FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
Inspiring Trust, Assuring Safe & Nutritious Food
Ministry of Health and Family Welfare, Government of India

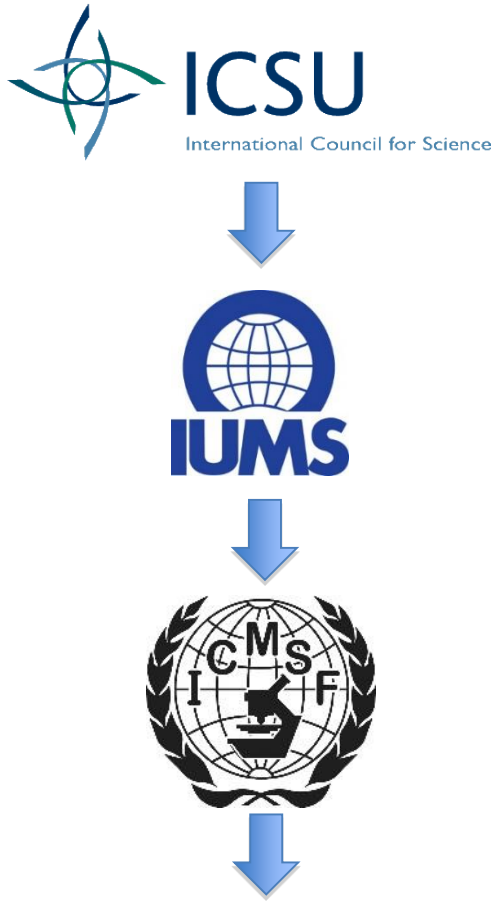
ICMSF's History and approach to useful testing for food safety, including Microbiological Criteria concept

Martin B. Cole, Ph.D.

Science Director CSIRO Agriculture and Food

ICMSF Chairman

ICMSF and its Food Safety World audiences



books, position papers,
advice to governments, Codex, FAO WHO

Annually meeting as a working party since 1962, 50 meetings in 28 countries

Raison d'etre Statement

Be a leading source for independent and impartial scientific concepts, that when adopted by governmental agencies and industry, will reduce the incidence of microbiological food-borne illness and food spoilage worldwide and facilitate global trade.

About the ICMSF

- 19 food microbiologists from 17 different countries
- Broad professional background
- Selected on technical expertise, not as national delegates
- Use of extensive network of consultants/experts
- All work is voluntary and without honoraria
- The recommendations have no official status

Publications & Position Papers

International Journal of Food Microbiology, 4 (1987) 227–247

227

Food Control, Vol. 7, No. 4/5, pp. 203–208, 1996

Food Control, Vol. 9, No. 6, pp. 379–384, 1998

Available online at www.sciencedirect.com

Food Control 20 (2009) 967–979

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/foodcont

ELSEVIER

Relating microbiological criteria to food safety objectives and performance objectives

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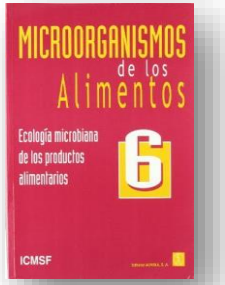
Panels and Workshops

Sub-Commissions & Working groups

Translate and Communicate ICMSF Principles

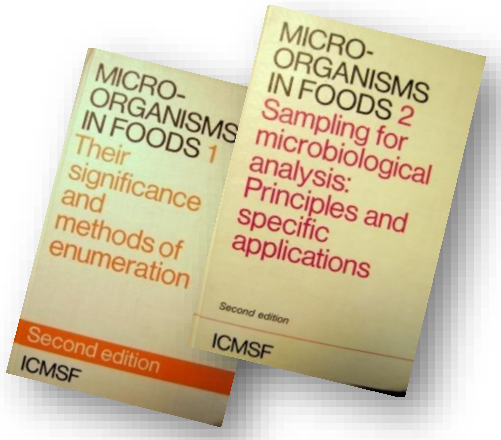


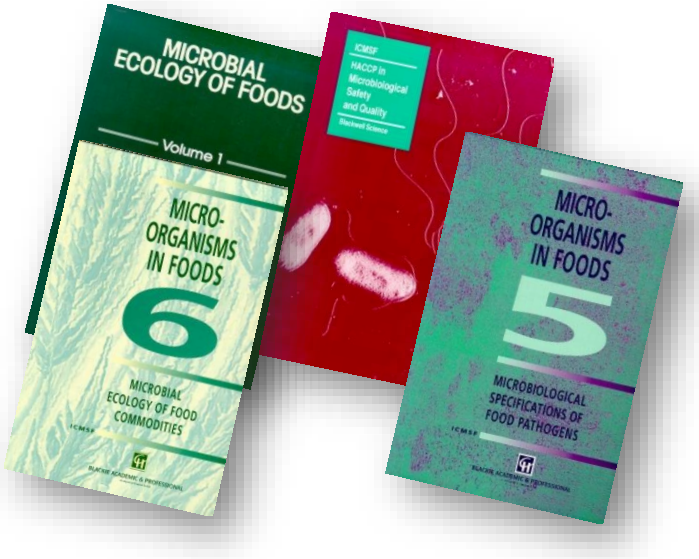
Portuguese & Spanish

Japanese

Chinese

Evolution of Food Safety Management



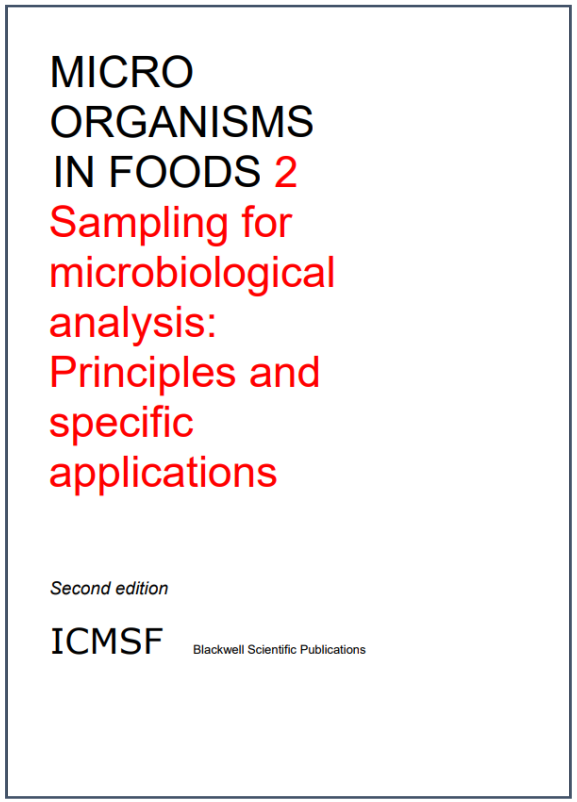


1960s – 1980s
Methods and Testing

1980s-2000s
Microbial Ecology
HACCP

2000s-2020s
Risk Management

Microbiological Criteria



1st Edition, 1974
2nd Edition, 1986

- Concept first published in ICMSF Book 2
- The concept recommends 15 Cases to manage safety and suitability of food in trade
- It follows a risk-based approach, using sampling plans for proportional stringency

ICMSF Cases

Rationale

The greater the risk, the more stringent the management of the hazard needs to be

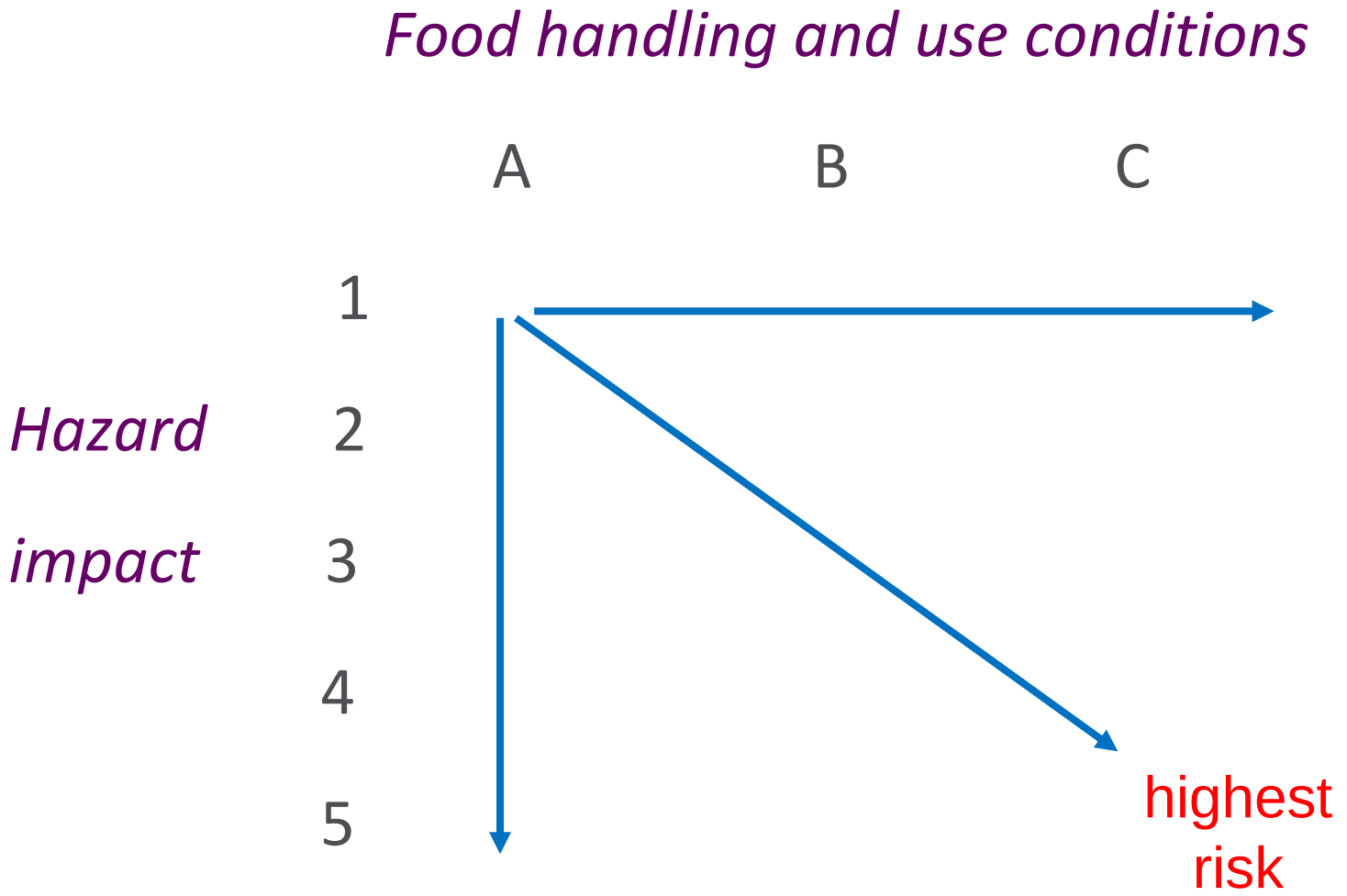
- A greater risk posed by a hazard is reflected by a higher Case number
- For increasingly higher Case numbers, sampling plans have been selected with proportionally higher performance

ICMSF Cases (cont.)

15 cases reflecting relative risk

- Considering:
  - Harmfulness and severity of the hazard
  - Intended consumer population
  - Conditions of food handling and use

Risk Categorization Matrix



ICMSF Categories of Microorganisms

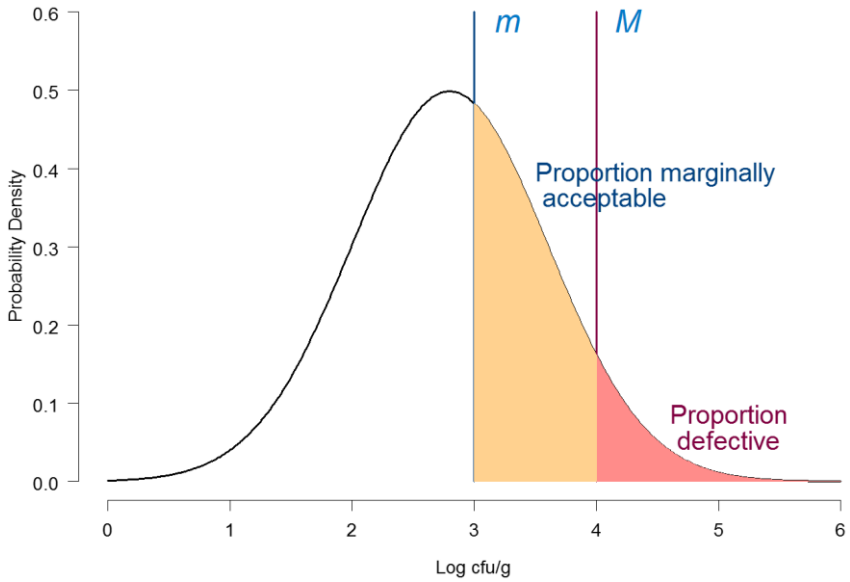
Utility	Spoilage, reduced shelf life, no health concern	*e.g.* total counts (TVC, etc.), yeast and mold
Indicator	Measure of GHP	*e.g.* Coliforms, Enterobacteriaceae.
Moderate hazard	Not life threatening, short duration, self limiting, no sequelae	*e.g. S. aureus, B. cereus, C. perfringens*, Norovirus.
Serious hazard	Incapacitating, usually not life threatening	*e.g.* Salmonellae, *Shigella flexneri*, *Yersinia enterocolitica*.
Severe hazard	Life threatening, chronic sequelae, *or* long duration *or* designed for sensitive sub-population	*e.g. E. coli* O157:H7, *C. botulinum* toxin or *Cronobacter* (infants).

Lot Acceptance

- Food lots represent units produced under uniform conditions
- Different microorganisms may be present in food lots at different levels
- Sampling plans with proportional performance are used to determine whether a lot of food is acceptable

Sampling plan types

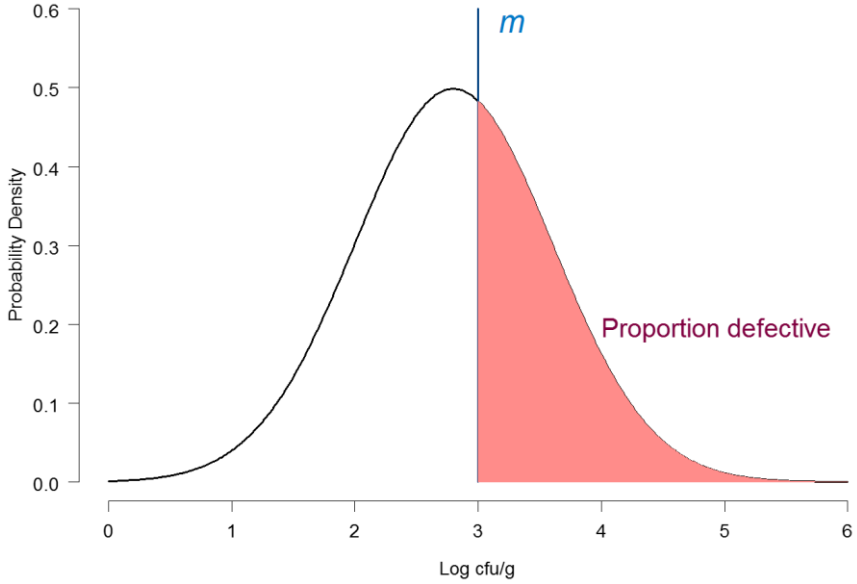
Three-class sampling plan:



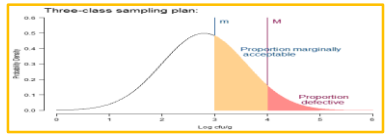
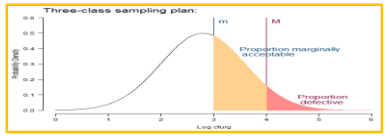
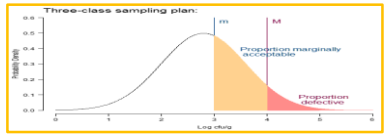
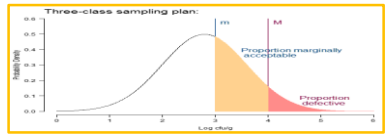
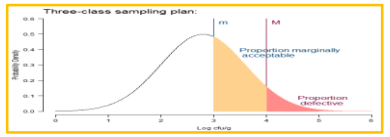
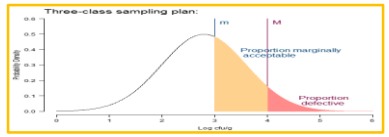
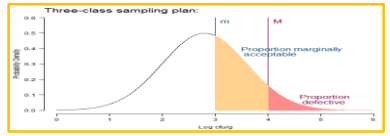
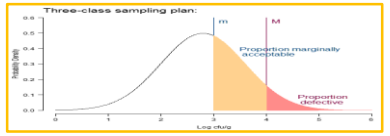
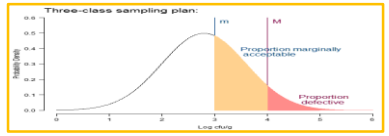
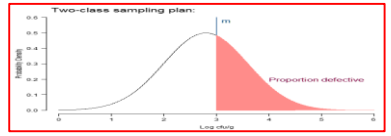
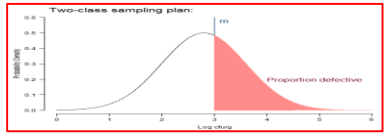
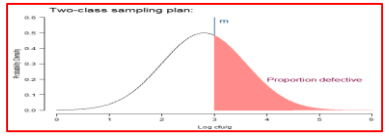
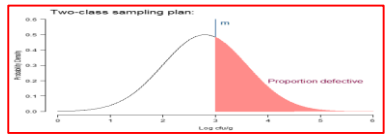
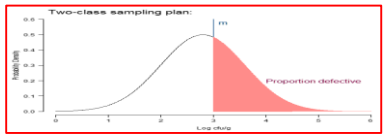
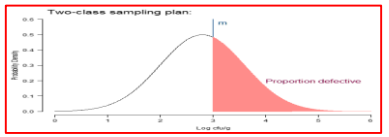
- *n* – number of sample units
- *m* – microbiological limit for good quality
- *M* – microbiological limit for unacceptable
- *c* – maximum number allowed between *m* and *M*

- *n* – number of sample units
- *m* – microbiological limit for unacceptable
- *c* – maximum number positive or over *m*

Two-class sampling plan:



Sampling Plans for Lot Acceptance

		Likely Change Before Consumption		
	Category	Reduce	No Change	Increase
Enumeration (CFU/g)	Utility			
	Indicator			
	Moderate			
Analytical unit = 25g	Serious			
	Severe			

Sampling Plans for Lot Acceptance (cont.)

Category	Likely Change Before Consumption		
	Reduce	No Change	Increase
Utility	Case 1 n=5, c=3	Case 2 n=5, c=2	Case 3 n=5, c=1
Indicator	Case 4 n=5, c=3	Case 5 n=5, c=2	Case 6 n=5, c=1
Moderate	Case 7 n=5, c=2	Case 8 n=5, c=1	Case 9 n=10, c=1
Serious	Case 10 n=5, c=0	Case 11 n=10, c=0	Case 12 n=20, c=0
Severe	Case 13 n=15, c=0	Case 14 n=30, c=0	Case 15 n=60, c=0

Analytical unit = 25g

New Approaches to Risk Management

ALAR
ie 'As low as Reasonable'

BUT:
-Technological capabilities vary
-Idea of 'reasonable' varies

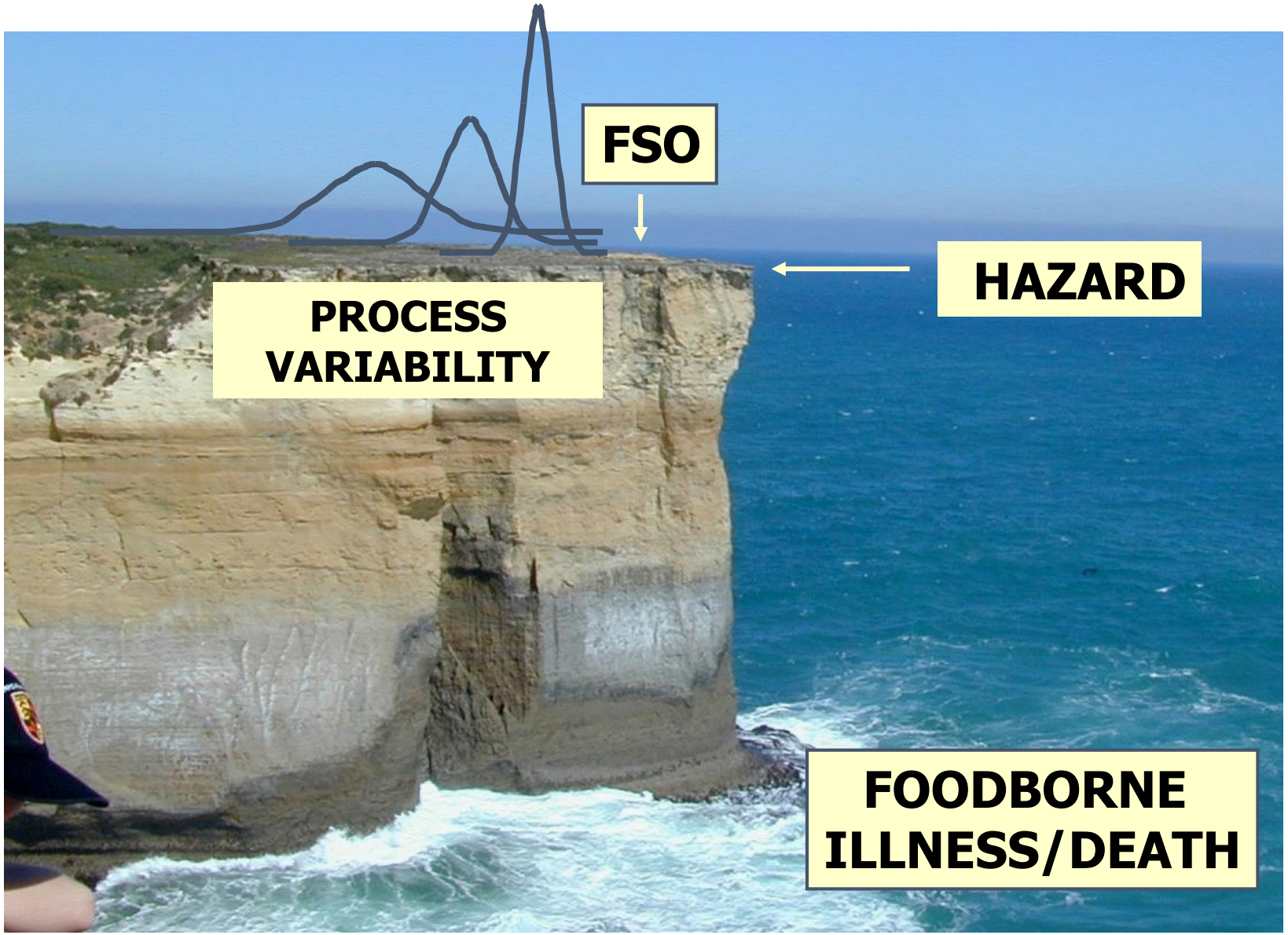
→

Public Health Based Goals
-eg yearly incidence of Listeriosis below 4 cases/million of pop.
BUT:
-in terms of population
-not related to specific foods

The Issue Behind the Issue:

Equivalence: Do two systems of food safety risk management (e.g. inspection, HACCP, processing) provide the same degree of public health protection?

Managing the 'Food Safety Cliff



Performance Criteria

$$H_o - \Sigma R + \Sigma I \leq FSO$$

- FSO = food safety objective
- H_o = initial level of the hazard
- ΣI = total increase (growth or recontamination)
- ΣR = total reduction (inactivation or removal)

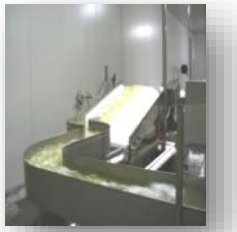
Risk-based use of preventative controls in the production chain of fresh produce

Production & Primary Handling

Minimizing initial levels

Water management
Choice of fertilizer
Sanitation of equipment
Rapid cooling
Hygiene of personnel
Monitoring

Processing & Packaging



Reducing levels

Processing & Washing steps
Environmental surveillance
Monitoring

Distribution & Shelf-life

Minimizing an increase in levels

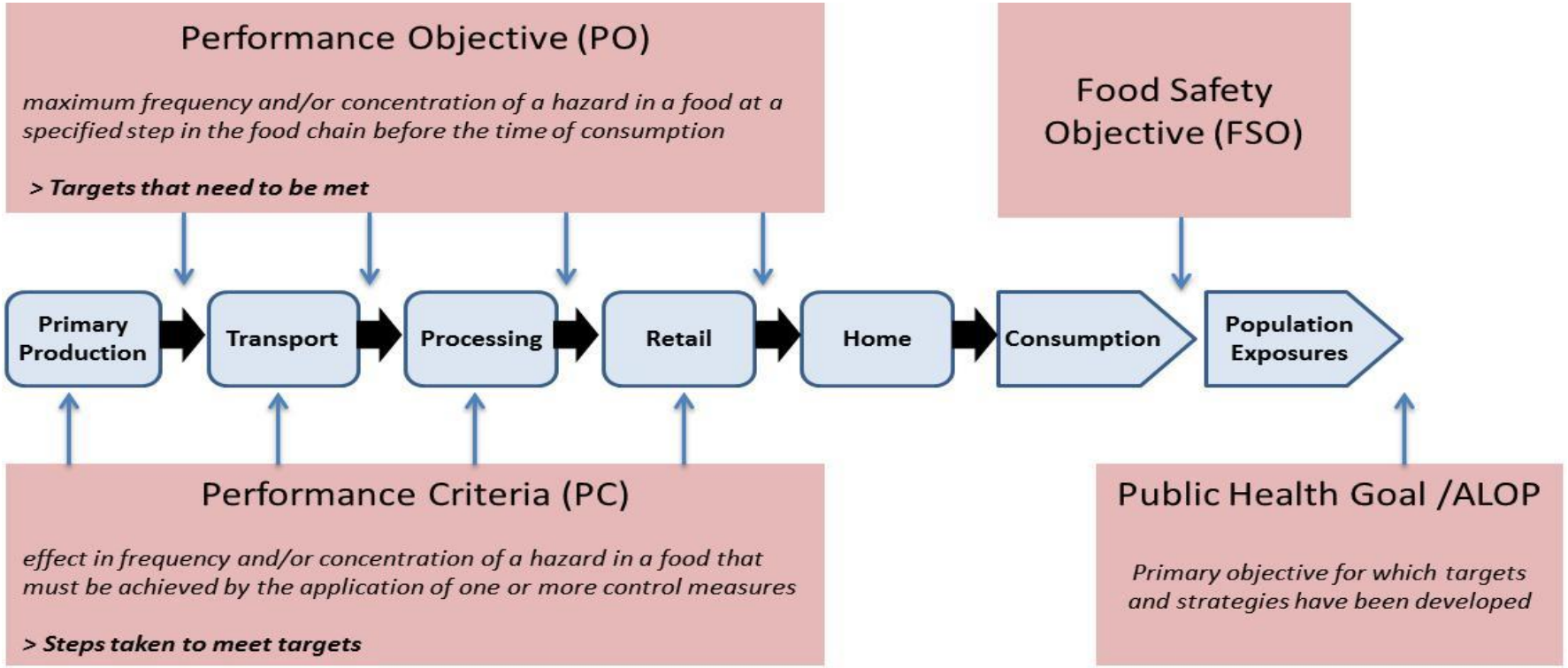
Minimum Standards

Temperature management
Choice of storage atmosphere
Shelf-life
Monitoring

Good Agricultural Practice (GAPs)
Good Manufacturing Practice (GMPs)
Hazard Analysis Critical Control (HACCP)
Performance Standards
Guidelines/Regulations

Testimony before the US House of Representatives
"Food and Drug Administration Globalization Act of 2009", March 11, 2009

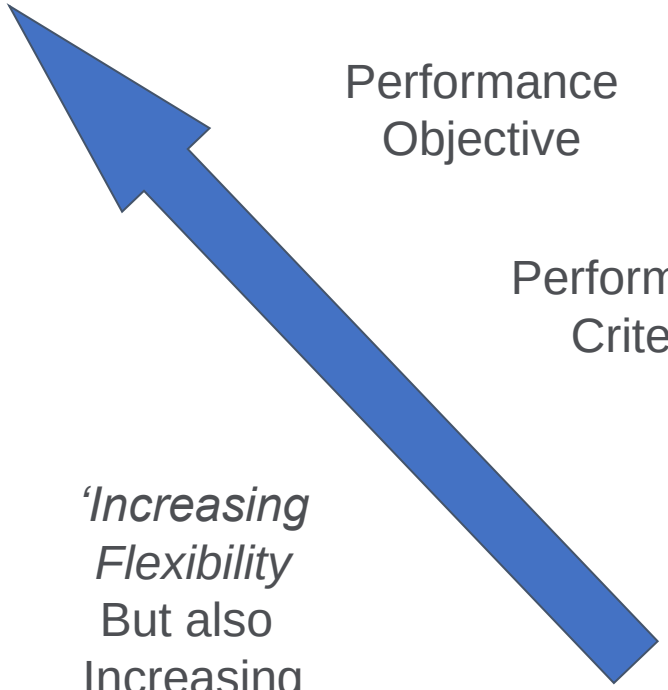
Overview of setting public health targets and performance metrics



Acceptable Level of Protection (ALOP); Food Safety Objective (FSO); Performance Objective (PO); Performance Criteria (PC)

Fazil, 2013

Hierarchy of Risk Management Options

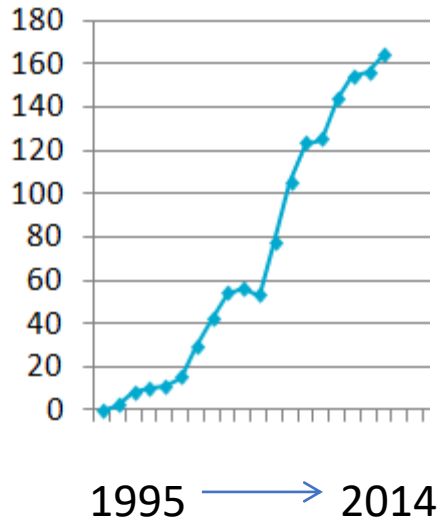


Food Safety Objective	Target max. level at consumption
Performance Objective	Target max. level at specific step
Performance Criteria	Required control on H_0 at specific step
Process/Product Criteria	Specific process or Product conditions

'Increasing Flexibility
But also
Increasing
Complexity'

Impact of New Risk Management

- Increased flexibility….innovation
- Science based & increased transparency
- Will impact
  - Shared responsibility across chain
  - Stringency of HACCP
  - Micro Criteria more science based
  - Equivalency of new processes



No. Papers with Food Safety Objective in title

When & Where to Test for Food Safety Management

- When there is good evidence that:
  - There is a microbiological problem
    - Food safety or quality
    - Historical or current

AND

- Testing will help to control the problem

Relating Criteria to other risk management metrics

Determining the concentration of microorganisms controlled by attributes sampling plans

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Relating microbiological criteria to food safety objectives and performance objectives

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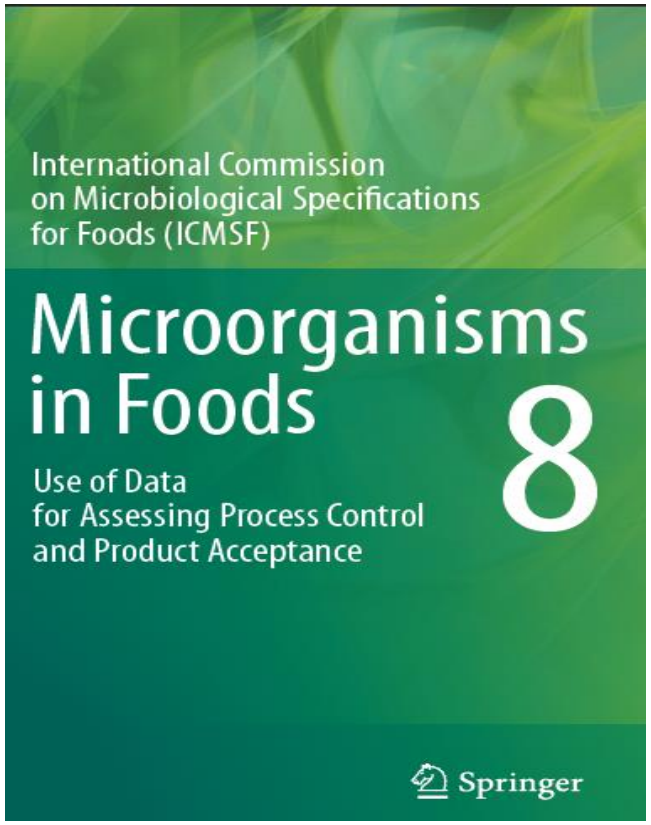
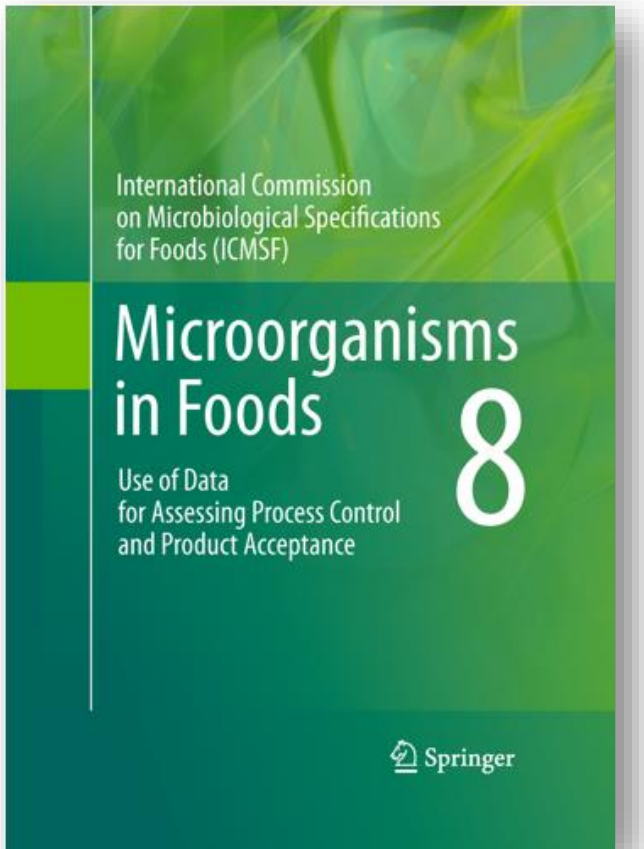
www.icmsf.org

Performance of ICMSF cases

Type and likely change to level of hazard	Reduce	No change	May increase
Indirect *e.g.* *Aerobic plate counts (APC)*	Case 4 (3-class, *n*=5, *c*=3) e.g. *m*=1000/g, *M*=10000/g 5100cfu/g	Case 5 (3-class, *n*=5, *c*=2) e.g. *m*=1000/g, *M*=10000/g 3300cfu/g	Case 6 (3-class, *n*=5, *c*=1) e.g. *m*=1000/g, *M*=10000/g 1800cfu/g
Moderate *e.g.* *S.aureus*	Case 7 (3-class, *n*=5, *c*=2) e.g. *m*=100/g, *M*=10000/g 2600cfu/g	Case 8 (3-class, *n*=5, *c*=1) e.g. *m*=100/g, *M*=10000/g 1100cfu/g	Case 9 (3-class, *n*=10, *c*=1) e.g. *m*=100/g, *M*=10000/g 330cfu/g
Serious *e.g.* *Salmonella sp*	Case 10 (2-class, *n*=5, *c*=0) e.g. *m*=0/25g 1 cfu/55g	Case 11 (2-class, *n*=10, *c*=0) e.g. *m*=0/25g 1 cfu/100g	Case 12 (2-class, *n*=20, *c*=0) e.g. *m*=0/25g 1 cfu/490g
Severe *e.g.* *E.coli 0157:H7*	Case 13 (2-class, *n*=15, *c*=0) e.g. *m*=0/25g 1 cfu/330g	Case 14 (2-class, *n*=30, *c*=0) e.g. *m*=0/25g 1 cfu/850g	Case 15 (2-class, *n*=60, *c*=0) e.g. *m*=0/25g 1 cfu/2000g



- ***Objectives***
  - Provide guidance on appropriate and inappropriate testing of food processing environments, during processing, and finished product testing.
  - Expands on the use of trend analysis and across-lot data.
- ***Available through Springer:***
  - http://www.springer.com/food+science/book/978-1-4419-9373-1
  - Can purchase individual electronic chapters



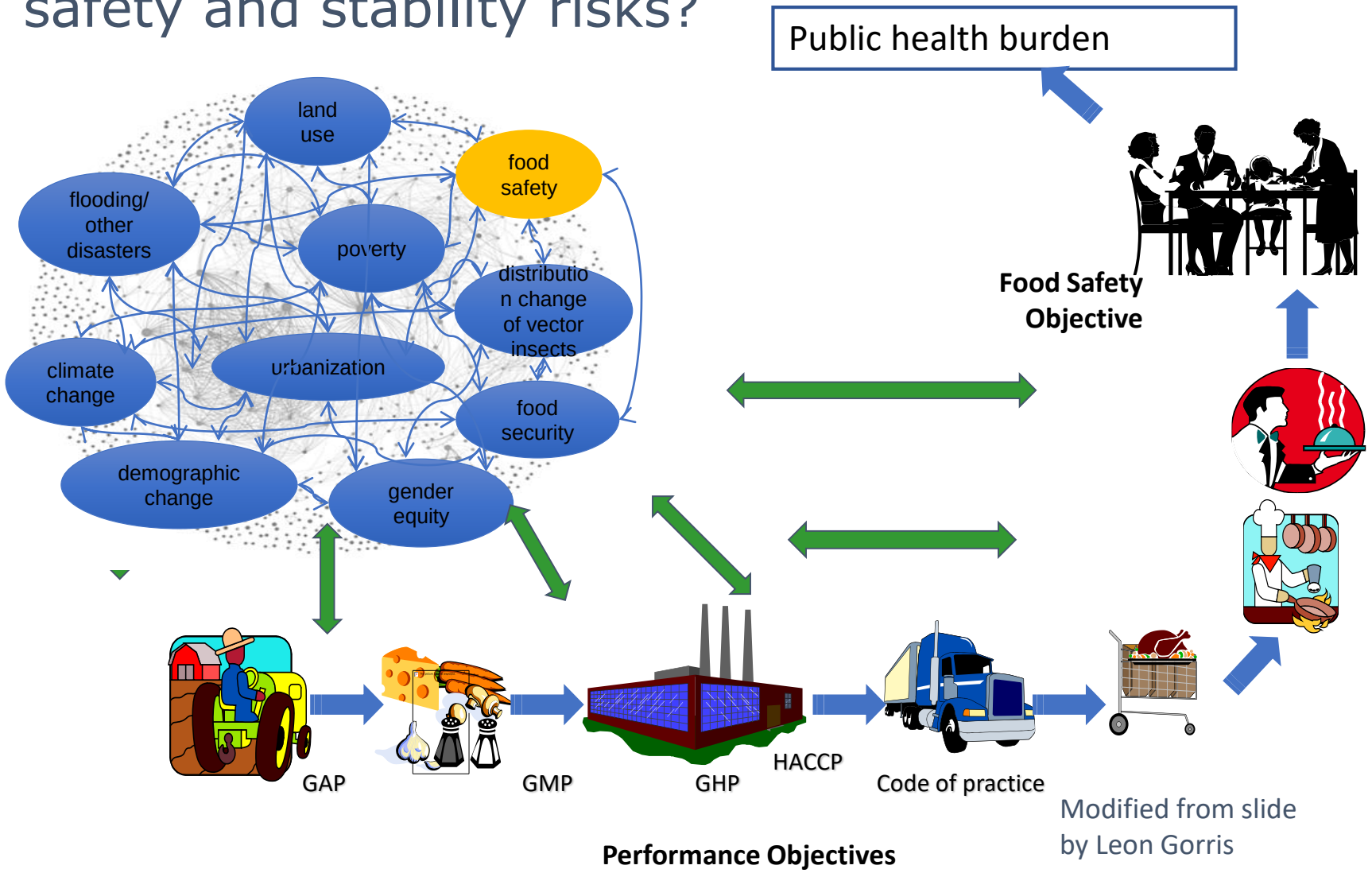
Relative importance		Useful testing
Critical ingredients	Low	Initial contamination is highly dependent on implementation of good agricultural practices (see Sect. 12.2).
In-process	High	Monitoring antimicrobial concentration is recommended to prevent cross contamination via wash water, flume water, etc.
	Low	Periodic microbiological testing of paired (i.e., before and after) produce samples may be useful to assess effectiveness of these controls.
Processing environment	Medium	Periodic testing of food contact surfaces and processing environments are recommended to verify adequacy of cleaning and sanitization protocols. Potential assays include aerobic colony counts and *E. coli*.
		Consider environmental testing for *Salmonella* in environments with a history of issues with birds or vermin.
		Consider environmental testing for *Listeria* spp. or *L. monocytogenes* for refrigerated fresh-cut vegetables when growth may occur within usable shelf life.
Shelf life	Low	Where shelf life of fresh-cut vegetables is limited by microbiological activity, validate shelf life after major change in process technologies. Periodic verification through microbiological analysis for spoilage species may be beneficial for such products.
End product	Medium	Routine testing is not recommended but periodic testing for specific indicators using internal standard or those below may be useful to verify process control and trend analysis.

				Sampling plan & limits/g*			
Product	Microorganism	Analytical method [a]	Case	n	c	m	M
Fresh-cut vegetables	*E. coli*	ISO 7251	6	5	1	10^1	10^2

Routine microbiological testing for pathogens is not recommended. Test for pathogens only when other data indicate potential for contamination.

					Sampling plan & limits/25g*			
	Product	Microorganism	Analytical method [a]	Case	n	c	m	M
Low	Fresh-cut vegetables	*Salmonella*	ISO 6579	12	20[b]	0	0	-
Low		*E. coli* O157:H7	ISO 16654	15	60[b]	0	0	-
Low		*L. monocytogenes*	ISO 11290-1	NA[c]	5[b]	0	0	-

How do we use a systems approach to manage global food safety and stability risks?



Modified from slide by Leon Gorris

(Fumico Kasuga, 2016)

2017