Microbial Risk Assessment

Mark Powell
U.S. Department of Agriculture
Office of Risk Assessment and Cost-Benefit Analysis

Johns Hopkins University
Baltimore, MD
March 2017

OUTLINE

BIOLOGICAL STRESSORS

HAZARD IDENTIFICATION

- ACUTE OUTCOMES
- CHRONIC SEQUELAE

EXPOSURE ASSESSMENT: DISCRETE NATURE OF MICRO-ORGANISMS

- BINOMIAL DISTRIBUTION
  - PARAMETER ESTIMATION AND UNCERTAINTY
  - ESTIMATING TRUE PREVALENCE
- POISSON DISTRIBUTION
  - PARAMETER ESTIMATION AND UNCERTAINTY
  - ESTIMATING POISSON PREVALENCE
  - MIXTURE DISTRIBUTION: POISSON-LOGNORMAL

DOSE-RESPONSE ANALYSIS

- BETA-POISSON DOSE-RESPONSE MODEL

GENERAL RISK ANALYSIS TOPIC

- SEPARATING UNCERTAINTY AND VARIABILITY

Environmental Stressors

- Chemical (organic and inorganic)
- Physical (e.g., flood, drought, fire)
- Biological
  - Human health (e.g., water- and foodborne microbial pathogens)
  - Animal health (e.g., veterinary diseases, harmful non-indigenous species)
  - Plant health (e.g., insect pests, plant disease, invasive weeds)

Distinguishing Characteristics of Biological Stressors

- Grow, reproduce, multiply, and die
- Disperse both actively and passively, often exhibiting “jump dispersal” (long distance transport, cross-contamination)
- Complex population-, community-, and ecosystem level dynamics, potentially chaotic
- Evolve

Comparison to Chemical Risk Assessment

- Uncertainty for chemical risk assessments span multiple orders of magnitude (factors of 10)
- Chemical risk assessment methods and data far more "developed" than for biological stressors
- Biological stressors may be inherently more uncertain, but only perhaps. Many simplifying assumptions have become generally accepted practices in chemical risk assessment
- Less acceptance of *in vitro* and animal models in microbial RA
- Often greater certainty about biological hazard identification (suspected carcinogens v. known pathogens) & more epidemiologic evidence available, at least for acute effects.
- Many parallels between risk assessment for chemical and biological stressors

Biological	Chemical
• Differential pathogenicity of microbial species	• Differential toxicity of chemical species
• Extrapolation from human clinical trial subjects to general population	• Extrapolation from surrogate test species to human population
• Identifying non-indig. invasive species	• Identifying human toxicant
• Population of invasive species in the env.	• Population of invasive cells in the body
• Inactivation	• Sequestration
• Dispersal	• Fate and Transport
• Community dynamics	• Chemical mixtures

2 Strawman Approaches to Risk Assessment for Biostressors

- Mimic chemical risk assessment – seeks to be predictive, focus on reducing uncertainty.
  - Physics envy. Paralysis by analysis?
- Epidemiology/Ecology – prediction is impossible, measure everything everywhere.
  - Ignores constraints. Basis for decisions?