International Commission on Microbiological Specifications for Foods (ICMSF)
www.icmsf.org

Introduction of ICMSF

Risk-based food safety management - link between government and food industry

Leon Gorris

Foodsafetyfutures.org

The Netherlands

ICMSF Point of contact for Codex, FAO, WHO

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International Commission on Microbiological Specifications for Foods (ICMSF)
www.icmsf.org

International Science Council

IUMS

www.icmsf.org

"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,

may help facilitate fair trade and reduce the incidences of

microbiological food-borne illness and food spoilage.

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ICMSF recommendations have no official status!

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Annual meetings – coordination and output

ICMSF meets annually as a working party since 1962

58 meetings in 31 countries

1969

Since 1962

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Recent ICMSF Annual meetings

57th ICMSF Annual meeting, Kenya, March 2024

58th, Bogor, October 2025

- 23 experts from 16 different countries
- 9 academic, 6 government and 8 industry experts
- a network of experts engaged as regional or country sub-commissions, consultants, reviewers and collaborators.
- all work is voluntary and without honoraria

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Publications & Position Papers

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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 (MCs) = sampling plans and limits; 15 Cases for lot acceptance

Inputs for solid Food Safety Management System (GHP + HACCP based)

Risk-based Food Safety Management and Food safety metrics (FSO, PC, PO linking to MC)

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Risk-based food safety management - link between government and food industry

Risk-based metrics
(FSO, PC, PO, PC, MC)

Government:

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

Industry:

– **Meets risk-based standards & metrics** through using Good Practices, HACCP and other food safety management system components

– **Uses risk-based** metrics for operational design (e.g. PO/PC) and operational verification (MCs)

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Verification confirms acceptability of food lots and adequate process control

– Food safety MCs are set considering the:

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

b) the **stringency of hazard control** required for **lot acceptance**; **MCs** relate to the level of control needed to reduce a hazard posing a risk to consumers to an acceptable level in the final product

c) use of **MCs** for **process control**

Photo: courtesy of Tim Jackson, Nestlé

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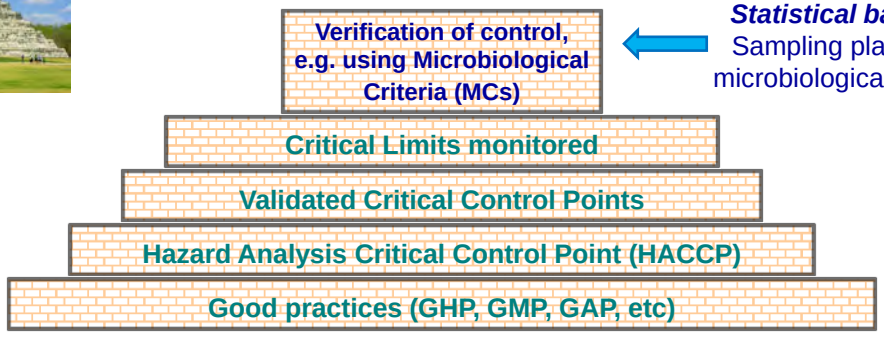
Verification of hazard control as part of a robust food business operation



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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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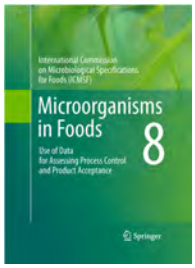
Stringency of control is implemented by selecting proportional MCs (performance)

1st Edition, 1974
2nd Edition, 1986



1st Edition, 2011

- The higher the consumer risk, the more stringent the performance of the **Microbiological Criterion** that verification of control is based on
- The **ICMSF 15 Cases** risk management framework represents a proportional approach to manage risks associated to food lots to acceptable levels

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The 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

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ICMSF 15 risk cases matrix
(5 categories of microorganisms/hazards)

	Organism/Hazard	Impact	Examples
Ingredients; Operation	**Utility organism**	Spoilage, reduced shelf life, no health concern	*e.g.,* total counts (TVC, etc.), yeasts and molds
	Indicator organism	Indicator of GHP/process control	*e.g.,* Coliforms, Enterobacteriaceae
HAZARD SEVERITY	**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* spp.; *Yersinia* spp.
	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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ICMSF 15 risk cases matrix
(3 categories of level changes before consumption)

HAZARD LEVEL CHANGES

Reduces *No change* *Increases*

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ICMSF 15 risk cases matrix
(MOs performance stringency proportional to consumer food safety risk)

HAZARD LEVEL CHANGES

Reduces *No change* *Increases* Risk increases

HAZARD SEVERITY INCREASES

Risk increases

highest risk

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ICMSF 15 risk cases matrix

(MOs performance stringency proportional to consumer food safety risk)

HAZARD LEVEL CHANGES

Risk increases

HAZARD SEVERITY INCREASES	*Reduces*	*No change*	*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

Risk increases

highest risk

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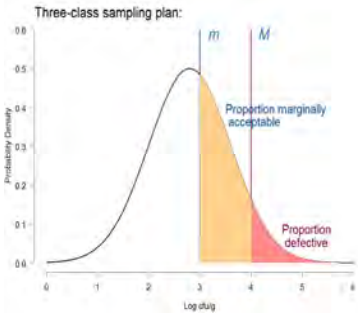
Sampling plan types and parameters

Quantitative plans (enumeration)

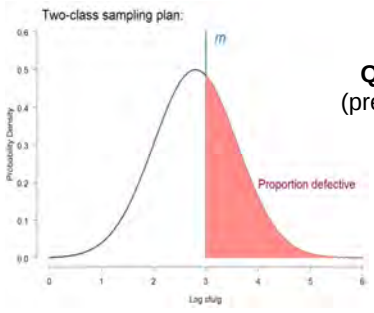
Relatively low stringency

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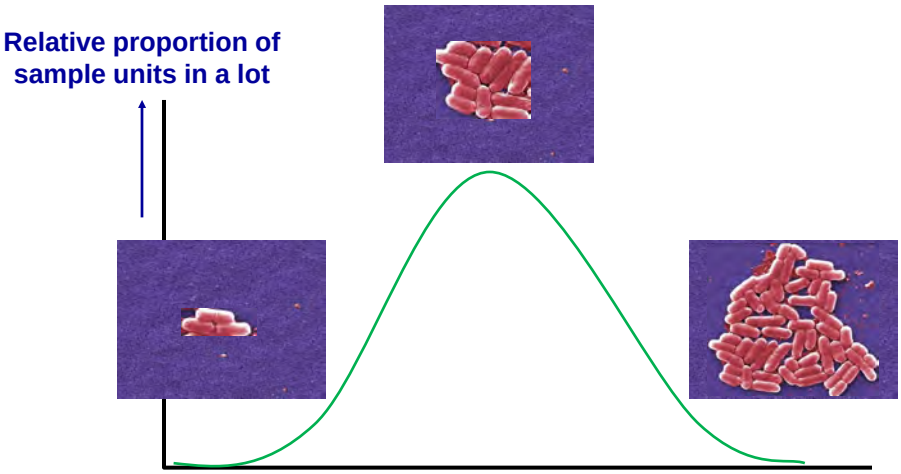
MCs/sampling plans consider the distribution of microorganisms in a food lot (batch)



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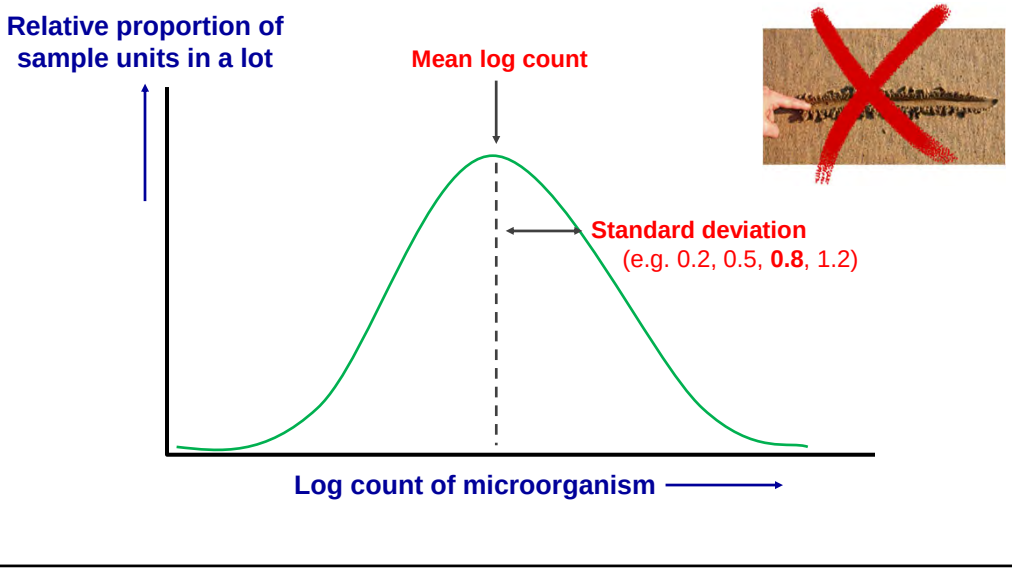
Key parameters for the distribution of microorganisms in a lot (batch)



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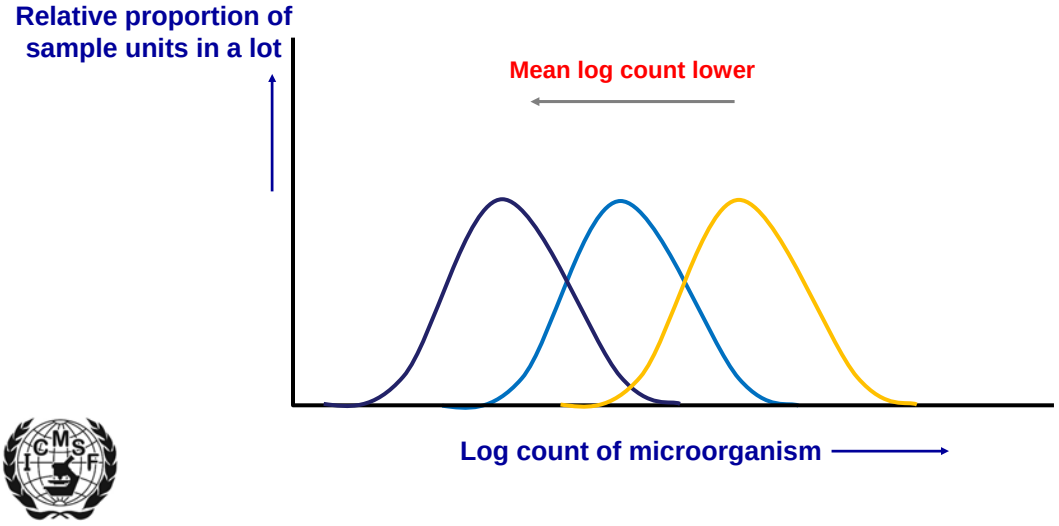
Representing batches with different mean log counts but same standard deviation (SD)



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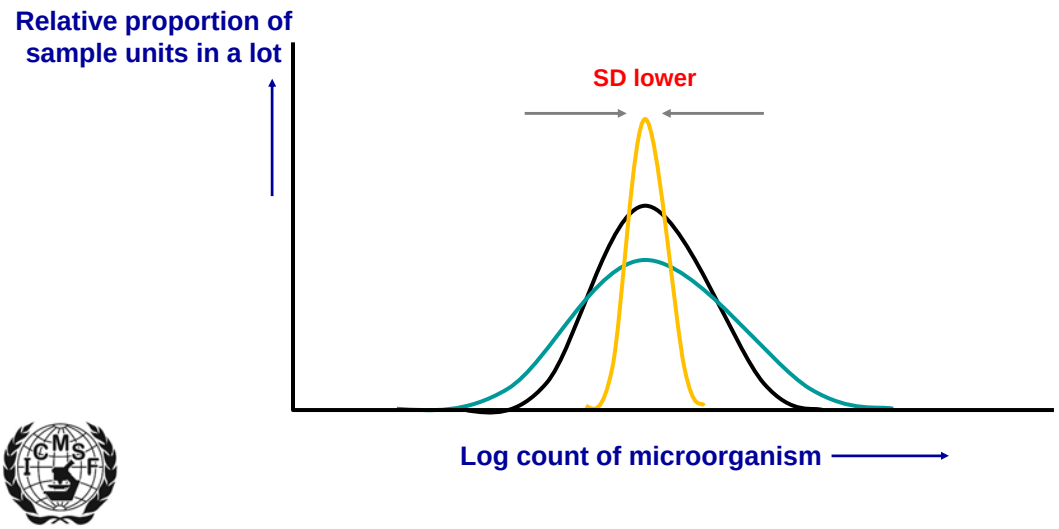
Representing batches with a different SD but the same mean log count



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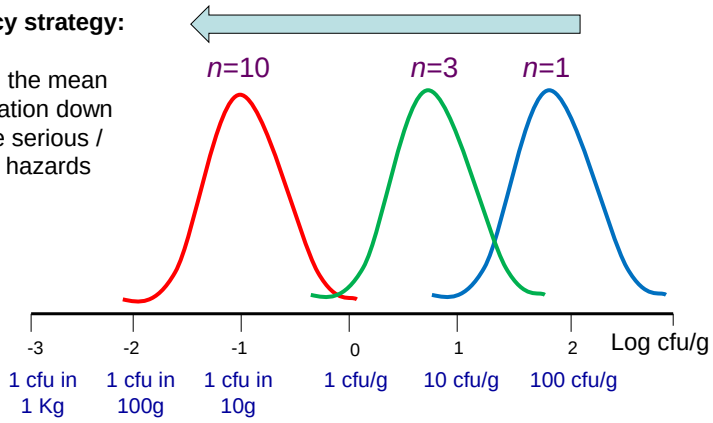
Stringency example: effect of number of samples

Stringency strategy:

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



Mean arithmetic concentration of compliant batches, assuming (*m*=1/g; SD=0.8; confidence=95%)

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Food Safety Risk Management: a case example

CODEX ALIMENTARIUS International Food Standards

http://www.fao.org/fao-who-codexalimentarius/en/

Codex Alimentarius has adopted the Risk Analysis framework for all its decision-making

Codex Alimentarius food safety standards, codes of practice and guidelines are equivalent to **Risk Management** decisions

- Codex Committees are the actual Risk Managers;
- FAO and WHO (and others) act as Risk Assessors, providing science input based on expert meetings;
- **But Codex Risk Management decisions are not mandatory**

National and local governments

- National governments (members of Codex) may choose to adopt Codex decisions into their national Food Law/Regulatory systems
  - Without change
  - Adapted as they consider necessary

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Food safety Risk Manager

Codex Committee on Food Hygiene (CCFH)

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

Developed key Microbiological food safety management guidelines:

- 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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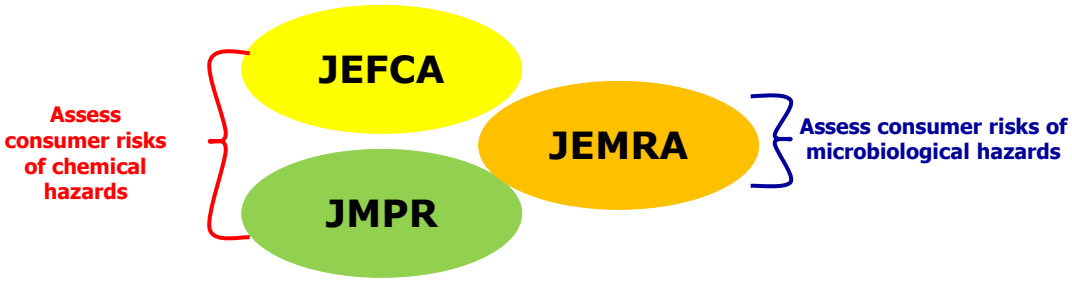
Food Safety Risk Assessment expert meetings



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Codex follows the Risk Analysis approach

JEMRA

SCIENCE

- *Salmonella* spp. in broiler chickens and eggs
- ***Listeria monocytogenes* in ready-to-eat food**
- *Campylobacter* spp. in broiler chickens
- ***Cronobacter* spp., *Salmonella* spp. in powdered infant formulae (PIF)**
- *Vibrio* spp. in seafood

CODEX ALIMENTARIUS International Food Standards

STANDARDS

- Risk management strategies for *Salmonella* spp. in poultry
- **General principles of food hygiene for management of *L. monocytogenes***
- Risk management strategies for *Campylobacter* spp. in poultry
- **Code of hygienic practices for powdered formulae for infants and young children**
- Risk management strategies for *Vibrio* spp. in seafood

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JEMRA articulated the risk posed by *L. monocytogenes* in RTE foods

- The vast majority of listeriosis cases results from ingestion of very high numbers of pathogen cells
- Consumption of low numbers of pathogen cells (~100 CFU/g) has a low probability to cause illness in healthy consumers
- At-risk subgroups may be >3 orders of magnitude (>1000 times) more vulnerable than generally healthy consumers
- **Ready-To-Eat food products differ in their ability to support growth of the pathogen**

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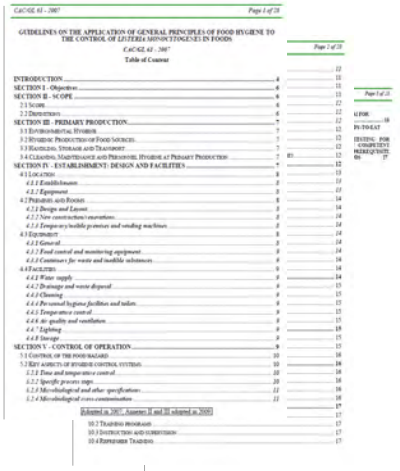
CCFH decided on appropriate risk management and made guidance, incl. MCs

Guidance for Codex Member Countries

Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods (CAC/GL 61 – 2007)

- **Annex**: Microbiological Criteria suggested for *Listeria monocytogenes* in Ready-To-Eat Foods



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Codex advice regarding control of *L. monocytogenes* in RTE foods (CAC/GL 61–2007)

Codex suggested tailored MCs for these two food types:

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

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

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Codex advice regarding control of *L. monocytogenes* in RTE foods (CAC/GL 61–2007)

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

Guidance: certain low levels of the organism may be acceptable

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

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**

Guidance: levels of the organism must be very low

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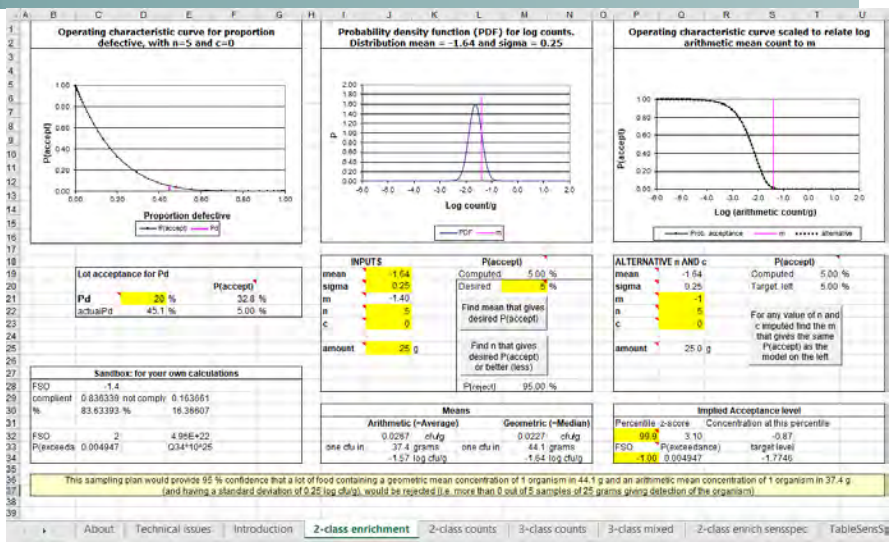
The ICMSF sampling plan - dashboard

- **The ICMSF sampling plan tool can help to understand sampling plan performance**
- It can be used to compare the stringency of different sampling plans and determine performance equivalent plans that may be more resource efficient



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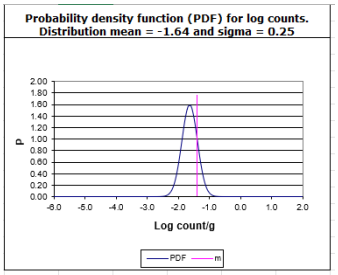
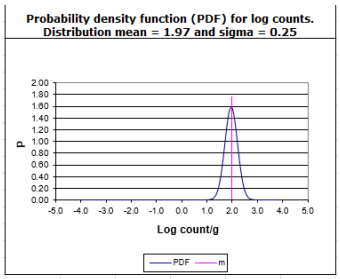
Performance of the two Codex MCs for *L. monocytogenes* in different RTE foods

Growth supported



INPUTS		P(accept)	
mean	-1.64	Computed	5.00 %
sigma	0.25	Desired	5 %
m	-1.40		
n	5	Find mean that gives desired P(accept)	
c	0		
amount	25 g	Find n that gives desired P(accept) or better (less)	
		P(reject)	95.00 %

Means			
Arithmetic (=Average)		Geometric (=Median)	
0.0267	cfu/g	0.0227	cfu/g
one cfu in	37.4 grams	one cfu in	44.1 grams
	-1.57 log cfu/g		-1.64 log cfu/g



INPUTS		P(accept)	
mean	1.97	Computed	5.00 %
sigma	0.25	Desired	5 %
m	2		
n	5	Find mean that gives desired P(accept)	
c	0		
		Find n that gives desired P(accept) or better (less)	
		P(reject)	95.00 %

Means			
Arithmetic (=Average)		Geometric (=Median)	
109.9	cfu/g	93.1	cfu/g
2.04	log cfu/g	1.97	log cfu/g

Growth NOT supported

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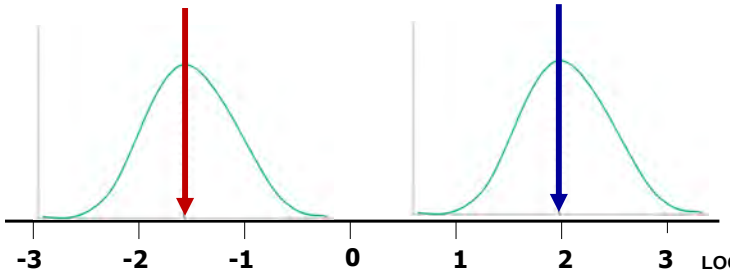
Performance of the two Codex MCs for *L. monocytogenes* in different RTE foods

Foods supporting *Lm* growth | **Foods NOT supporting *Lm* growth**

0.023 CFU/g
(- 1.64 Log CFU/g)

93 CFU/g
(1.97 Log CFU/g)



Geometric mean

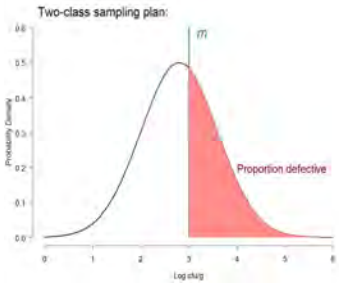
L. monocytogenes distribution of log CFU/g-values for a just compliant food lot/batch*

** For Standard Deviation: **0.25** and Confidence Level: **95%** to reject a non-compliant batch*

MC for RTE foods <u>not supporting</u> *Lm* growth

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



Status of a "just compliant" lot as described by Codex:

- such a lot may consist of 55% of the samples being below 100 cfu/g and
- up to 45% of all the samples from this lot may be above 100 cfu/g, whereas
- 0.002% of all the samples may be above 1000 cfu/g, and
- 0.00000000000005% ($5*10^{-13}$) of all the samples may be above 9000 cfu/g

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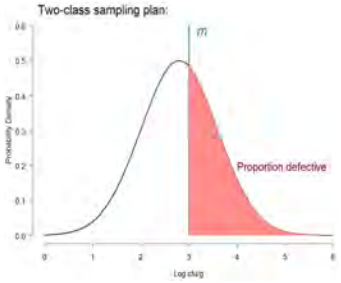
MC for RTE foods <u>supporting</u> *Lm* growth

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



Status of a "just compliant" lot as described by Codex:

- Such a lot may consist of 55% of the 25g samples being negative, and
- up to 45% of 25 g samples may be positive *(> 0.04 cfu/g detection limit)*, and
- 0.5 % of this lot may harbour concentrations above 0.1 cfu/g, and
- 0.000000000002% ($2*10^{-9}$) of this lot may have concentrations over 1 cfu/g

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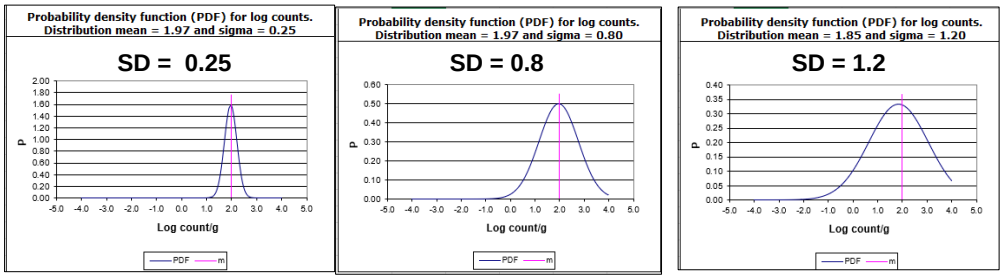
Importance of understanding distribution (SD)

(Foods not supporting growth example)



Food not supporting growth

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

SD	Proportion of a food lot over			
	100 cfu/g	1000 cfu/g	10000 cfu/g	100,000 cfu/g
0.25	45 %	0.002 %	∞	∞
0.8	48 %	9.9 %	0.56 %	0.008 %
1.2	48 %	19.5 %	4.5 %	0.006 %

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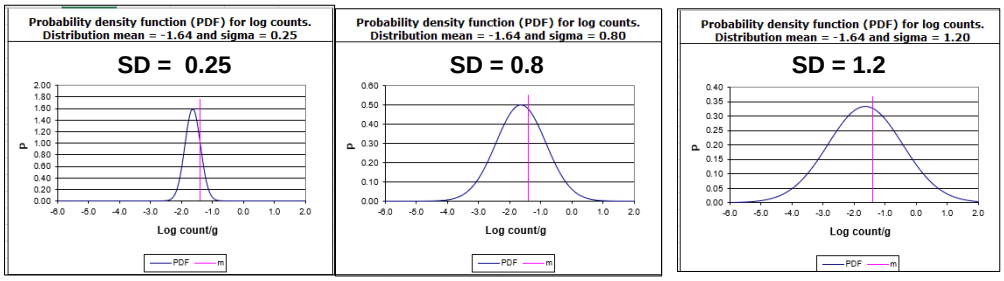
Importance of understanding distribution (SD)



Food supporting growth

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

[b] Not detected in 25 g sample

SD	Proportion of a food lot over		
	≥0.1 cfu/g	≥1.0 cfu/g	≥10 cfu/g
0.25	0.5 %	$2*10^{-9}$ %	∞
0.8	2 %	0.05 %	0.00026 %
1.2	8 %	1.2 %	0.12 %

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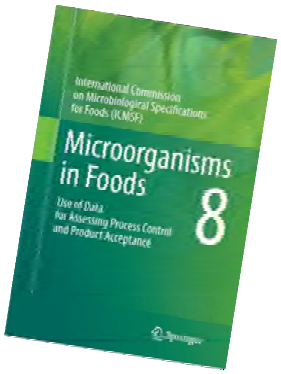
Summary: Risk-based Food Safety Management

- "Safe" means "no undue harm" or in line with the "appropriate level of protection"
- Risk analysis provides a framework for managing hazards proportional to the risk to consumers
- Microbiological criteria and sampling plans operationalize proportional risk management

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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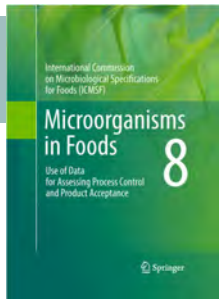
Latest ICMSF "useful testing" advice



Part I: Principles of using Data in Microbiological Control

1. Utility of Microbiological Testing for Safety and Quality
2. Validation of Control Measures
3. Verification of Process Control
4. Verification of Environmental Control
5. Corrective Actions to Reestablish Control
6. Microbiological Testing in Customer–Supplier Relations

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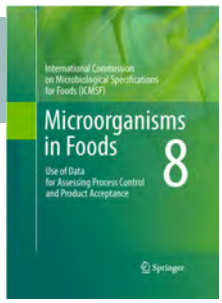
Latest ICMSF "useful testing" advice



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

Since 1962

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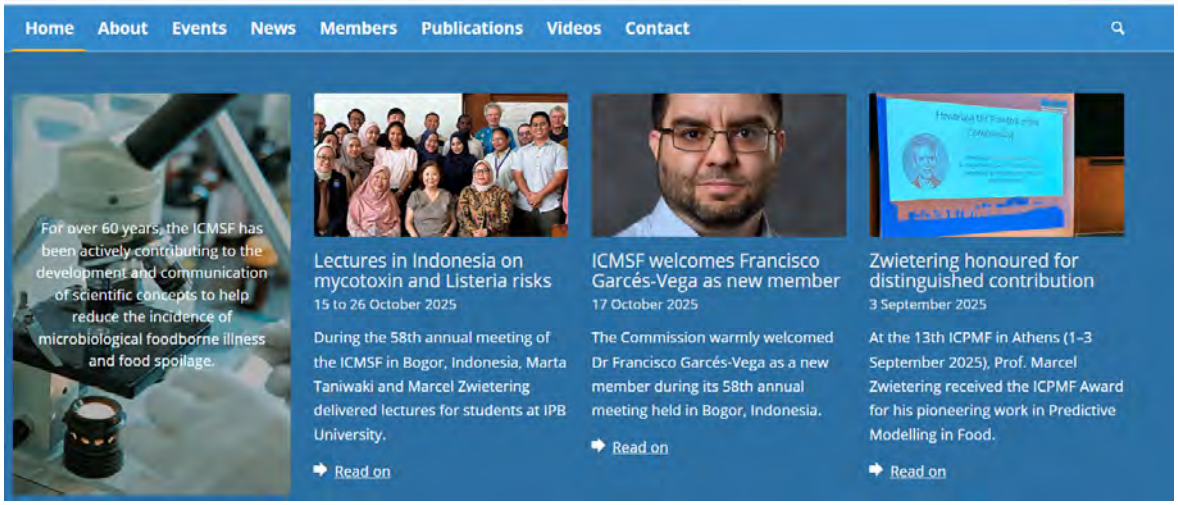
ICMSF online



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Video clips

(In English with subtitles in several languages)

ICMSF 2017 01 "History of ICMSF", Martin B. Cole

ICMSF 2017 02 "Microbiological Testing...

ICMSF 2017 03 "Microbiological Testing for...

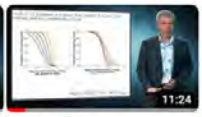
ICMSF 2017 04 "Microbiological testing for...

ICMSF 2017 05 "Microbiological testing for...

ICMSF 2017 06 "Anatomy of a sampling plan", Marcel H....

ICMSF 2017 07 "The ICMSF cases", Leon G.M. Gorris

ICMSF 2017 08 "Microbiological Testing an...



ICMSF 2017 09 "Microbiological testing and...

ICMSF 2017 10 "Examples 'sampling plan performance...

ICMSF 2020 11 "WhySoManySamplingPlan...

ICMSF 2020 12 "Introduction ICMSF tool", Leon G.M. Gorris

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