Introduction to ICMSF Approach to *Useful* Microbiological Testing and Role of Microbiological Criteria

Tom Ross

Centre for Food Safety and Innovation, Tasmanian Institute of Agriculture, University of Tasmania, AUSTRALIA

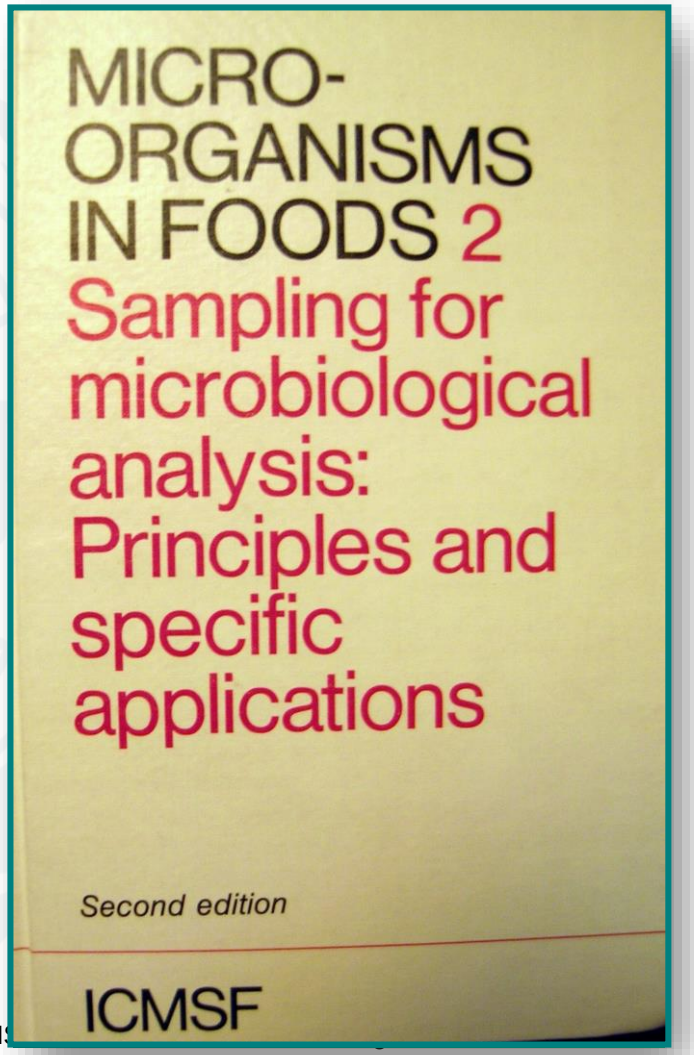
International Commission on Microbiological Specification for Foods

Food Safety and Standards Authority of India

Overview

- **Part 1: Background: Microbiological Criteria**
  - microbial ecology of foods
  - microbiological criteria for foods
    - types of criteria
    - defining a criterion
    - specifying a meaningful and useful criterion

- **Part 2: Where and what to test**
  - indicators *vs.* specific organisms
  - places to test
    - primary production
    - ingredients
    - processing
    - environment
    - shelf life
    - end product



Microbiological quality and safety of foods

- *microbes can cause quality loss (spoilage)*
  - quality
    - related stoichiometrically to numbers and types of microbes (usually bacteria or fungi); can cause odours, taints, slimes, loss of colour, loss of texture, etc.
  - spoilage
    - not usually evident until microbe numbers exceed 100,000 cells/gram, or -/ml
- *microbes (pathogens) can cause harm to consumers*
  - infection
    - food may contain viable organisms that colonise the consumer and cause illness (various mechanisms); *even one cell of some organisms can cause infection leading to death*
  - intoxication
    - food may contain organisms that grow in the food and leave toxic residues (that cause human illness by various mechanisms)

Microbiological testing and criteria relevant to industry

Microbiological criteria are used to determine the acceptability of a food.

Microbial ecology of foods

microbes in foods can:

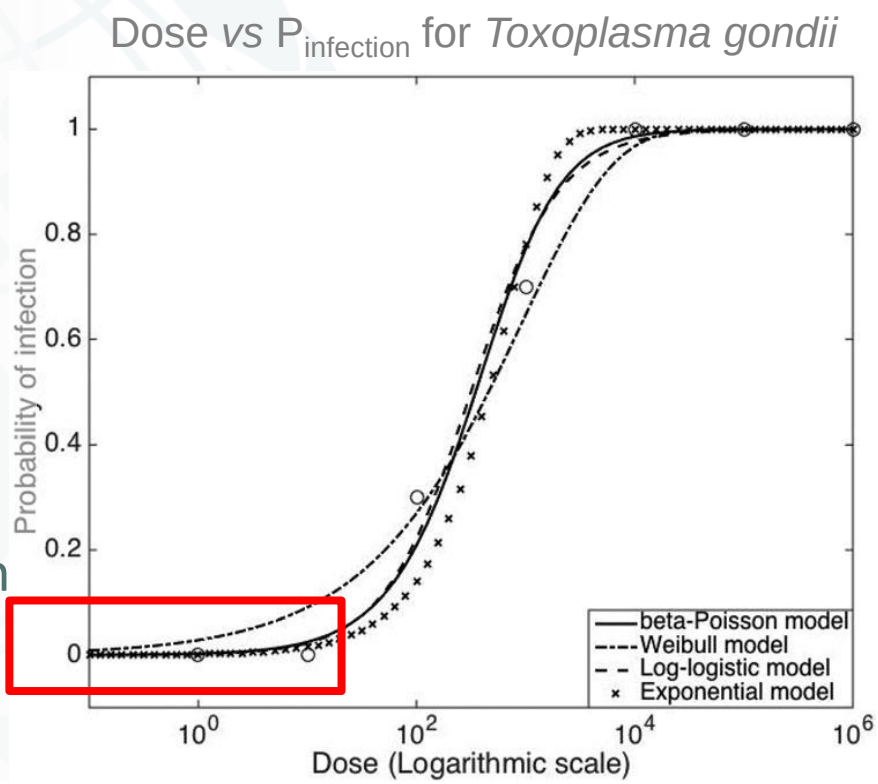
- grow
- survive
- die

these processes are not instantaneous and the amount of growth or death, or whether survival occurs, depends on the characteristics of the organism itself and:

- food composition and additives
- storage conditions
- other microbes in the food
- processing steps
- ***time***

Numbers, and the potential for growth

- spoilage/quality loss is related to the numbers (concentration) of 'specific spoilage organisms'
- potential for human illness increases in proportion with the number (concentration) of pathogens in the food
- Nonetheless, sometimes the presence of one cell of a pathogen is considered unsatisfactory and dangerous to human health



(Figure reproduced from: Guo, M. (2015). Development of Dose-Response Models to Predict the Relationship for Human *Toxoplasma gondii* Infection Associated with Meat Consumption. *Risk Analysis*, DOI: 10.1111/risa.12500).

Microbial ecology of foods

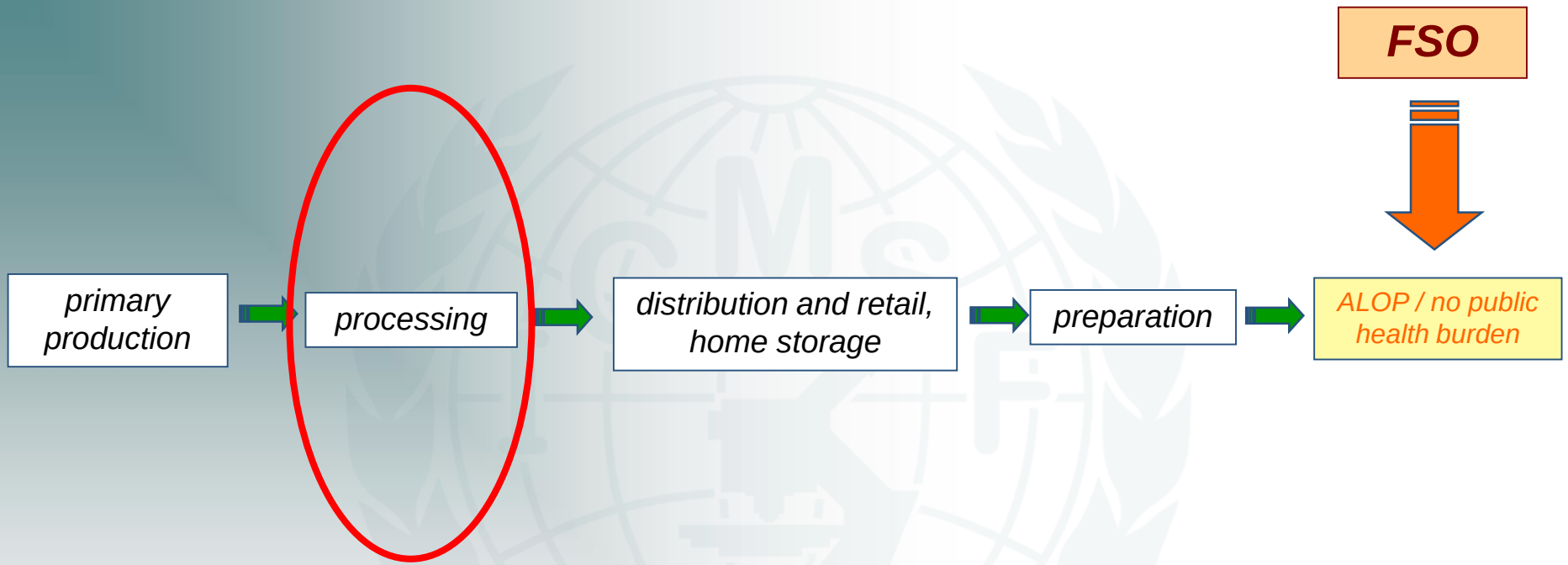
- microbial *levels* determine quality, or safety
- *need to specify acceptable levels at a particular time/stage in the product's history*
- *time of consumption* is most relevant
- but we cannot test at the *time of consumption*…

Microbiological Criteria

- define the "*acceptability*" of a product based on the presence/absence* or number of microorganisms (and/or their toxins/metabolites) per unit of mass, area or volume (or lot)

- * the rigour of 'presence/absence' criteria effectively specifies a numerical limit as well, but at very low concentrations.

Food Supply Chains



Food Safety Objectives

(ICMSF, 2002; CAC, 2005)

- specify the maximum permissible level and/or frequency of a microbiological hazard in a food at the moment of consumption (commensurate with the ALOP*)

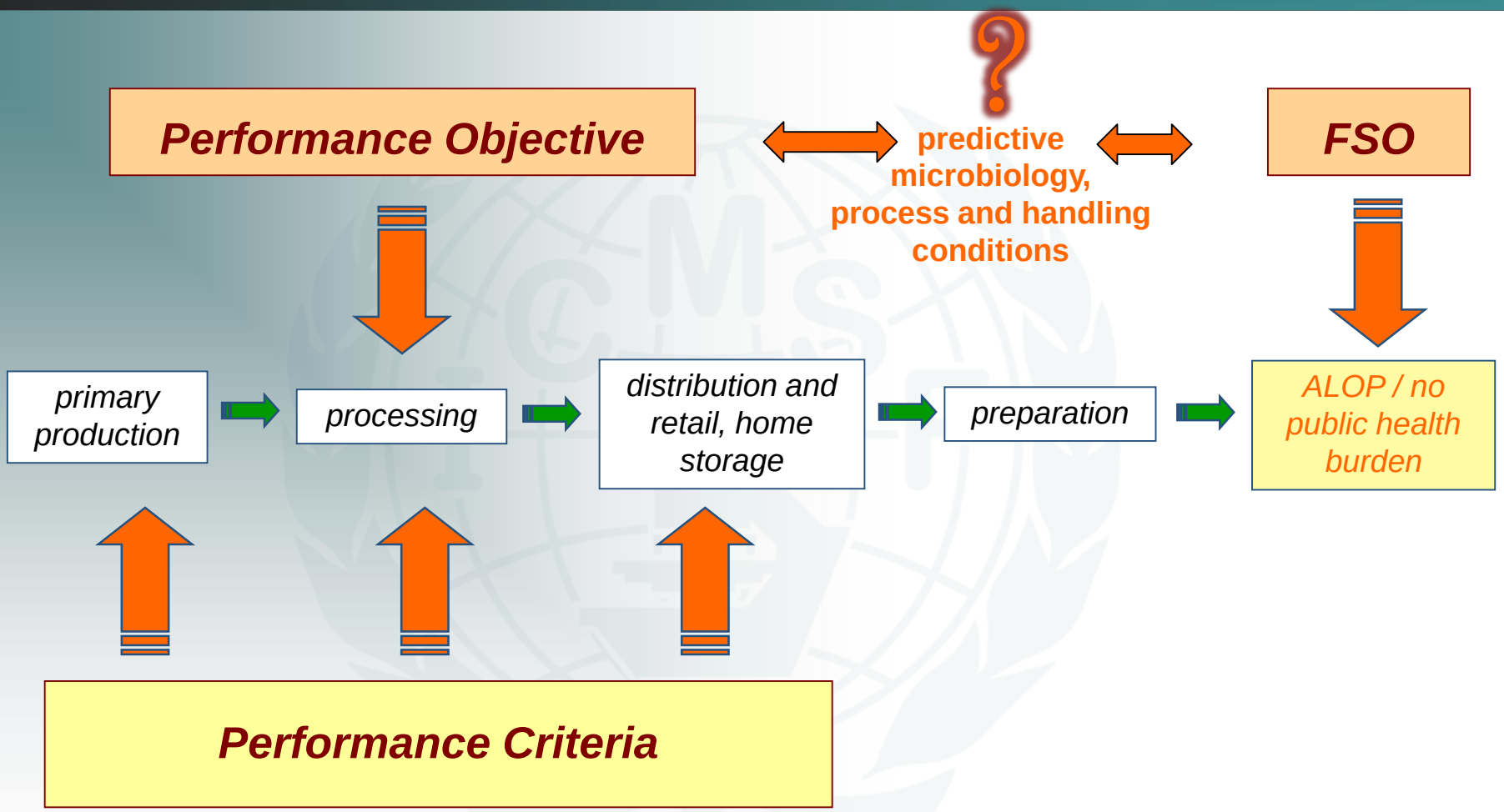
*Appropriate Level of Protection

Determining ‘industry-relevant’ criteria and testing

- Usually testing can’t be applied at the point of the FSO’s application…

- need to define **Performance Objective**(s), and corresponding **Performance Criteria** for food businesses

Performance Objectives and FSOs



New approach: from Microbiological Risk Assessment

ALOP → FSO/PO → MC

FSO/PO

Goal for process design to obtain acceptable food.

Applied to processing operations

Micro. Criteria

Statement of conditions that differentiates acceptable from unacceptable lots of food.

Applied to individual lots or consignments of food.

Microbiological Criteria

define

- the “acceptability” of a product based on the presence/absence* or number of microorganisms (and/or their toxins/metabolites) per unit of mass, area or volume (or lot) *at specified points in the food chain*
- the performance of either
  - a process
  - a food safety control system

Types of microbiological criteria

Performance criterion

- the required outcomes of one or more control measures at a step or combination of steps that contribute to ensuring the safety of the product

Process criterion

- are the control parameters (*e.g.,* time, temperature, acidity, chlorine dosage, *etc.*) at a step that can be applied to achieve the performance criterion

Product criterion

- consist of parameters that ensure that the level of hazard does not increase to unacceptable levels before preparation or consumption

Default criterion

- conservative values established to ensure the safety of a process or a food (may be applied if insufficient knowledge exists to establish more specific criterion)

How are criteria established ?

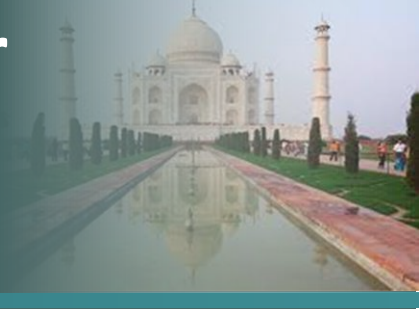
Basic Texts — Codex Alimentarius

PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS (Revised and Renamed 2013)

CAC/GL21 -1997

Based on principles of the ICMSF (Vol 2)

Codex: general principles for establishing Microbiological Criteria



- an MC should be appropriate to protect the health of the consumer and/or ensure fair practices in trade
- the purpose of establishing and applying an MC should be clearly articulated
- the establishment of an MC should be based on scientific advice and analysis and follow a structured and transparent approach
- the required stringency of an MC should be appropriate to its intended purpose
- MC should be established based on a knowledge of the microorganisms and their occurrence and behaviour **along the food chain**
- A MC should be practical and feasible and established only when necessary
- Periodic reviews of MC should be conducted, as appropriate, to ensure that MC continue to be relevant to the stated purpose under current conditions and practices.

- based on “proposed draft principles and guidelines for the establishment and application of microbiological criteria related to foods”, Codex CX/FH 12/44/6

Who establishes Microbiological Criteria?

- Criteria at ***retail*** are often specified by governments or international agencies, including Codex Alimentarius Commission, EFSA, USFDA
- criteria at ***earlier points*** are often determined and imposed by businesses, rather than governments
- may be different to those applicable at retail

Types of Microbiological Criteria

- Standards
  - a mandatory criterion that is part of law, legal ordinance
- Specifications
  - commercial agreement
- Guidelines
  - advisory

Microbiological *Standards*

Codex Principles

Public Health Authorities

Are used to determine the acceptability of a food or compliance with regard to a regulation or policy

Industry

Control Authorities

Microbiological *specifications*

Industry
Retail

Purchase specifications defining the microbiological limits for an ingredient or a finished product.

Supplier

Customer

Microbiological guidelines

Control Authorities
Industry
Associations

Are advisory and may be established to indicate expectations when best practices are applied to manufacture safe foods

Control Authorities

Industry

‘anatomy’ of an MC

A microbiological criterion consists of:

- a statement of the **microorganisms of concer**n and/or their toxins/metabolites and the reason for that concern;
- the **analytical methods** for their detection and/or quantification;
- a plan defining the **number of field sample**s to be taken and the size of the analytical unit;
- **microbiological limits** considered appropriate to the food at the specified point(s) of the food chain;
- the number of analytical **units that should conform to these limits**.

A microbiological criterion should also state:

- the food to which the criterion applies;
- the point(s) in the food chain where the criterion applies; and
- any actions to be taken when the criterion is not met

Microbiological Testing: When and where to test for food safety/quality 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

Useful Testing

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- **Part 2: Where and what to test**
  - indicators *vs.* specific organisms
  - recommended criteria
  - places to test
    - primary production
    - ingredients
    - processing
    - environment
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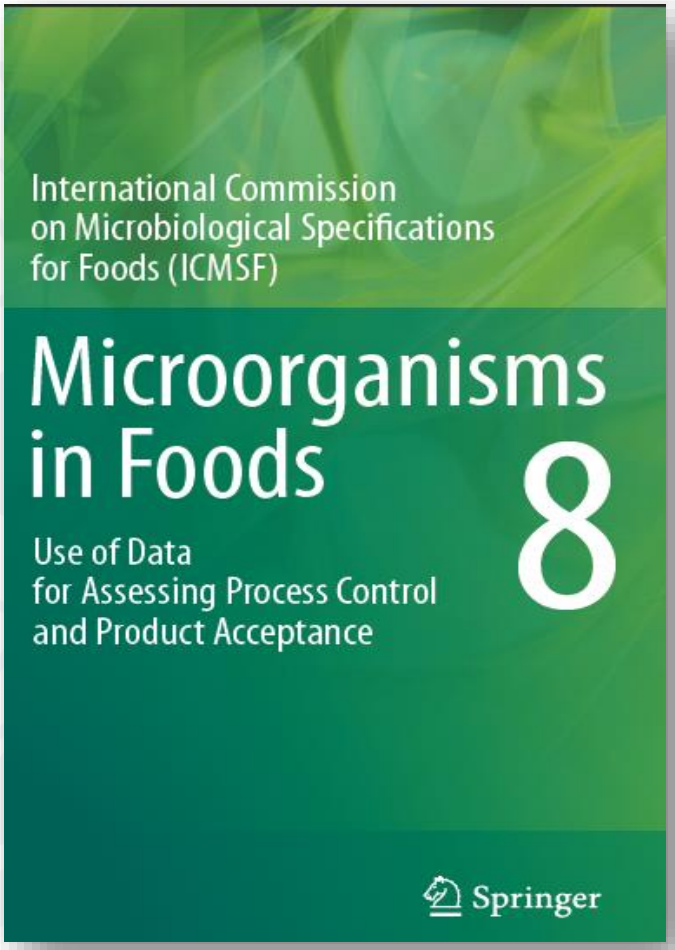
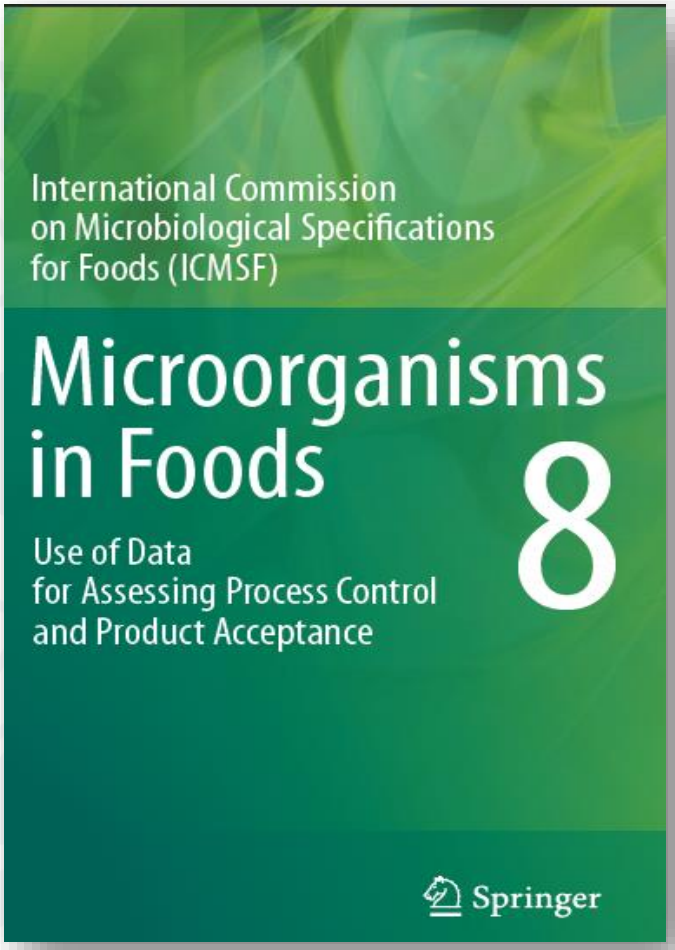
    - end product



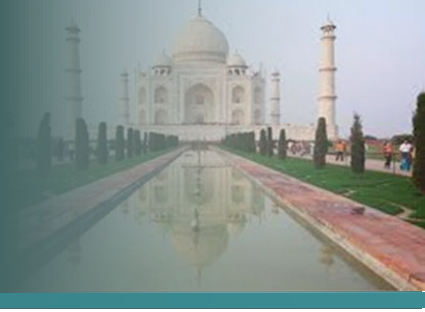
Testing applications

Microbial safety & quality

- Validation of control measures
- Verification of process control
- Verification of environmental control
- Corrective action to re-establish control
- Microbial testing in customer-supplier relationships
- Shelf-life testing
- End-product testing



Changes in Book 8



- there have been significant changes in the understanding of food production and processing, microbial ecology of foods, risk management, and the statistics of sampling

- recommendations for end-product testing replace those of ICMSF Book 2

- additionally, Book 8 provides recommendations for tests *other than end-product*, that provide useful information for microbiological quality and safety management

Recommendations for Criteria

- *while considerable effort was given to develop appropriate, risk-based criteria,* ***ICMSF recommendations have no official status***
- *Official recommendations and standards are set by:*
  - *National governments: for national standards and regulations*
  - *Intergovernmental agencies for international standards, e.g. Codex Alimentarius Commission*
- *where relevant international standards exist these are cited*

International Commission on Microbiological Specifications for Foods – ICMSF

International Union of Microbiological Societies

Division of Bacteriological & Applied Microbiology

ICMSF

- Founded in 1962 through the International Union of Microbiological Societies (IUMS)
- Goal – to provide timely, science-based guidance to government and industry on appraising and controlling the microbiological safety of foods.

The primary objectives of ICMSF include:

1. Providing the scientific basis for microbiological criteria and to promote principles for their establishment and application.
2. Overcoming the difficulties caused by nations' varying microbiological standards and analytical methods.

Useful Microbiological Testing

- Different tests serve different purposes
- Testing to achieve maximum benefit

ICMSF Microbe Hazard Categories

	Degree of concern	Examples
Utility	General contamination, reduced shelf life, incipient spoilage	Aerobic colony counts, yeasts and molds, specific spoilage compounds (e.g histamine, TVN)
Indicator	Low, indirect hazard. Potential measure of GHP or process control	*Enterobacteriaceae* or coliforms, generic *E. coli*
Moderate hazard	Not usually life threatening, normally short duration, symptoms self limiting, usually no sequelae	*B. cereus,* *V. parahaemolyticus* *S. aureus,* or enterotoxins
Serious hazard	Incapacitating but not usually life threatening, sequelae rare, moderate duration	*Salmonella*, *L. monocytogenes,* aflatoxins
Severe hazard	For the general population or in foods targeted for susceptible populations, causing life threatening or substantial chronic sequelae or illness of long duration	For general population, *E. coli* O157:H7, *C. botulinum* toxin; For restricted populations, *Salmonella, Cronobacter* spp.; *L. monocytogenes*

Sensitivity of ICMSF cases

Relative performance of ICMSF Cases in terms of the mean concentrations that will be rejected with at least 95% probability (assuming a standard deviation of 0.8).

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

The purpose of a test determines:

The target	Utility, indicator or pathogen
The method	Time to results, accuracy, repeatability, etc.
The sample	Environment, ingredient, line residue, end product, location collected, size/ number of samples
The frequency	Routine (daily, weekly, monthly, quarterly, etc.) or event triggered
The interpretation	Investigational sampling, routine sampling, regulatory sampling, etc.
The action	Lot rejection, process adjustment, recall, outbreak investigation, etc.

Useful Microbiological Testing

- Identification of contamination sources
- Environmental monitoring to identify potential pathogen harborage sites
- Utility and indicator organisms to verify effectiveness of controls, or trends and deviations
  - Effective processing
  - Effective control of post process contamination
- Investigation sampling for problem solving
- Less emphasis on ‘end-product’ testing

Conclusions (Useful Testing)

- Ecology (microbe/product) determines the hazards
- Testing only recommended where it will have most effect in risk reduction
  - Focus attention on process control, environmental monitoring and selected sampling to verify control
- Testing can never build safety into a product
  - Testing is useful to validate and verify the effectiveness of a HACCP program and adherence to GHPs

Conclusions (Criteria)

- Microbiological criteria (MC) translate expert knowledge of the microbial ecology of foods into science-based rules to manage the microbial quality and safety of foods in commerce
- because microbes grow and die, MC have to be defined for a particular point in the food chain
- MC should only be defined and imposed when there is a problem to be managed, and where testing could assist in management, and must be scientifically based
- MC must be carefully specified in terms of food, hazard, stage in the food supply-chain as well as the numerical limits and methods to be applied

Food Safety and Standards Authority of India