2003 SRA Annual Meeting

Perspectives on Pathogen Performance Standards

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Traditional Performance Criteria (government specifications)

Poultry cooked to minimum of 165°F

Shellfish frozen < -35°C for 168 h for parasites

Whole eggs pasteurized at 140°F for 3.5 min

Milk pasteurized at 72°C for 15 sec

Food code safety criteria $A_w < 0.95$ & pH < 5.5 for Lm

5 log reduction of *E. coli* O157:H7 in juice

Traditional Performance Criteria

Major components in HACCP plans

- **Critical control points**

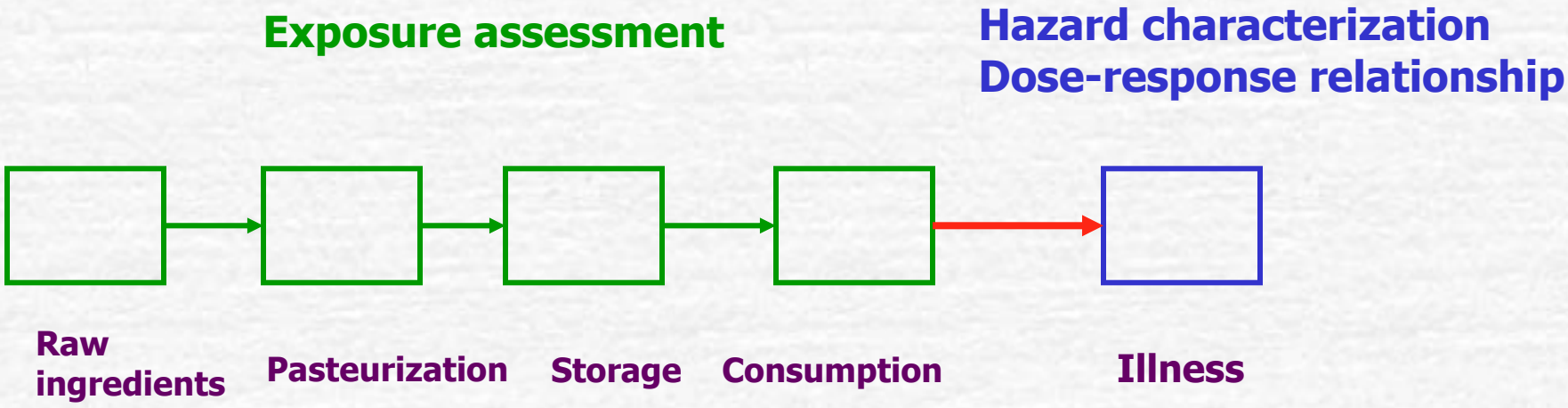
Not directly related to public health and the rate of illness

Inflexible, not conductive to innovation

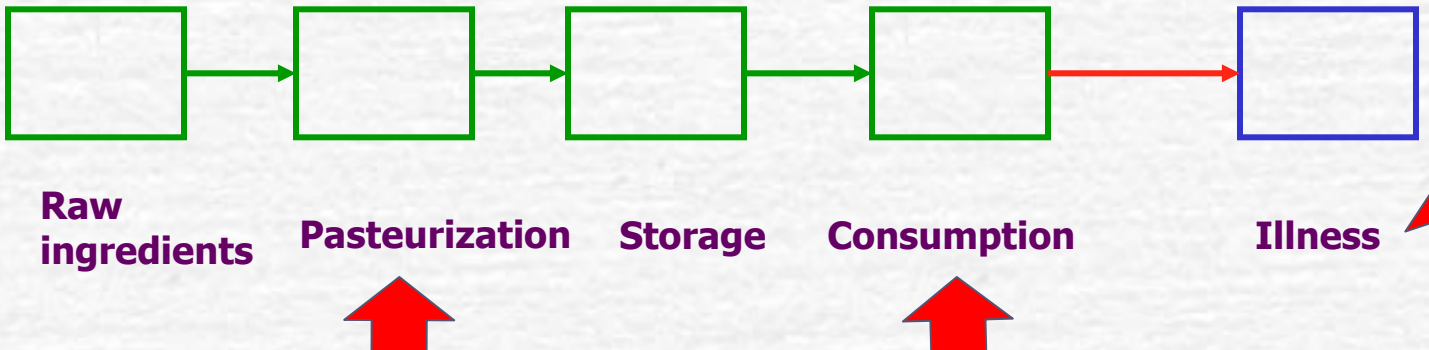
Deterministic analysis

$$MC > H_o - \Sigma R_n + \Sigma I_n$$

Process risk assessment

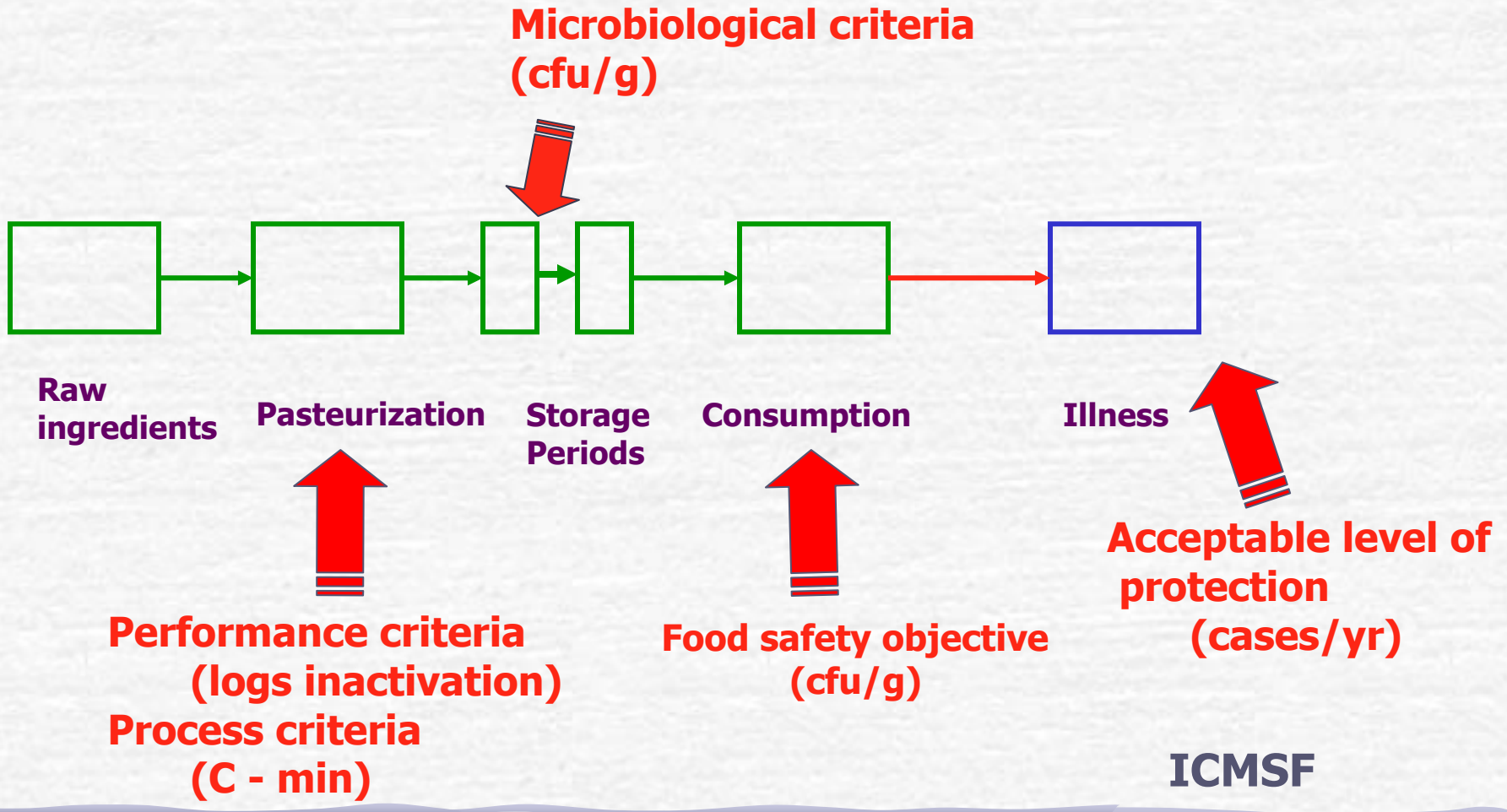


Process risk assessment



ICMSF

Process risk assessment



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Appropriate Level of Protection (ALOP)

- Degree of risk that a society is willing to tolerate/accept
- The "costs" that society is willing to bear to achieve a specific degree of control over a hazard
  - "Costs" includes: human, quality, nutritional, economic, ethical, medical, legal, etc

ALOP

U.S. goal for 2005—less than 0.25 cases of listeriosis per 100,000 people per year

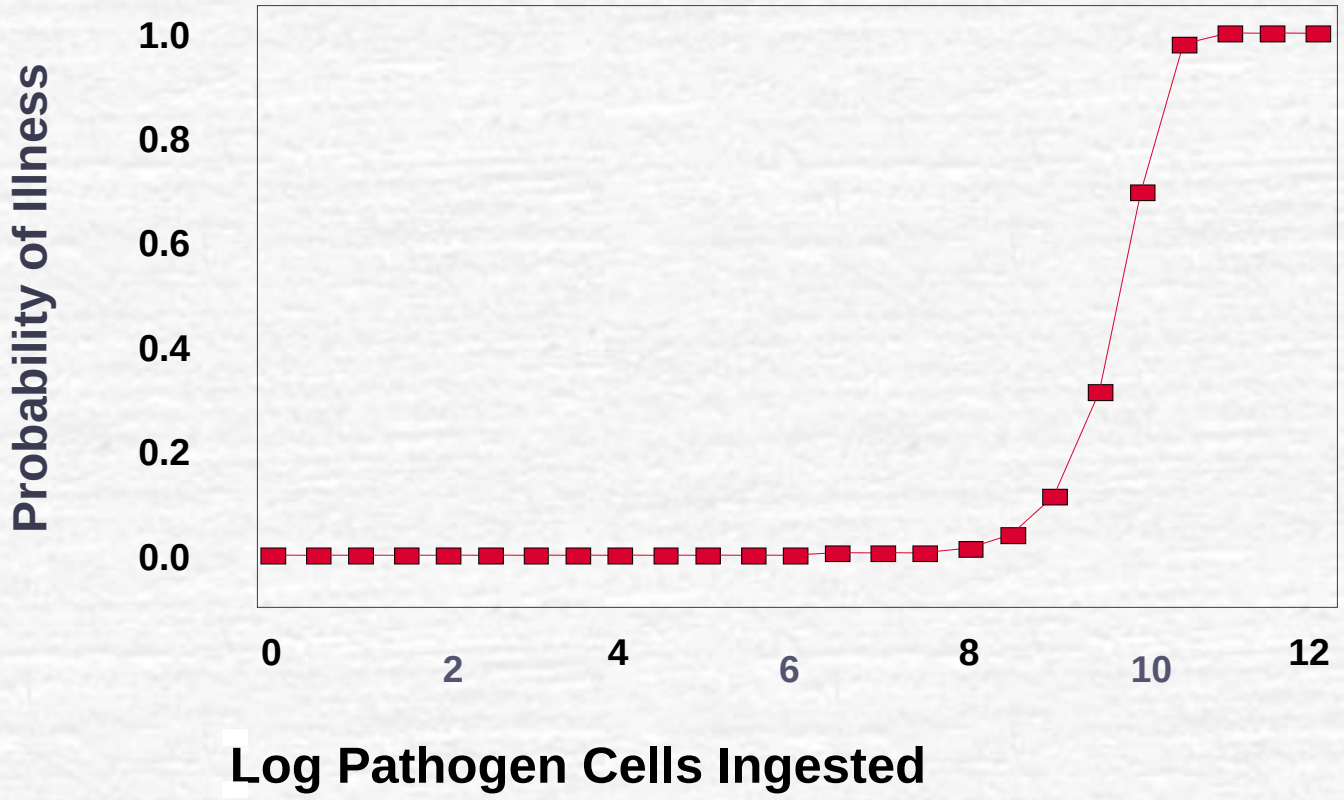
About 1 case per 1 million servings

Food Safety Objective
FSO

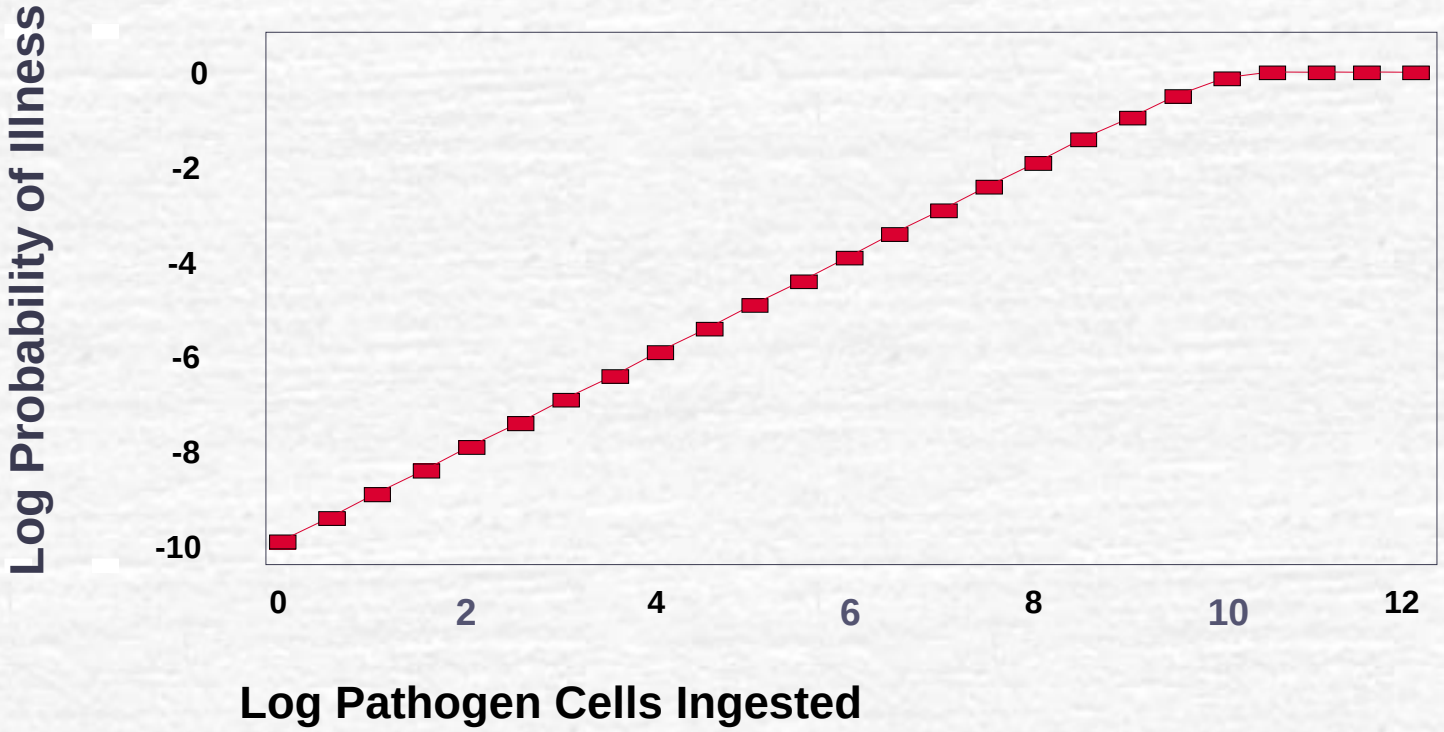
The maximum frequency and/or concentration of a microbial hazard in a food at the moment of consumption that provides the appropriate level of protection

Codex Committee Food Hygiene

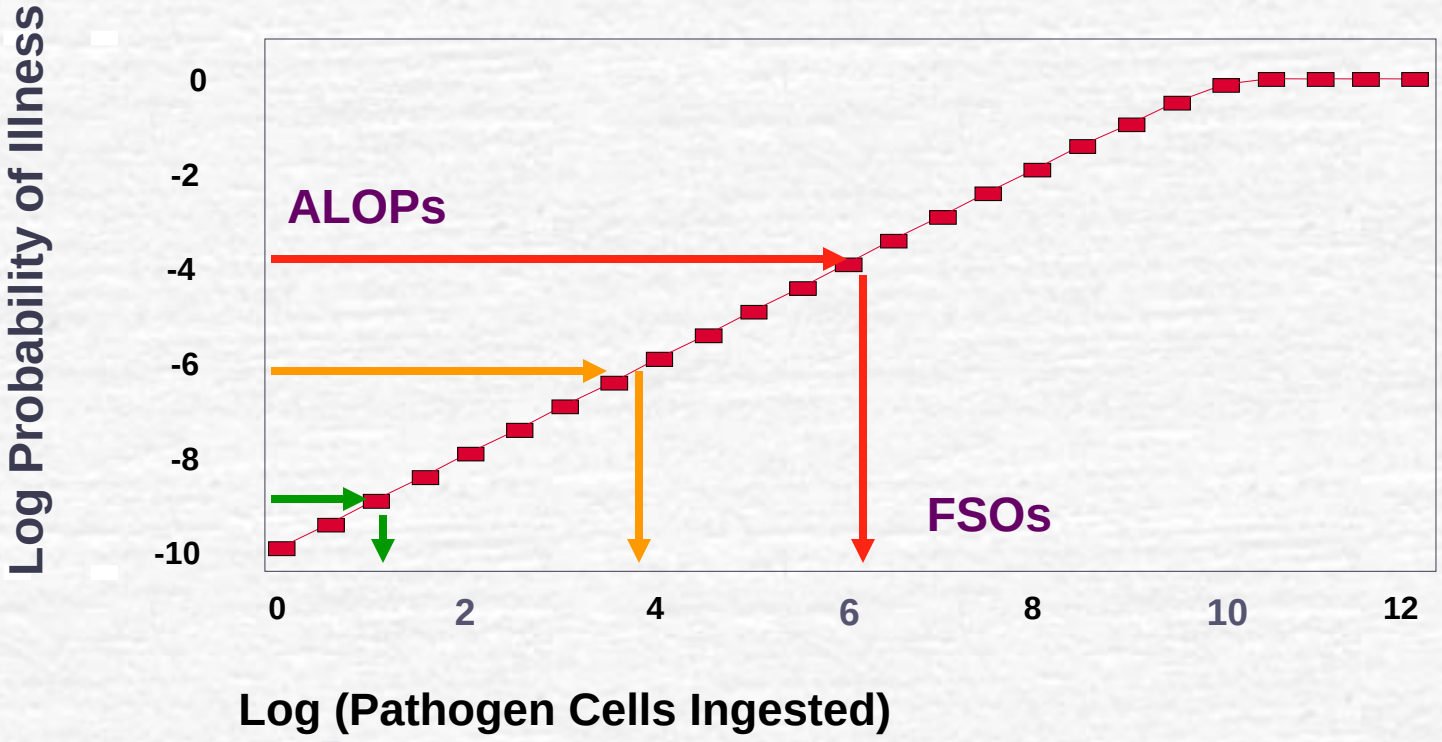
Dose-Response Curve



Dose-Response Curve



ALOP to FSO

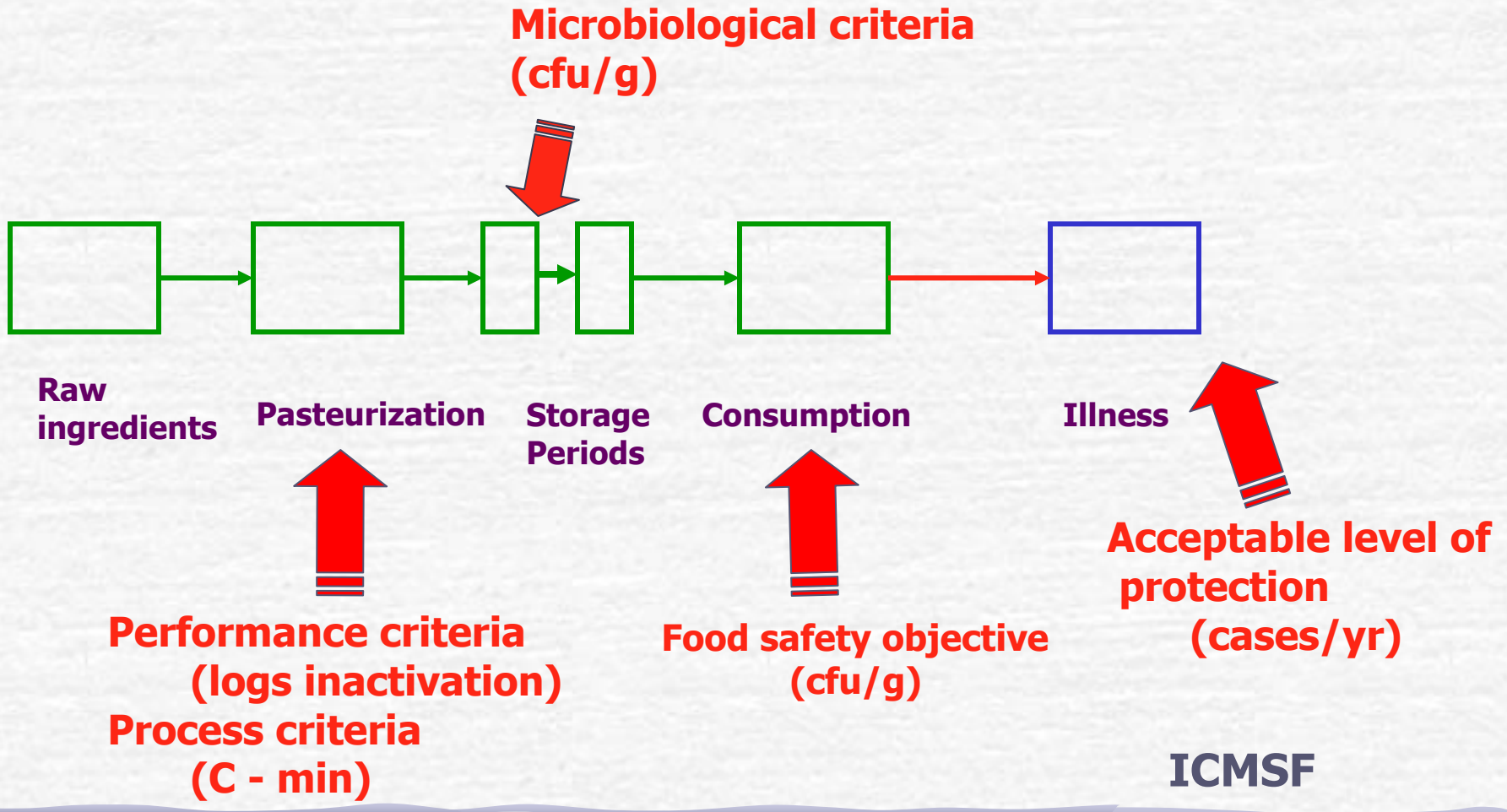

Log Probability of Illness
0
-2
-4
-6
-8
-10
ALOPs
FSOs
0
2
4
6
8
10
12
Log (Pathogen Cells Ingested)

Food Safety Objective

FSO is a "line in the sand"

Articulates for a particular food the level of a specified pathogen that will not be exceeded

Process risk assessment



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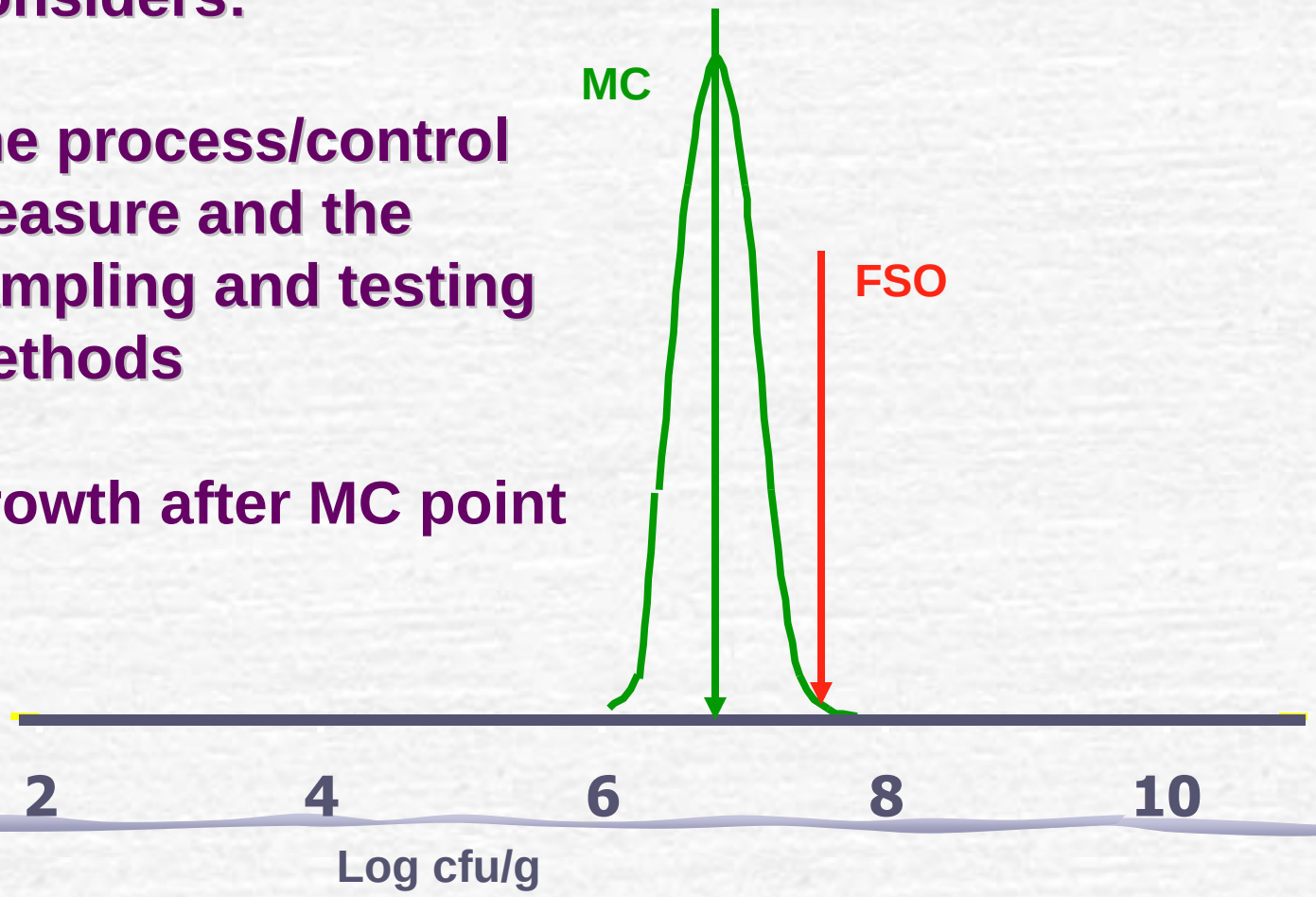
Microbiological Criteria

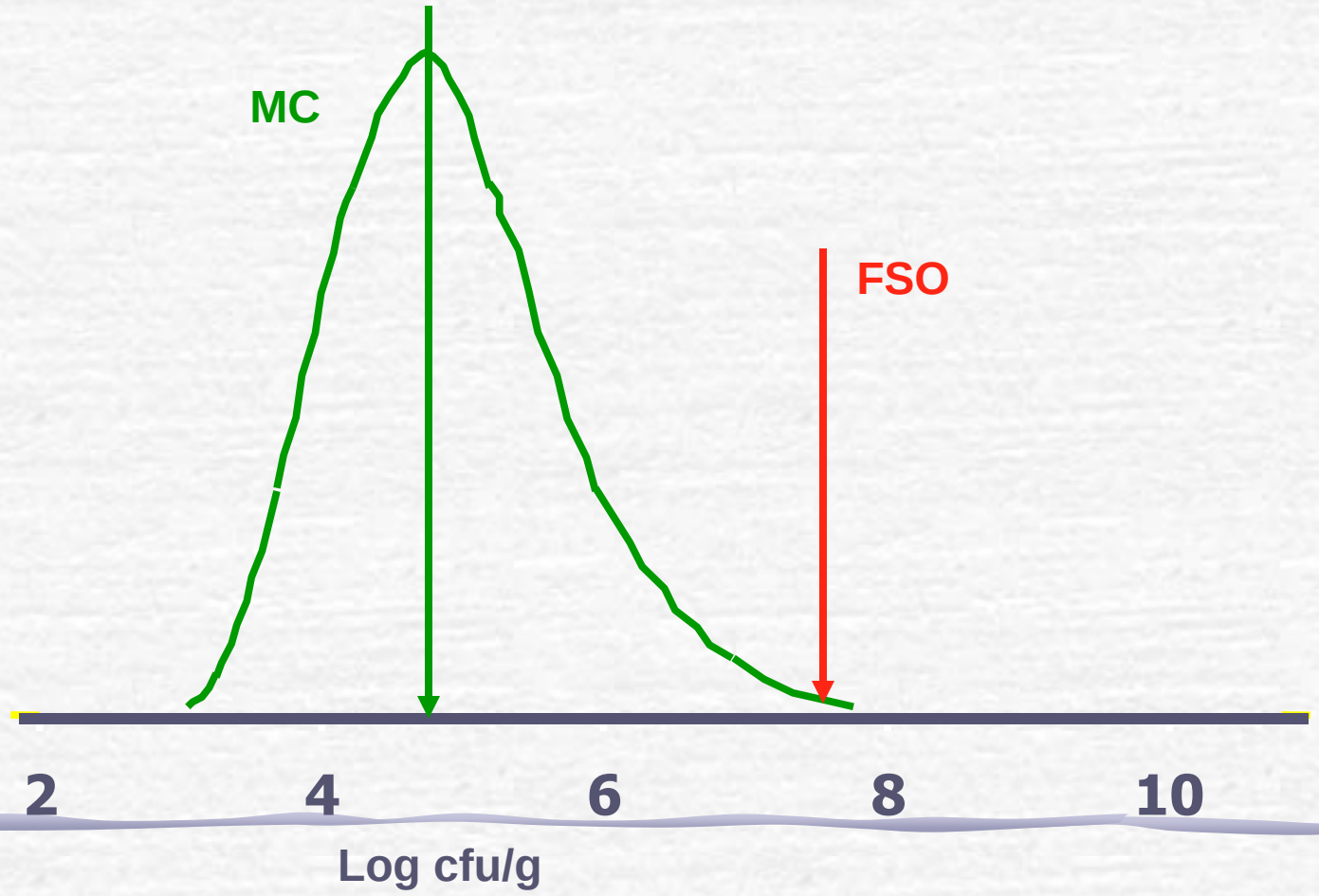
Considers:

The process/control measure and the sampling and testing methods

Growth after MC point



Microbiological Criteria



Sampling to meet FSO

Assume:

- **FSO = 100 CFU/g**
- **95% confidence desired**
- **Sampling program n = 10, c = 0**

Then if:

- **σ = 0.2, then MC $\leq$ 32 CFU/g**
- **σ = 0.8, then MC $\leq$ 0.86 CFU/g**

Establishing FSO, MC & PCs

Conduct risk assessment of food process pathway

Articulate public health goal (e.g., cases/100,000, probability of disease)

Calculate level of exposure that would achieve goal

Evaluate for feasibility

(including consideration of variability and uncertainty)

Industry implements food control systems that achieve that level of stringency

Establishing FSO, MC & PCs

Given an FSO Industry would:

Analyze process, conduct detailed process risk assessments (sensitivity analyses, spider plots, scenarios)

Design/select specific process

Choose Performance and Process criteria that achieve MC and FSO

Challenges:

Requires an increased degree of sophistication by government and industry

Safe harbors for small processes

Relies on microbial data, modeling and risk assessment

Relating food law to the concepts

Challenges:

- ALOP
  - Will public accept this approach?
  - How set ALOP?
    - Set by
      - Current practices
      - Best current practices
      - Best available technology
      - Designated standard
    - Variable for different
      - Foods
      - Populations

Challenges:

FSO

- **Can we rely on DR models?**
- **Do we know enough about host susceptibility, virulence factors and food matrices?**

Challenges:

- Microbial Criteria and Performance Criteria
  - Can these calculations be conducted with sufficient accuracy and precision?
    - Do we have all the necessary data?
    - Do we know about consumer/food preparer behavior?
  - How validate the calculation?
  - How integrate into HACCP program?

Concluding thought:

We have to control foodborne pathogens, therefore, despite all the unknowns, wouldn't this system be better than the current non-risk assessment approach?

Opinions are by the author and not necessarily FDA policy