



# Importance of Codex's Quantitative, Risk-Based Metrics and Innovation

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&

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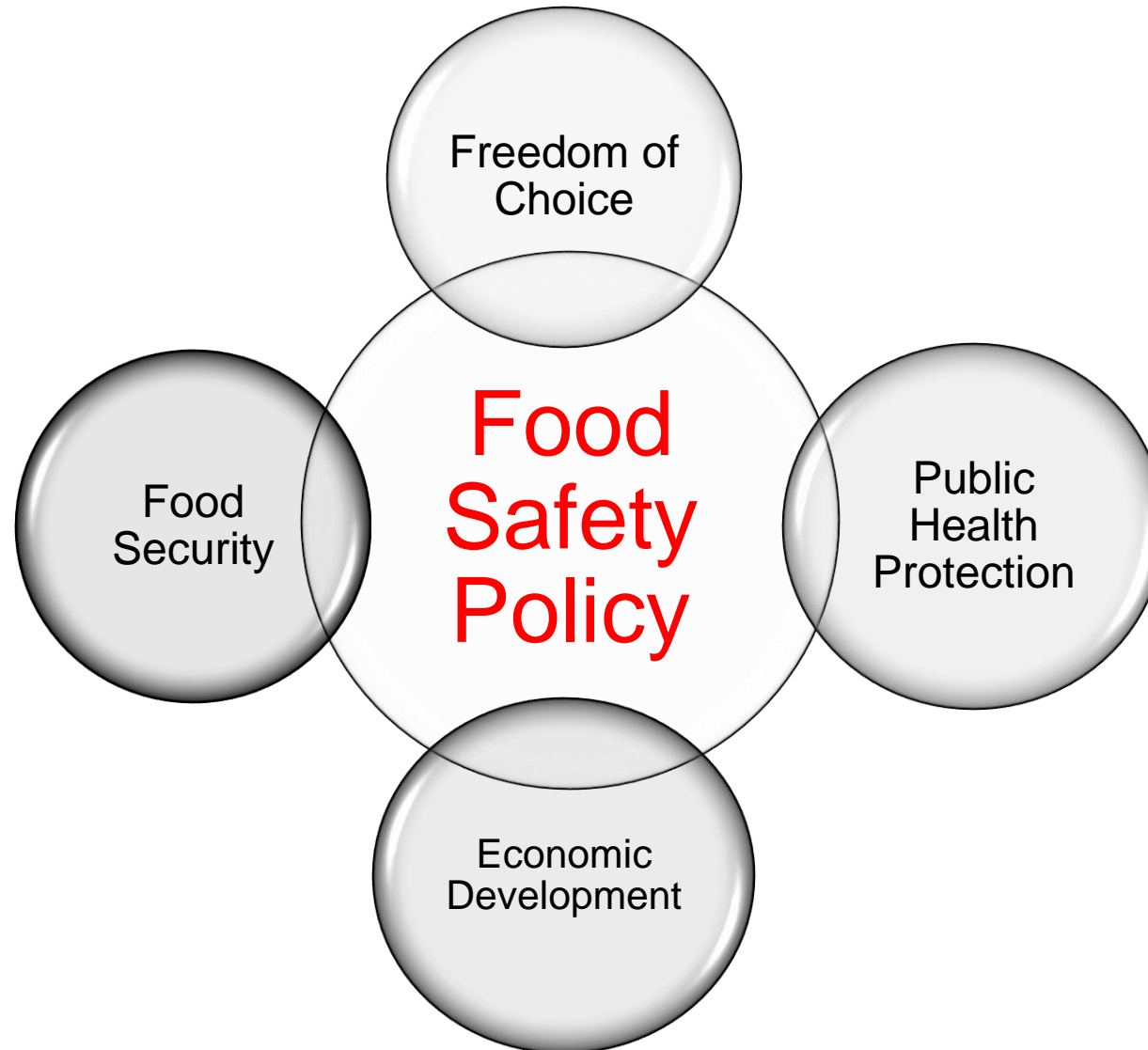


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# Responsibility of Governments as it Relates to Food Safety



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# Codex: Microbiological Risk Management - Annex II 2007

## Traditional Metrics

- *Product criterion (PdC)*
    - Chemical and physical characteristics of a food
  - *Process criterion (PcC)*
    - Specific treatment for safety
  - *Microbiological criterion (MC)*
    - Acceptability of a 'lot' of food or verification of a process
- 
- **Food Safety Objective (FSO)**
    - maximum frequency and/or concentration of a pathogen in a food at the time of consumption that provides or contributes to the ALOP
  - **Performance Objective (PO)**
    - maximum frequency and/or concentration of a microbiological hazard in a food at that point in the food chain
  - **Performance Criterion (PC)**
    - outcome that should be achieved by a control measure or a series or a combination of control measures



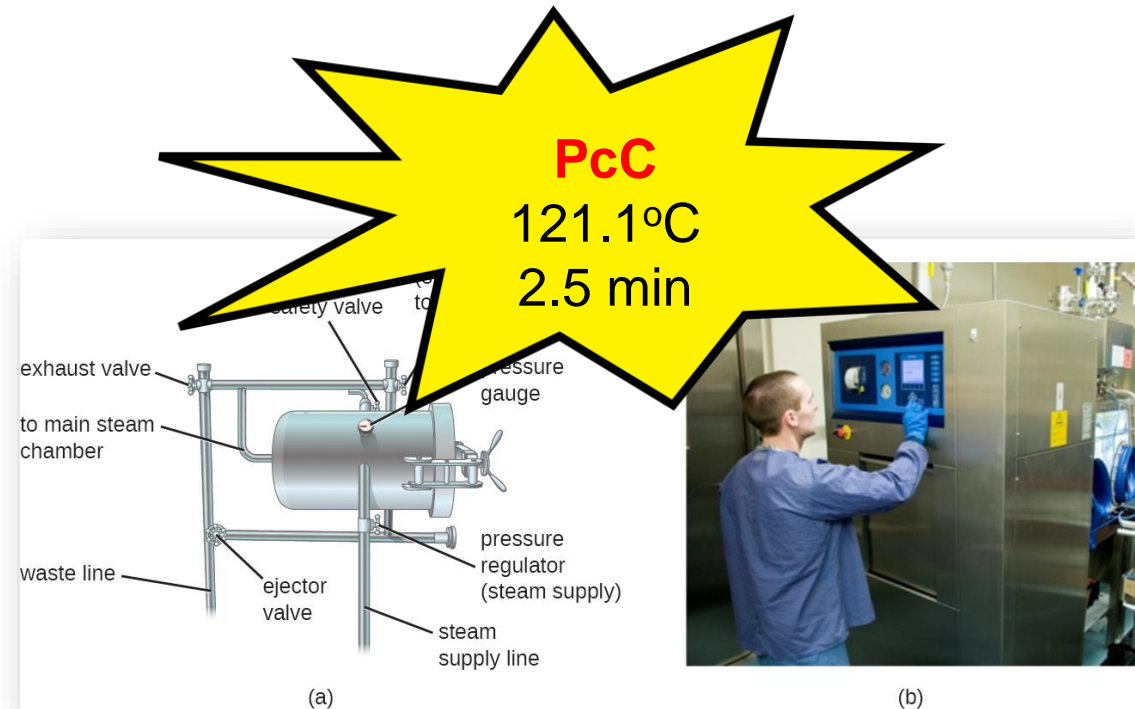
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# Example: Product and Process Criteria



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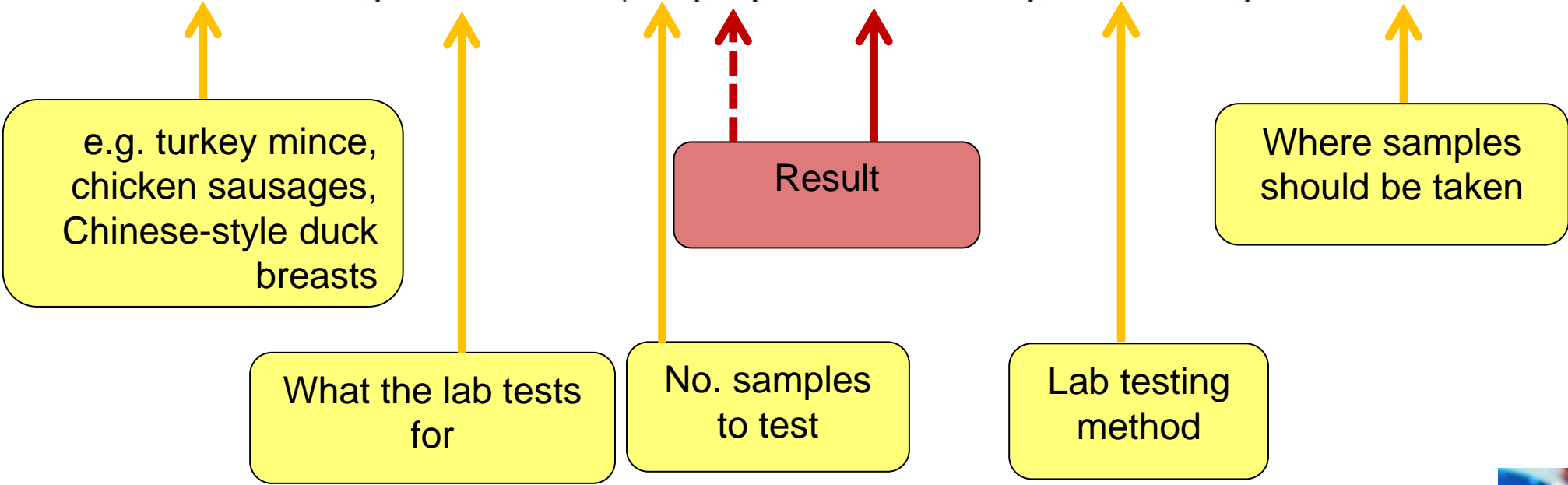


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# Reg. 2073/2005: Micro Criteria

Food category	Micro-organisms/their toxins, metabolites	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies
		n	c	m	M		
1.5 Minced meat and meat preparations made from poultry meat intended to be eaten cooked	Salmonella	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life



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# Codex: Microbiological Risk Management - Annex II 2007

## Traditional Metrics

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## 'Newer' Metrics

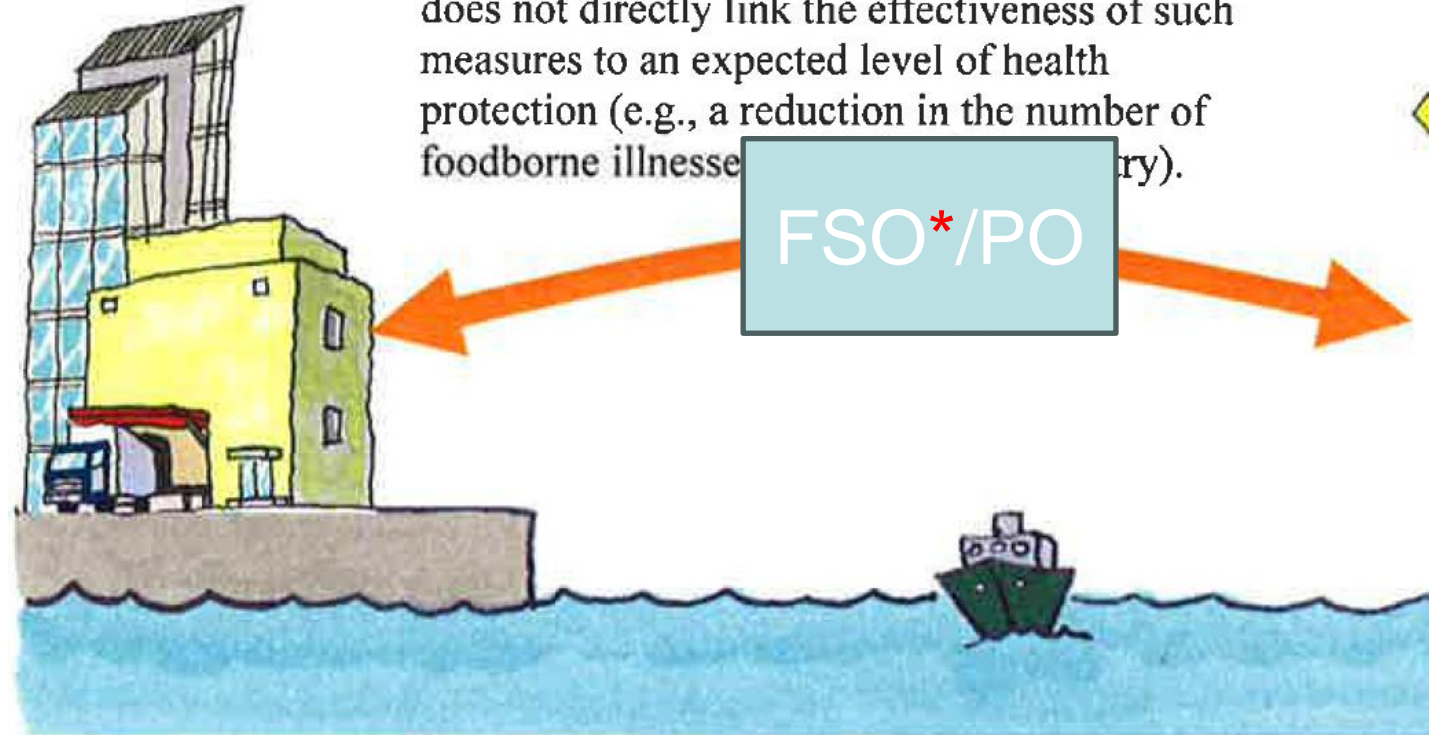
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# What we are trying to achieve

However, HACCP is plant/factory-specific and does not directly link the effectiveness of such measures to an expected level of health protection (e.g., a reduction in the number of foodborne illnesses (per million people per year)).



Number of foodborne illnesses



Per million people per year

**ALOP**



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\* Set at the point of consumption



# SPS Agreement and the Appropriate Level of Protection



## Sanitary and Phyto-Sanitary Agreement (SPS) Annex A: Definitions No. 5:

**“Appropriate level of sanitary or phytosanitary protection** — The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”

- NOTE: Many Members otherwise refer to this concept as the “acceptable level of risk”.



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# Problems with the ALOP Concept

- Expression : Qualitative or Quantitative (SPS Agreement)
- Qualitative examples exist but are vague
  - e.g. “A high level of protection of human life and health should be assured in the pursuit of Community policies.” EU General principles of food law 178/2002
- Quantitative examples don't seem to exist at Government level



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# To set an FSO you need a Quantified ALOP

- “A common factor in all documents [Kiel MRM 2000, 2002] is that the ALOP is preferably expressed as the (allowable) incidence of illness in a certain exposure scenario (per 100,000 population per year, per 10,000 servings, etc.).”
- “the ALOP would be specified as the maximum incidence of illness or infection in a population that is considered tolerable under the current conditions”



Current conditions e.g.:

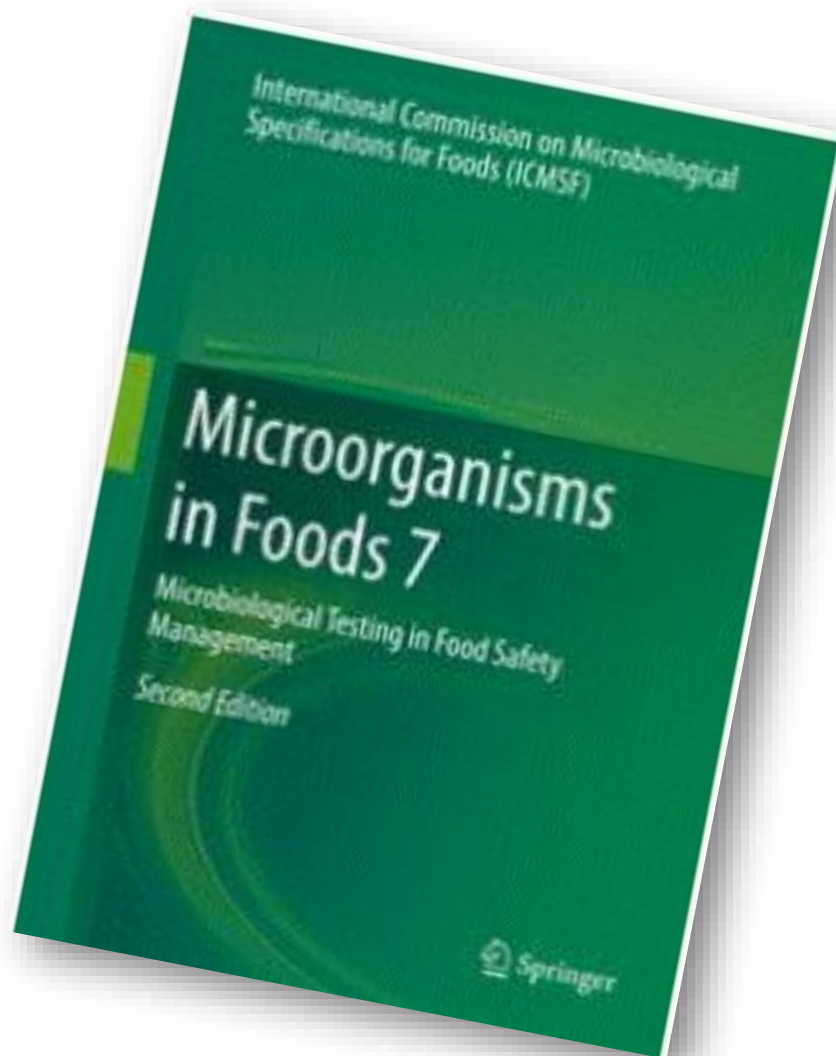
- Food safety controls
- Population variability
- Food consumption patterns



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Illustration: How ALOP, FSO and POs could be set to control *Campylobacter* in Chicken.



Chapter 19  
*Campylobacter* in Chicken  
Meat



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# Example: Quantified ALOP for *Campylobacter* in Chicken meat

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 17, No. 1,  
January 2011

## Foodborne Illness Acquired in the United States—Major Food Groups

Elaine Scallan,<sup>1</sup> Robert M. Hoekstra, Frederick J. L. Tauxe, Sharon L. Roy, Jeffrey D. Widdowson,

**ALOP= 848 domestic cases of campylobacteriosis per million population USA due to consumption of broiler meat**

**Good Quantified Epidemiological Evidence**

Foodborne cases campylobacteriosis (26 cases / million population)

Scallan et al. (2000) proposed by broiler meat to  
in the EU<sup>1</sup>  
Biological Hazards (BIOHAZ)<sup>2,3</sup>  
Food Safety Authority (EFSA), Parma, Italy

**Good Quantified Attribution Evidence**

“Handling, preparation and consumption of broiler meat may account for 20% to 30% of human cases of campylobacteriosis”



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# Relating FSO to ALOP

$$\text{ALOP} = S * 1E6 * r * D \longrightarrow \text{Dose (cfu)} = M * (10^{\text{FSO}})$$

Where:

ALOP = the Appropriate level of protection (cases per million population)

S = number of servings of chicken consumed per person per year

r = the probability of illness following ingestion of one *Campylobacter* cell

D = the dose (number of *Campylobacter* cells) consumed on an eating occasion



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# Relating FSO to ALOP Needs Data

## ALOP

848 cases/million  
population

## Consumption data

1. Number of servings per person per year (**S**)
2. Mass of chicken consumed per person per serving (**M**)

$$FSO = \text{Log}_{10}(ALOP / (S * 1E6 * r * M))$$

## Dose Response data

1. Probability of infection given consumption of 1 bacterium (**P<sub>inf</sub>**)
2. Probability of illness given infection (**P<sub>ill</sub>**)



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Food Control 16 (2005) 817–823

FOOD  
CONTROL

[www.elsevier.com/locate/foodcont](http://www.elsevier.com/locate/foodcont)

## Practical considerations on food safety objectives

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Laboratory of Food Microbiology, Wageningen University, P.O. Box 8129, 6700 EV Wageningen, The Netherlands

Received 12 August 2004; accepted 14 October 2004



# Example: FSO for *Campylobacter* in Chicken meat

Calculate 'FSO'

$$\text{FSO} = \text{Log}_{10}(\text{ALOP} / (S * 1\text{E}6 * P_{\text{ill}} * P_{\text{inf}} * M))$$

$$\text{FSO} = \text{Log}_{10}(848 / (106 * 1\text{E}6 * 0.33 * 0.0035 * 100))$$

$$\text{FSO} = -4.16 \log_{10} \text{ cfu/g}$$

(geometric mean 1cfu per ~14.5kg **cooked** broiler meat)

Where

M=100 g/person/serve – Irish food consumption data

S=106 serves/year/person– Irish food consumption data

ALOP = 848 cases/million population (slide 12)

P<sub>ill</sub>=0.33 - WHO/FAO *Campylobacter* RA dose response curve

P<sub>inf</sub>=0.0035 - WHO/FAO *Campylobacter* RA dose response curve



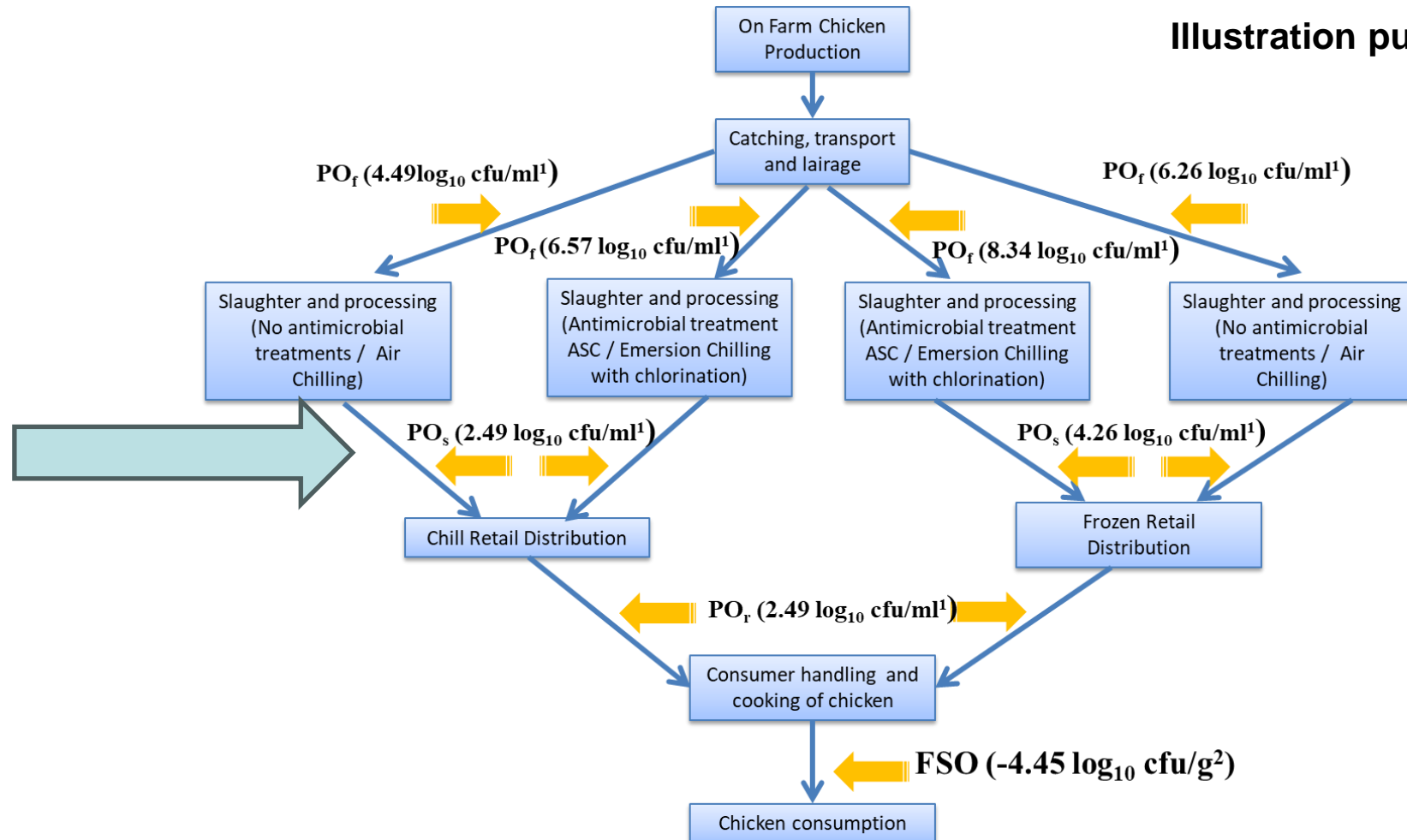
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# Farm to Fork Performance Objectives

Illustration purpose only

Opportunity to set a  
Micro-criterion to  
verify compliance

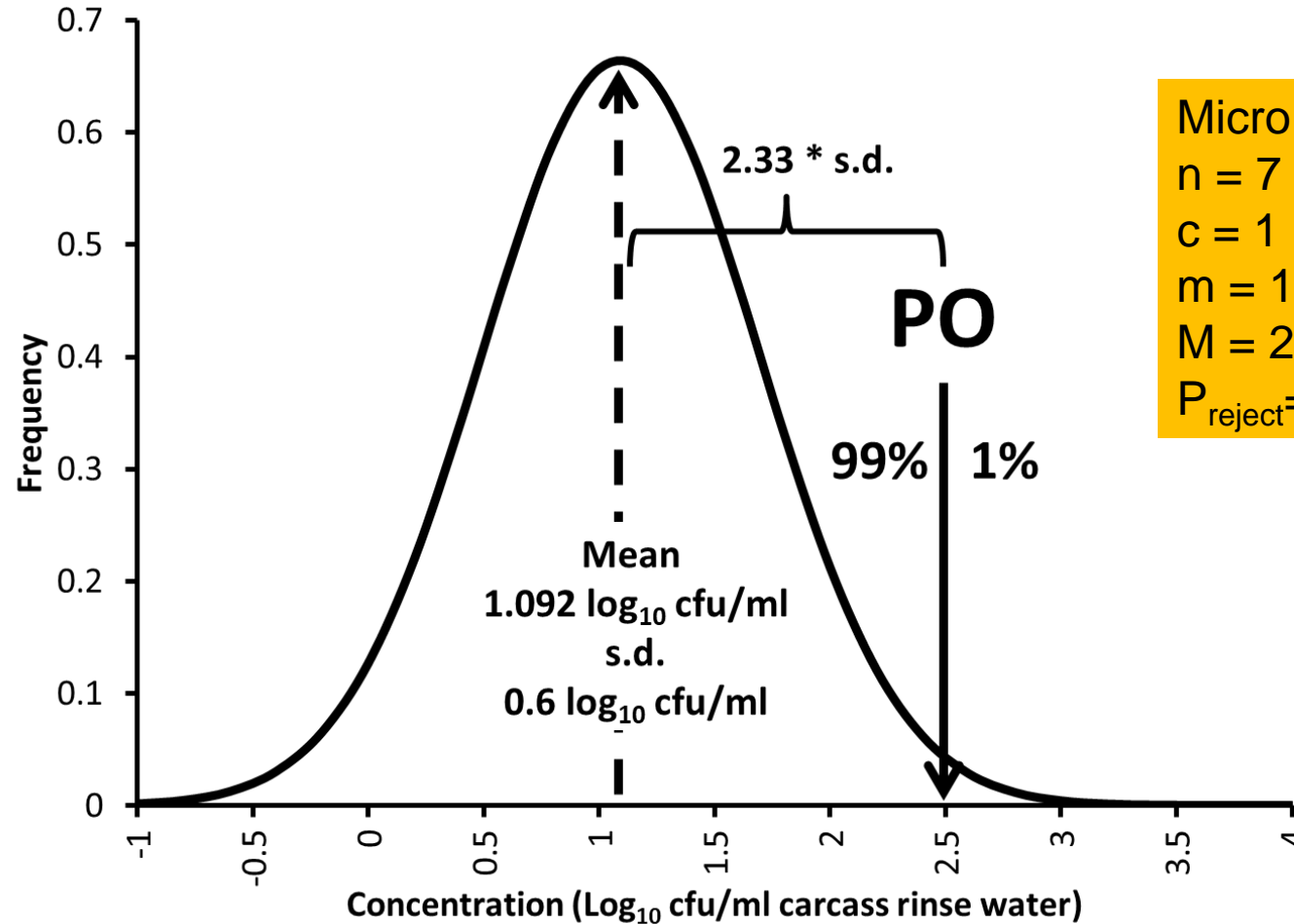


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<sup>1</sup> per ml rinsate assuming testing by carcass rinse with 100ml; <sup>2</sup> FSO per gram cooked chicken to meet the public health goal



# Verifying the PO at end retail with a Microbiological Criterion



Micro Criterion

$n = 7$

$c = 1$

$m = 1 \log \text{ cfu/ml}$

$M = 2 \log \text{ cfu/ml}$

$P_{\text{reject}} = 0.95$

Illustration purpose only



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Distribution of *Campylobacter* on chickens in a compliant batch



# Thoughts on Barriers to Adoption of 'newer' RM Metrics by Governments

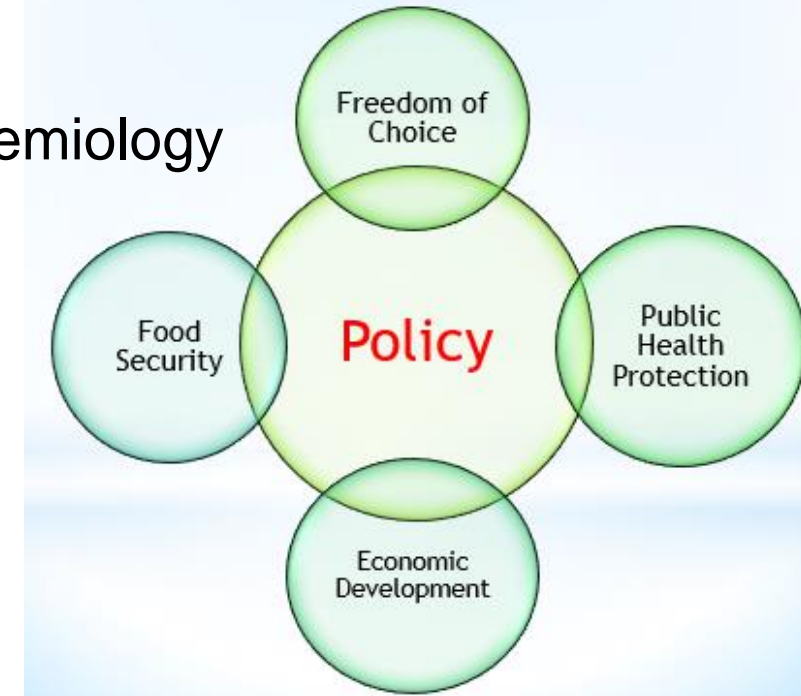
- Technical issues

- Lack of good data on food-borne disease and epidemiology
- Lack of attribution studies
- Lack of good quantitative consumption data
- Uncertainty in, or lack of dose response curves
- Lack of quantitative data on steps in the food chain

- Political issues

- Low Industry push and no public pull

- Smaller industry lacks technical ability to meet FSO - prefers clear direction (PcC, PdC)
    - Consumers just want safe food



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## Political reluctance

- Difficult to 'sell' a non-zero tolerance target for foodborne disease
- Cost of data generation





## Summary and Conclusions

- Literature and the ICMSF has established routes for developing the ‘newer’ metrics, but there are extensive data requirements.
- The future is uncertain for the adoption of ‘newer’ metrics unless data and confidence in using it improves at Government level. (*“moving beyond the familiar”*)
- Despite uncertainties and difficulties with data, even ‘rough’ estimates might be useful for scoping the possible impact of legal micro-criteria on public health (*“in the right ball-park”*).
- Adoption of the ‘newer’ risk management metrics would facilitate innovation by food businesses whilst protecting public health.

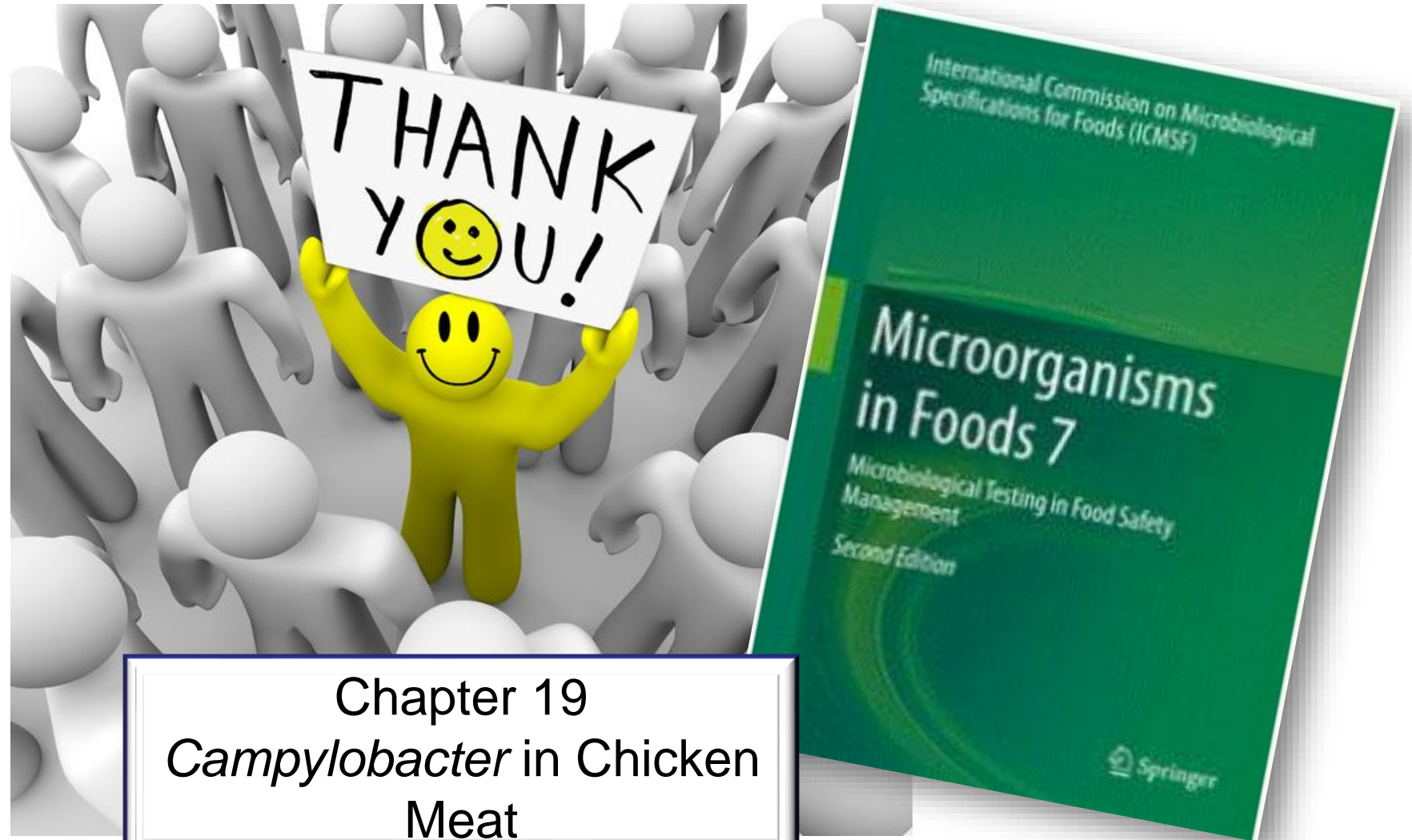


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*“Rarely are opportunities presented to you in the perfect way, in a nice little box with a yellow bow on top. ... Opportunities, the good ones, they’re messy and confusing and hard to recognize. They’re risky. They challenge you.”* – **Susan Wojcicki, chief executive officer (CEO) of YouTube from 2014 to 2023**



## International Commission on Microbiological Specifications for Foods (ICMSF)



### Chapter 19 *Campylobacter* in Chicken Meat



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