Emerging Risk Management Tools

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Presentation

- Background on International Food Safety Organizations
- Appropriate Level of Protection
- Food Safety Objectives and Performance Objectives
- Verifying a Performance Objective or a Performance Criterion
- Example – Powdered Infant Formula
- Concluding Remarks

International Food Safety Organizations

“The Goal”

- The degree of “regulatory control” placed on a pathogen-food pair should be a function of the risk to public health

“The Problem”

- **We have been seldom able to:**
  - **Measure the risk**
  - **Relate the stringency of food safety control measures to the degree of risk mitigation**
  - **Translate the stringency of a food safety system into its public health impact**
  - **Objectively compare the relative effectiveness of different control measures (equivalence)**
- **Finding solutions has been increasingly important with the emerging global marketplace for foods**

World Trade Organization (WTO)

- For international trade in food, two of the most important agreements are the "Sanitary and Phytosanitary (SPS) Agreement (SPS)" and the "Technical Barriers to Trade (TBT) Agreement"

- Recognizes Codex Alimentarius Commission as the international food safety standards setting body

SPS Agreement

- **Desires of Agreement:**
  - To improve public health
  - To establish multilateral framework for development, adoption, and enforcement of SPS measures to minimize trade impact
  - To harmonize SPS measures between countries via Codex Alimentarius Commission in the case of foods

SPS Agreement

- A country can require higher level of SPS protection than international standard if it can:
  - Provide scientific justification
  - Establish an "Appropriate Level of Protection" (ALOP) based on assessed risk
- Underlined phrase has had a tremendous impact on how international standards are being developed

Codex Alimentarius

- International standards setting body for foods
  - Enhance public health
  - Prompt fair international trade practices for food
- Established in 1962 under the auspices of the United Nations (FAO and WHO)

Codex: Risk Analysis

- Codex has had a long history of using risk assessment as a tool for some of its activities
- New role under the WTO/SPS Agreement, Codex has accelerated adoption of risk analysis as the framework for dealing with many of its activities
- Has had to develop and/or adapt a framework wherein risk analysis principles could be effectively applied to highly complex and varied food control systems

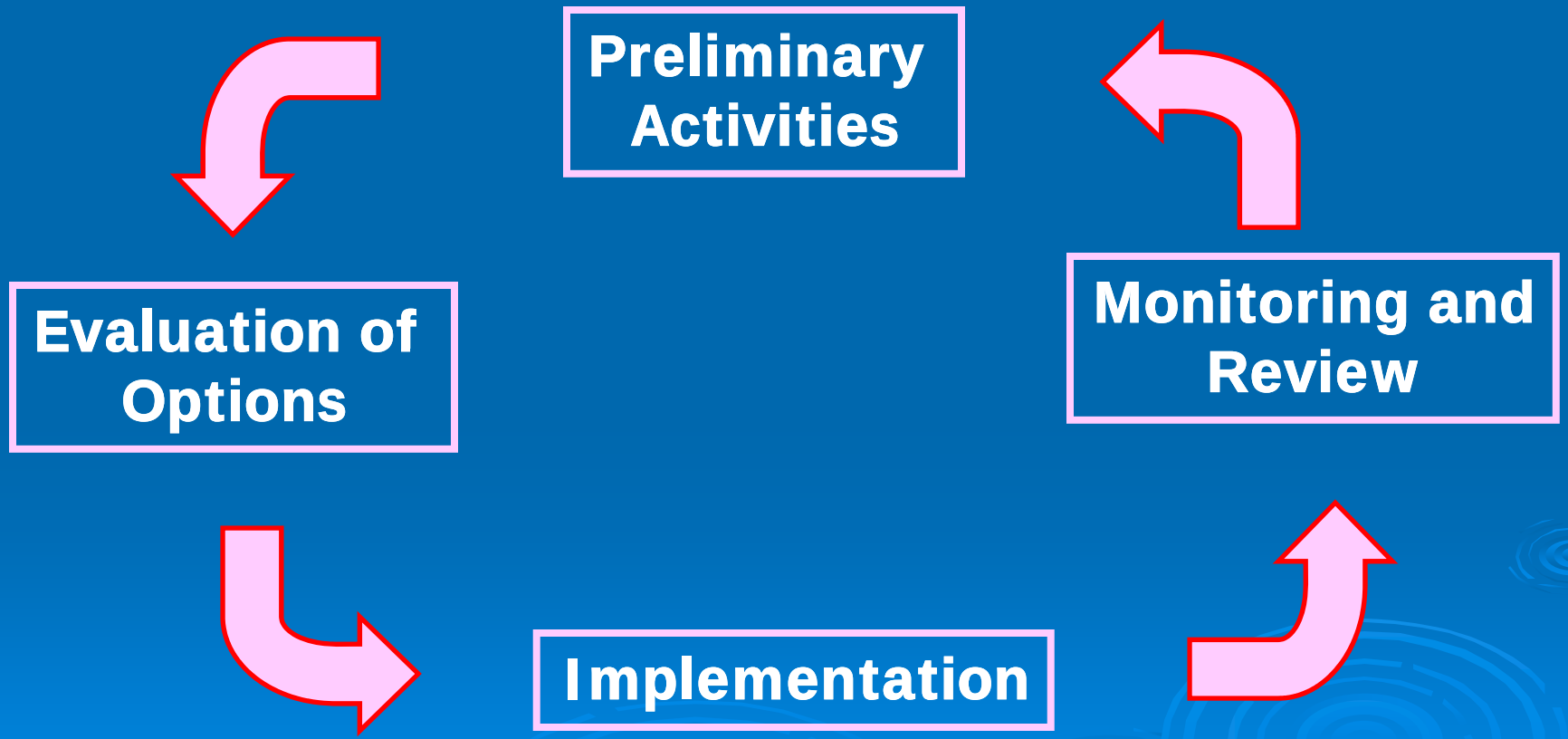
Codex: Risk Analysis

- Four Codex committees have been particularly active in developing risk analysis principles
  - Food Hygiene (United States) ❋
  - Contaminants in Foods (Netherlands)
  - Food Additives (China)
  - General Principles (France)

Codex: Risk Analysis

- **Four key Codex references:**
  - **"Working Principles for Risk Analysis for Food Safety for Application by Governments" (*CAC/GL 62-2007*)**
  - **"Working Principles for Risk Analysis Application in the Framework of the Codex Alimentarius" (Procedure Manual)**
  - **"Principles and Guidelines for the Conduct of Microbiological Risk Assessments" (CAC/GL-30 (1999))**
  - **"Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)" (CAC/GL 63-2007)**

Codex Framework for Microbiological Risk Management



General Principles of MRM

- 1. Protection of human health is the primary objective of MRM
- 2. MRM should take into account the whole food chain
- 3. MRM should follow a structured approach
- 4. MRM process should be transparent, consistent and fully documented
- 5. Risk managers should ensure effective consultations with relevant interested parties

General Principles of MRM

- 6. Risk managers should ensure effective interaction with risk assessors
- 7. Risk managers should take account of risk resulting from regional differences in hazards in food chain and regional differences in available risk management options
- 8. MRM decisions should be subject to review and revision

Impact of Risk Analysis Framework

- **Advances in risk assessment and its ability to better link food safety activities to public health outcomes has allowed:**
  - **New concepts emerging**
    - **Appropriate Level of Protection (ALOP)**
    - **Food Safety Objective (FSO)**
    - **Performance Objective (PO)**
  - **Old concepts put on a more scientific basis**
    - **Performance criteria**
    - **Process criteria**
    - **Product criteria**
    - **Microbiological criteria**

New Risk Analysis Vocabulary Emerging

- **Food Safety Objective:** "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)"
- **Performance Objective (PO):** "The maximum frequency and/or concentration of a hazard in a food at a specified point in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable"
- **Performance Criterion (PC):** "The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application on one or more control measures to provide or contribute to a PO or FSO"

New Risk Analysis Vocabulary Emerging

- **Process Criterion (PrcC):** The processing conditions that must be met to achieve the PO/PC
- **Product Criterion (PrdC):** The characteristic(s) of a food that must be maintained or achieved to achieve a PO/PC/FSO
- **Microbiological Criterion (MC):** The level and/or frequency detected by a specified method and sampling plan that achieves the PO/PC

Codex Framework for Risk Management Metrics

- **"Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) / Annex II: Guidance on Microbiological Risk Management Metrics" (CAC/GL 63-2007)**
  - **Identification of microbiological risk management metrics**
  - **General principles for their use**
  - **Guidance on integration of the metrics into a public health oriented food safety system**
- **Finalized at 2007 CCFH meeting in New Delhi, India**

Metrics - Definition

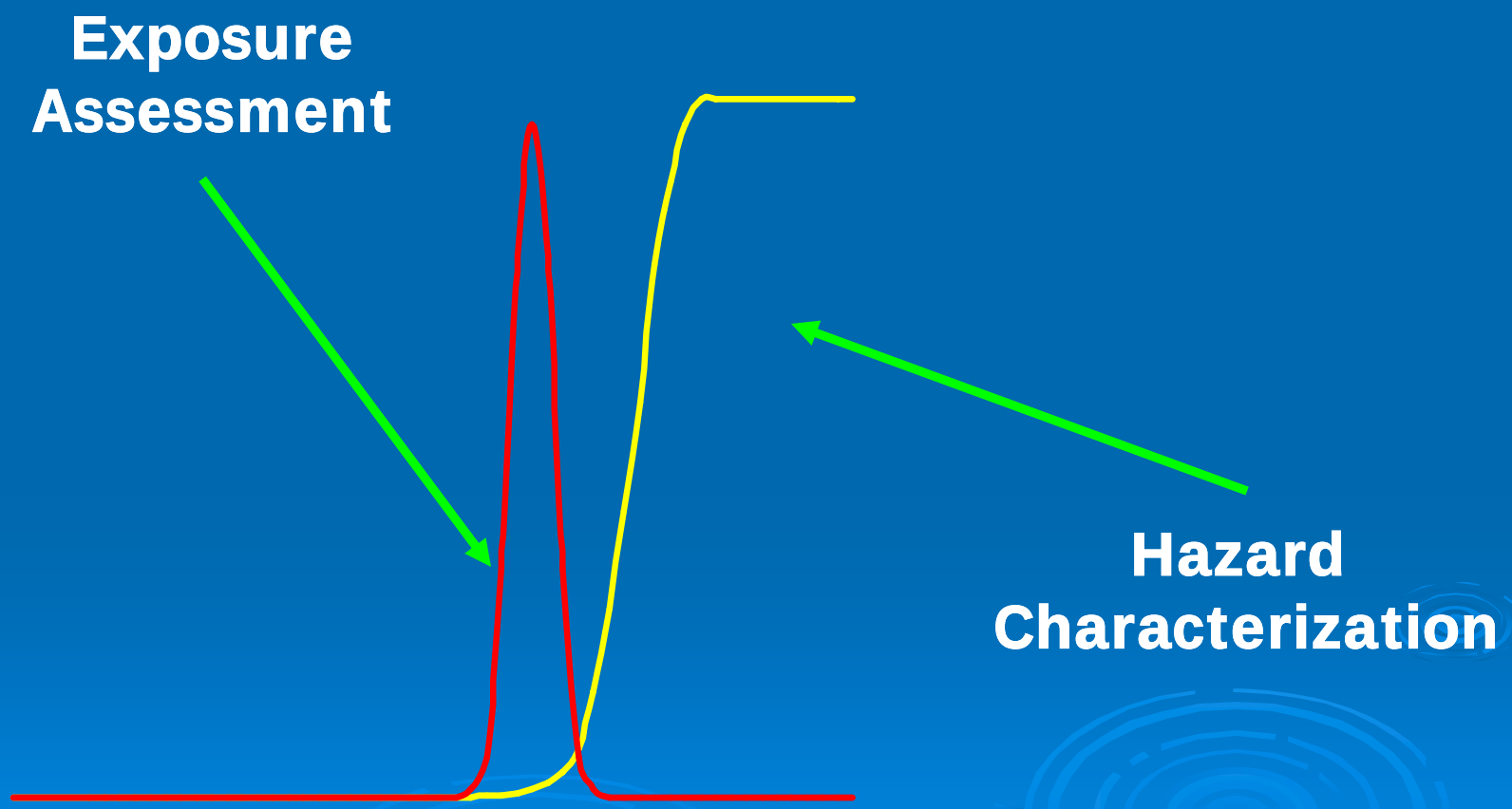
- A system of related measures that facilitates the quantification of some particular characteristic

Appropriate Level of Protection (ALOP)

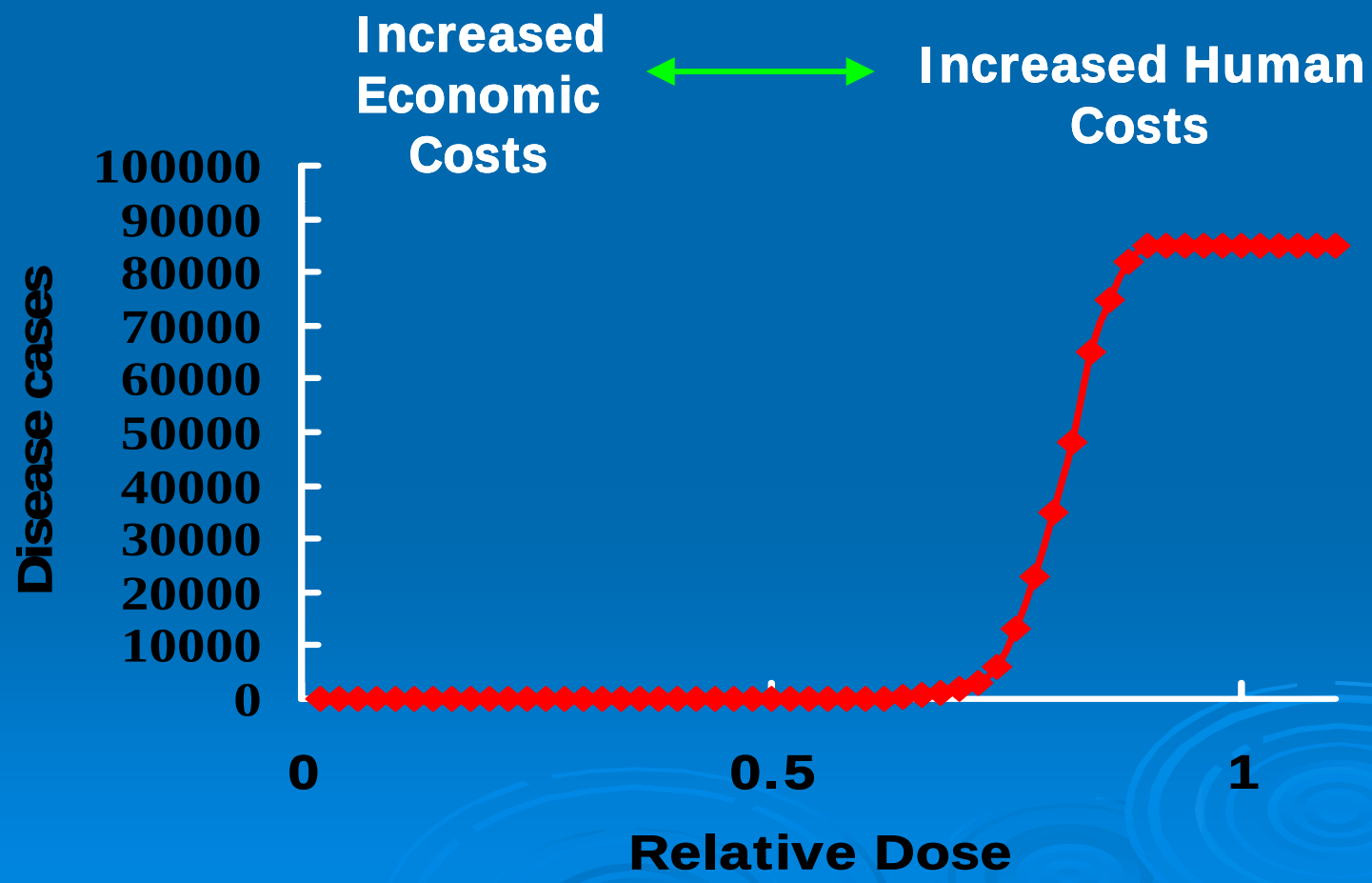
Appropriate Level of Protection

- Concept introduced by WTO SPS agreement
- "Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within a territory"

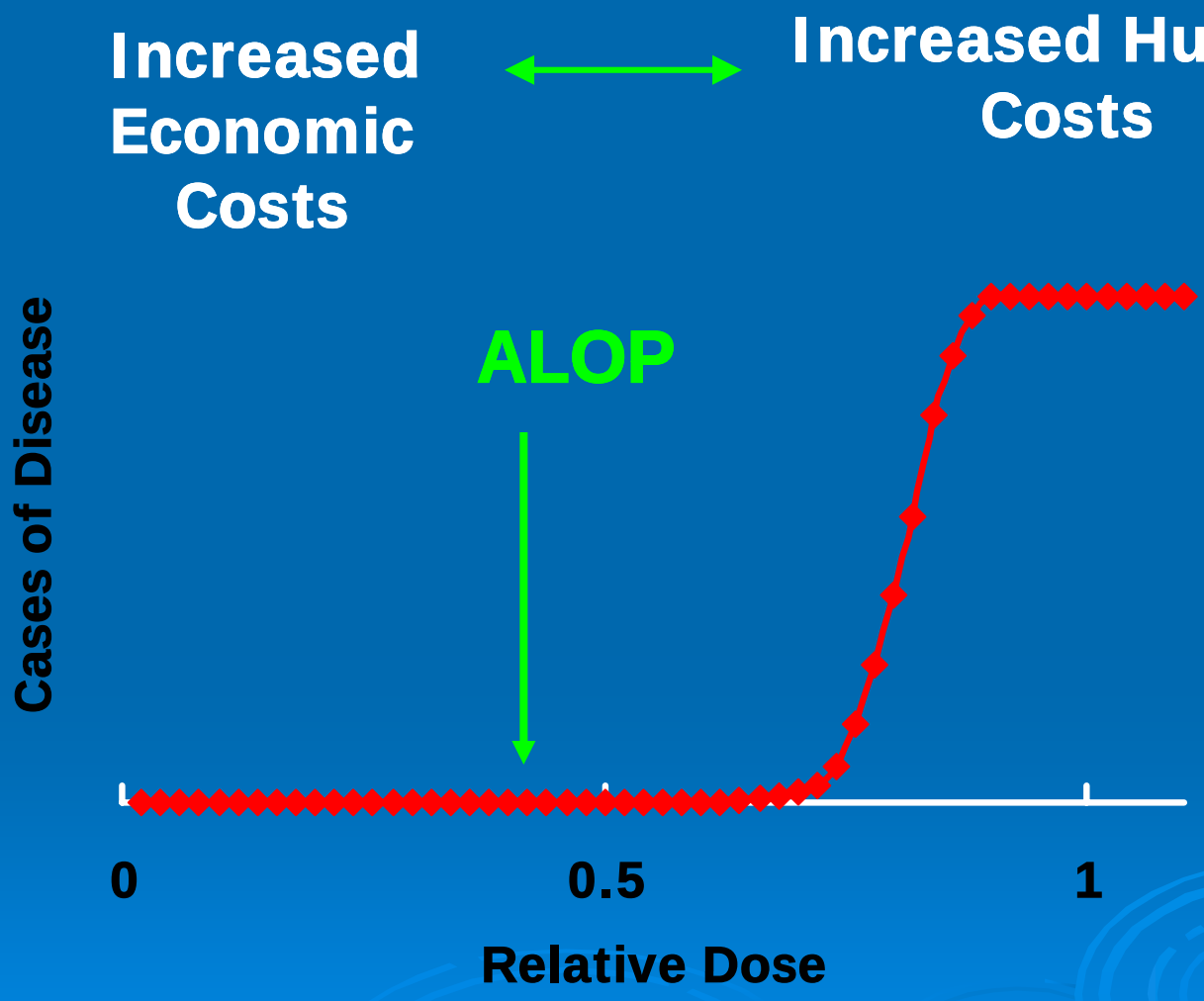
Risk Assessment



Appropriate Level of Protection

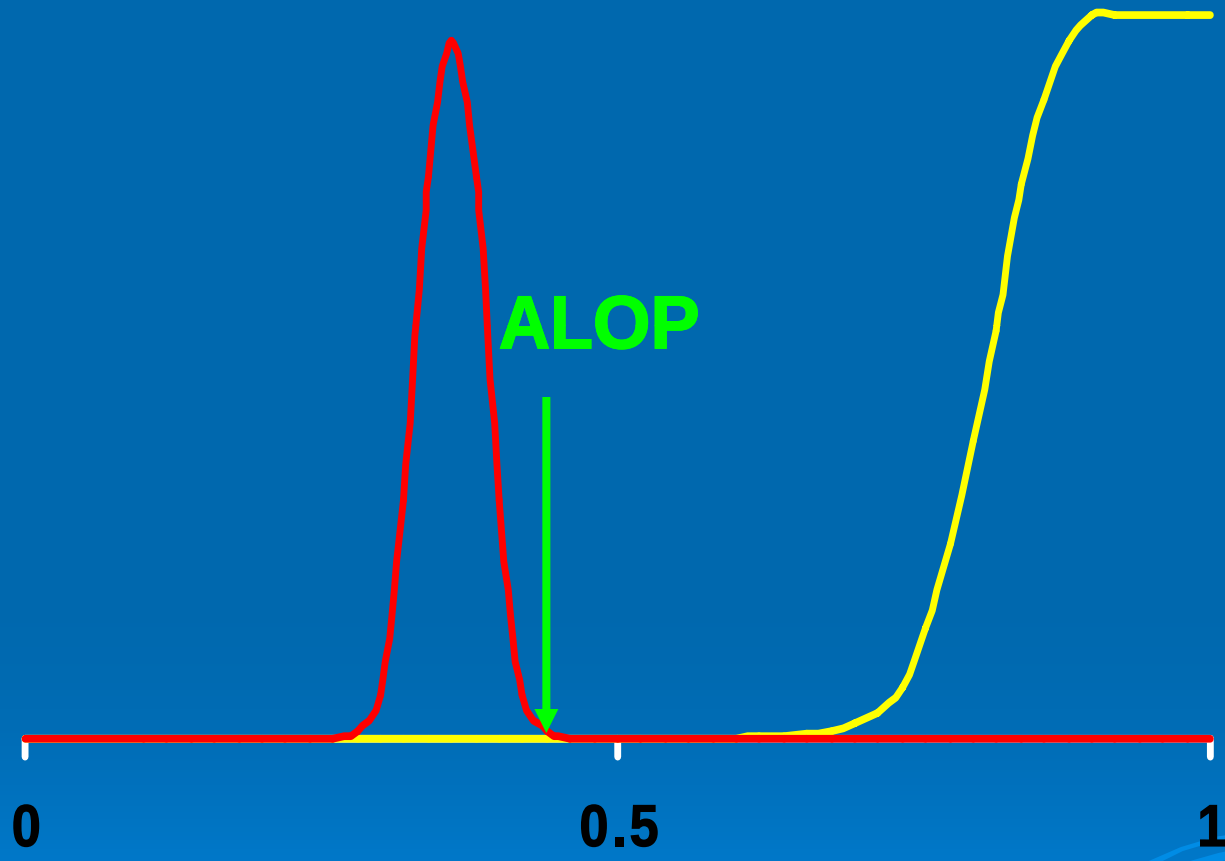


Appropriate Level of Protection



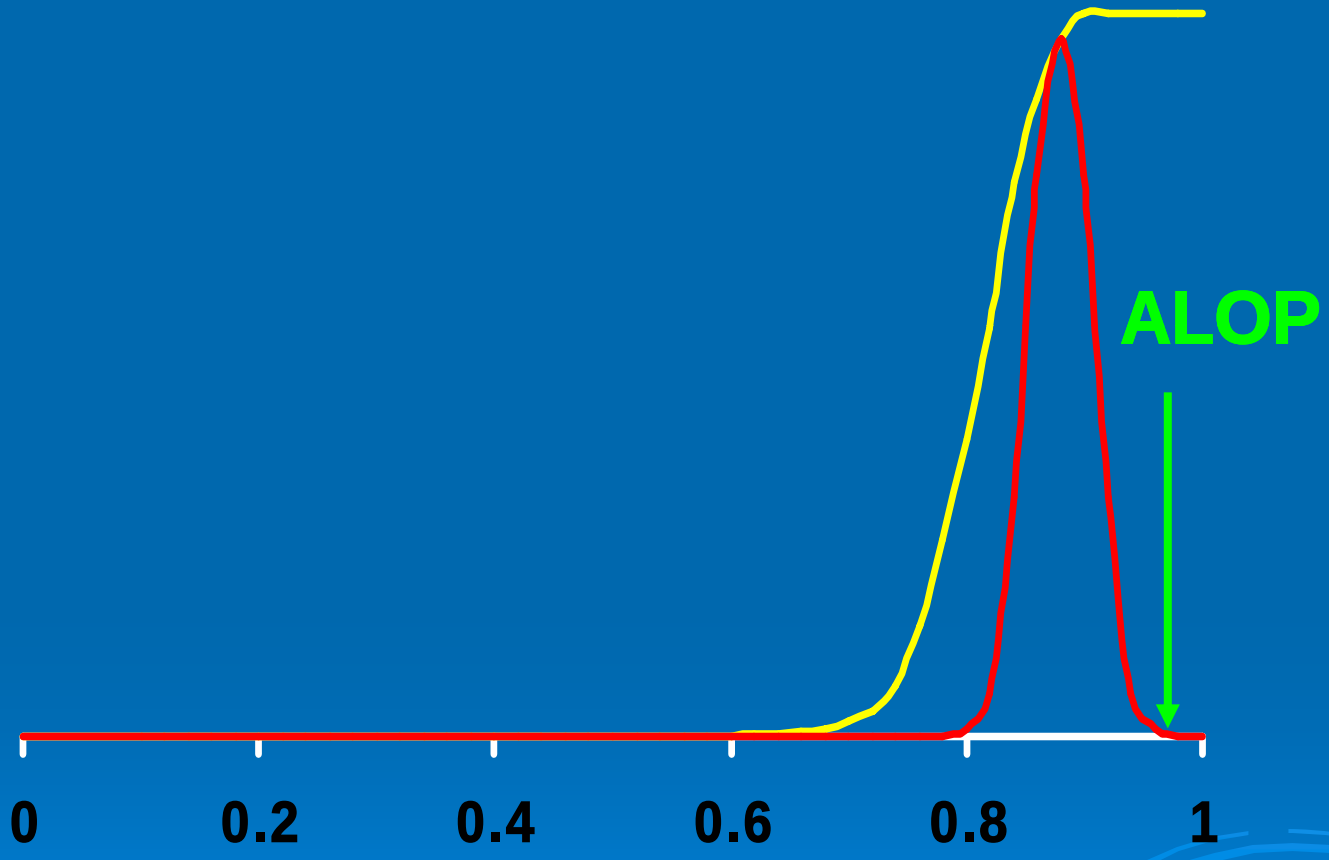
At some point, whether qualitatively or quantitatively, must make a decision on the degree of stringency required

Appropriate Level of Protection



"Risk Adverse" Decision

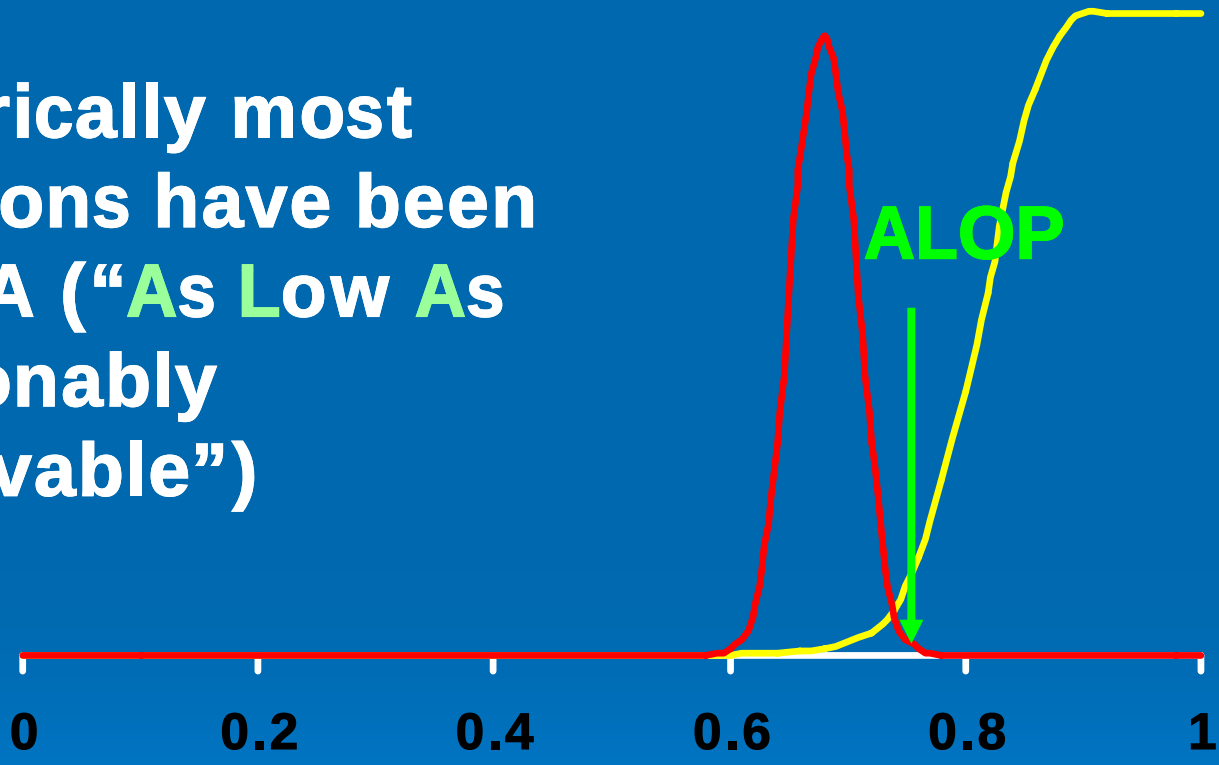
Appropriate Level of Protection



"Risk Tolerant" Decision

Appropriate Level of Protection

Historically most decisions have been ALARA ("As Low As Reasonably Achievable")



FSO / PO

"The Problem"

- ALOP is typically measured in terms of a "probability of disease," "number of cases per year, " or general legal terms
- Metrics that cannot be directly:
  - Controlled by food producers and processors
  - Regulated by food control agencies
- ALOP must be converted to something that can be controlled and measured in a food production or processing facility through GAPs/GMPs/GHPs and HACCP

“The Problem”

- Need these metrics to develop a means of relating public health risks to the presence of a hazard in a food in order to reach agreement on the stringency of food safety systems

Risk Management Metrics

- An integral part of a risk analysis approach is being able to relate the stringency of a food control system to its intended public health outcome
  - Chemical contaminants: Maximum levels
  - Microbial contaminants: Food Safety Objectives, Performance Objectives, Performance Criteria
- Involves a risk assessment component

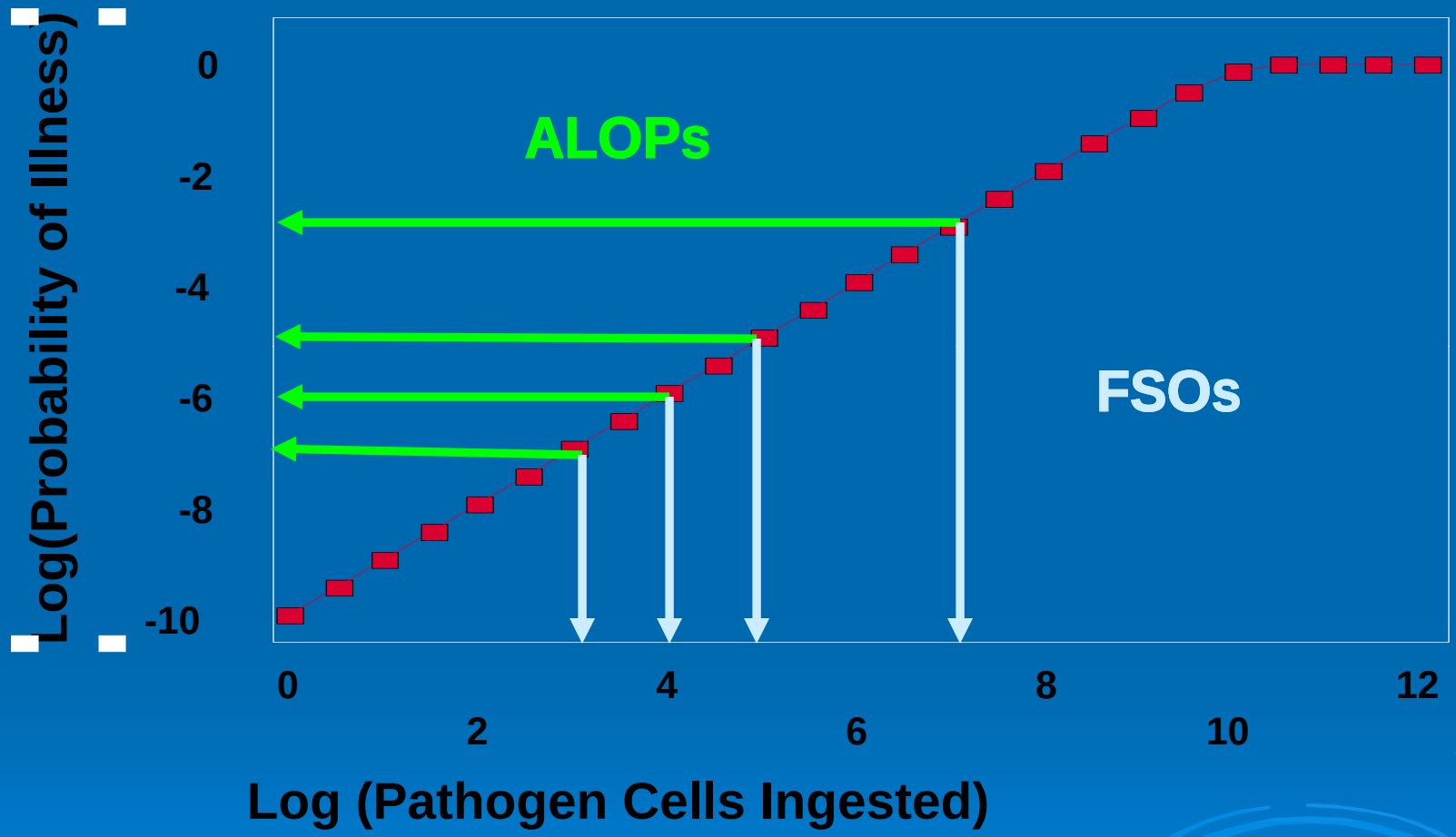
MRM Metrics - Challenge

- Quantitative microbial risk assessments deal in distributions and probabilities while law is a binary system, e.g., safe or not safe
- Establishing the stringency of a food control system is meaningless unless it can be verified
- Can consider variability in establishing decision criteria but ultimately a consistent "yes or no" decision must be reached
  - Need a means to convert a risk distribution to a yes/no decision
  - Need to deal with type I and type II sampling errors

“The Solution?”

- CCFH has advanced the concepts of Food Safety Objectives and Performance Objectives as a bridge between an ALOP and performance /process criteria

ALOP vs. FSO



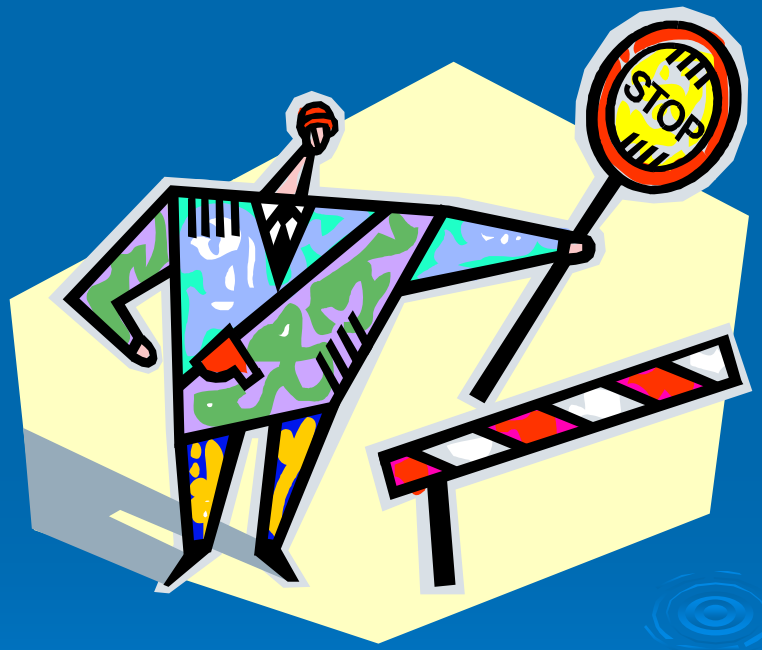
Use risk characterization curve to relate ALOP to a frequency and/or concentration in food

FSO / PO / MC

- Establishing a FSO or a PO is both a scientific and a societal decision
- FSO is means of relating stringency of the entire farm-to-table system to public health outcomes
- PO is the primary means of articulating the level of stringency to level of performance at a specified step in the food chain
- MC is a means of verifying that a PO is being achieved

FSO / PO

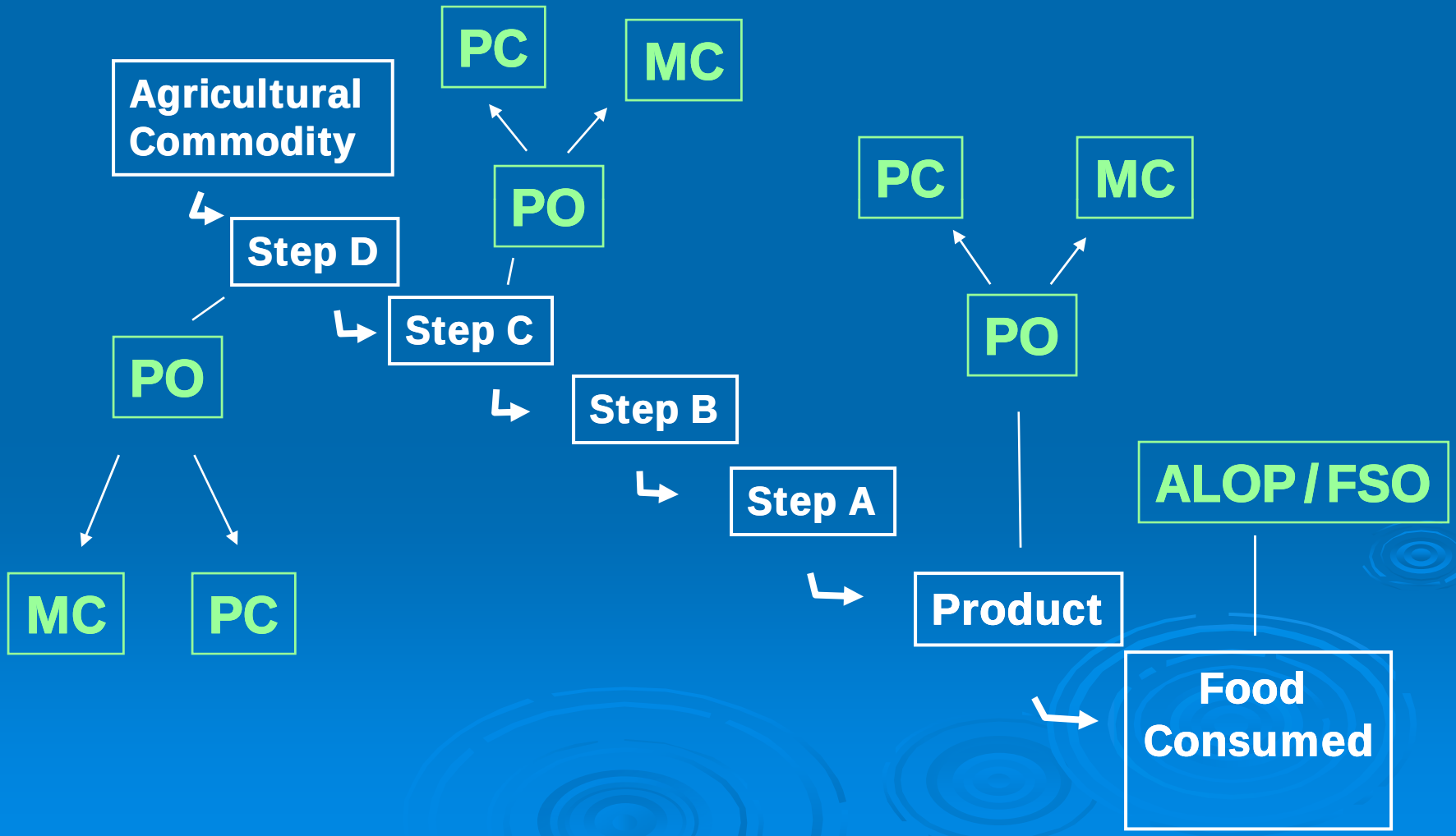
- To be a useful concept an FSO / PO must be able to be integrated into the legal systems upon which safety decisions are based
- Must be able to use to define stringency expected:
  - Below is safe
  - Above is not safe
- Requires that FSO and PO be "operationalized"
  - e.g., PO at manufacture that 99% confident that 99% of servings are pathogen free



Striving for an Integrated System

- In a fully developed risk analysis framework there is "connectivity":
  - FSOs based on a public health goal (ALOP)
  - Performance criteria (PC) and/or performance objectives (PO) based on the FSO
  - Process/Product Criteria based on PC/PO
  - Microbiological Criteria based on PC/PO/FSO

Microbial Risk Management Framework



Verifying a PO or a PC

Performance Objectives

- Whenever possible, a PO should be quantitative and verifiable
- Does not have to be verifiable via microbiological testing
  - Example: Probability of a viable spore of *C. botulinum* is < 0.000000000001 per can of low acid canned food

PO Verification

- A FSO or PO is not a microbiological criterion, though it is a value upon which a microbiological criterion should be based
  - FSO/PO are limits
  - MC are tools for verifying the limit is being achieved

Microbiological Criteria

- As soon as one attempts to verify a PO or PC through microbiological testing, must convert to microbiological criterion
  - Have to articulate the method, sample size and sampling plan
- Microbiological criterion must:
  - Consider the degree of confidence expected by the risk manager that a PO is not being exceeded
  - Take into account the variability and uncertainty associated with the product and the sampling / testing methods
  - Distinguish microbiological testing as a control measure (testing of every lot) vs. as a verification tool (testing occasional lots)

Example – *Enterobacter sakazakii* (*Cronobacter*) in Powdered Infant Formula

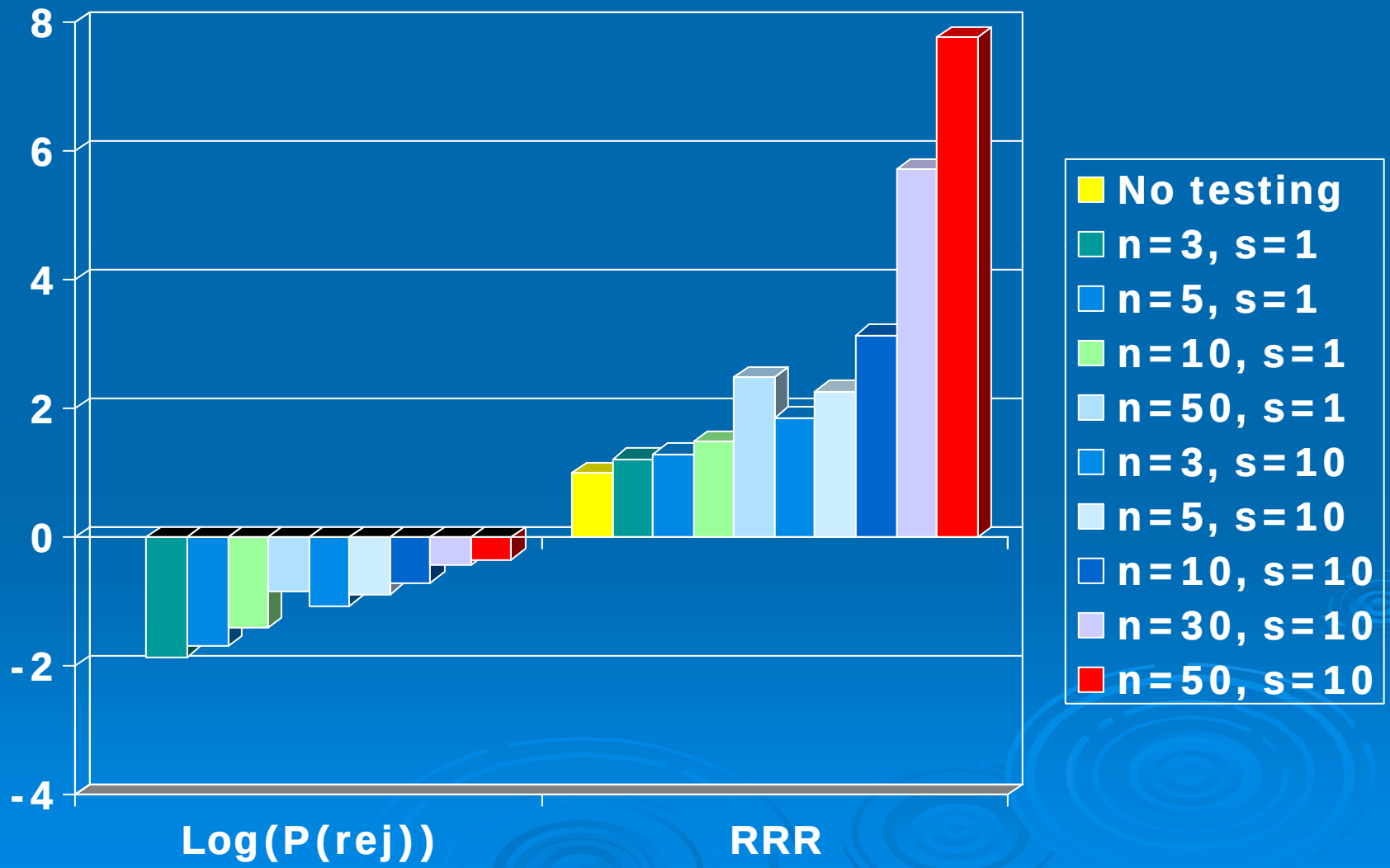
Example – *Enterobacter sakazakii*

- **Code of Hygienic Practice for Powdered Formulae for Infants and Young Children** (CAC/RCP 66 – 2008)
  - **Annex I: Microbiological Criteria for Powdered Infant Formula, Formula for Special Medical, and Human Milk Fortifiers**

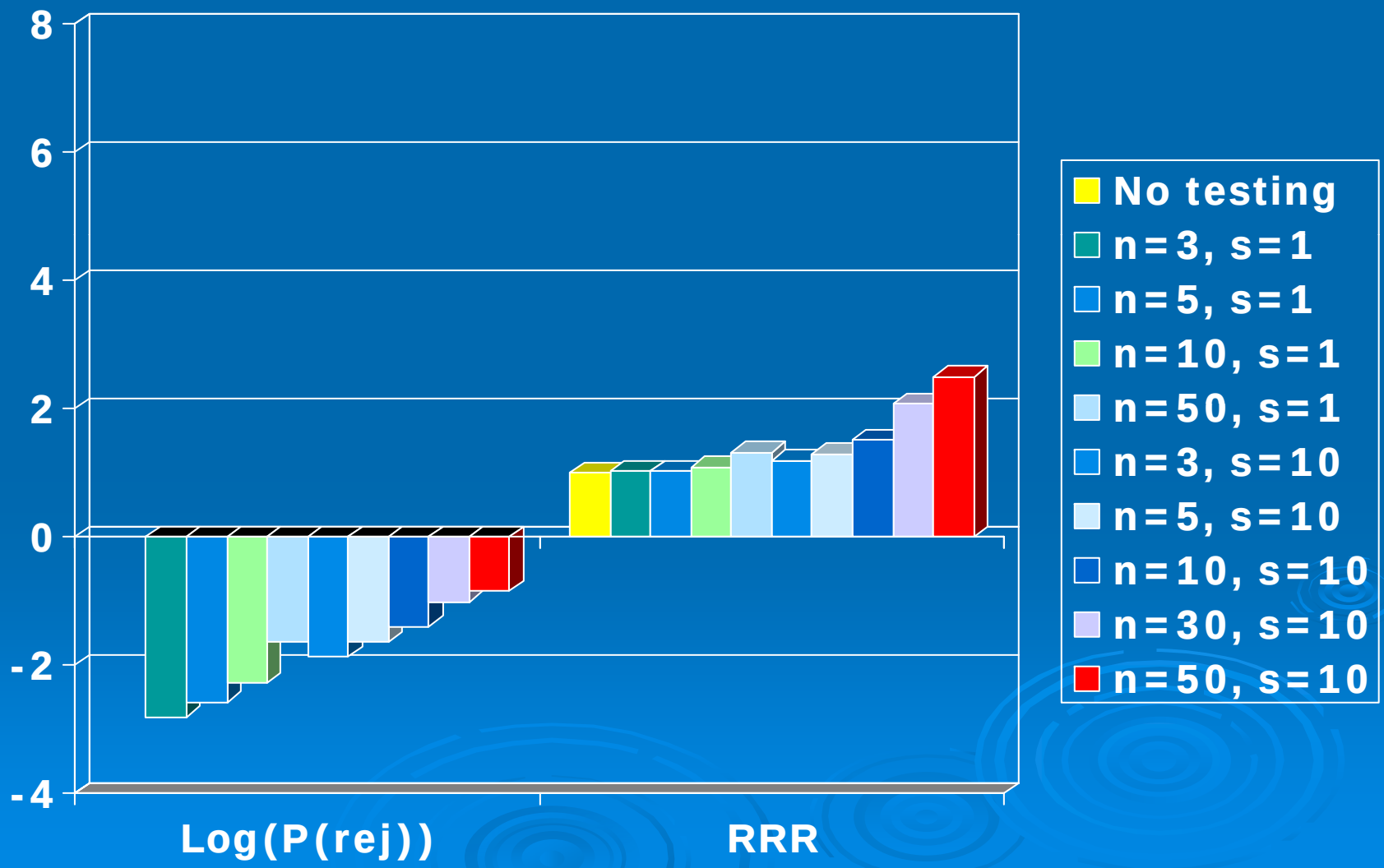
MRM Metrics – Public Health Outcomes

- ***Enterobacter sakazakii (Cronobacter)***
  - **Causes septicemia and meningitis in neonates and infants**
  - **Two risk assessments performed by FAO/WHO (JEMRA)**
  - **One examined the effect of lot-by-lot sampling on relative risk reduction**
  - **http://www.fao.org/ag/agn/agns/jemra_riskassessment_enterobacter_en.asp**

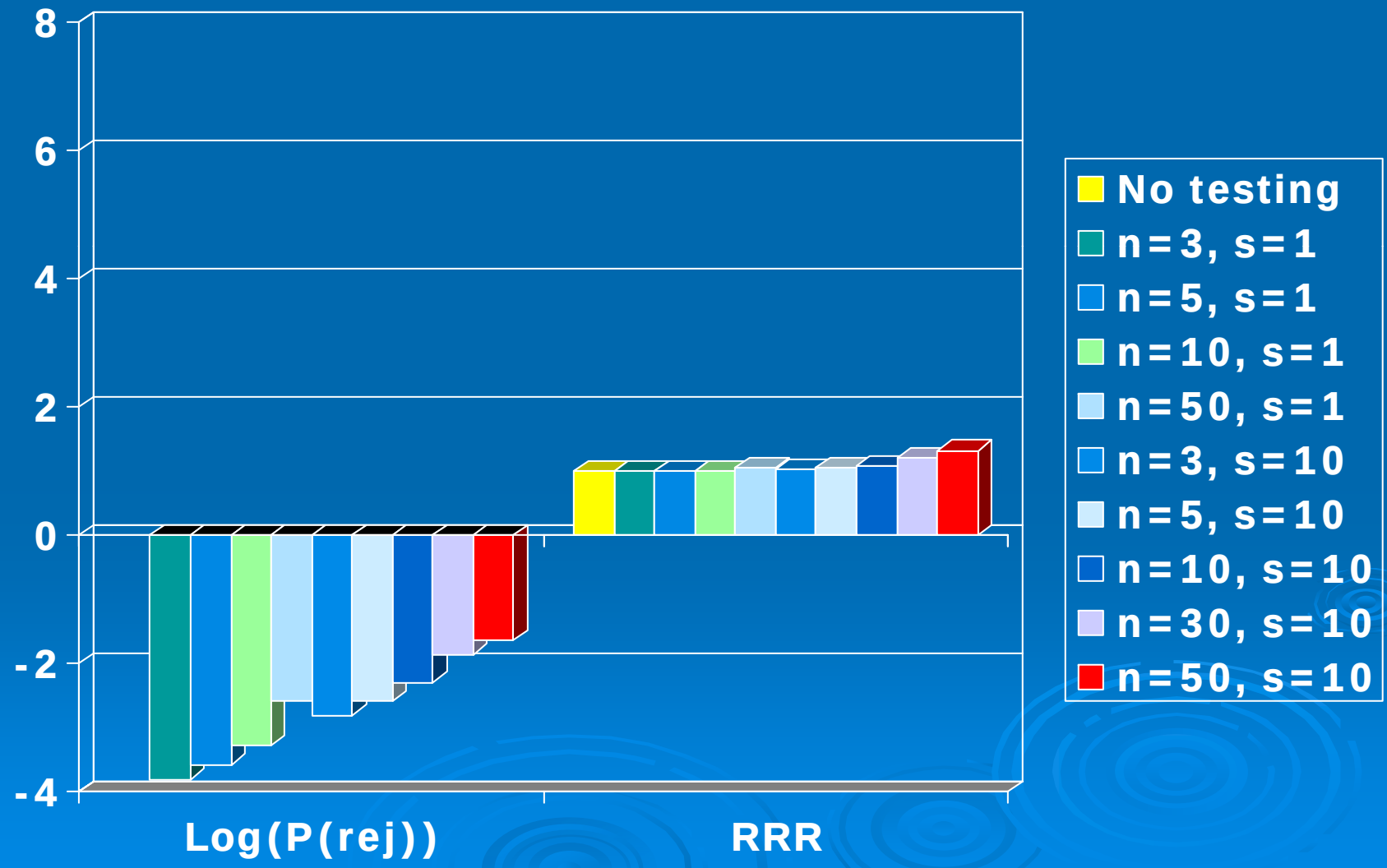
Mean Contamination: 10^{-3} CFU/g



Mean Contamination: 10^{-4} CFU/g



Mean Contamination: 10^{-5} CFU/g



Concluding Remarks

International Partnership

- Codex Alimentarius, through its members nations and in consultation with FAO, WHO, and various international scientific organizations such as ICMSF, ILSI, IAFP, and IFT, has advanced significantly the application of risk analysis to microbial food safety risk management
- Resulted in significantly advancing the scientific basis and transparency of international food safety standards

Framework for Public Health Goal-based Risk Management

- Establish the performance of a food safety system based on public health outcomes
- Evaluate system using risk analysis process to relate stringency of food control system to desired public health outcomes
- Target what needs to be achieved, with less emphasis on how it should be achieved
- Validation and verification of efficacy of food control options an integral part of system
- Develop metrics for examining public health effectiveness and equivalence of systems, periodically review, and modify programs / standards as necessary

Next “Food Safety Systems” Challenge?

- For almost 40 years HACCP (Hazard Analysis Critical Control Point) has been the gold standard worldwide

Next "Food Safety Systems" Challenge?

- **HACCP**
  - Semi-quantitative risk management system based on a largely qualitative hazard (?) assessment
  - Based on individual facilities but attempts to consider entire food chain
  - Well established and recognized worldwide
- **Need to mature?**
  - Deal with risks instead of hazards
  - Take advantage of the risk analysis concepts and tools that have been developed in the past 15 years

Further Reading

- International Commission on Microbiological Specifications for Foods