Health Canada

What Is Risk Assessment ?

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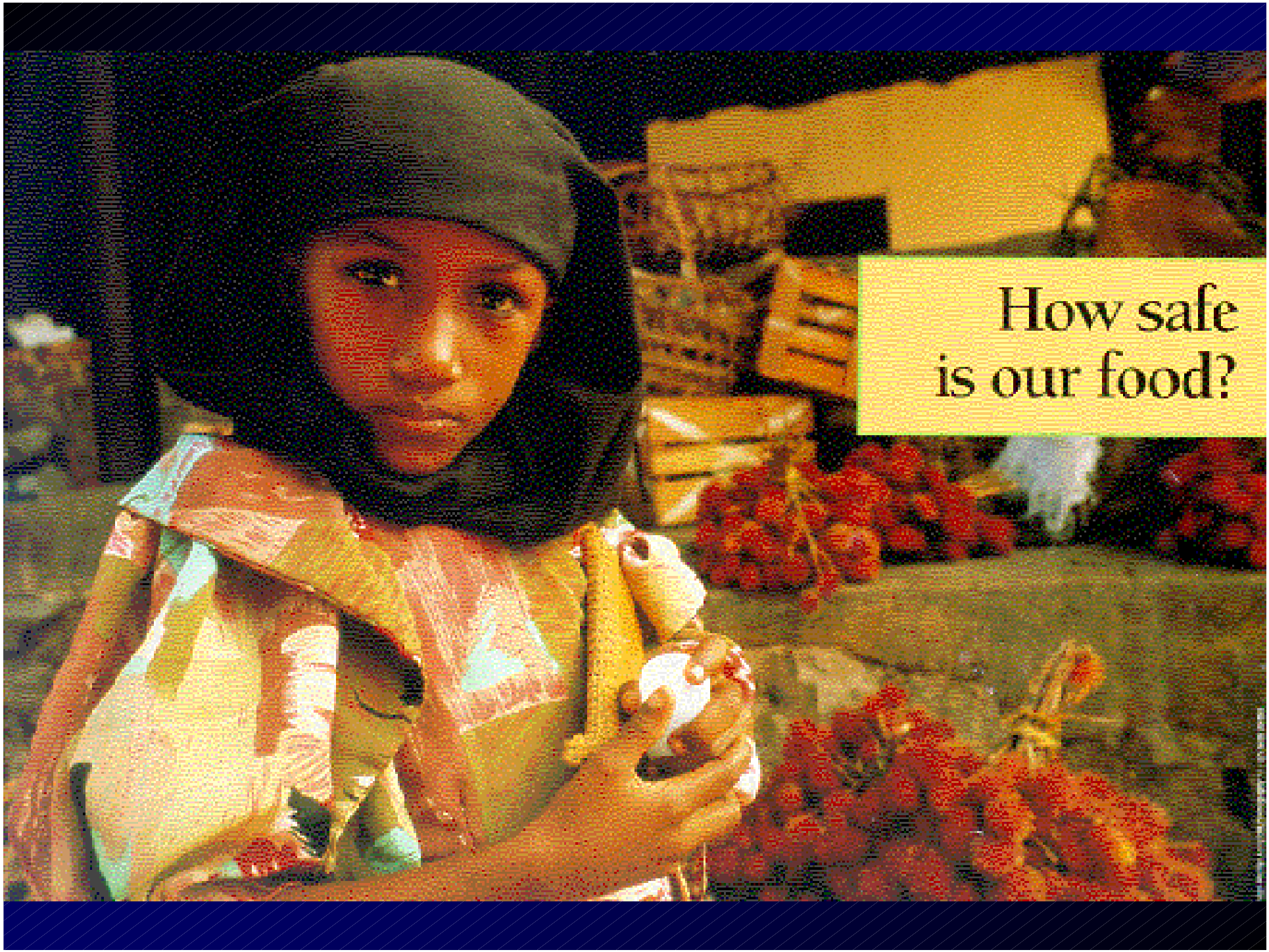

How safe
is our food?

International Trade

- World Trade Organization: "Agreement on Sanitary and Phytosanitary Measures" (SPS Agreement):
  - **Barriers to trade must be based on scientific evaluation of risk to human health…**
    - Implications for national regulatory standards

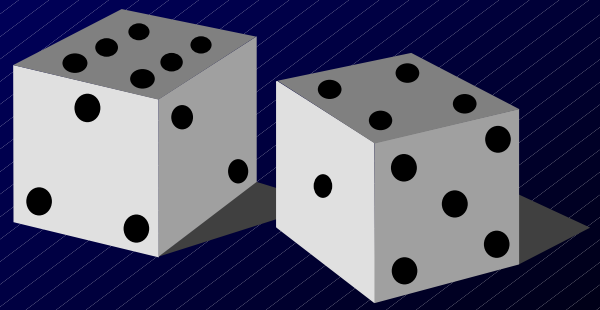
National Risk Management Policies:

Basic Assumptions:

- The degree of "regulatory control" placed on a foodborne pathogen should be a function of its risk to public health

Risk Assessment

A systematic process to collect and evaluate relevant information about an issue, to estimate the *probability* AND *impact* of adverse outcomes, based on what we know now ….



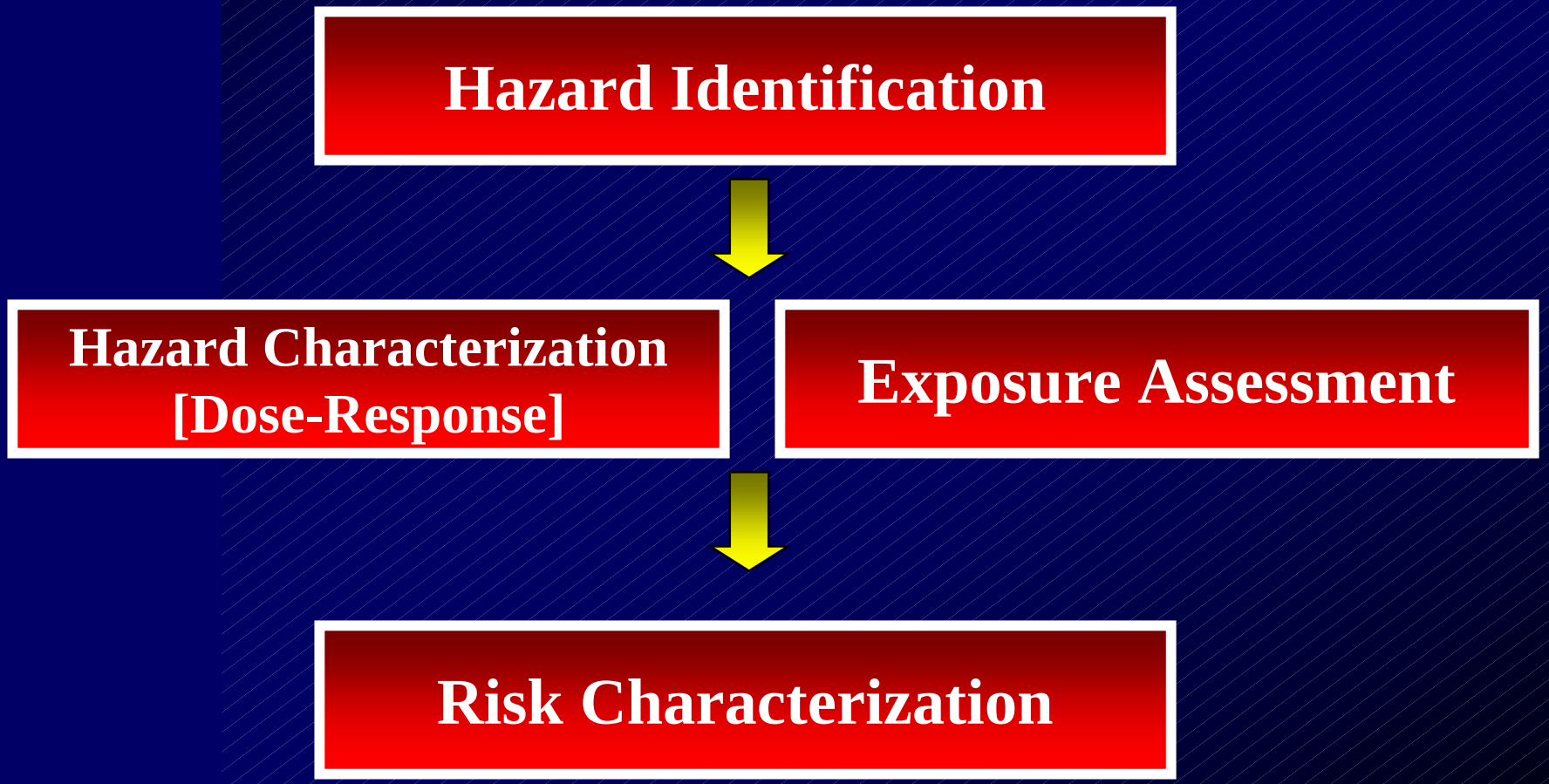
3 Risk Questions

- What can go wrong?
- How likely is that to happen?
- What would the consequences be?

Kaplan & Garrick, 1981 Risk Anal. 1:11-27

Risk = f (hazard, likelihood, impact)

Risk Assessment Framework



Risk Assessment Framework

Hazard Identification

IS THERE A PROBLEM ?

WHAT IS THE EVIDENCE?

Description of the hazard (agent in the food) and adverse effects

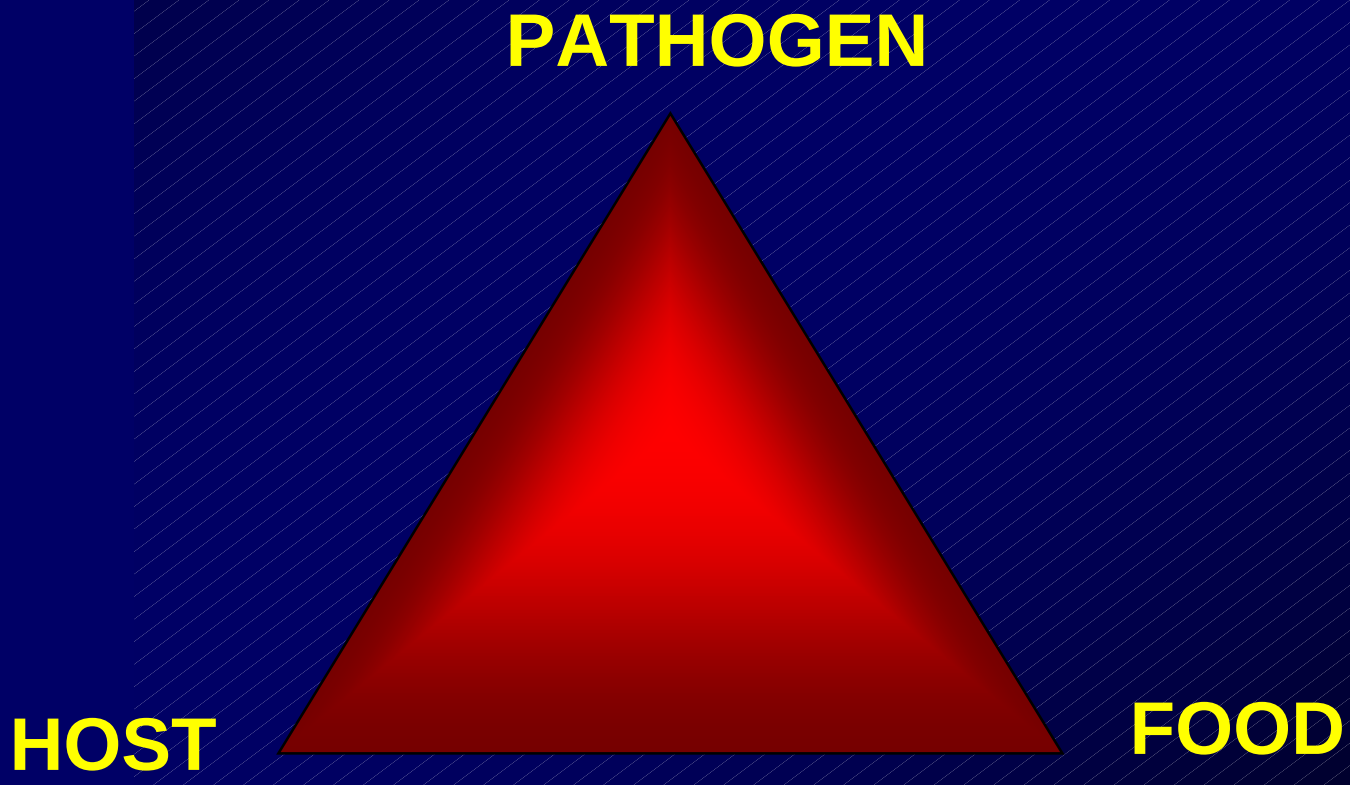
Risk Assessment Framework

Hazard Characterization [Dose-Response]

How much of the pathogen will make you sick, and how sick will you be?

The *Dose-Response* assessment is a mathematical model which predicts the probability of an adverse effect from a given dose.

Dose-Response Relationships



Risk Assessment Framework

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

Exposure Assessment

Exposure Assessment

- Cannot measure exposure at time of consumption directly
- Therefore must consider:
  - Sources, frequency & level of contamination
  - Factors affecting behaviour of pathogen
  - Distribution of food, potential for temperature abuse
  - Food preparation, consumption patterns

Risk Assessment Framework

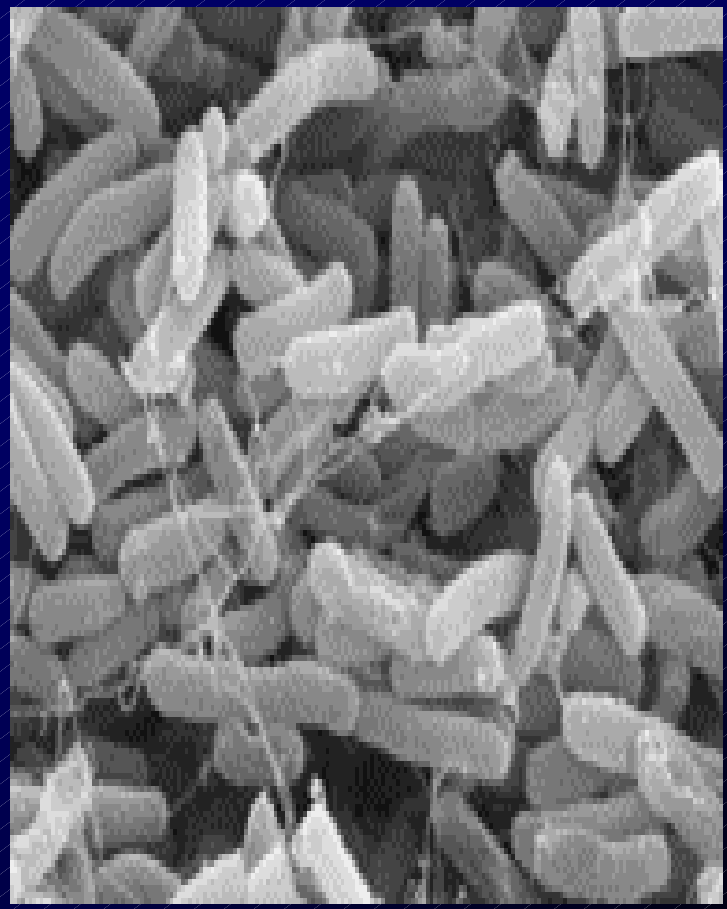
- Provides a **RISK ESTIMATE**
- What is the nature and likelihood of the health risk?
- **Who** and how many are likely to become ill?
- What are the sources of **variability** and **uncertainty** in the information used?

Risk Characterization

Variability

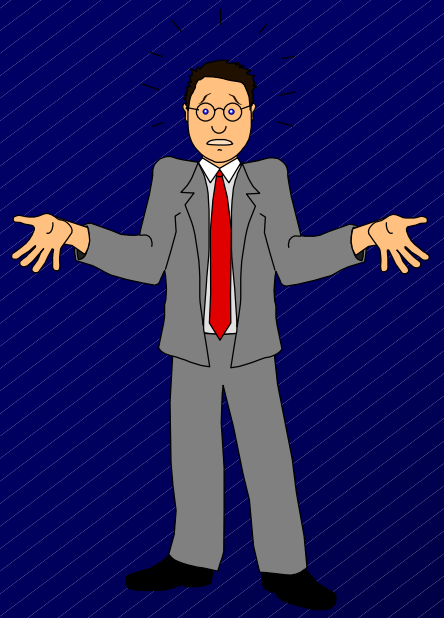
- A property of nature
- Diversity

- In a well-characterized population or parameter: defined by mean, standard deviation



Uncertainty

???

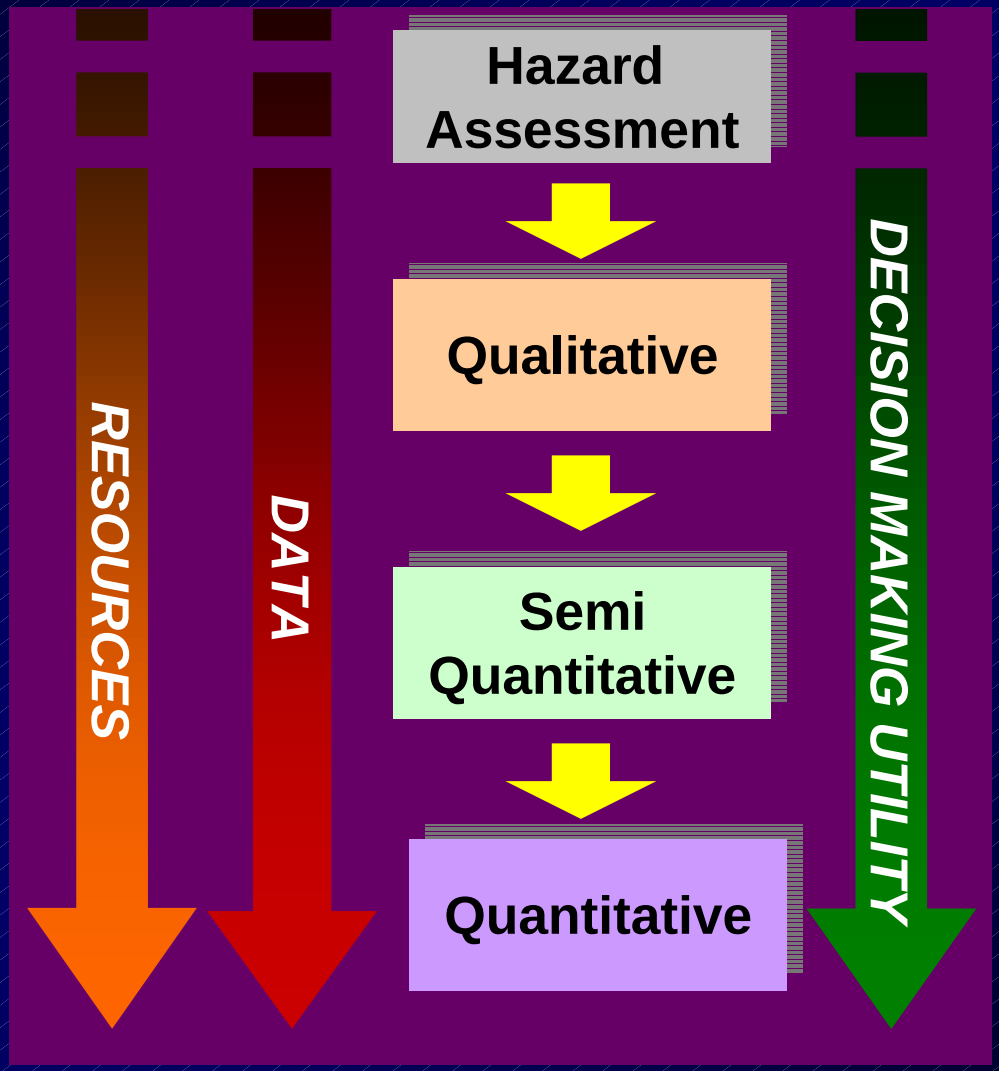


Uncertainty **is our ignorance**
- lack of knowledge

Sources of Uncertainty

- Measurement Uncertainty
- Conditions of Observation
- Poor Understanding of System

Risk assessment approaches



What is the right approach to use?

- The "right" approach captures the essentials of the risk issue *to answer the risk management question*. Too much detail complicates, too little detail misses the essentials.

"Things should be made as simple as possible, but no simpler" (Einstein).

Quantitative Risk Assessment

- Mathematical description of exposure, dose-response relationship
- Numerical risk estimate

- Point – Estimate
- Probabilistic (Stochastic)

Point-Estimate Assessment

Uses averages or “worst-case” single numbers

Eg. Exposure inputs:

- 100 pathogen cells per gr food
- 2-log increase in cell numbers: storage
- 3-log reduction by cooking
- 50 gr food eaten

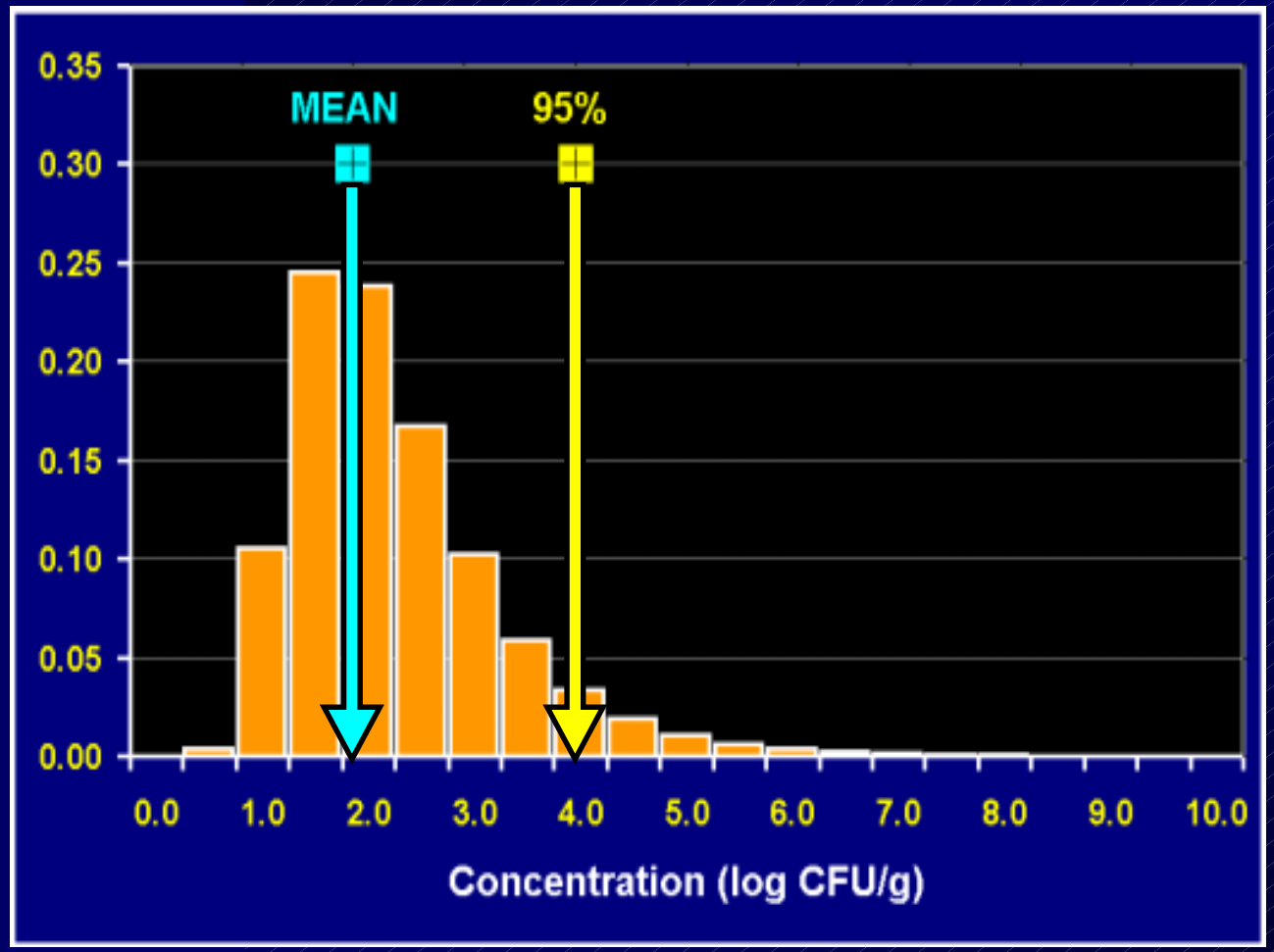
Ignores Variability and Uncertainty

Probabilistic Analysis

- Uses entire distribution of data
- Evaluates almost all the possibilities
- Recognizes the variation that exists in the real world
- Allows the uncertainty associated with our knowledge of the real world to be accounted for

Point Estimate vs. Probabilistic

Concentration of a pathogen in a food.



POINT ESTIMATE

Mean = 2.0

95% = 4.0

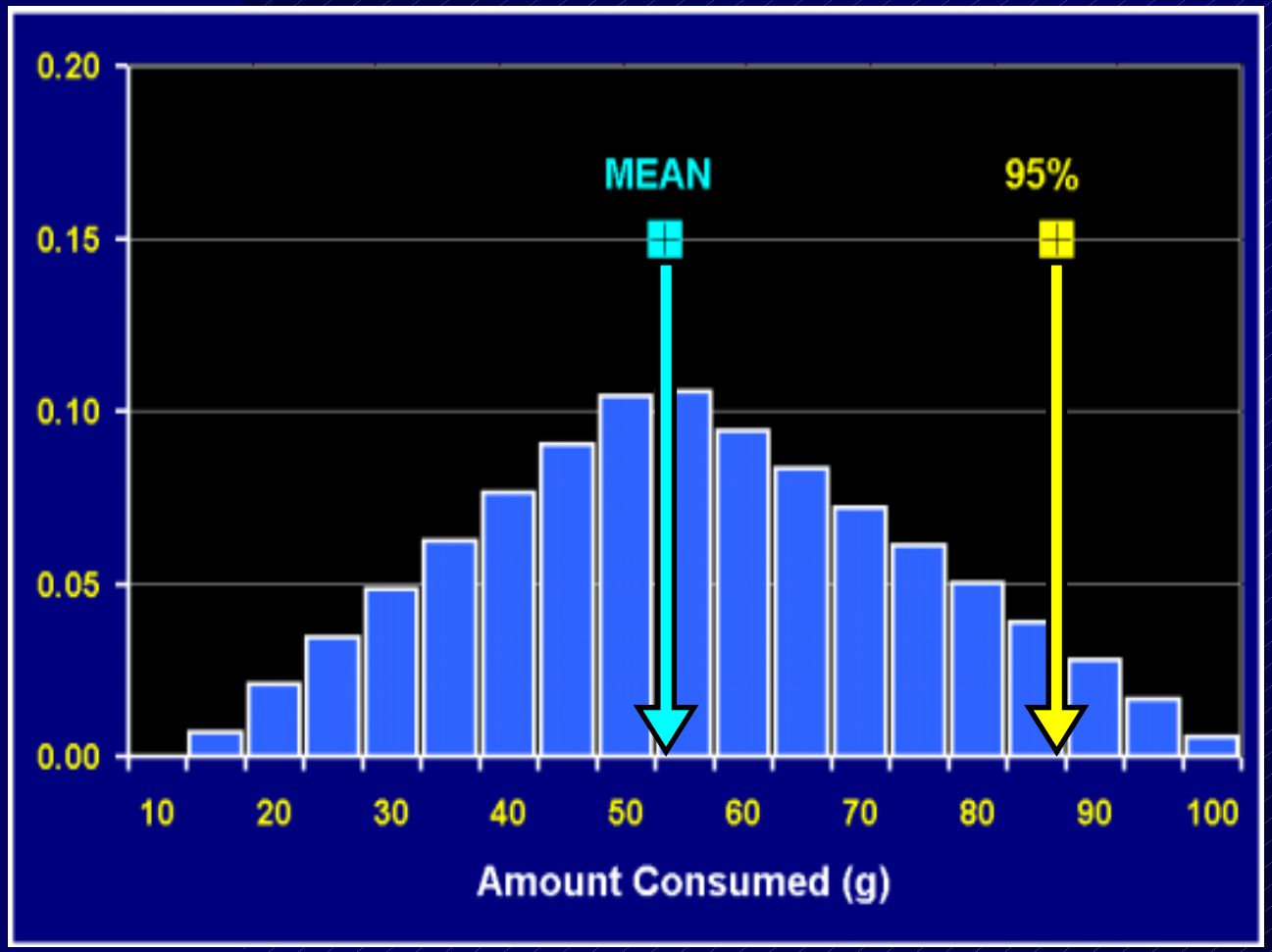
DISTRIBUTION

Log-Normal

μ = 2.0

σ = 1.0

Point Estimate vs. Probabilistic:
Amount of Food Eaten



POINT ESTIMATE

Mean = 53.3

95% = 85.0

DISTRIBUTION

Triangular

Min = 10

Mode = 50

Max = 100

Risk Assessment Outputs

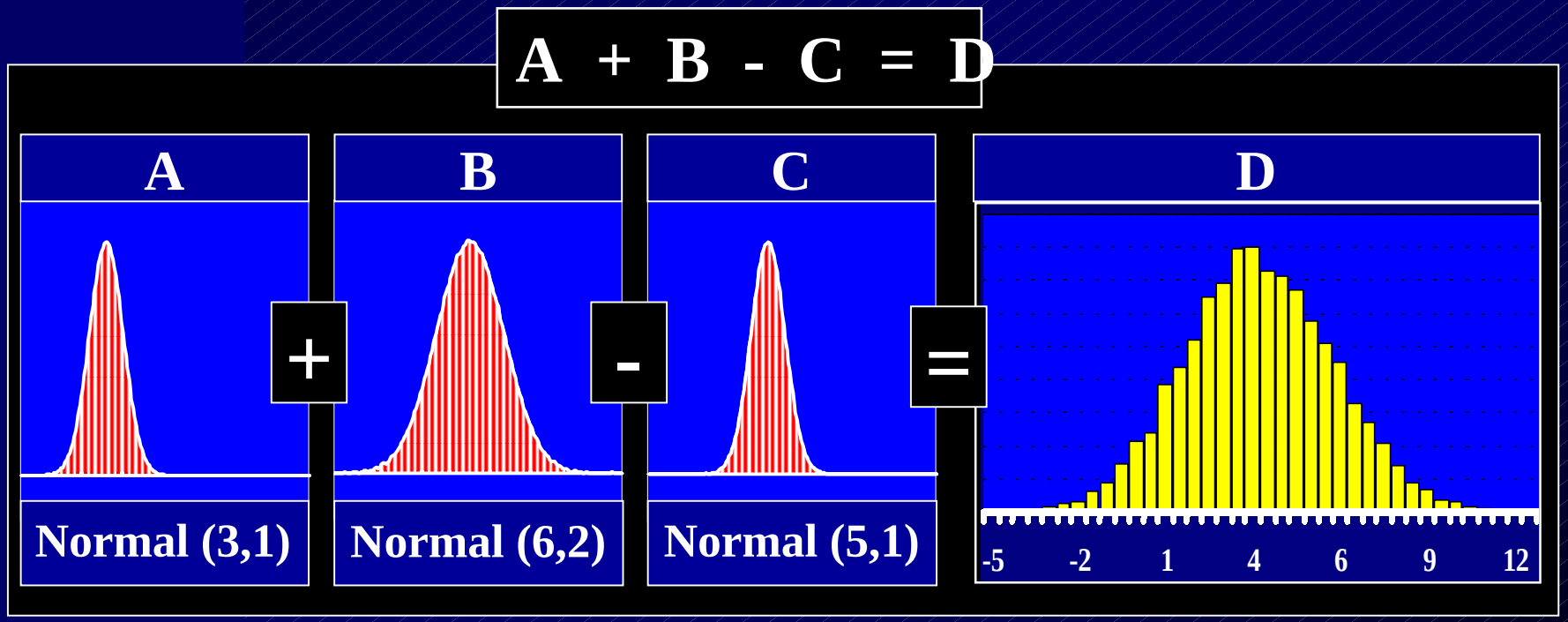
- Point-estimate: single values for risk estimate

E.g:

- 1-in-1 million likelihood of illness per meal
- Per year
- 500 illnesses in a population per year

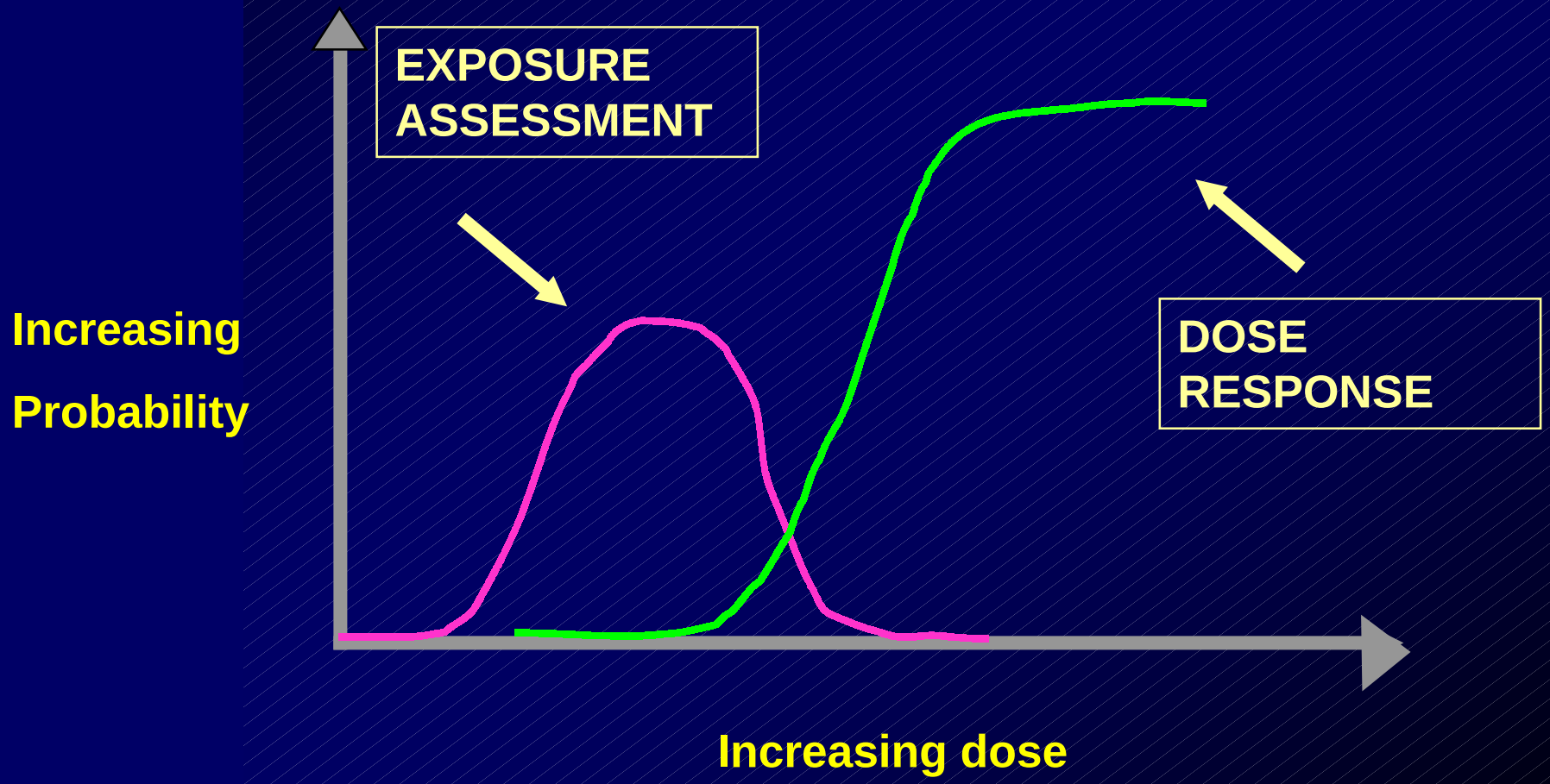
Probabilistic Calculations: Monte Carlo Simulation Techniques

- to accommodate variability and uncertainty in the input and output values

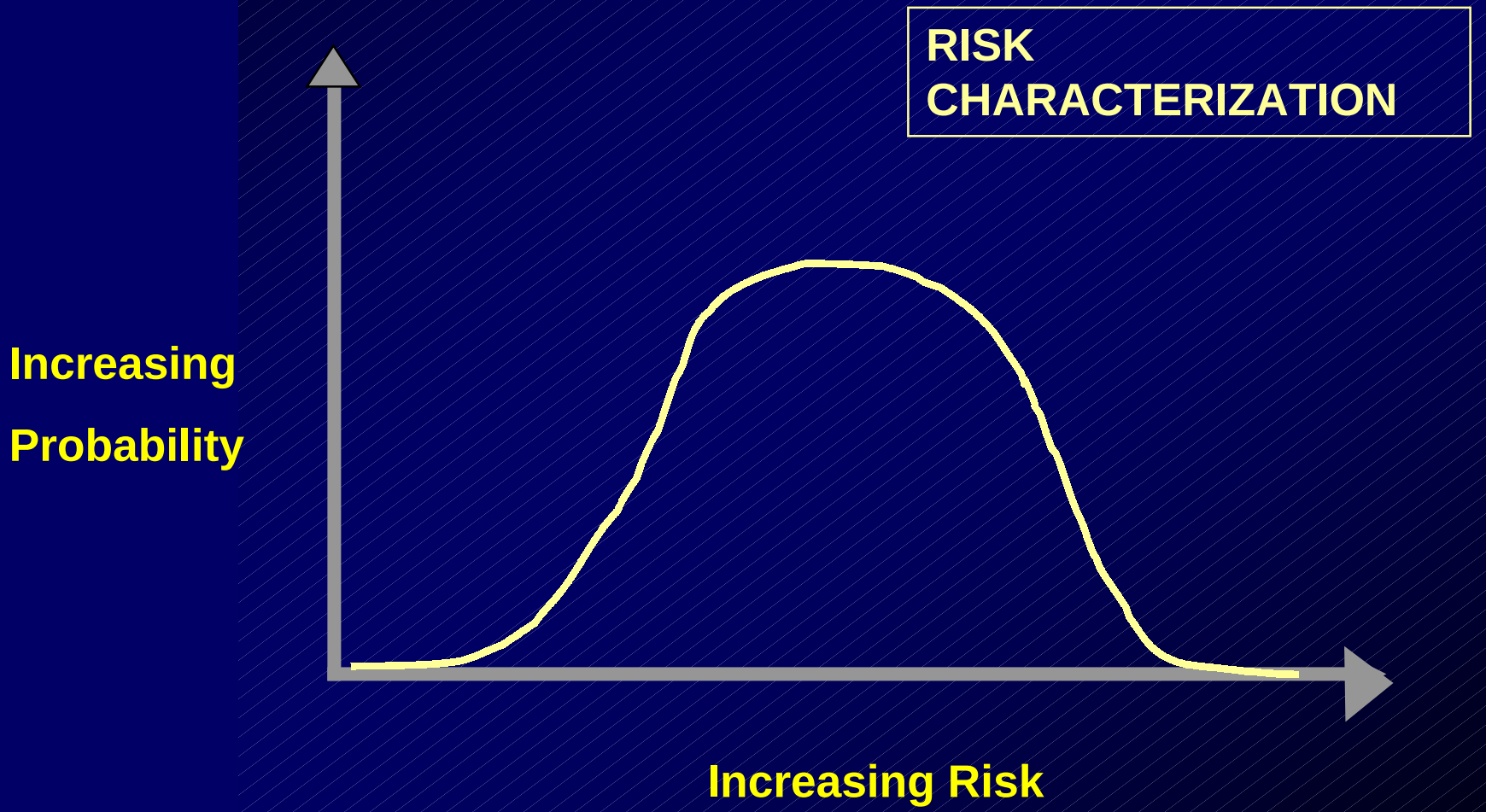


- Range of values for “D” and probability of occurring can be determined.

Probabilistic Outputs



Probabilistic Risk Estimate



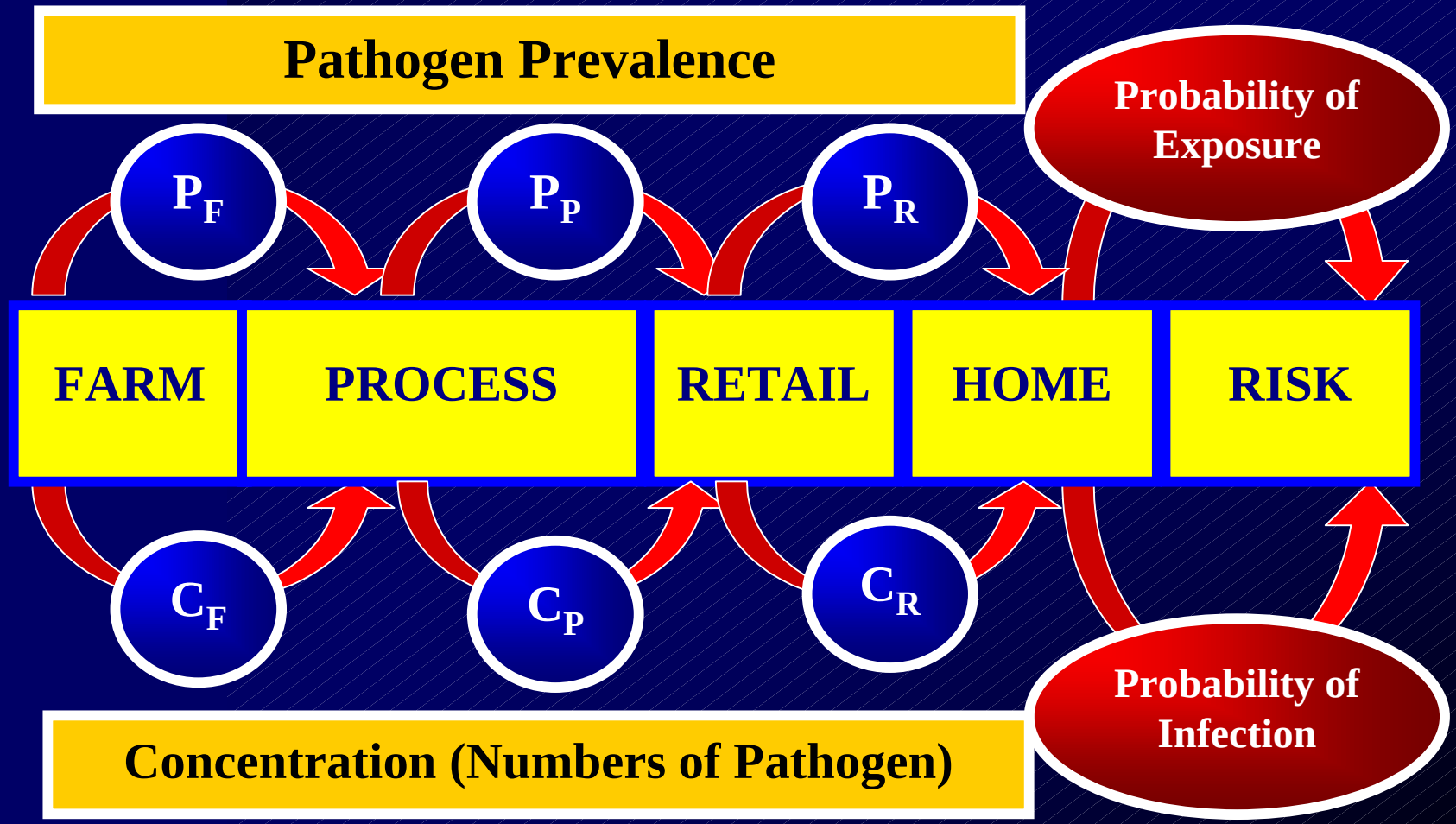
Why do we do risk assessment?

- **To estimate the magnitude of the risk**
  - **Regulation**
  - **Acceptability**
  - **Priorities**

Added value:

- To gain an understanding of the “system”
  - Identify effective interventions to reduce risk
  - Focus research directions to reduce uncertainty

“Farm-to-Fork” Risk Assessment



Modeling Approaches

"All models are wrong, some are useful"

- This quote captures the essence of why we model a system:
  - The intention is not to create a perfect and exact duplicate of reality
  - rather to create a tool that will provide insight into the system

Goals of 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 how small) the risk*

Microbiological Risks

- Assessing and characterizing risks is different from setting “acceptable” or “tolerable” levels of risk
  - The latter is both a scientific and societal question

Decision-making

- Risk management decisions will be made with or without a risk assessment
- Risk assessment will hopefully add to more enlightened decisions
  - Separate facts, opinions, and perceptions

Using a systematic process

- The discipline of risk assessment assembles information on the determinants of disease into a single framework …

- This includes biological determinants & their interaction with environmental and behavioural factors …

- Allows social and economic considerations to be factored into the decision-making framework

Transparency

- A **fundamental characteristic** of the risk analysis concept (risk assessment, risk management, risk communication)

- The data, logic of development, assumptions, limitations and uncertainties of the process are fully and systematically stated, documented and accessible for review.