Introduction to the Codex Risk Management Framework for Relating Food Safety Control Measures to Public Health Goals

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Presentation

- Introduction to Codex Alimentarius
- Codex Committee on Food Hygiene (CCFH) Microbiological Risk Management Framework
- Concept of Appropriate Level of Protection (ALOP)
- Concepts of Food Safety Objective (FSO) and Performance Objective (PO)
- Verifying POs
- Concluding remarks

Codex Alimentarius

CODEX ALIMENTARIUS

FAO/WHO Food Standards - Normes Alimentaires FAO/OMS - Normas Alimentarias FAO/OMS

Basic Assumptions

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

Risk Analysis

- Codex has long used risk assessment as a tool
- In its 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

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 as 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

- 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

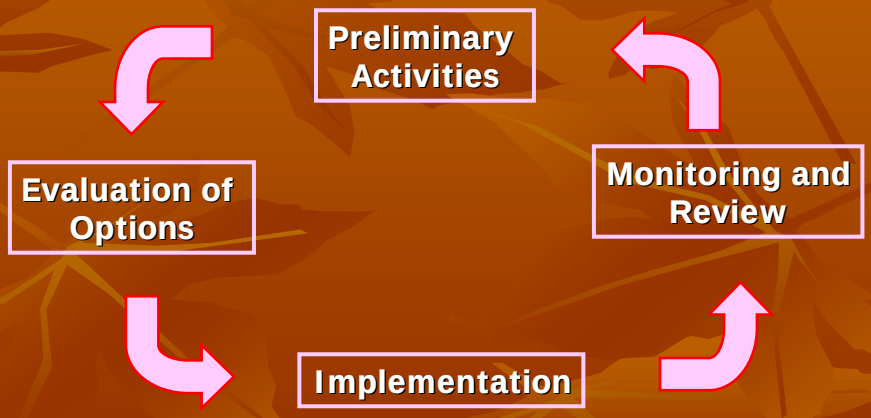
Codex General Subject Matter (Horizontal) Committees

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

Risk Analysis

- Three key Codex references
  - "Working Principles for Risk Analysis Application in the Framework of the Codex Alimentarius"
  - "Principles and Guidelines for the Conduct of Microbiological Risk Assessments"
  - "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (Step 5)

CCFH 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

- Being able to better link food safety activities to public health outcomes via risk assessments 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

ALOP

Appropriate Level of Protection

- One of the concepts 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”

Appropriate Level of Protection

- Most often expressed in terms of a public health goal
- Ongoing discussion on whether the "Healthy People 2010" report is an example of an ALOP

Healthy People 2010

Food Safety Goals

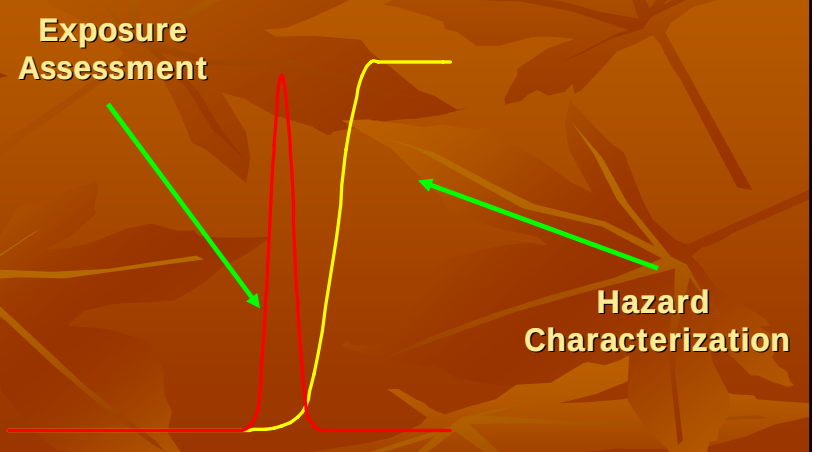
Infectious Agent	1997 Baseline*	2010 Goal*
Campylobacter	23.6	12.3
Listeria monocytogenes	0.5	0.25
Escherichia coli O157:H7	2.1	1.0
Salmonella spp.	13.7	6.8

* Cases per 100,000

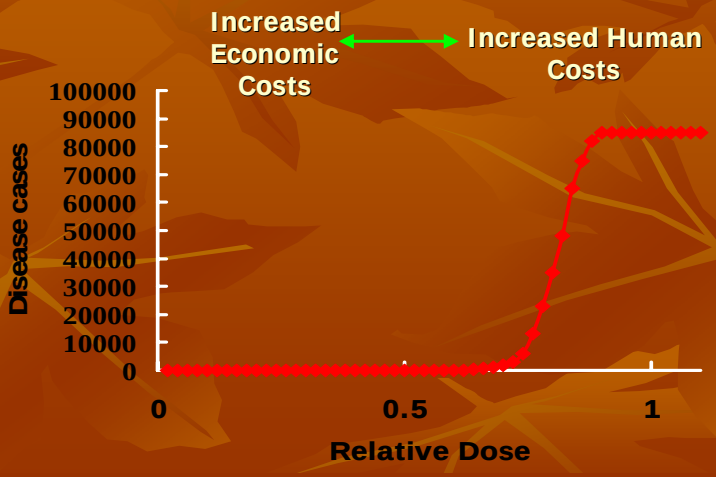
Appropriate Level of Protection

- ALOP is not a determination of "how many bodies" we are willing to accept
  - Always striving to find ways to reduce reduce the impact on public health
- ALOP measures what is achievable today before "costs" to society become too great
  - Not just economic cost!!!

Risk Assessment



Appropriate Level of Protection



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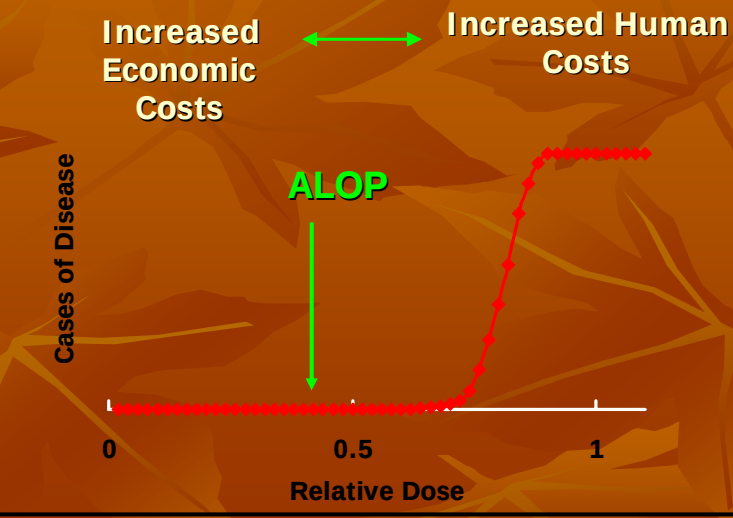
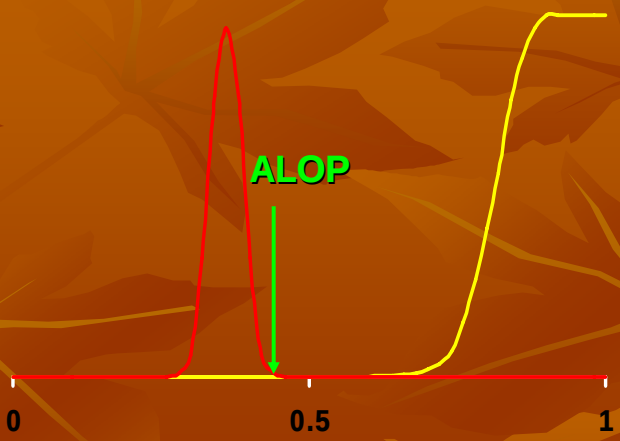


At some point, whether qualitatively or quantitatively, must make a decision on the degree of stringency required

Appropriate Level of Protection



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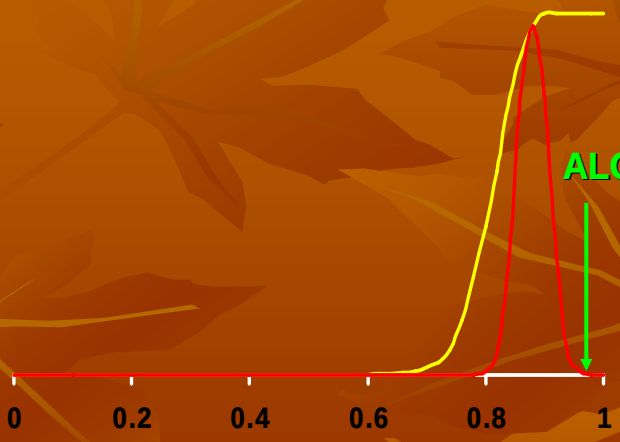

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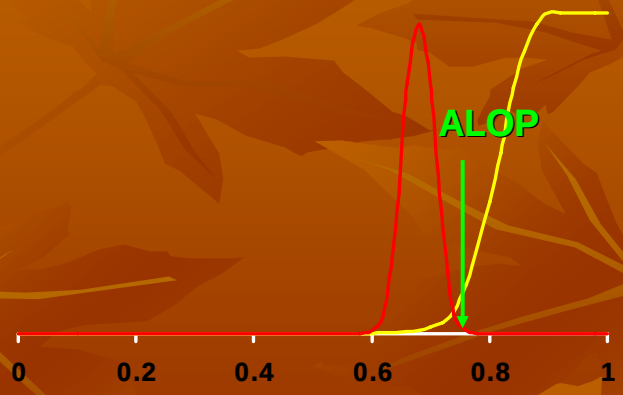
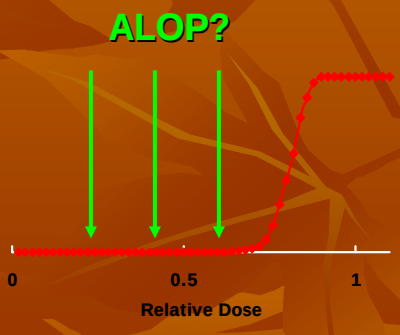


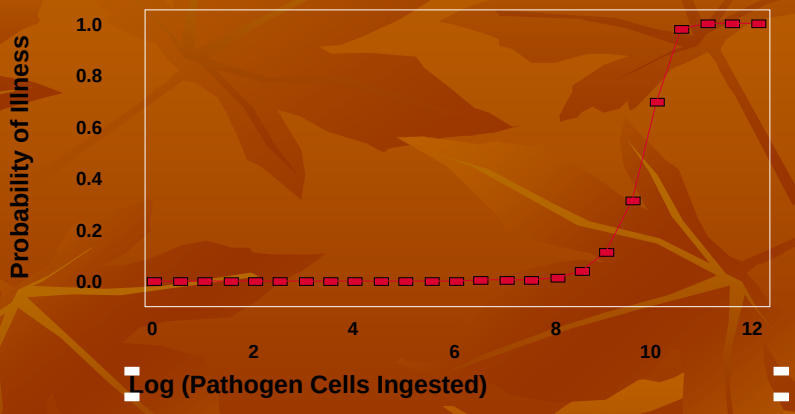
Appropriate Level of Protection

- ALOP includes safety margins deemed appropriate
- Ideally is based on the level of uncertainty associated with the underlying scientific data



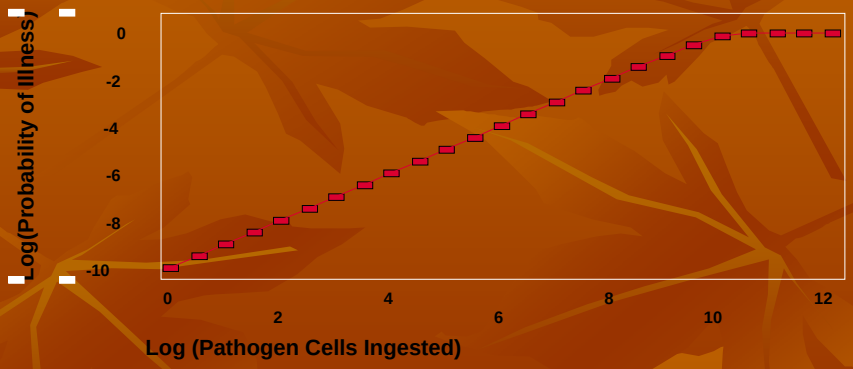
FSOs / POs

Dose-Response Curves / Risk Characterization Curves



Log(dose) vs. response plot

Dose-Response Curves / Risk Characterization Curves



Log(dose) vs. log(response) plot

"The Problem"

- ALOP is typically measured in terms of a "probability of disease" or "number of cases per year"
- Not something that can 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 GMPs and HACCP

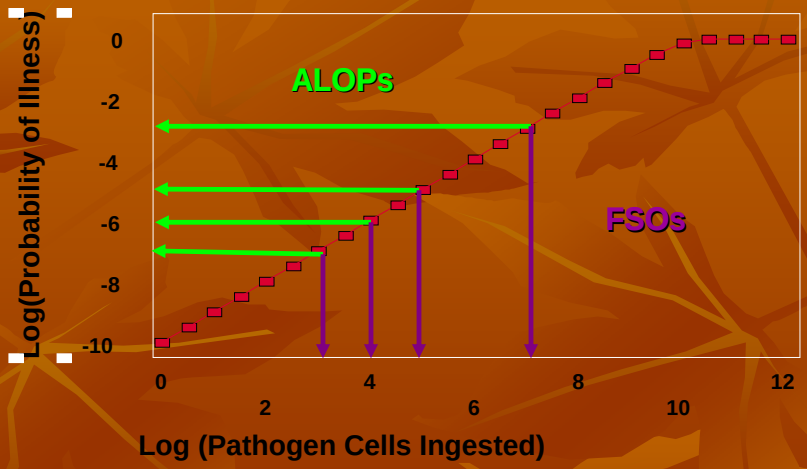
"The Problem"

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

"The Problem"

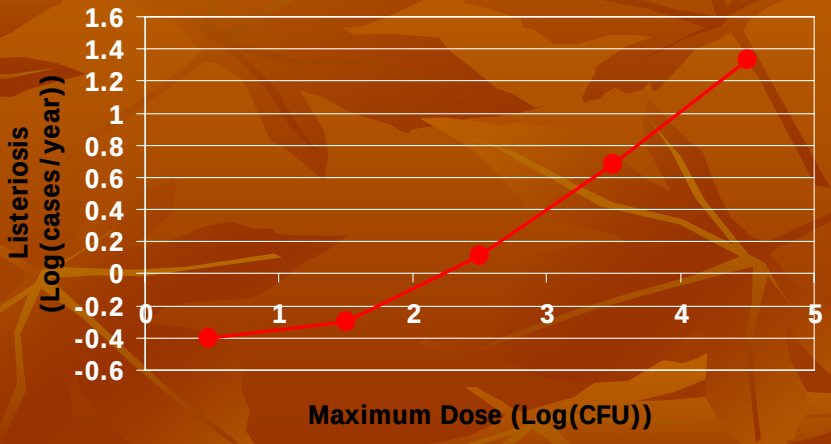
- Need these metrics to develop a means of relating public health risks to the presence of a hazard in a food in order to reach agreement on the stringency of food safety systems

ALOP vs. FSO



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

FAO/WHO *L. monocytogenes* Risk Assessment – "Current Levels Scenario"



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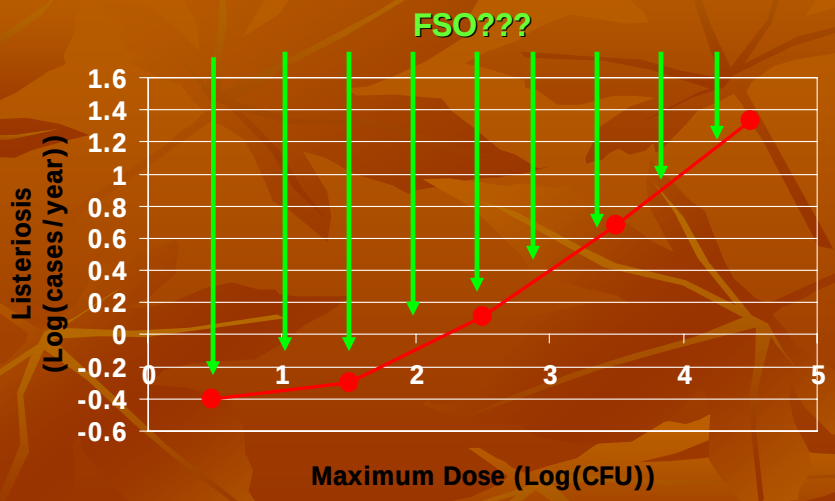
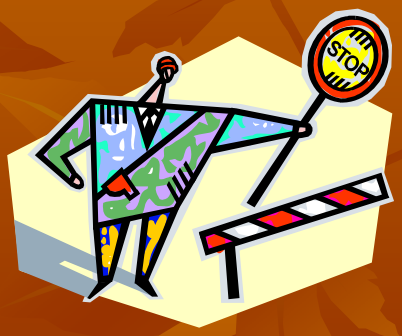


Food Safety Objectives

- Establishing a FSO is both a scientific and a societal decision

Food Safety Objective

- An FSO can be viewed an a “bright shining line”
- By definition
  - Below is safe
  - Above is not safe
- PO is the equivalent at a specified point earlier in the food chain



Performance Objectives

- Ideally, PO should be a scientifically derived value based on the FSO and take into account the impact of control measures step in food chain of the the PO and the FSO
- Examples:
  - RTE food that supports growth: PO < FSO
  - RTE food that does not support growth: PO = FSO
  - Food that is cooked prior to consumption: PO > FSO

Verifying POs/PCs

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

FSO/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
- In general, a microbiological criterion would be more stringent
  - Have to take into account the variability and uncertainty associated with the product and the sampling / testing methods

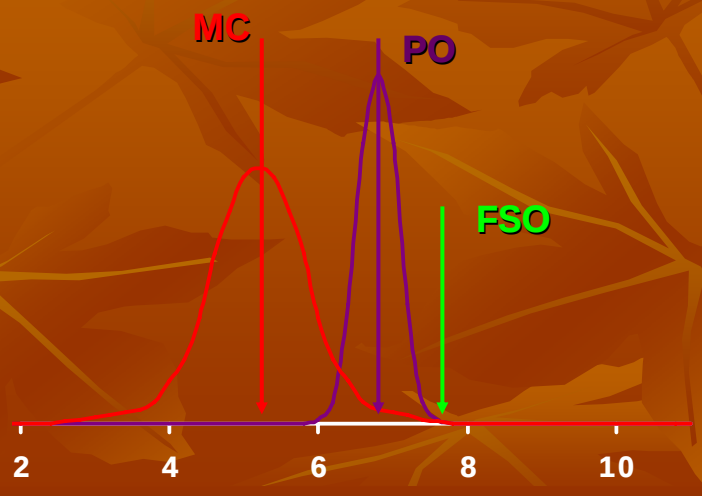
Microbiological Criteria

- As soon as one attempts to verify a Performance Objective and/or Performance Criteria through microbiological testing, must convert to Microbiological Criterion
  - Have to articulate the method, sample size and sampling plan
- Have to deal with variability, uncertainty, and confidence of both the food and the analytical process

Microbiological Criteria

- If based on a FSO or PO, a MC has to be more stringent than the corresponding PO/FSO
- Have to provide confidence that FSO/PO not exceeded while taking into account the variability and confidence of
  - the process/control measure
  - the sampling and testing methods

Relationship Between Microbiological Criteria and Other Metrics



Concluding Remarks

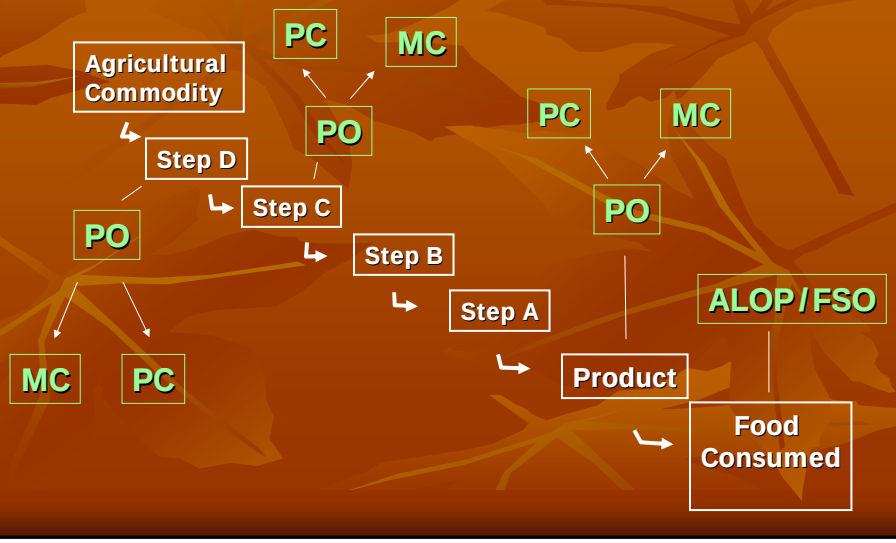
Framework for Public Health Goal-based Risk Management

- Establish public health or technologically-based goal, understanding that “zero-risk” is unattainable
- Evaluate system using risk analysis process to relate stringency of food control system to 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 of system and periodically review (and correct as necessary)

Risk Analysis Framework

- 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



Concluding Remarks

- Over the course of the last 5 years CCFH, through its members nations and in consultation with FAO, WHO, and scientific organizations such as ICMSF, ILSI, IAFP, and IFT, has devoted substantial time in advancing conceptual thinking about the application of risk analysis to microbial food safety
- Is looking forward to further advances derived from conferences such as this one and upcoming FAO/WHO consultations