Risk Assessment at USDA's Food Safety and Inspection Service

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FSIS

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

Public Health Regulatory Context

- Ensure the safety of meat, poultry and egg products
- Food safety statutory requirements
  - FMIA, PPIA, EPIA
- Administrative statutory and oversight requirements
  - Executive Order 12866
  - Administrative Procedures Act
  - Information Quality Act
  - OMB Peer Review Guidelines
- Effective and practical public health decisions

Statutory Authority

- FSIS is authorized to prevent products from entering commerce that are adulterated or misbranded
  - Federal Meat Inspection Act (FMIA)
  - Poultry Products Inspection Act (PPIA)
  - Egg Products Inspection Act (EPIA)
- Key provisions for this authority can be found in FMIA Section 601(m) and (n), PPIA Section 453(g) and (h), and EPIA Section 1033(a) and (l)

Purpose of Microbiological Risk Assessments

- Inform Agency decisions
  - Establish industry standards
  - Allocate inspection resources
  - Guide recall decisions
  - Basis for some trade decisions
  - Target consumer messages
  - Industry guidance
  - Prioritize food safety research
- Support science-based policies

Risk Assessment Process

Codex process for microbiological RA

- Hazard Identification
  - In-depth literature review
- Hazard Characterization
  - Dose-response
- Exposure Assessment
  - Likely intake of pathogen
- Risk Characterization
  - Consequences, given

National Resource Council (NRC) process for chemical RA

- Hazard Identification
- Dose-Response
- Exposure Assessment
- Risk Characterization

Risk Assessment

- A scientific process for estimating the probability of exposure to a hazard and the resulting public health impact
- Used to facilitate the application of science to policy formulation

How the RA Process Works in FSIS

- Risk managers formulate questions
- A risk assessment plan is developed
- Risk assessors analyze data and develop models to address questions
- Model outputs are used to inform the decision-making process

Types of Risk Assessments

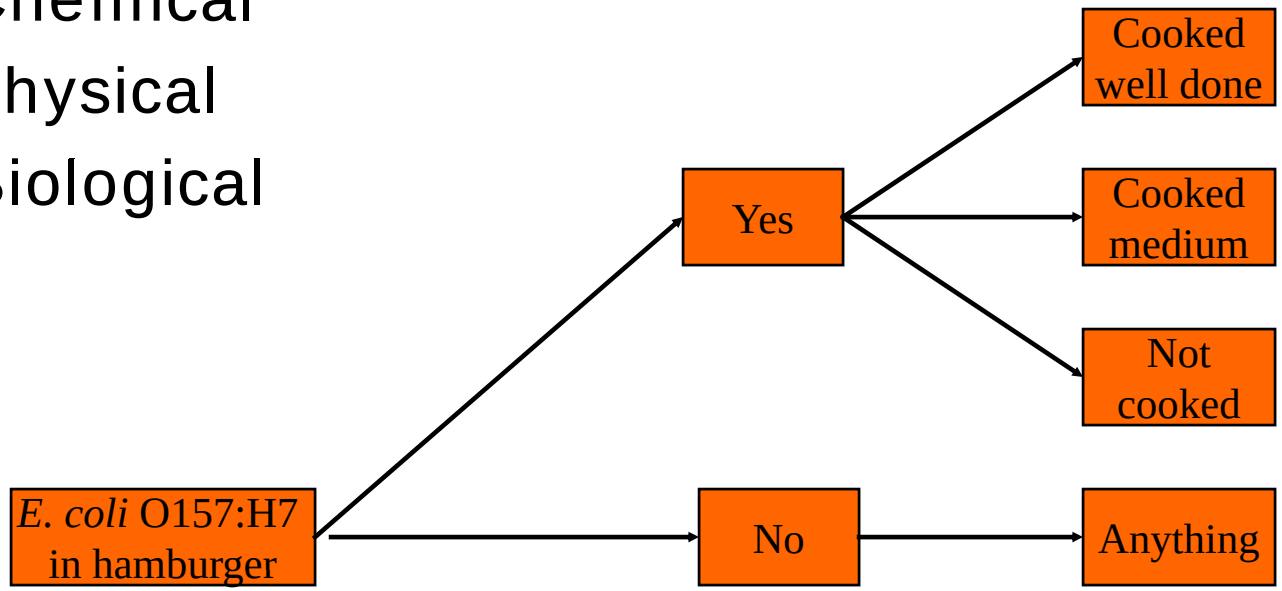
- Quantitative RA (risk of illness is described numerically)
- Qualitative RA (risk is described as likelihood (high vs. low))
- Safety assessment
- Relative risk ranking
- Comparative RA

What Is Risk?

- Scenario
  - What could happen?
- Consequence
  - What is the result given the scenario?
- Likelihood
  - What is the probability of the scenario?

Scenario

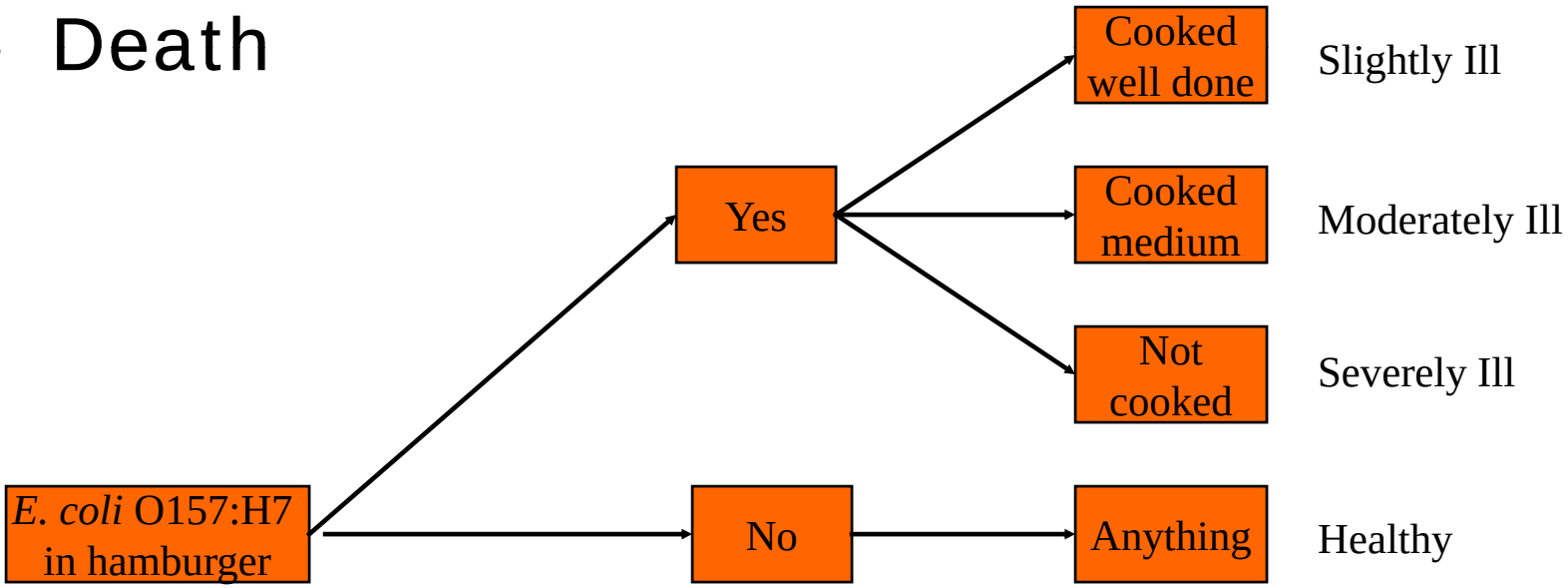
- Exposure to hazard (agent that could cause illness or death)
  - Chemical
  - Physical
  - Biological



Illustrative example only

Consequence

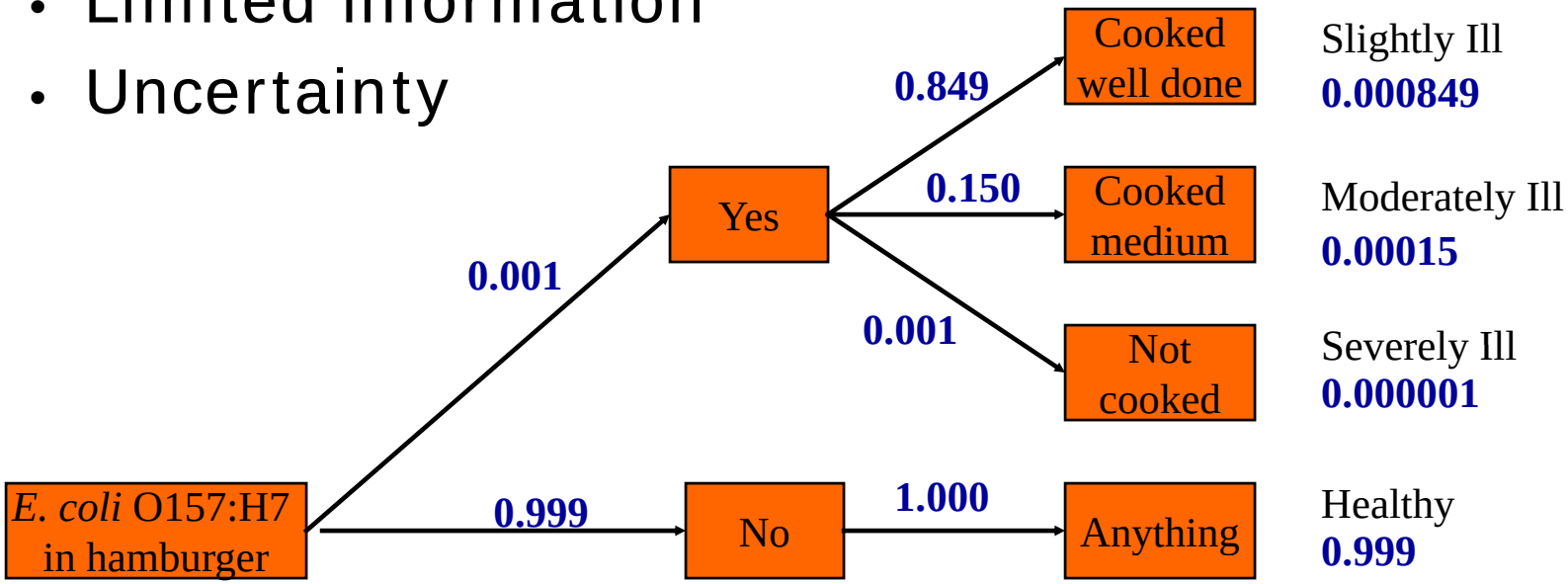
- Illness
- Death



Illustrative example only

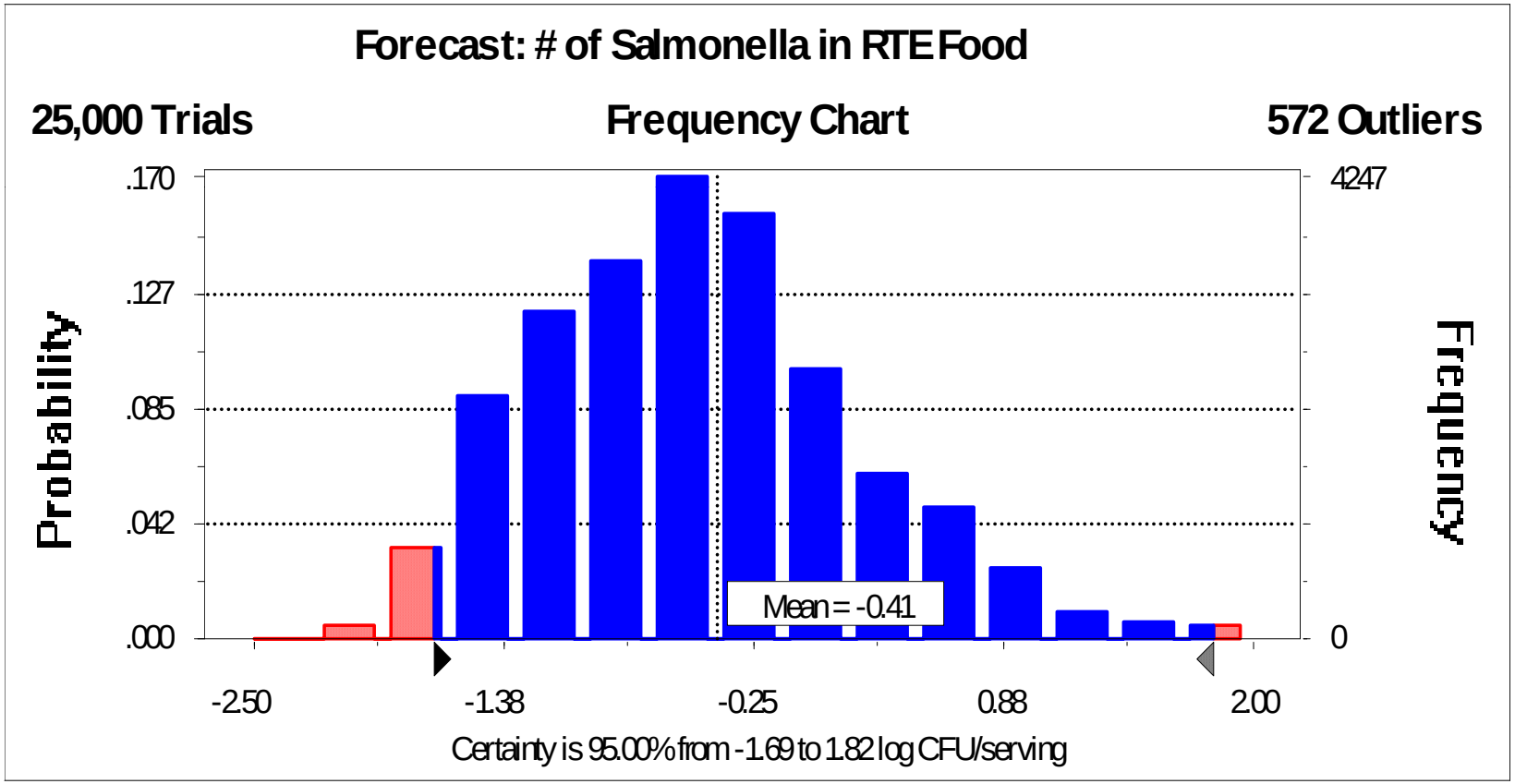
Likelihood

- Probability that specific event occurs
- Most difficult part to determine
  - Limited information
  - Uncertainty



Illustrative example only

RA Output (Exposure) with Uncertainty

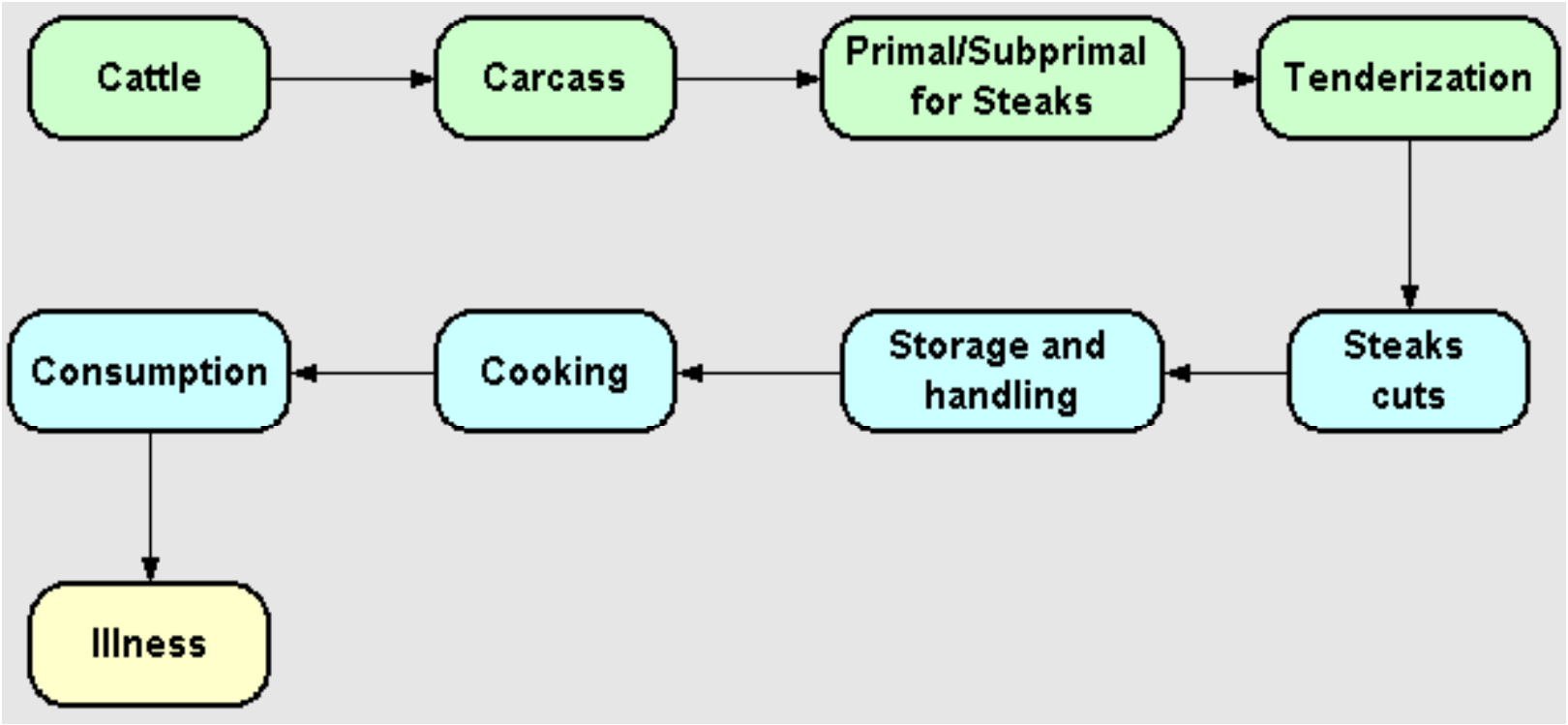


Mean = 0.39 CFU/serving (95% CI=0.02 ~ 66.1CFU)

Risk Assessment Tools

- Data
  - Published literature
  - Baseline studies
  - Representative data from industries and/or other organizations (i.e., FAO/WHO, CSFII, UEP, etc..)
- Model
  - Robust, transparent, user-friendly
  - Software: Analytica, @risk, Crystal Ball, GoldSim
  - Language: Basic/VBA, Fortran, Pascal, C++

Conceptual Model

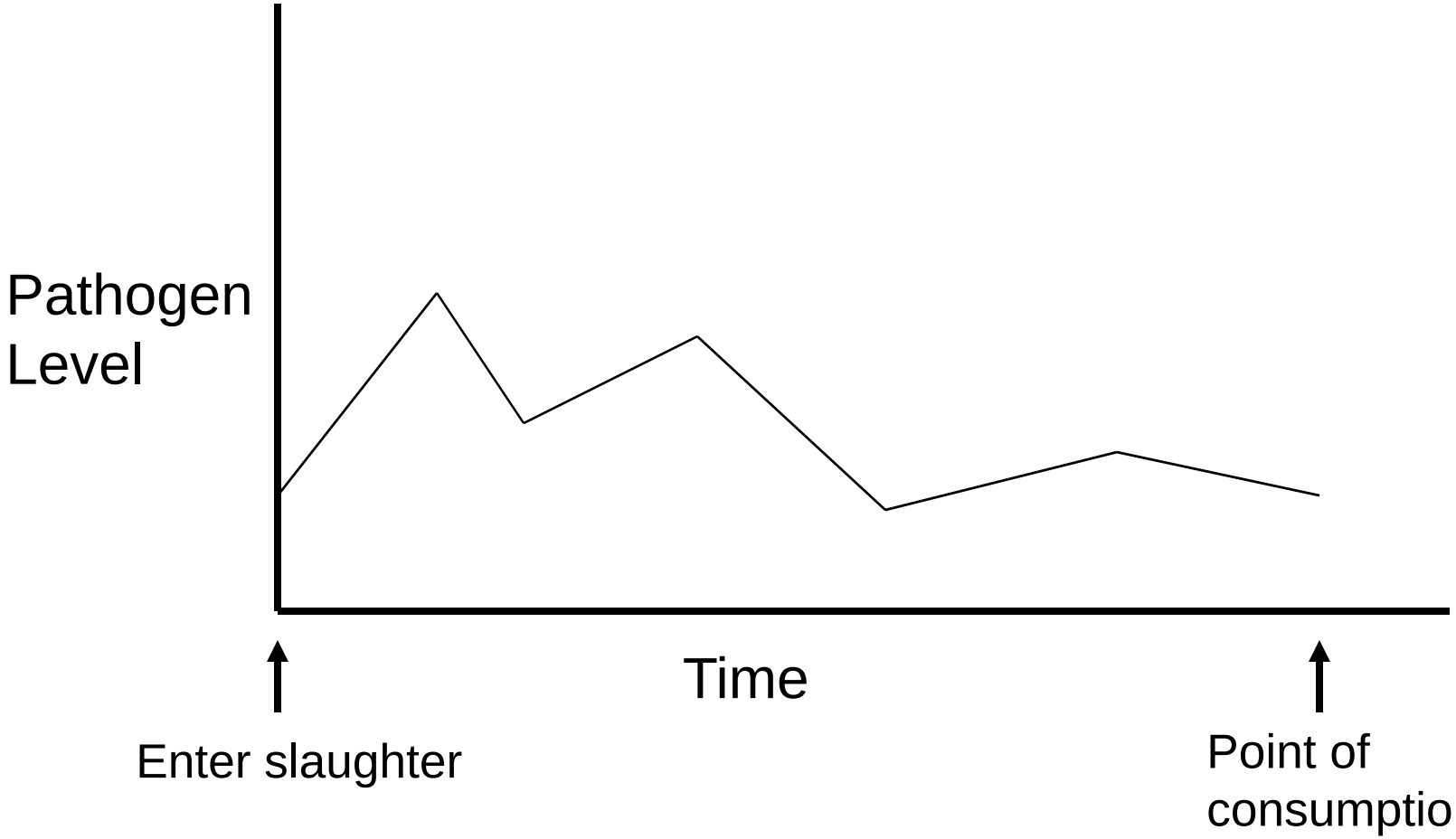


Influence Diagram for the production, preparation, and consumption of intact (non-tenderized) and non-intact beef (tenderized)

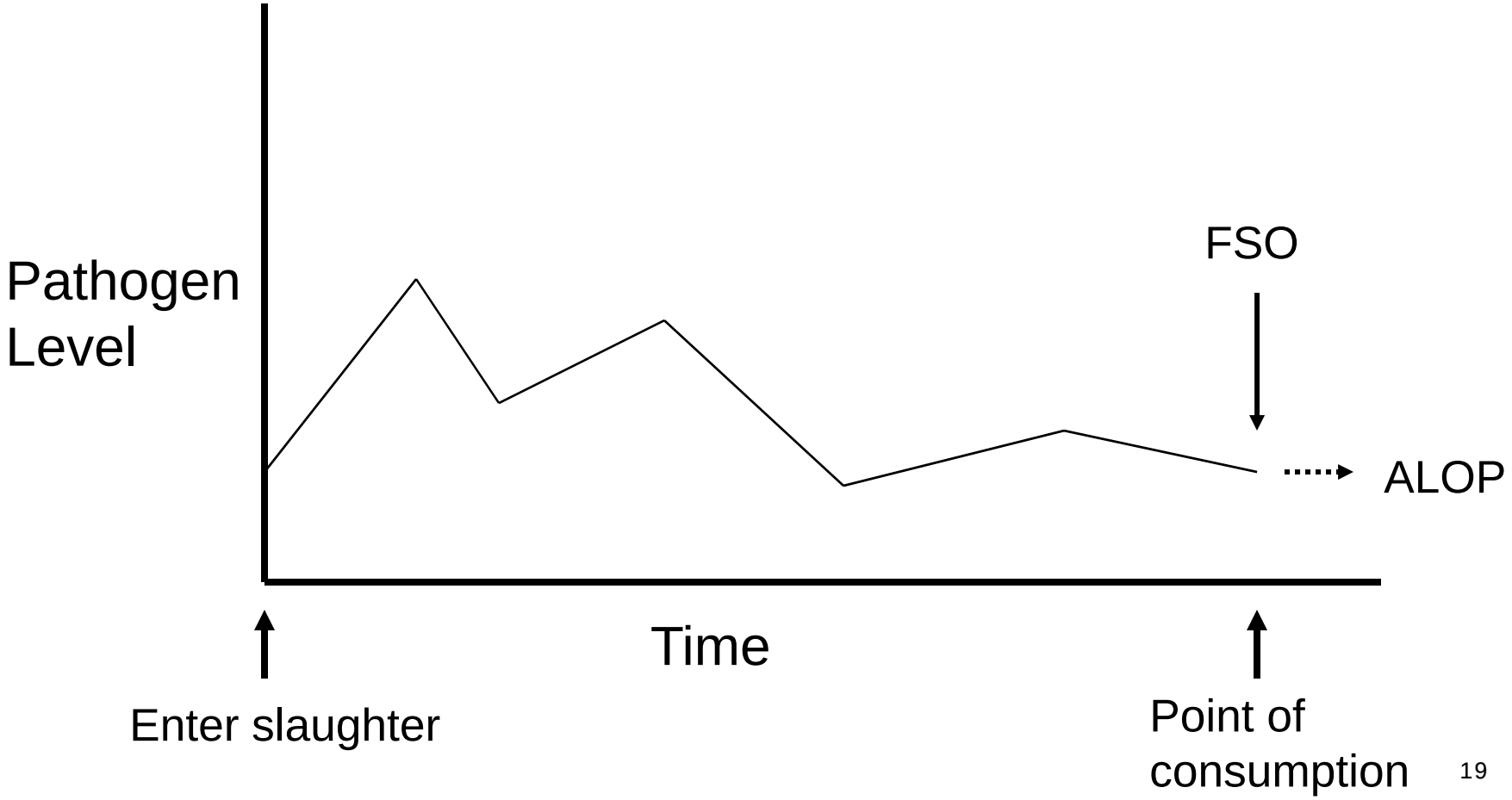
Risk Management Metrics

- ALOP: appropriate level of protection
- Traditional metrics
  - Product Criterion (PdC)
  - Process Criterion (PrC)
  - Microbiological Criterion (MC)
- Emerging metrics
  - Food Safety Objective (FSO)
  - Performance Objective (PO)
  - Performance Criterion (PC)

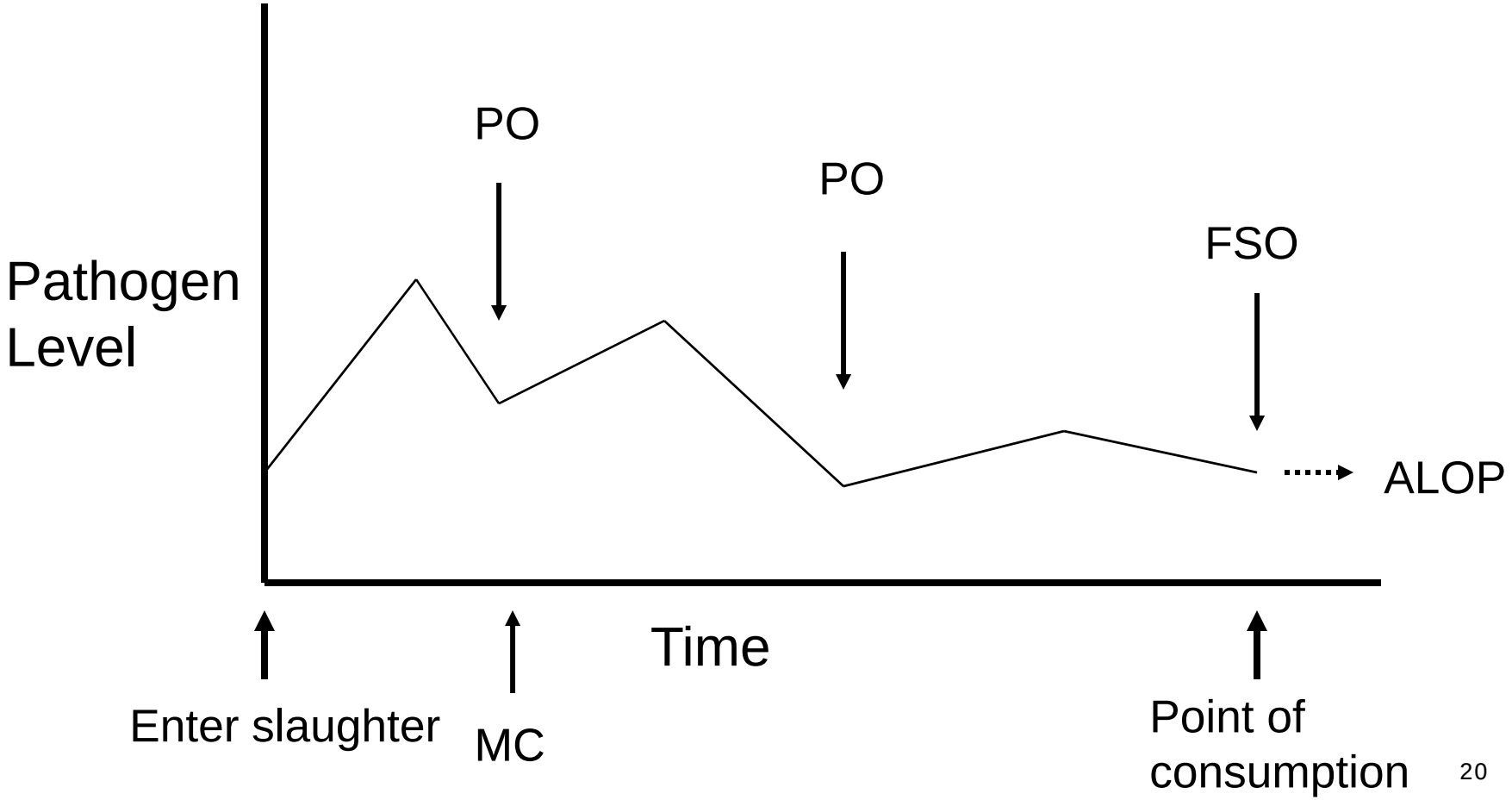
Food Process



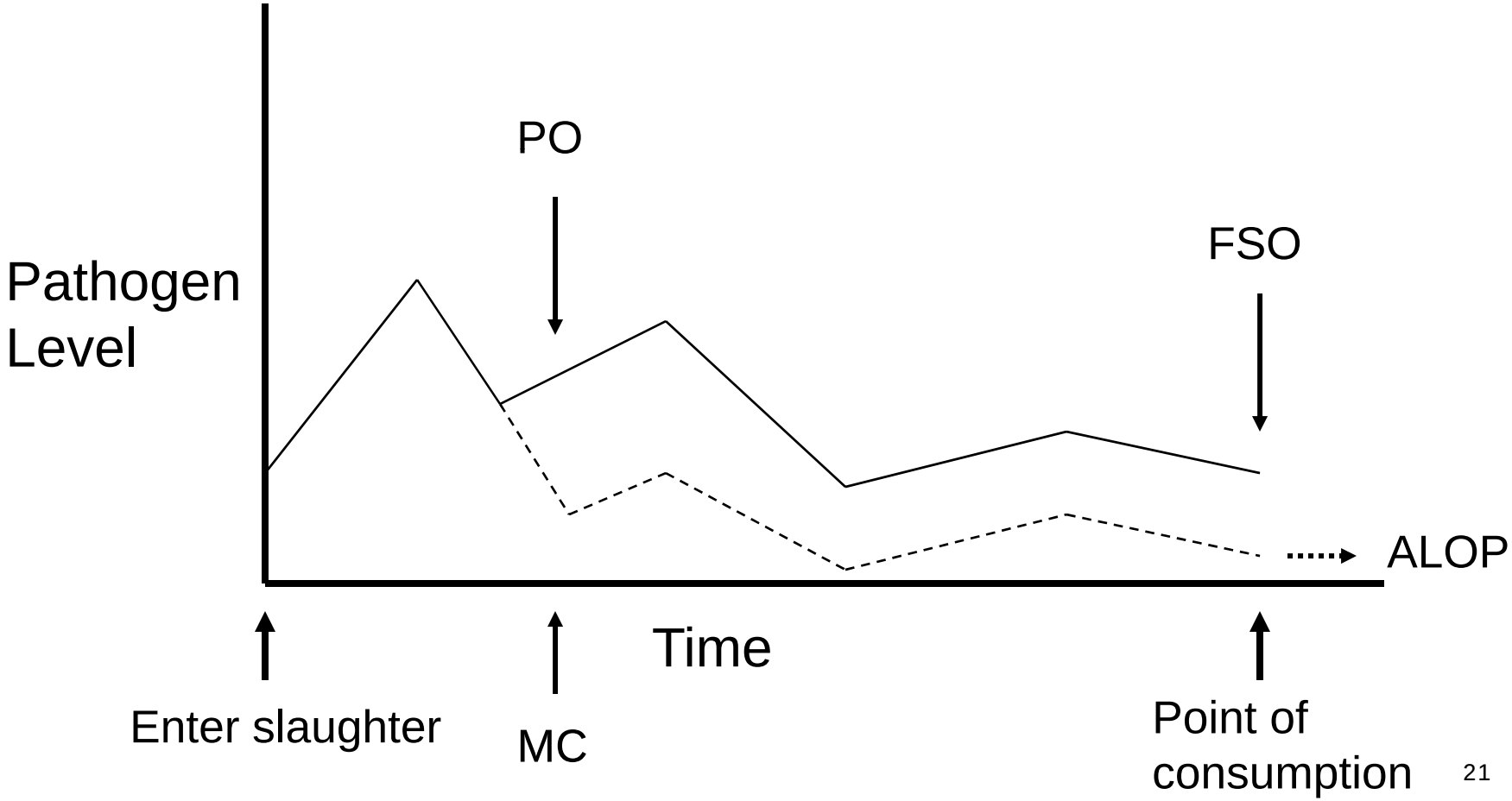
FSO, ALOP


Pathogen Level
FSO
ALOP
Time
Enter slaughter
Point of consumption

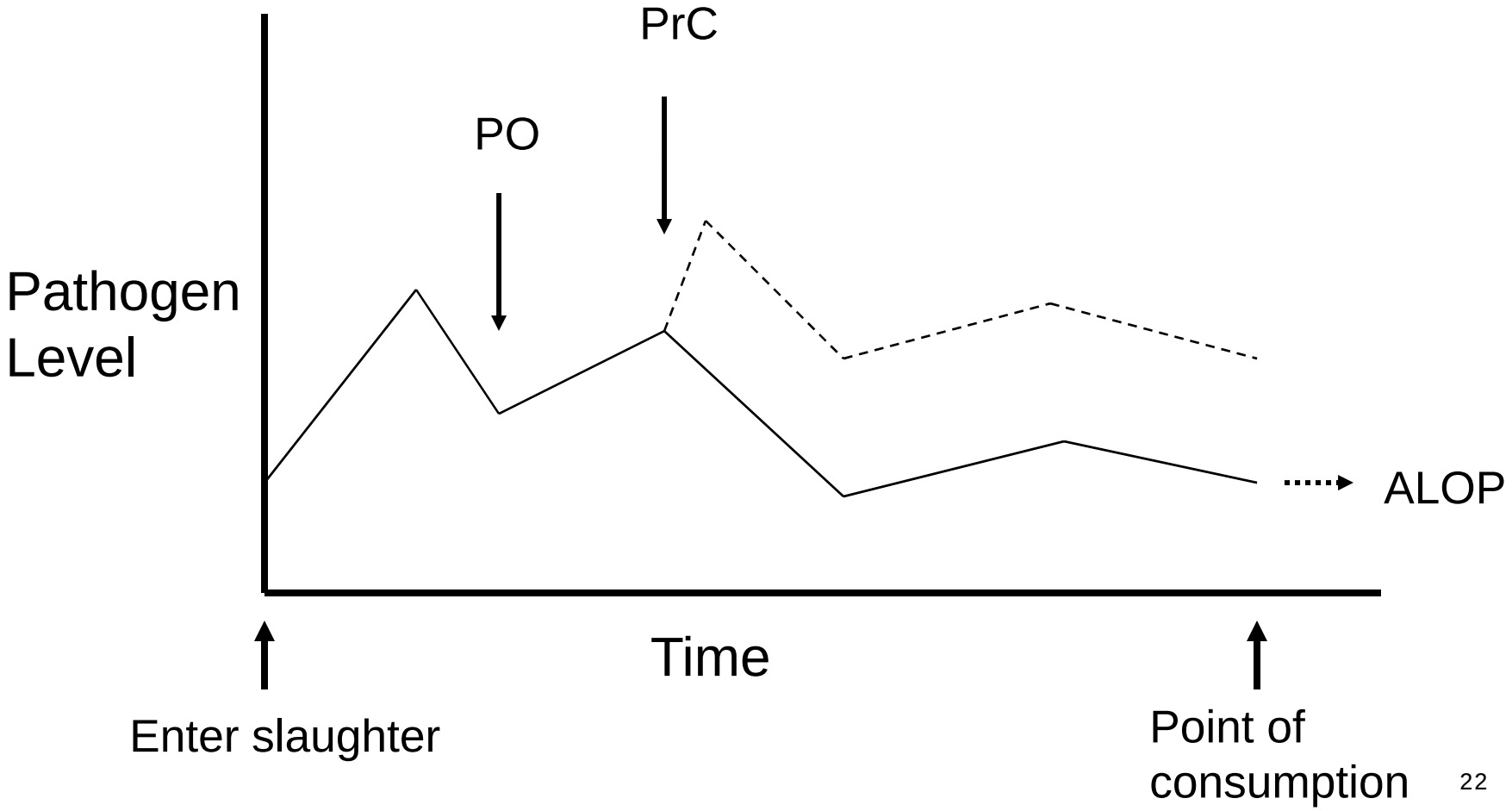
Performance Objective (PO)



New ALOP Goal



Process Criterion (PrC)



The End

Thank you very much

Any questions?

Except where noted, the views presented in this presentation are solely those of the presenter.