International Commission on Microbiological Specifications for Foods (ICMSF)

www.icmsf.org

USEFUL MICROBIOLOGICAL SAMPLING AND TESTING UNDERPINNING RISK-BASED FOOD SAFETY MANAGEMENT WORKSHOP

Side meeting to CCFH54

14 March 2024, Nairobi

14:30 – 18:00

Since 1962

14:30 – 14:50: ICMSF introduction / Key r-b FSM concepts, Leon Gorris (The Netherlands)

14:50 – 15:15: The *Listeria* management challenge, incl. aspects of microbiological sampling & testing and standard development, Lucia Anelich (South Africa)

15:15 – 15:40: Complexity of useful microbiological sampling & testing, Marcel Zwietering (The Netherlands)

15:40 – 16:00: Useful microbiological sampling & testing for products in the meat and poultry supply chains, Kiran Bhilegaonkar (India)

16:00 – 16:20: Coffee/tea break

16:20 – 16:40: Big Data impacting food safety risk management and decision-making of government and food supply chains, Bobby Krishna (Dubai)

16:40 – 17:00: Importance of Codex's quantitative, risk-based metrics (e.g. Microbiological Criteria) and innovation in such metrics, Wayne Anderson (Ireland)

17:00 – 18:00: Free flowing Q&A discussion

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Introduction to ICMSF and key risk-based Food Safety Management (FSM) concepts

Leon Gorris
Food Safety Futures
The Netherlands

ICMSF Secretary

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foodsafetyfutures.org

International Commission on Microbiological Specifications for Foods (ICMSF)

www.icmsf.org

International Science Council

IUMS

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"Observer" with Codex Alimentarius for over 40 years

CODEX International Food Standards ALIMENTARIUS

Links to WHO

World Health Organization

Links to FAO

Food and Agriculture Organization of the United Nations

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ICMSF's mission

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.**

*ICMSF recommendations have no official, regulatory status;

**They are the *best science* views of the ICMSF membership

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Our books mirror the evolution of food safety management

1960s – 1980s
Methods and Testing

1980s-2000s
Microbial Ecology
HACCP

2000s-2020s
Risk Management

Microbiological Criteria - 15 Cases lot acceptance concept

Inputs for a Food Safety Management System

Risk-based Management and Food safety Metrics (FSO, PC, PO, MC)

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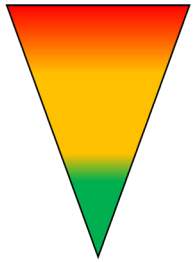
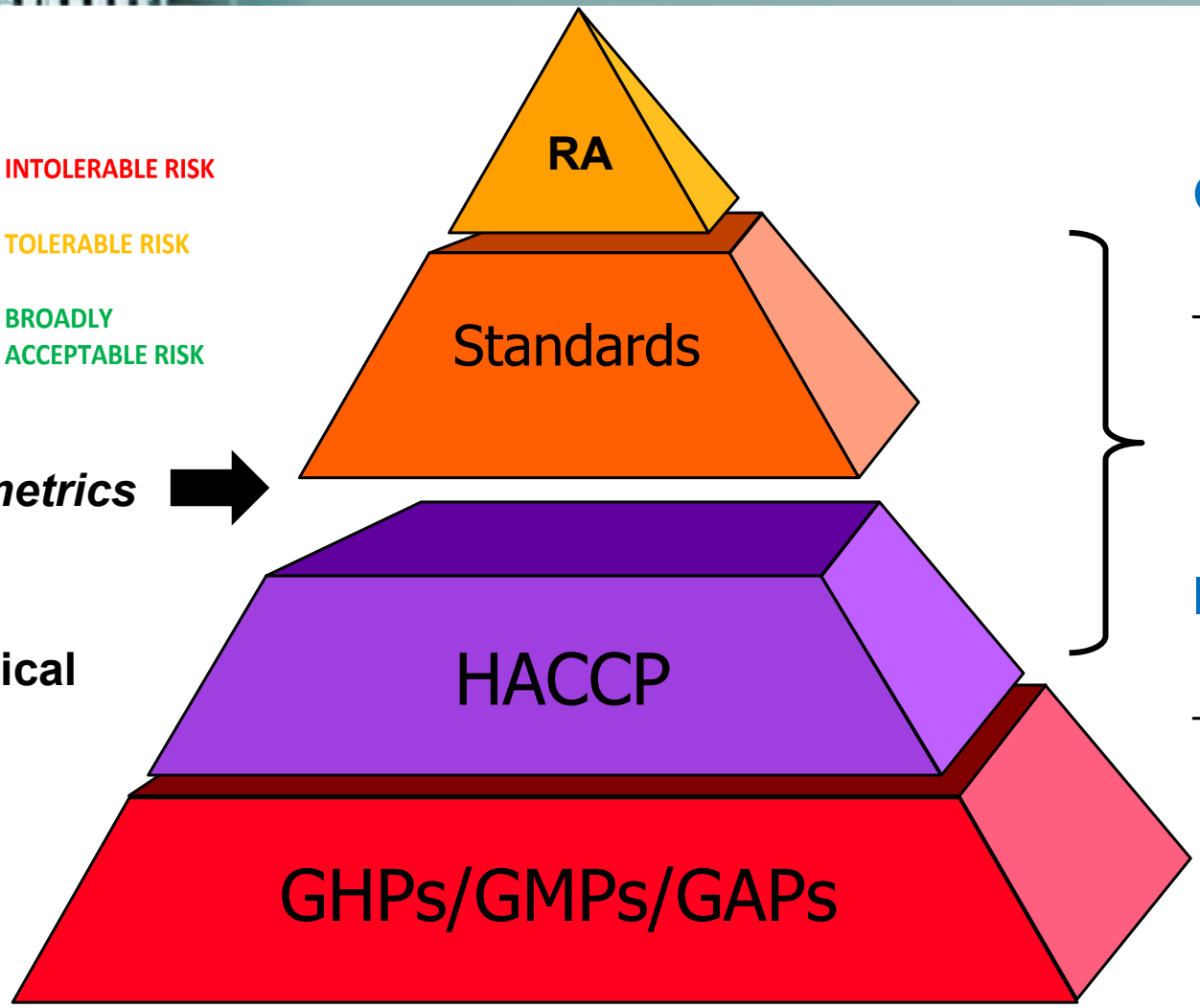
Risk Analysis: systematic approach to set standards, including risk-based metrics



Risk-based metrics

e.g., Microbiological criteria



Government:

– Uses "**Risk Analysis**" approach to set **risk-based standards,** possibly **incl. metrics (FSO, PC, PO, MC)**

Industry:

– Meets risk-based standards/metrics using Good Practices and HACCP

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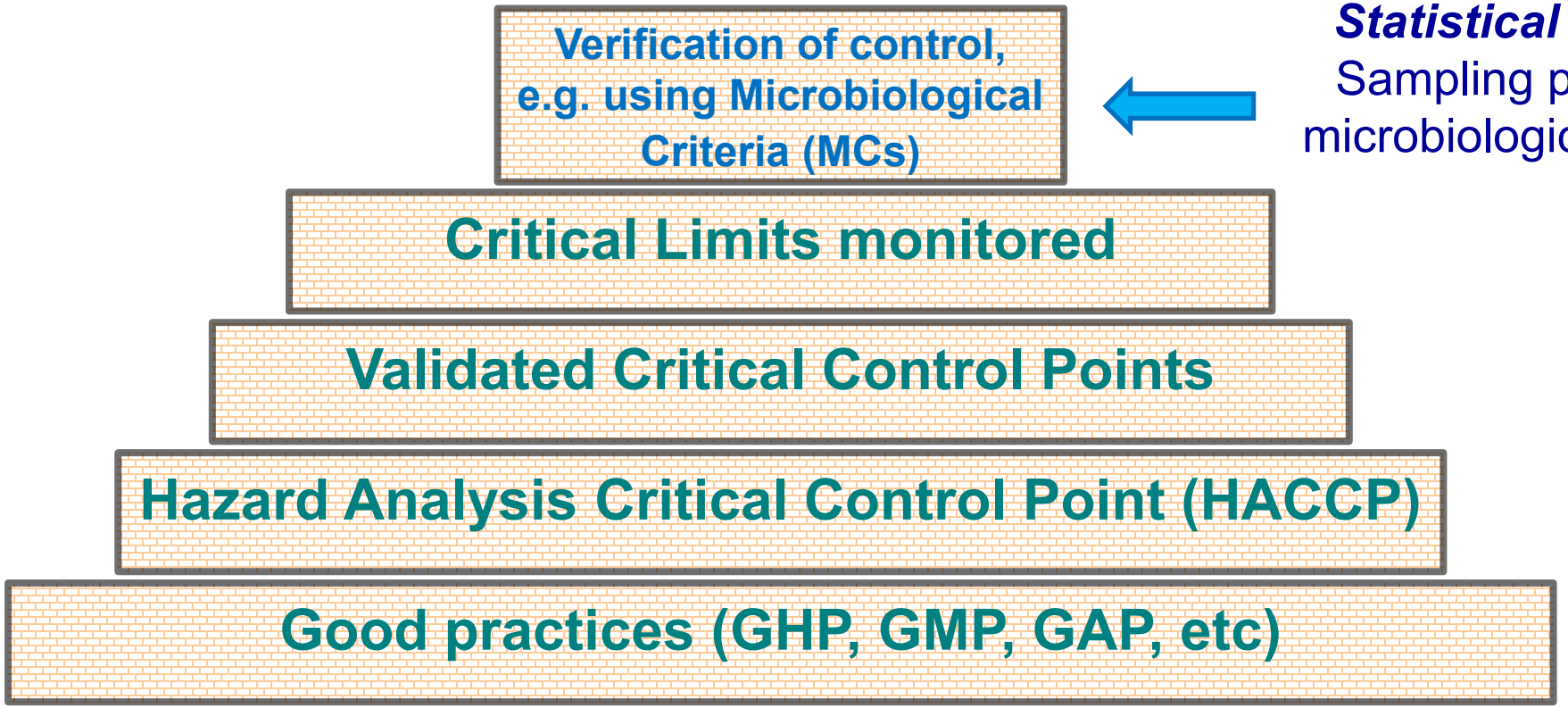
Industry use of Microbiological Criteria: Verification of hazard control in FSMS operation



Statistical basis:
Sampling plans & microbiological limits

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Verification confirms acceptability of food lots (batches)

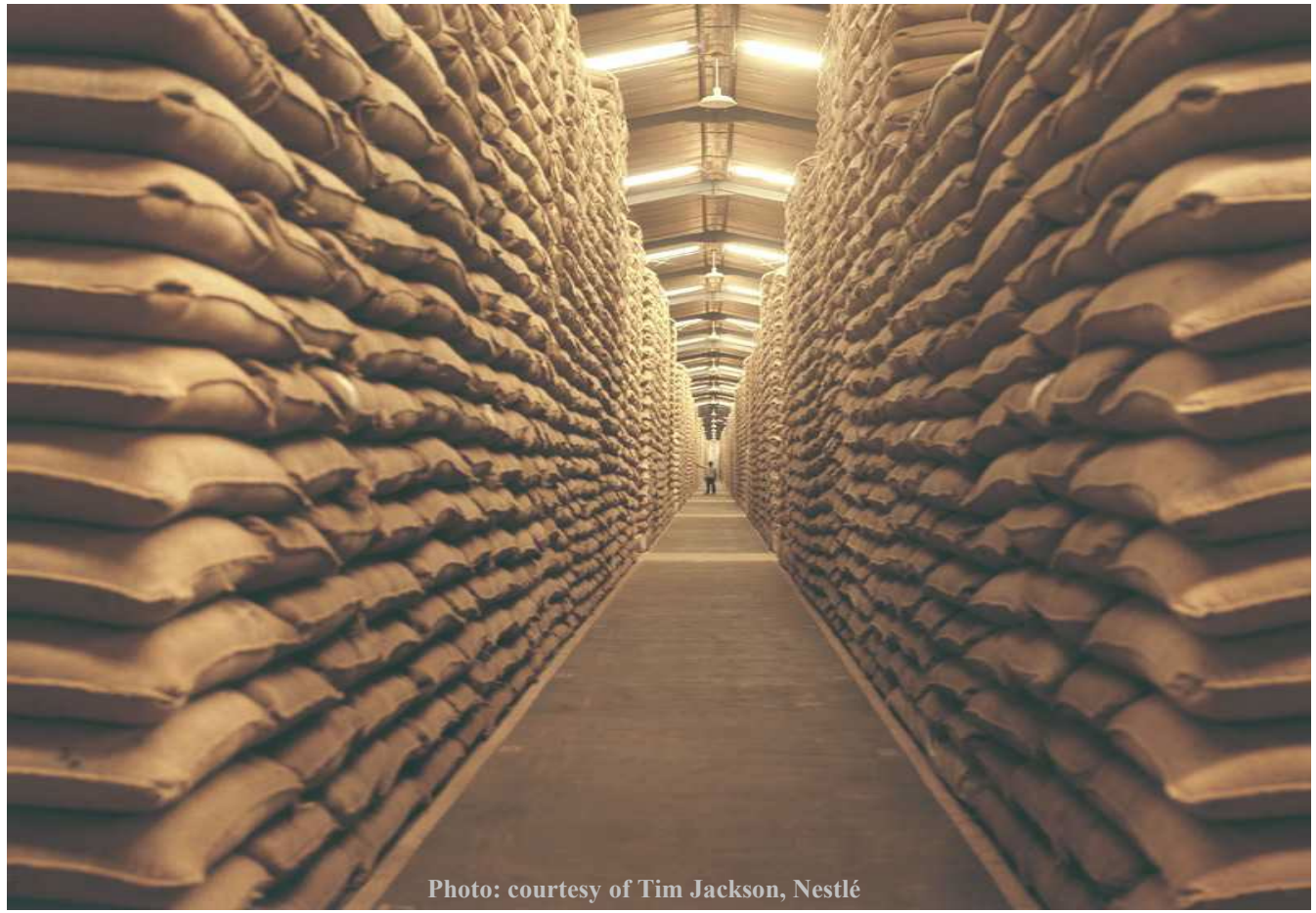
How do we know this is safe?

- MCs are set considering the

  a) likely **distribution** of hazardous microorganisms in foods

  b) stringency of hazard control required for lot acceptance; relates to the level of risk that relevant microorganisms pose to consumers

- MCs reflect the "acceptable level of microorganisms in a specific food product; the acceptable performance of a process; etc."



* MCs = Microbiological criteria

Verification confirms acceptability of food lots (batches)

A food lot or food batch represents:

"*a unit that has been produced under uniform conditions*"

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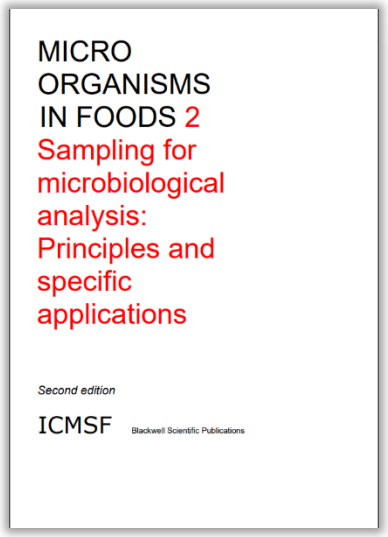
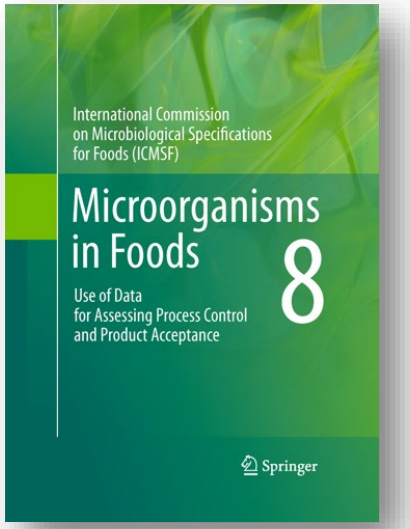
Control stringency implemented through MCs



1st Edition, 1974
2nd Edition, 1986



1st Edition, 2011

- The higher the consumer risk, the more stringent the **Microbiological Criterion** that verification of control is based on
- The **ICMSF 15 Cases** risk management framework represent a practical and proportional approach to manage the risk of accepting food lots

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"ICMSF 15 Cases" framework

The 15 cases reflect relative risk levels*

- Considering:
  - ***- Hazard severity***
    - – Harmfulness of the microorganism/hazard
    - – Intended consumer population
  - ***- Hazard level***
    - – Conditions of food handling and use

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* Risk level = hazard severity & hazard level & probability

ICMSF 15 risk cases matrix
5 categories of microorganisms/hazards

HAZARD SEVERITY

Organism/Hazard	Impact	Examples
Utility organism	Spoilage, reduced shelf life, no health concern	*e.g.,* total counts (TVC, etc.), yeasts and molds
Indicator organism	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., Salmonella* spp., *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, *Cronobacter* (infants)

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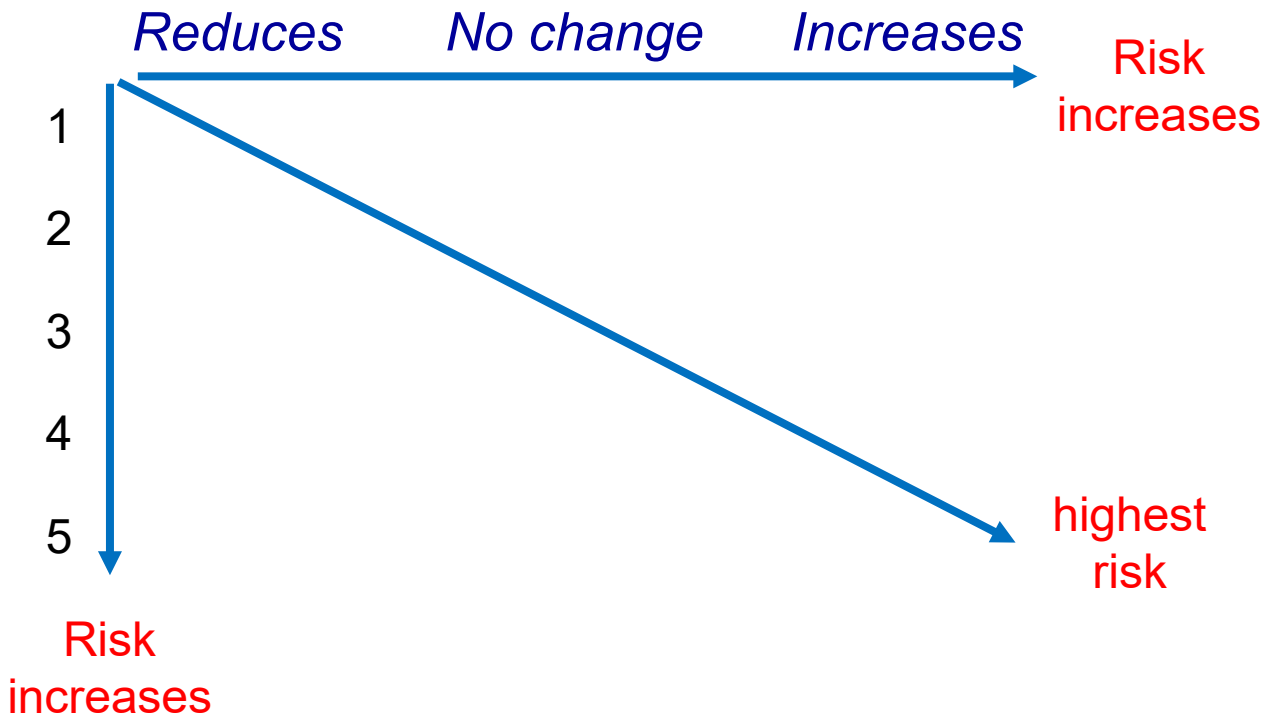
Risk Categorization Matrix

***HAZARD LEVEL** changes before consumption*

HAZARD SEVERITY INCREASES



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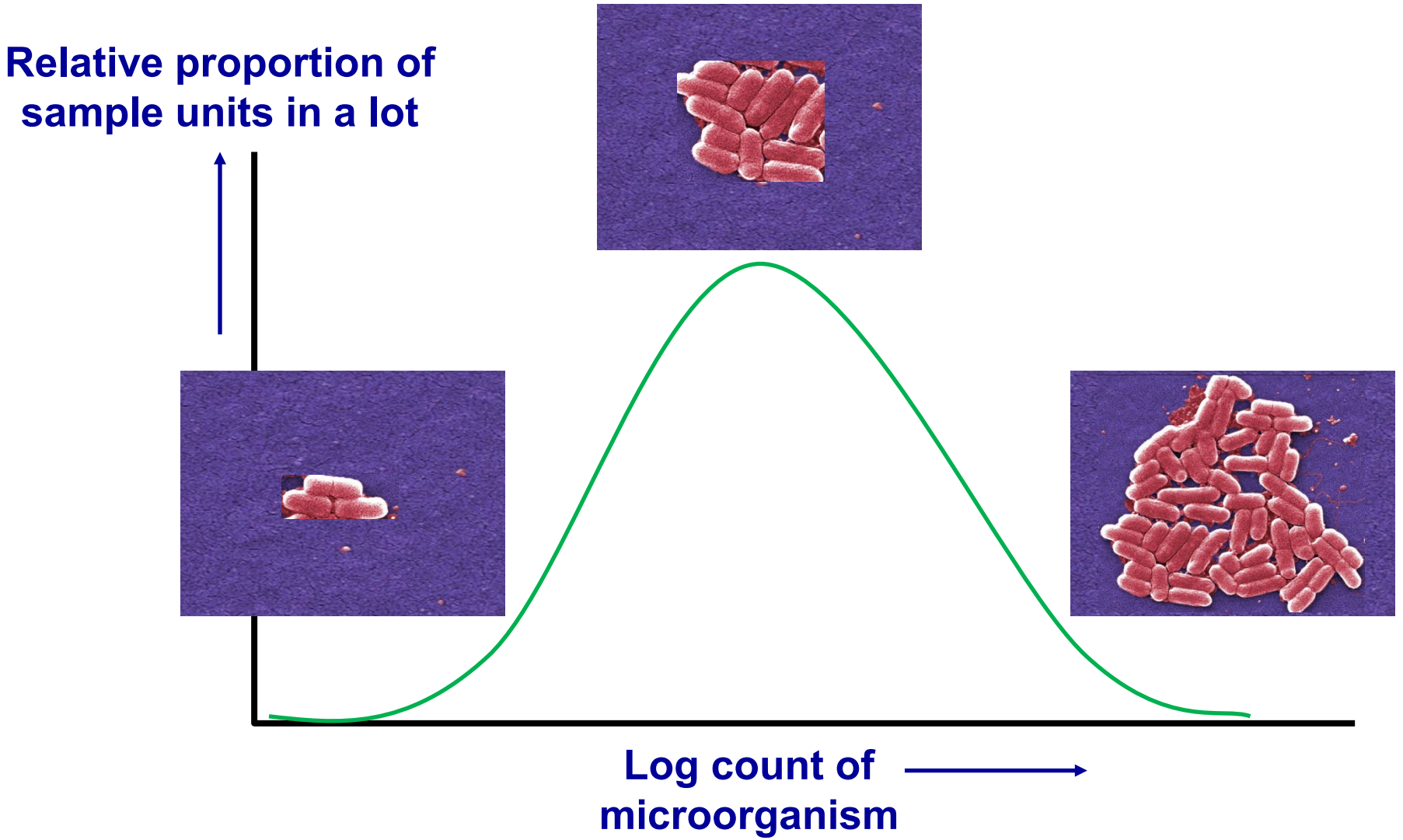
MCs/sampling plans consider the distribution of microorganisms in a food lot (batch)



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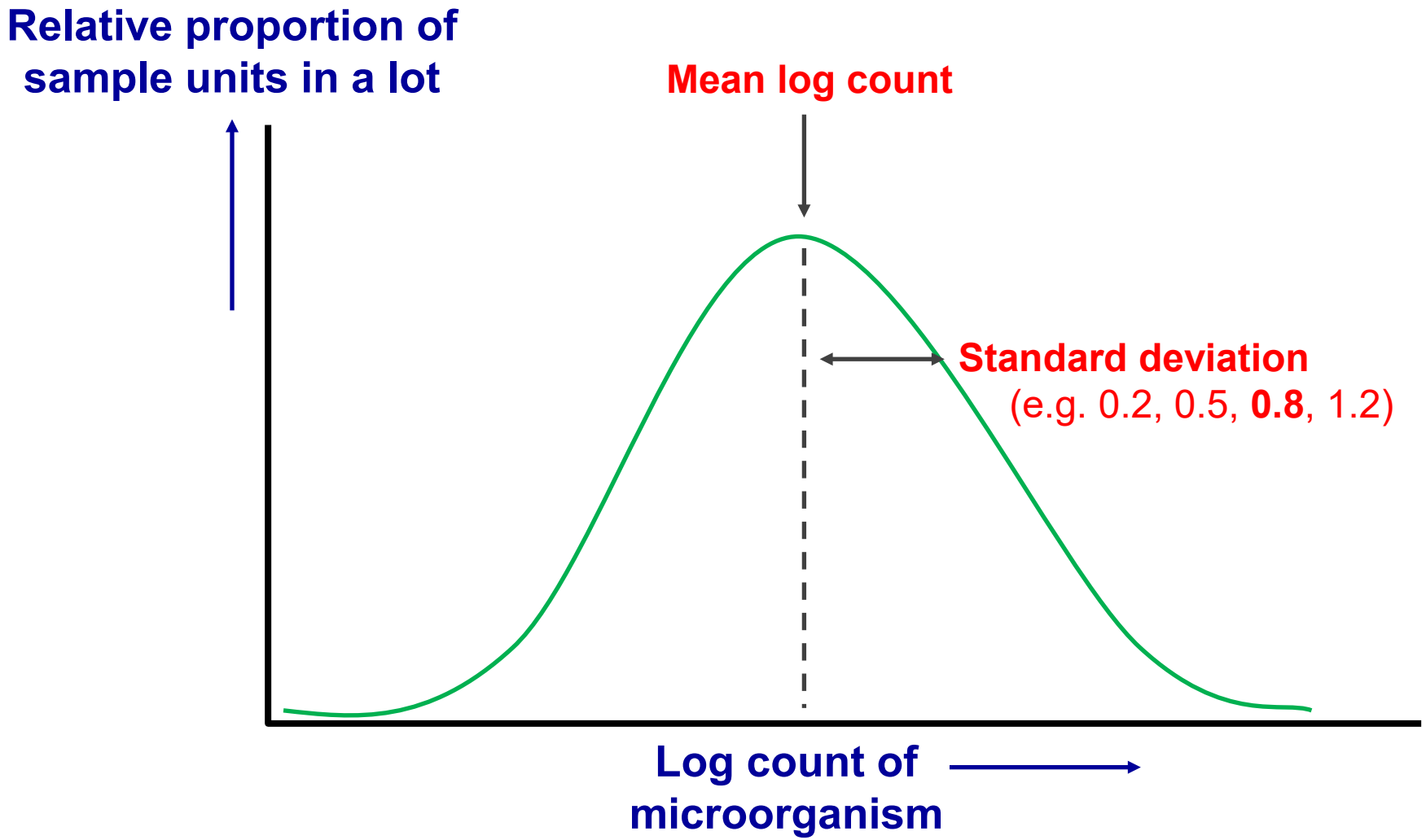
Key parameters for the distribution of microorganisms in a lot (batch)



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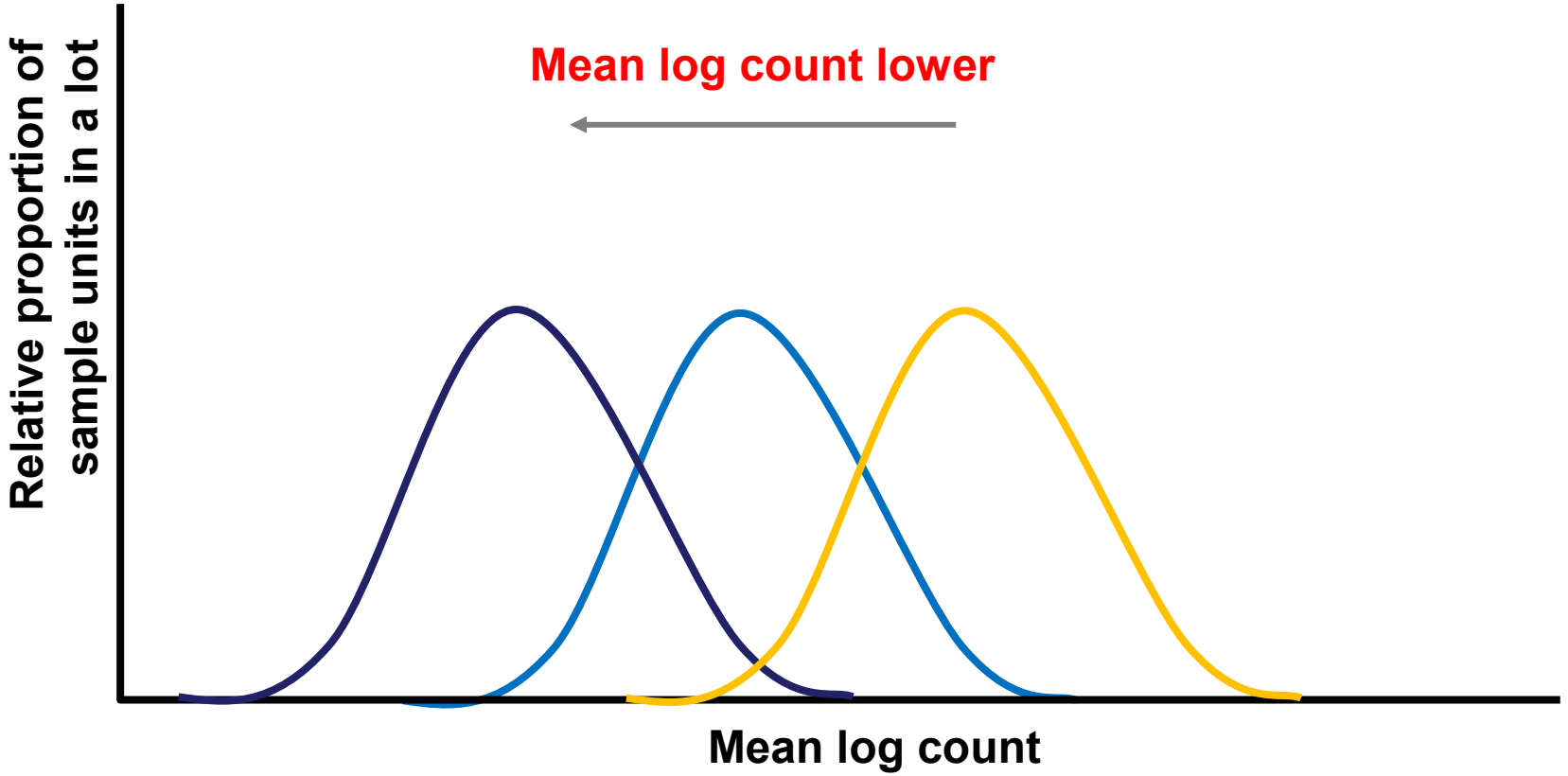
Representing batches with different mean log counts but same standard deviation



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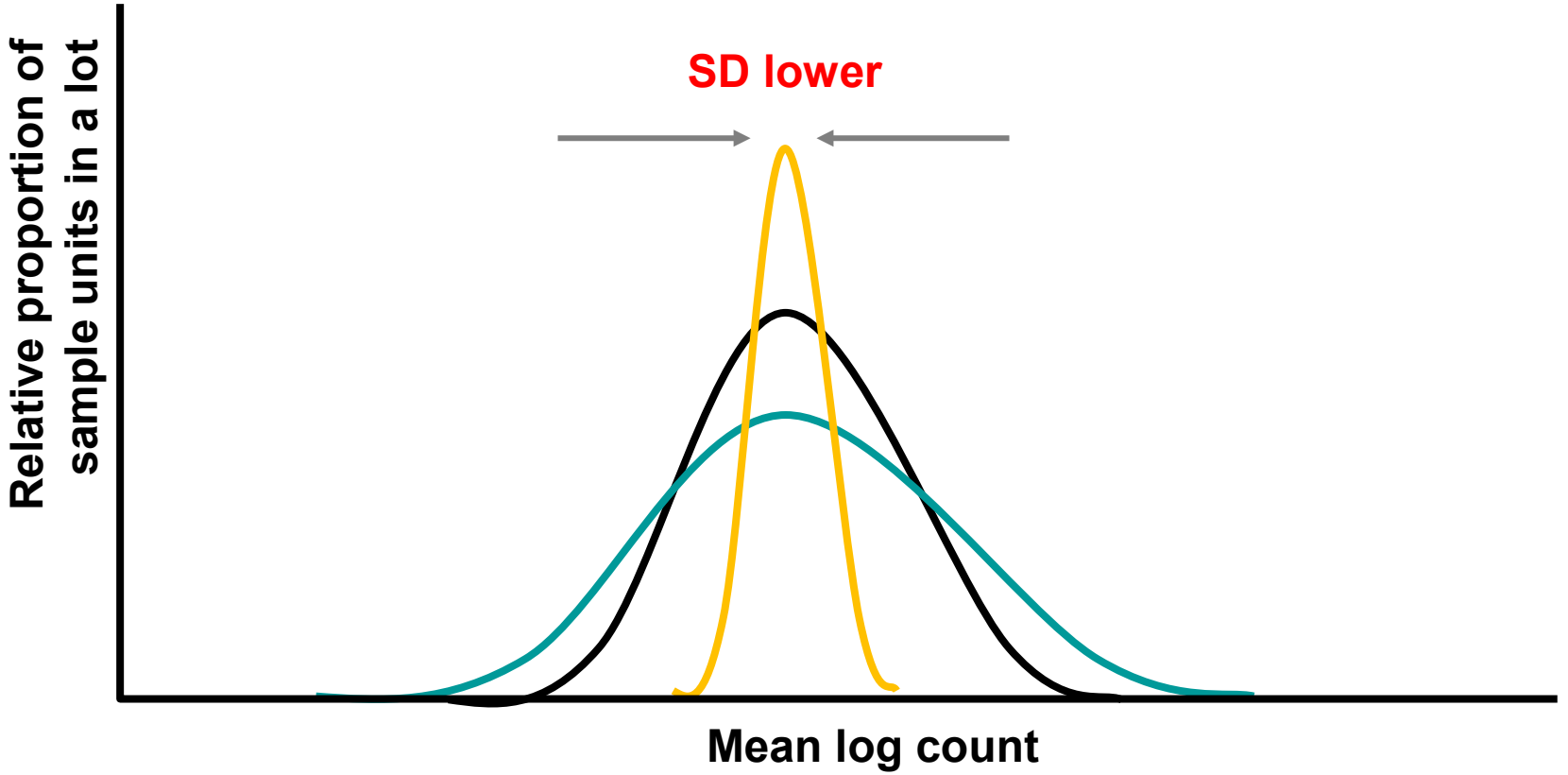
Representing batches with a different standard deviation but the same mean log count



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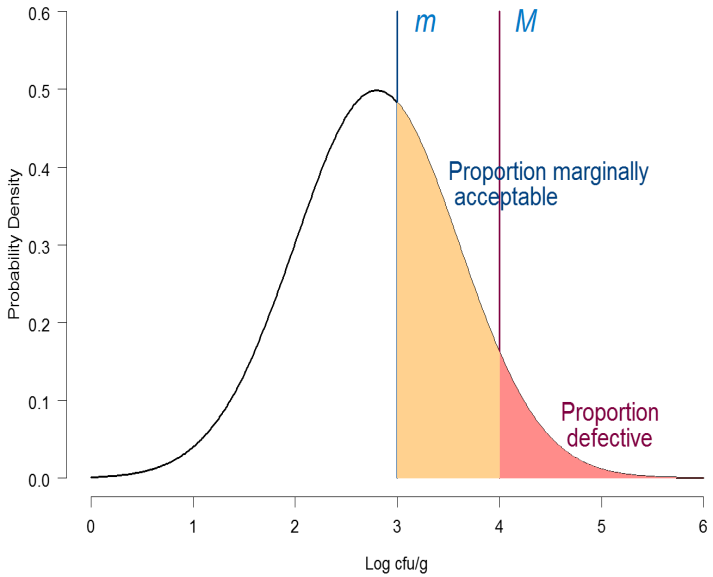
Sampling plan types and parameters

Quantitative plans
(enumeration)

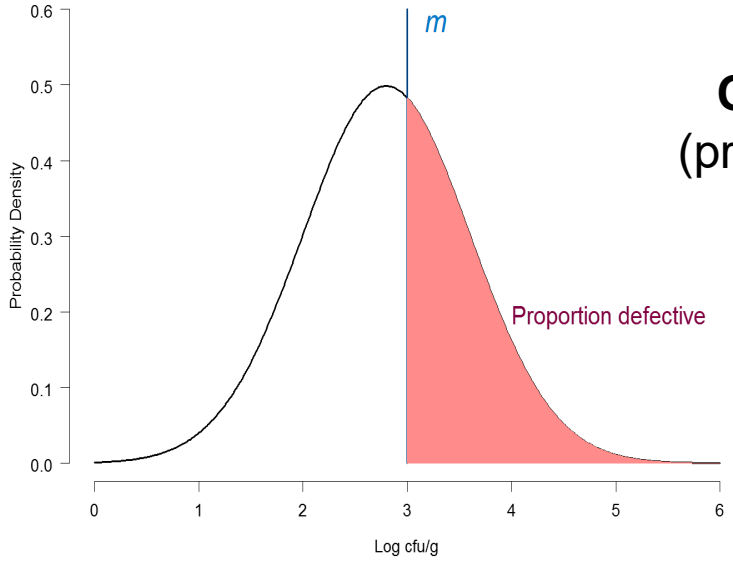
Relatively low stringency

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*

Two-class sampling plan:



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

Qualitative plans
(presence/absence)

Relatively high stringency

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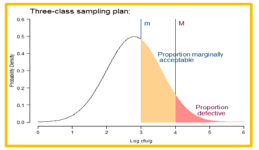
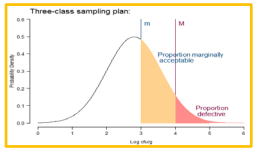
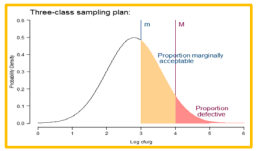
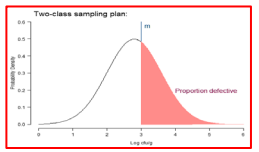
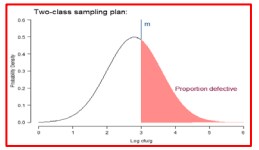
Relative performance of ICMSF cases*

***HAZARD LEVEL** changes before consumption*

Risk increases

HAZARD SEVERITY INCREASES

	Risk typically reduces	No change in risk	Risk typically increases	
Utility	**Case 1,** 3-class: n= 5, c= 3, m= 1000/g, M=10000/g Mean conc.: 2748/g	**Case 2,** 3-class: n= 5, c= 2, m= 1000/g, M= 10000/g Mean conc.: 17904/g	**Case 3,** 3-class: n= 5, c= 1, m= 1000/g, M= 10000/g Mean conc.: 9976/g	
Indicator	**Case 4**, 3-class: n= 5, c= 3, m= 100/g, M= 1000/g Mean conc.: 2785/g	**Case 5**, 3-class: n = 5, c = 2, m = 100/g, M= 1000/g Mean conc.: 1790/g	**Case 6**, 3-class: n= 5, c= 1, m= 100/g, M= 1000/g Mean conc.: 998/g	
Moderate hazard	**Case 7**, 3-class: n = 5, c = 2, m = 10/g, M= 100/g Mean conc.: 179/g	**Case 8**, 3-class: n = 5, c = 1, m = 10/g, M= 100/g Mean conc.: 100/g	**Case 9**, 3-class: n = 10, c = 1, m = 10/g, M= 100/g Mean conc.: 32/g	
Serious hazard	**Case 10**, 2-class: n = 5, c = 0, m = 0/25g Mean conc.: 1/10g	**Case 11**, 2-class: n = 10, c = 0, m = 0/25g Mean conc.: 1/33g	**Case 12**, 2-class: n = 30, c = 0, m = 0/25g Mean conc.: 1/91g	
Severe hazard	**Case 13**, 2-class: n = 15, c = 0, m = 0/25g Mean conc.: 1/60g	**Case 14**, 2-class: n = 30, c = 0, m = 0/25g Mean conc.: 1/157g	**Case 15**, 2-class: n = 60, c = 0, m = 0/25g Mean conc.: 1/373g	

Risk increases

highest risk

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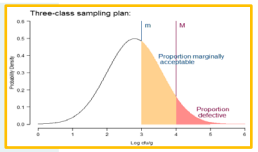
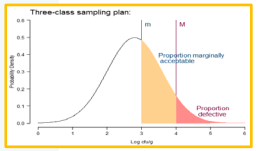
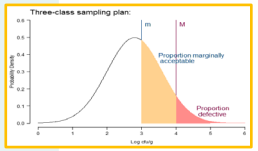
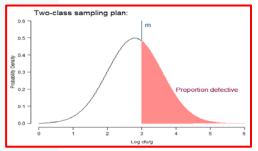
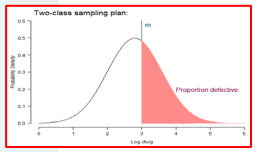
Relative performance of ICMSF cases*

	Risk typically reduces	No change in risk	Risk typically increases	
Utility	**Case 1,** 3-class: n= 5, c= 3, m= 1000/g, M=10000/g **Mean conc.: 27848/g**	**Case 2,** 3-class: n= 5, c= 2, m= 1000/g, M= 10000/g **Mean conc.: 17904/g**	**Case 3,** 3-class: n= 5, c= 1, m= 1000/g, M= 10000/g **Mean conc.: 9976/g**	
Indicator	**Case 4**, 3-class: n= 5, c= 3, m= 100/g, M= 1000/g **Mean conc.: 2785/g**	**Case 5**, 3-class: n = 5, c = 2, m = 100/g, M= 1000/g **Mean conc.: 1790/g**	**Case 6**, 3-class: n= 5, c= 1, m= 100/g, M= 1000/g **Mean conc.: 998/g**	
Moderate hazard	**Case 7**, 3-class: n = 5, c = 2, m = 10/g, M= 100/g **Mean conc.: 179/g**	**Case 8**, 3-class: n = 5, c = 1, m = 10/g, M= 100/g **Mean conc.: 100/g**	**Case 9**, 3-class: n = 10, c = 1, m = 10/g, M= 100/g **Mean conc.: 32/g**	
Serious hazard	**Case 10**, 2-class: n = 5, c = 0, m = 0/25g **Mean conc.: 1/10g**	**Case 11**, 2-class: n = 10, c = 0, m = 0/25g **Mean conc.: 1/33g**	**Case 12**, 2-class: n = 20, c = 0, m = 0/25g **Mean conc.: 1/91g**	
Severe hazard	**Case 13**, 2-class: n = 15, c = 0, m = 0/25g **Mean conc.: 1/60g**	**Case 14**, 2-class: n = 30, c = 0, m = 0/25g **Mean conc.: 1/157g**	**Case 15**, 2-class: n = 60, c = 0, m = 0/25g **Mean conc.: 1/373g**	

* illustrated in terms of the **arithmetic** mean concentration that will be rejected with at least **95% probability** and a **standard deviation of 0.8** assuming hypothetical criteria. Calculations were performed with ICMSF Microbiological Sampling plan tool Version 2.10 (www.icmsf.org).

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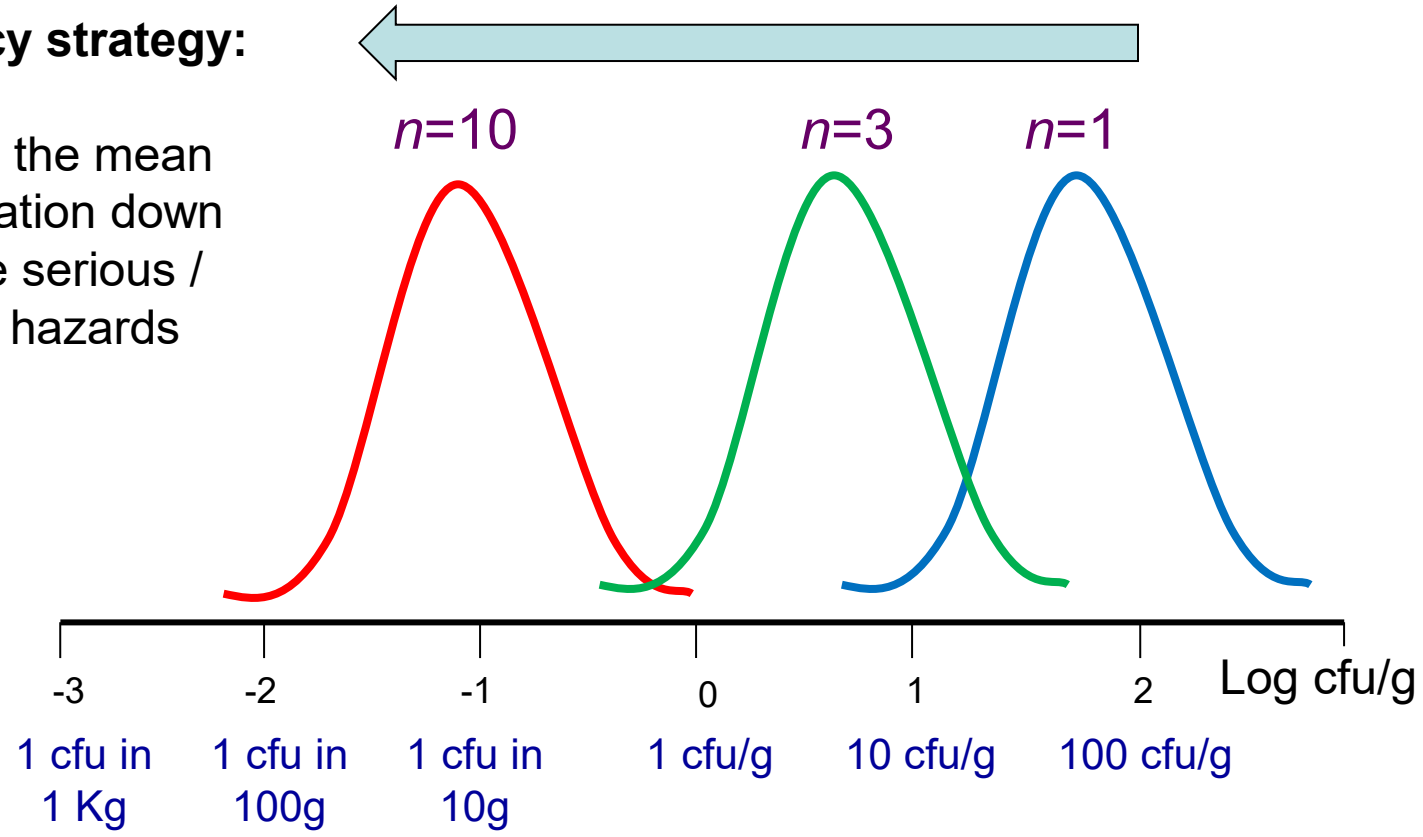
Stringency example: effect of number of samples
(m=1/g; s.d. =0.8; 95% confidence)

Stringency strategy:

To move the mean concentration down for more serious / severe hazards



Mean arithmetic concentration of compliant batches

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Codex Alimentarius – CCFH

Codex Committee on Food Hygiene (CCFH)

- The key **Food Safety Risk Management** committee of Codex
- Focus: general hygiene, microbiological hazards and allergens

Microbiological food safety guidelines developed by CCFH:

- Principles and Guidelines for the Conduct of **Microbiological Risk Management** and its annex on Guidance on Microbiological Risk Management Metrics (CAC/GL 63-2007)
- Principles and Guidelines for the Conduct of **Microbiological Risk Assessment** (CAC/GL 30-1999 + rev 2014)
- Principles for the Establishment and Application of **Microbiological Criteria** for Foods (CAC/GL 21-1997, update 2013)

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Codex advice regarding control of *L. monocytogenes* in RTE foods

Decision on Risk Management Options by CCFH:

Annex II: Establish Different Microbiological Criteria for the two RTE food types that are different in sustaining the growth of *L. monocytogenes*

Foods in which growth of *L. monocytogenes* **will not occur**, *i.e.,* foods that **do not support pathogen growth**

Foods in which growth of *L. monocytogenes* **can occur**, *i.e.,* foods that **do support pathogen growth**

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Codex advice regarding control of *L. monocytogenes* in RTE foods

n	*c*	*m*	Class Plan
5 [a]	0	100 cfu/g [b]	2 [c]

Assuming a log-normal distribution of cells, a standard deviation of cells of **0.25 log CFU/g**, and **95% confidence** for detecting non-compliant batches

Foods in which growth of *L. monocytogenes* will not occur, i.e., **foods that do not support pathogen growth**

n	*c*	*m*	Class Plan
5 [a]	0	Absence in 25 g (< 0.04 cfu/g) [b]	2 [c]

Assuming a log-normal distribution of cells, a standard deviation of cells of **0.25 log CFU/g**, and **95% confidence** for detecting non-compliant batches

Foods in which growth of *L. monocytogenes* can occur, i.e., **foods that do support pathogen growth**

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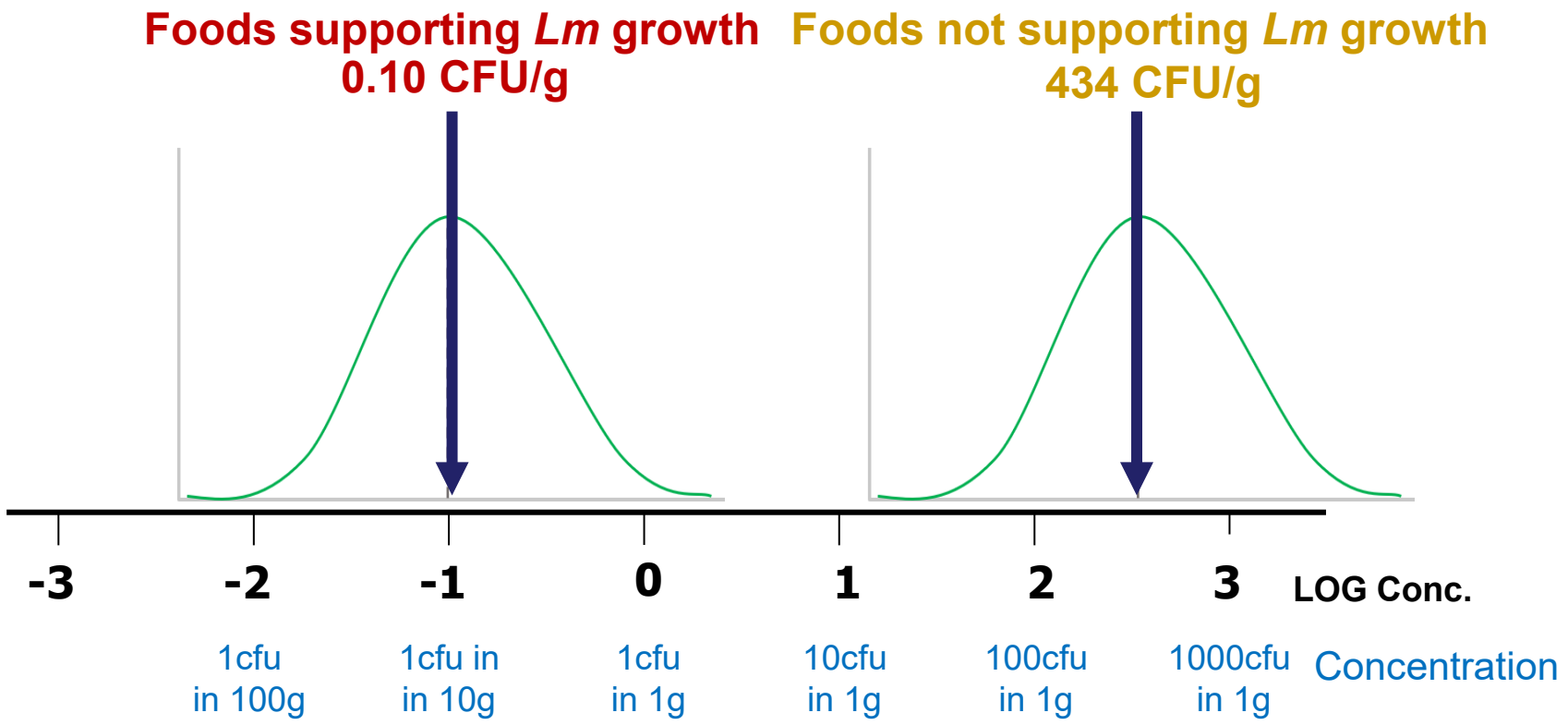
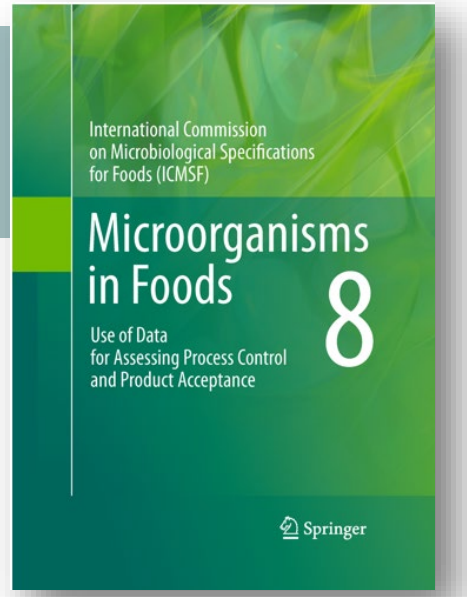
Tailored control based on *Lm* growth opportunity



Arithmetic mean *L. monocytogenes* CFU-values of a food batch

(0.8 sd; 95% confidence)

Latest ICMSF commodity Advice



Part I: Principles of using Data in Microbiological Control

Part II: Application of Principles to Product Categories

8: Meat Products
9: Poultry Products
10: Fish and Seafood Products
11: Feeds and Pet Food
12: Vegetables and Vegetable Products
13: Fruits and Fruit products
14: Spice, Dry Soups and Asian Flavourings
15: Cereals and Cereal Products
16: Nuts, Oilseeds, Dried Legumes and Coffee
17: Cocoa, Chocolate and Confectionery
18: Oil- and Fat-Based Foods
19: Sugar, Syrups and Honey
20: Non-alcoholic Beverages
21: Water
22: Eggs and Egg Products
23: Milk and Dairy Products
24: Shelf-Stable Heat-treated Foods
25: Dry Foods for Infants and Young Children
26: Combination Foods

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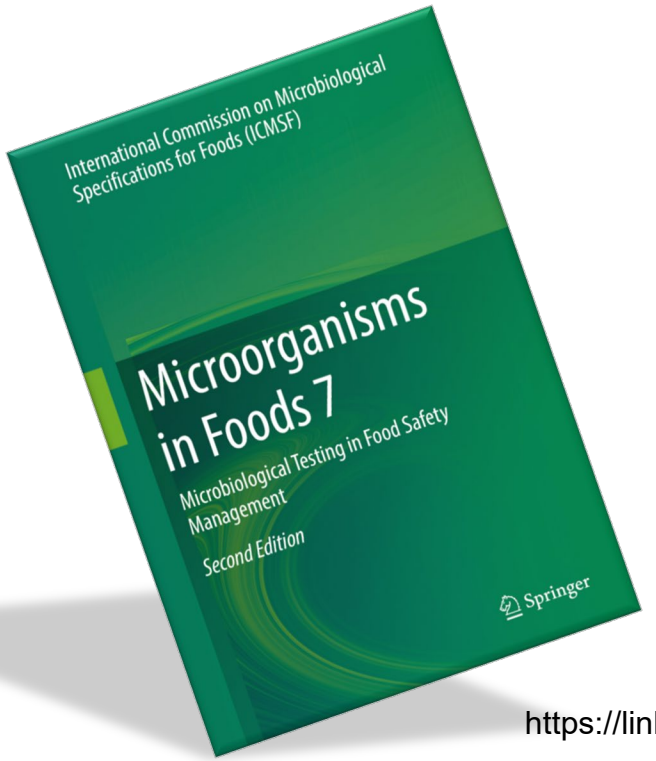
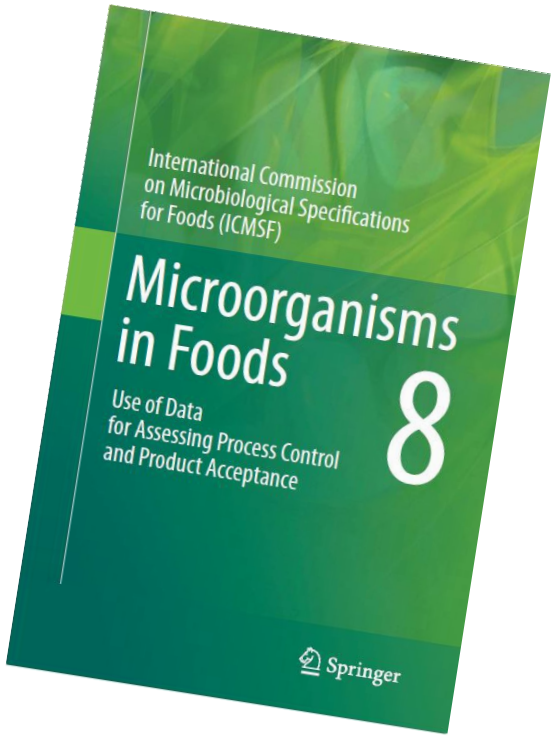
Summary: Risk-based Food Safety Management

- "Safe" means "no undue harm" or "its an acceptable risk"
- Risk analysis provides a framework for managing hazards proportional to the risk to consumers
- Microbiological criteria and sampling plans operationalize proportional risk management for consumers and industry

Book 7:
http://www.springer.com/la/book/9783319684581





Book 8:
https://link.springer.com/book/10.1007/978-1-4419-9374-8

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Visit the ICMSF website: ICMSF.org

VIDEOS

For many years, the ICMSF has published its work in books and publications. To complement these, the Commission has developed video clips to provide science-based advice and guidance on appraising and controlling the microbiological safety of food that supports public health protection and facilitates fair trade. All the ICMSF videos are accessible on our YouTube channel.

ICMSF sampling playlist

History of the ICMSF, Martin B Cole (2017)
- Video (8:50) | Presentation

Microbiological Testing Basics, Robert L Buchanan (2017)
- Video (14:46) | Presentation

Microbiological Testing for Validation and Verification, Katherine M J Swanson (2017)
- Video (6:55) | Presentation

Microbiological Testing for Food Lots, Katherine M J Swanson (2017)
- Video (7:28)| Presentation

Microbiological Testing for Process Control, Katherine M J Swanson (2017)
- Video (7:14) | Presentation

The Anatomy of a Sampling Plan, Marcel H Zwietering (2017)
- Video (4:27) | Presentation

The ICMSF Cases Concept, Leon G M Gorris (2017)
- Video (12:43) | Presentation

Microbiological Testing and Distribution of Microorganisms in Food, Marcel H Zwietering (2017)
- Video (11:24) | Presentation

Microbiological Testing and Performance of Sampling Plans, Marcel H Zwietering (2017)
- Video (7:02) | Presentation

Operating Characteristic Curves and Sampling Plan Performance, Martin B Cole (2017)
- Video (8:41) | Presentation

1 ICMSF 2017 01 "History of ICMSF", Martin B. Cole — The ICMSF — 8:50

2 ICMSF 2017 02 "Microbiological Testing Basics", Robert L. Buchanan — The ICMSF — 14:46

3 ICMSF 2017 03 "Microbiological Testing for Validation and Verification", Katherine M.J. Swanson — The ICMSF — 6:55

4 ICMSF 2017 04 "Microbiological testing for Food Lots", Katherine M.J. Swanson — The ICMSF — 7:28

5 ICMSF 2017 05 "Microbiological testing for Process Control", Katherine M.J. Swanson — The ICMSF — 7:14

6 ICMSF 2017 06 "Anatomy of a sampling plan", Marcel H. Zwietering — The ICMSF — 4:27

7 ICMSF 2017 07 "The ICMSF cases", Leon G.M. Gorris — The ICMSF — 12:43

8 ICMSF 2017 09 "Microbiological testing and performance of sampling plans", Marcel H. Zwietering — The ICMSF — 11:24

9 ICMSF 2017 08 "Microbiological Testing and Distribution of Microorganisms", Marcel H. Zwietering — The ICMSF — 7:02

10 ICMSF 2017 10 "Examples sampling plan performance", Martin B. Cole — The ICMSF — 8:41

11 ICMSF 2020 11 "WhySoManySamplingPlans", Marcel H. Zwietering — The ICMSF — 8:29

12 ICMSF 2020 12 "Introduction ICMSF tool", Leon G.M. Gorris — The ICMSF — 15:54

13 ICMSF 2020 13 "ICMSF Tool Explanation", Marcel H. Zwietering — The ICMSF — 8:42

14 ICMSF 2020 14 "Geometric and Arithmetic Means", Marcel H. Zwietering — The ICMSF — 5:47

15 ICMSF 2020 15 "Mixed Plans", Marcel H. Zwietering — The ICMSF — 6:18

16 ICMSF 2020 16 "Plan Performance Part 1", Leon G.M. Gorris — The ICMSF — 15:42

17 ICMSF 2020 17 "Plan Performance Part 2 NoGrowth", Leon G.M. Gorris — The ICMSF — 20:27

18 ICMSF 2020 18 "Plan Performance Part 3 Growth", Leon G.M. Gorris — The ICMSF — 16:28

19 ICMSF 2020 19 "Performance EU-Sampling Plan Campylobacter", Marcel Zwietering — The ICMSF — 8:54

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