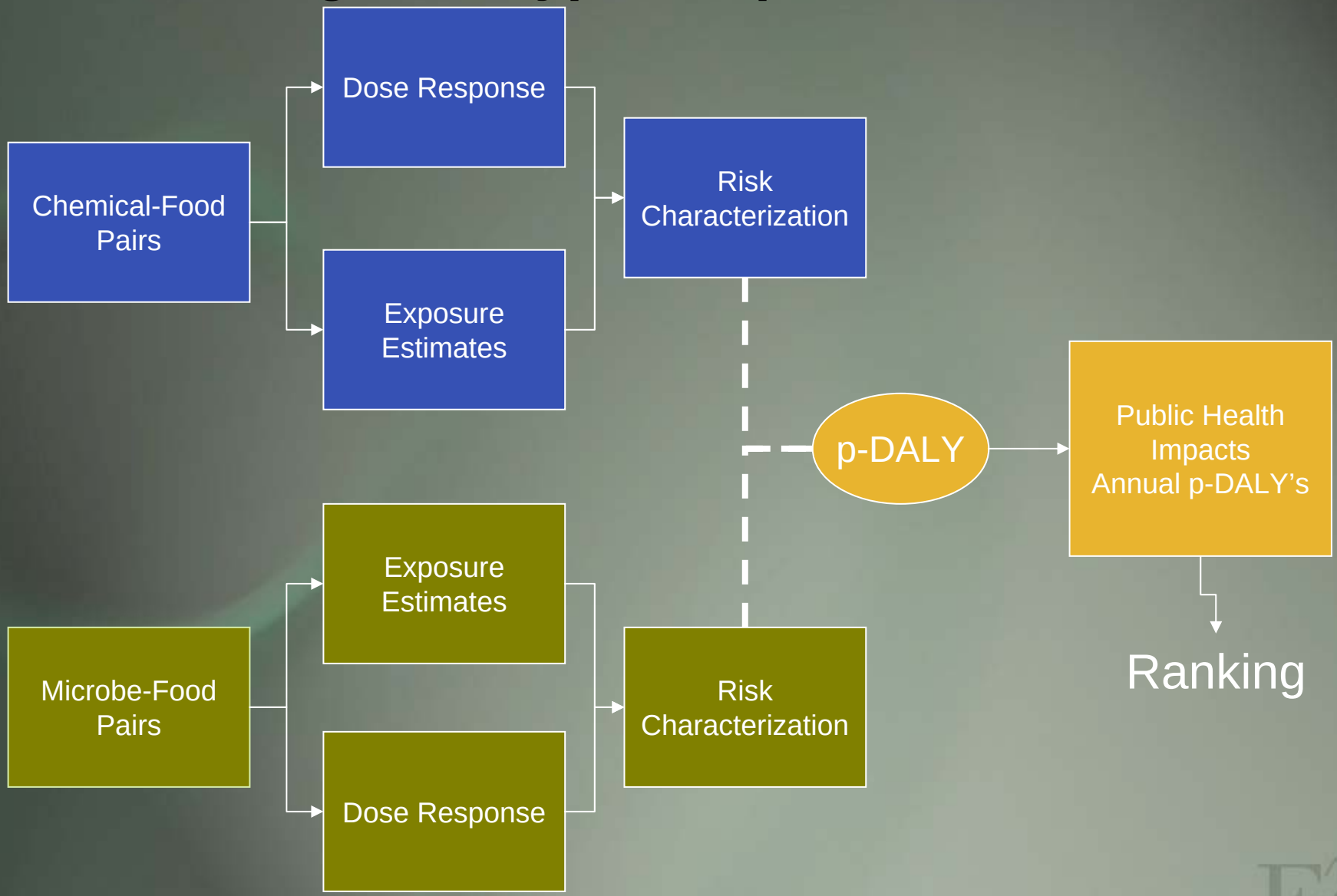
- Health impact is captured semi-quantitatively on 2 dimensions:
  - impact severity (mild, moderate, severe, and death) and
  - duration (short, medium, long)
  - 12 ways of describing a health impact.

- The p-DALY Template allows the impact of the hazard, whether cancer, infectious, or toxic, to be put on a relative scale.

Template Name: Escherichia coli O157:H7

Health Impact	Duration (Years)	Severity	pDALY	Fraction of Cases	Adjusted pDALY
Moderate, Short-Term Impacts	0.0055	0.050000	0.000274	0.970400	0.0002659
Severe, Short-Term Impacts	20.000000	0.300000	6.000000	0.027900	0.1674000
Severe, Long-Term Impacts	20.000000	0.300000	6.000000	0.001000	0.0060000
Childhood Mortality	75.000000	1.000000	75.000000	0.000600	0.0450000
Elderly Mortality	10.000000	1.000000	10.000000	0.000600	0.0060000
Total:				**1.000500**	**0.2246659**

Risk Ranking Prototype Simplified Schematic



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)