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Quantitative Risk Assessment and Its Use in HACCP:
Dose Response Assessment

This is used to predict — among other things — the probability of disease from ingestion of a given number of pathogens.

One approach to risk assessment has been promoted by the Codex Alimentarius Commission, a subsidiary of the United Nations' Food and Agriculture Organization.

In the Codex system, Risk Assessment is an element of Risk Analysis, along with Risk Management and Risk Communication.

- Risk Assessment determines the nature and extent of the risk.
- Risk Management decides what to do about the risk.
- Risk Communication is the process of telling the public what will be done (and acquiring feedback).

Risk Management

- Not necessarily to eliminate risk
- Balance level of risk vs.
  - ♦ cost of risk reduction
  - ♦ competing risks
  - ♦ benefits/risks of interventions
- Differentiate trivial, "tolerable" risk vs. significant, "non-tolerable" risk
- Risk assessment provides a measure of how big (or small) the risk

Risk Communication:

The *interactive exchange* of information and opinions concerning the risk among risk assessors, risk managers, consumers and other interested parties.

Rapid Review of Risk Assessment

- What is risk assessment?
- Why do risk assessment?
- How do we construct a risk assessment?

Risk Assessment

- In analyzing risk, we are attempting to envision how the future will turn out if we take a certain course of action (or inaction) ….
- Does not "solve" any problems
- It does provide an objective basis for management decisions based on current (imperfect) knowledge — *a decision-support tool*
- A framework to organize and evaluate all available information and knowledge relevant to the risk issue.

Three Risk Questions:

- What can go wrong?
- How likely is that to happen?
- What would the consequences be?
  Risk = f (hazard, likelihood, impact)

Chemical & Physical vs Microbial Hazards

- Physical hazards are either present or absent, in most instances.
- For chemical hazards, including microbial toxins, there is a "no observable adverse effect level" (NOAEL).
- For microbial hazards, one unit *might* cause infection, so probability becomes a major factor in risk assessment.

Risk Assessment: Hazard Identification

- Is there a problem?
- What is the evidence?
- What are the microorganisms or microbial toxins of concern in the food?
- Typically a *qualitative* process
- Focus dependent on purpose of assessment:
  - Specific Pathogen?
  - Specific Food?
  - Commodity?
  - Process?
  - Food Handling Practices?

Risk Assessment: Exposure Analysis

What is the probability of consumption of a food contaminated with the pathogen AND what are the likely numbers of a pathogen in the food *at the time of consumption*?

Exposure Assessment:

- Sources, frequency & level of contamination
- Factors affecting behavior of pathogen
- Distribution of food, potential for abuse
- Control measures
- Seasonality
- Consumption patterns

Modeling the Food Chain:

A model characterizes the components of a system, and describes the interaction between these components.

- Predicting microbial growth/inactivation
- Fault trees, event trees
- "Flow" of food through system
- "Flow" of pathogen through system

Example: Risk assessment for *Listeria monocytogenes* (LM) in raw milk cheese

- On-farm sources of LM in raw milk
  - Intramammary: mastitic milk
  - Extramammary: "filth" from dairy (milking) environment
- Contamination in processing and packaging
- Retail and consumer storage or handling — will growth occur?

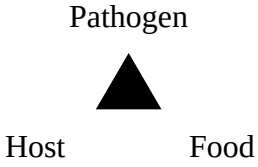
Risk Assessment: Hazard Characterization

- How much of the pathogen will make you sick, and how sick will you be?
- The Dose-Response assessment is a mathematical model that predicts the probability of an adverse effect from a given dose.

Consequences of Exposure ("outcomes"):

- None
- Infection without symptoms of illness
- Acute gastroenteritis
- Long-term effects (chronic)
- Mortality

Dose-Response Relationships:



Susceptible Populations:

- Very young
- Elderly
- Pregnant women
- Immunocompromised

Risk Assessment: Risk Characterization

Integrates exposure and dose-response information to provide an estimation of adverse effects likely to occur in a given population ➔ a Risk Estimate

Dose response assessment predicts the probability of disease from ingestion of a given number of pathogens.

Most experts agree that there is no minimal infective dose of microorganisms but that the probability of getting ill declines with declining numbers of pathogens ingested.

Prediction is based on exponential model or on beta Poisson distribution

beta Poisson:
$P = 1 - (1+N/b)^{-a}$

P is probability of getting ill
N is the number of organisms ingested
a and b are constants for different pathogens
formula applies to people with normal resistance

Risk Assessment and Predictive Microbiology: Probabilities of Infection Associated with <u>One</u> Cell of Different Pathogens.

Microbe	**a**	**b**	**Probability of Infection**
Campylobacter	0.039	55	7×10^{-3}
Salmonella	0.33	139.9	2.3×10^{-3}
S. flexneri	0.2	2000	1×10^{-4}
V. cholerae	0.097	13020	7×10^{-6}

Risk Characterization:

- What is the nature and likelihood of the health risk?
- Which individuals or groups are at risk?
- How severe are the adverse impacts or effects?
- Are the effects reversible?
- What scientific evidence is there, and how strong is it?
- What is uncertain about the nature of the risk?
- What is the range of informed views about the nature and probability of the risk?
- How confident are the risk analysts about their predictions?

Elements of a Risk Assessment:

- Data: Published scientific literature, surveillance reports, outbreak reports.
- Model: Description of the system under analysis; in Quantitative Risk Assessment, relationships between factors are described mathematically
- Assumptions: "Hypothesis, conjecture, guess, postulation, theory" (Webster).

What is the right model to use?

The "right" model to use captures the essentials of the system. Too much detail obscures, too little detail misses the essentials.

Risk Distribution, influenced by

- Variability
- Uncertainty

Variability

- A property of nature; diversity in a well-characterized population or parameter
- Defined by mean, standard deviation.

Dealing with Variability

- Variability is the diversity of things.
- *Cannot be reduced* through taking more measurements.
- May be reduced by implementing controls to limit deviations.

Uncertainty is our ignorance - lack of knowledge. Sources:

- Measurement Uncertainty – Sampling methods, testing methods
- Conditions of Observation – Lab studies vs. what happens in nature
- Inadequacy of Models – Poor understanding of the system, e.g. the food production system, the infection system.

Dealing with Uncertainty

- More research
- Expert judgment?
- Conservative decision? "Precautionary Principle"

HACCP and Risk Assessment: HACCP is a risk management strategy to ensure hazards are prevented, eliminated or reduced to an acceptable level.

- What hazards are essential to control?
- What is an "acceptable level"?
- Do the designated *Critical Control Points* actually reduce human health risk?
- Risk Assessment provides a measure of the human health risk associated with specific hazard(s) in a food.
- Forecasts outcome of HACCP in terms of human health risk
- Validates *Critical Control Points*.

Data needs for Risk Assessment

- Data

- The right data
- Uncertainty:
  What is sensitivity and specificity of sampling and test methods (precision details)?
- Variability:
  What is the distribution of observations?
- *International harmonization of data collection methods and approaches to risk assessment*

Risk assessment won't provide the solutions to all food safety problems, but should help in decision-making.