Microbiological Risk Assessments: Dealing with Biodiversity

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Historical Perspective

- **1995: WHO/FAO Consultation on "Application of Risk Analysis to Food Standards Issues,"**
  - **Risk assessment techniques for microbial food safety issues are not likely to be available in the near term**
  - **Microbiological food safety concerns were too complex to be amenable to use of formal risk assessment techniques**

- **1994 - 1996: First "research" attempts to conduct microbiological risk assessments are published**

Historical Perspective

- **1998 -2003: Microbial risk assessments become a tool for evaluating food safety risk management options**
  - ***Salmonella enteritidis*** **- eggs: USDA, 1998**
  - ***Listeria monocytogenes*** **- RTE foods: FDA/USDA, 1999-2003**
  - ***Vibrio parahaemolyticus*** **- raw shellfish: FDA, 1999-2003**
  - ***Escherichia coli*** **O157:H7 - USDA/FDA, 1999-2004**

Historical Perspective

- **Was at a time of expanding IT capabilities:**
  - **A PC on everyone's desk**
  - **Prior 10 years of international research in predictive microbiology**
  - **Availability of PC-based software for simulation modeling**

Historical Perspective

- **Strong international incentives because of the:**
  - **Signing of the WTO SPS & TBT Agreements**
  - **Drive for more objective determination of**
    - **Equivalence**
    - **Microbiological criteria**
  - **Codex Alimentarius adopts risk analysis framework**

Quantitative Microbiological Risk Assessment (QMRA)

- **Quantitative microbiological risk assessment (QMRA) has its roots in chemical risk assessment**
- **QMRAs have the same basic structure as chemical risk assessments**
  - **Hazard Identification**
  - **Exposure Assessment**
  - **Hazard Characterization**
  - **Risk Characterization**
- **General lack of the equivalent of "Safety Assessment"**

QMRA

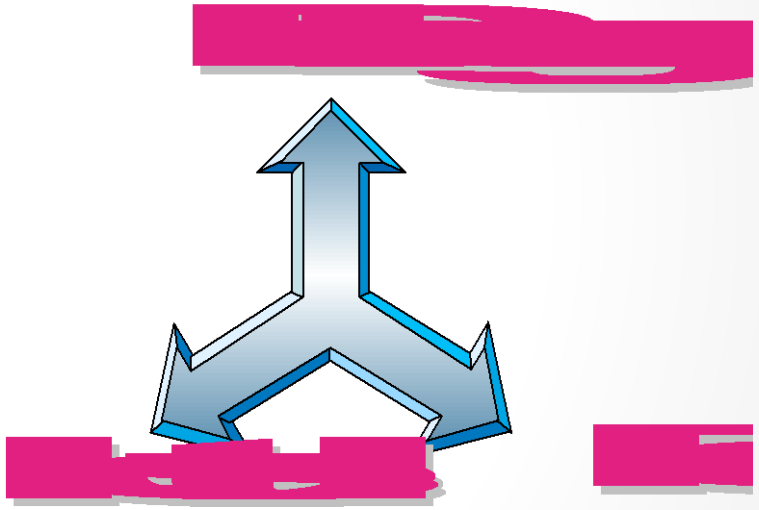
- **While the general approach is similar, there are differences between chemicals and microorganisms that require different approaches**
  - **How microorganisms cause disease**
  - **"Concentration" of microorganisms in foods**
  - **The susceptibility of humans to microorganisms**
  - **How foods affect microorganism and host responses**
  - **Biodiversity**

Why Are Microbial Risk Assessments Different?

- **The hazard identification phase is usually minimal**
  - **Well characterized syndromes often with substantial epidemiological data**
- **Use of animal models for dose response relations limited**
- **Much more emphasis on exposure assessment which are usually more complex**

Unique Features of Microbial Risks

- **“Disease” dependent on the "balance" between the biological agent, the consuming population, and the food**
- **Each are biological systems with high degrees of variability**

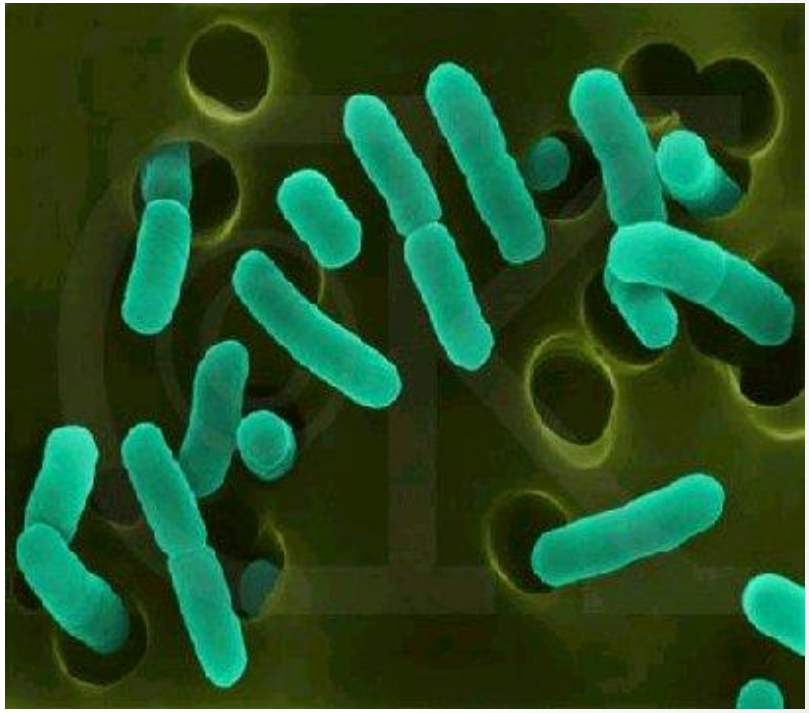


Unique Features of Microbial Risks

- **Microbial risks are generally acute in nature and the result of a single exposure**
  - **Includes foodborne disease caused bacteria, viruses, protozoa, fungi, toxic algae, and parasites and their chronic sequelae**
  - **Multiple exposures have a propensity to lead to immunity**
- **Exception: certain toxigenic fungi and possibly marine toxins that can bioaccumulate**

Microbial Dose-Response Relations

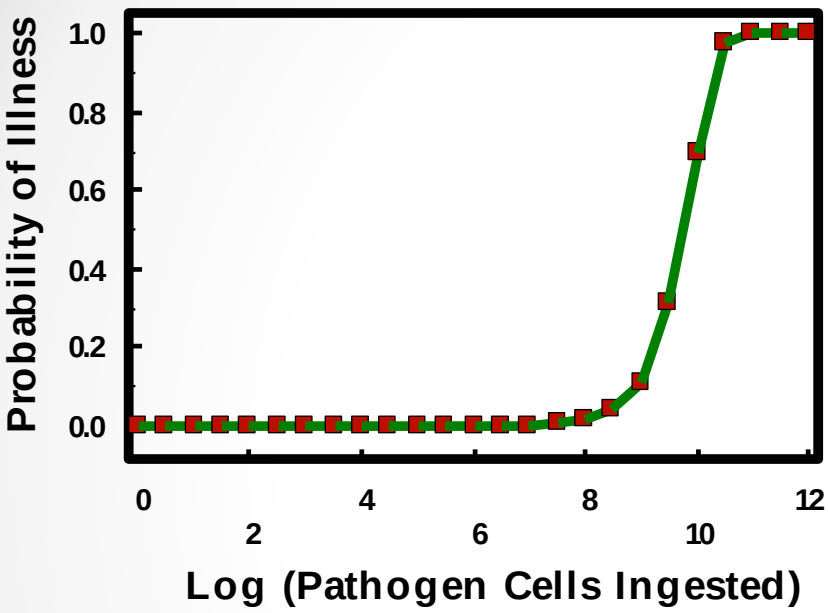
- **Varies with the underlying mechanisms of pathogenicity**
  - **Infectious**
  - **Toxicoinfectious**
  - **Toxigenic**
  - **Infestations (helminths)**

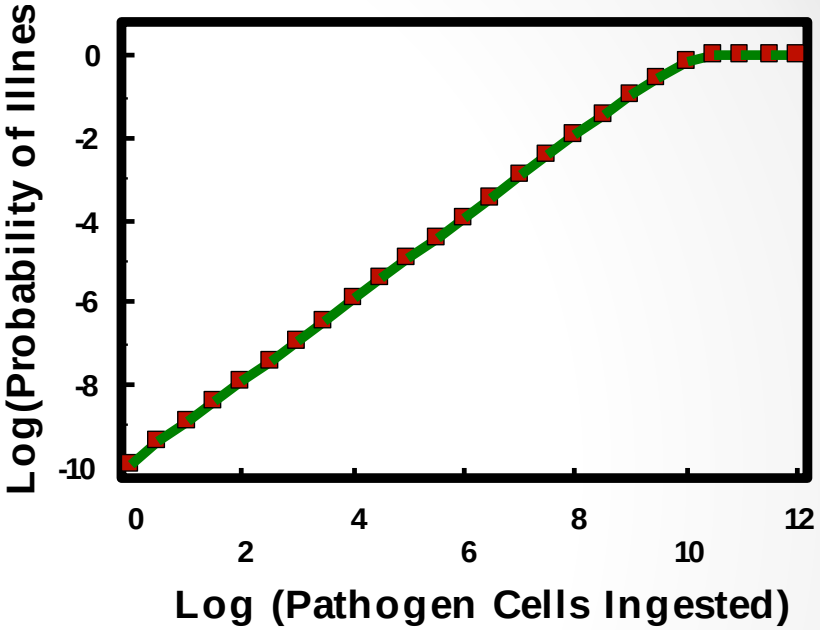


Microbial Dose-Response Relations

- **Toxigenic microorganisms**
  - **Acute chemical toxins (*C. botulinum* toxin, *S. aureus* enterotoxin) - Threshold models**
  - **Carcinogens/ mutagens (e.g., aflatoxin B_1 – Non-threshold models**
- **Infectious and toxicoinfectious microorganisms**
  - **Most microbial foodborne diseases – Non-threshold models**

Dose-Response Assessment

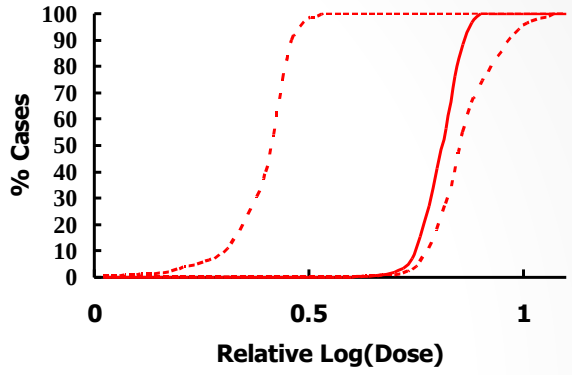


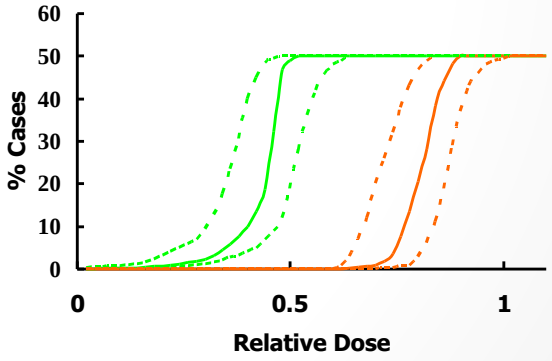


- A single cell has a definable probability of producing an infection
- Probability increases as the number of cells ingested increases
- Use non-threshold models that are linear or log linear in the low dose regions

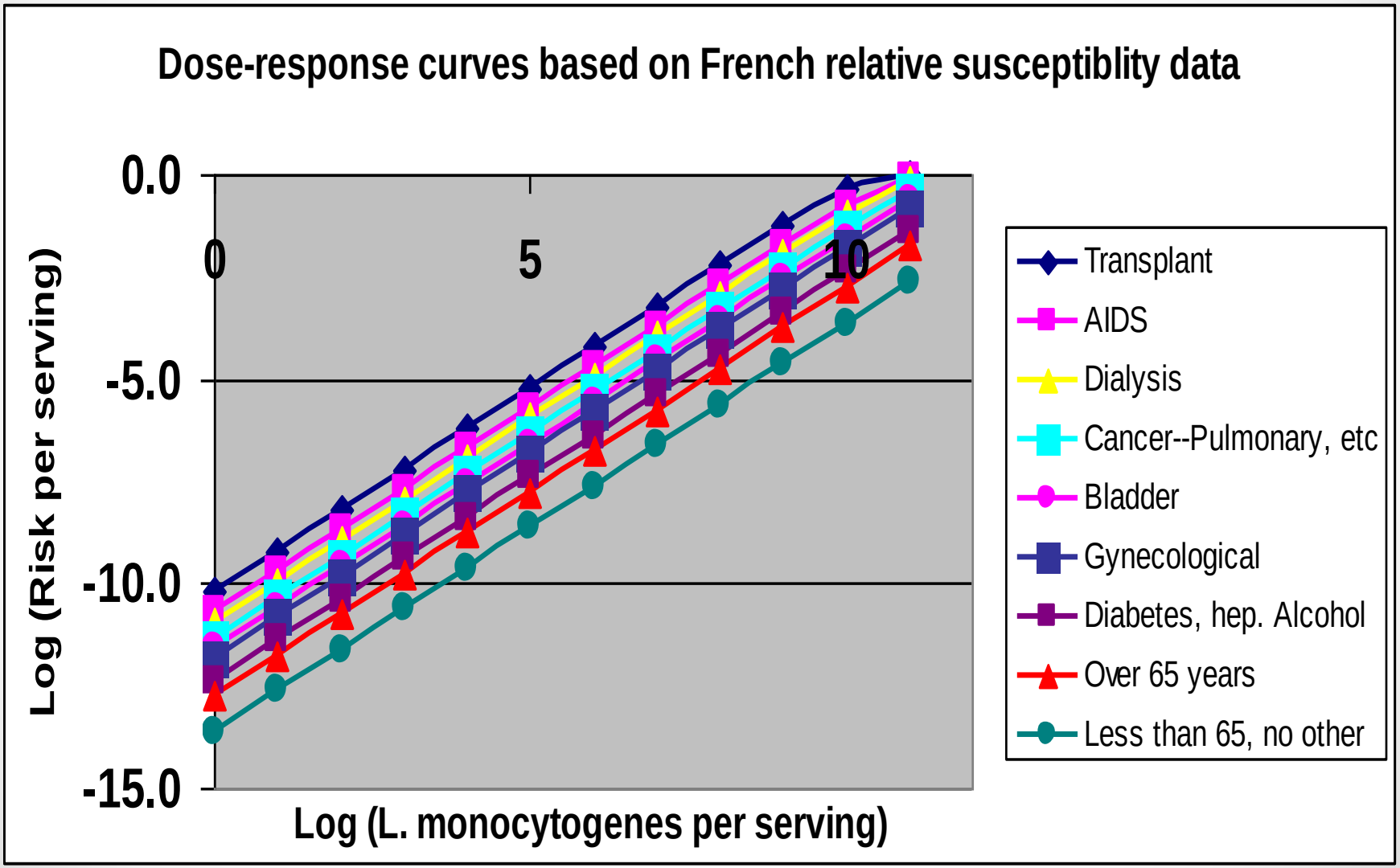
Dose-Response Assessment

- **If develop dose-response model for entire population, the variability in susceptibility represents a large uncertainty**
  - **Range from high risk individuals to those who are totally immune**
- **One way around this is to develop separate dose-response models for specific subpopulations**



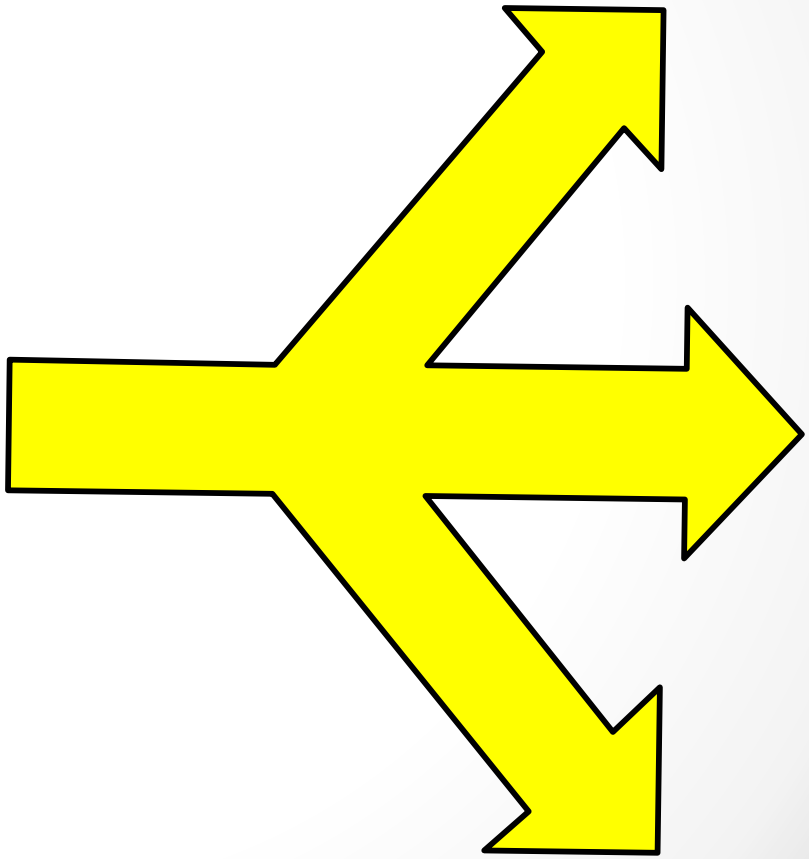


Dose-Response Assessment



Unique Features of Microbial Risks

- **The levels of pathogenic microorganisms can change drastically in a short time, confounding exposure estimates**



Exposure Assessment

- **The purpose of this risk assessment phase is to determine what actually went in the consumer's mouth to determine dose consumed**
  - **Frequency of contamination**
  - **Level of contamination**
  - **Serving sizes**
  - **Frequency of consumption**
  - **Storage conditions and duration**
  - **Cooking/pasteurization**
  - **Effect of processing**
  - **Cross Contamination**

Exposure Assessment

- **For most food safety risk assessments, available data are limited to the levels a hazard at a specified step in the food chain**
- **Means that need to estimate what was actually eaten by the consumer**
  - **For chemical hazards often assume that levels remain constant**
  - **For microbiological hazards generally use predictive microbiology models to estimate growth, survival, and/or inactivation of a target pathogenic microorganism**

Unique Features of Microbial Risks

- **Levels of a pathogen can change drastically in a short amount of time**
  - **Growth: Over night growth at abuse temperature can lead to 1 cell becoming 1,000,000,000/g**
  - **Inactivation: Cooking for a short time can reduce pathogen levels by 10,000,000,000-fold in minutes during cooking**
- **Presence of pathogen is often non-homogeneous and non-random both between servings and even within serving**

Unique Features of Microbial Risks

- **For some pathogens, may also need to consider**
  - **Secondary infections**
  - **Multiple biological end points**
  - **Multiple infections**
  - **Non-food vehicles**
  - **Asymptomatic carriers**
  - **Cross-contamination**
- **Predictive microbiology models available for most**

Concluding Remarks

- **Microbiological risks are diverse and typically characterized by**
  - **Adverse effects resulting from single exposures**
  - **Large variation in susceptibility of hosts**
  - **Potential for microbial growth or inactivation**
  - **Microbial diversity**
  - **Substantial amount of data on adverse effects - actual cases**
  - **Availability of a variety of models describing the behavior of pathogenic microorganisms in foods**

Concluding Remarks

- **While the differences in chemical and microbiological assessments have been substantial, these are becoming fewer as we move to more mechanistic approaches**

- **Of particular note was the "Key Event Framework" developed by ILSI which strove to provide a unifying approach focused on understanding risk through the lens of knowledge of the underlying key biological and genetic determinants that lead to adverse responses**