



International Commission on Microbiological
Specifications for Foods (ICMSF)

www.icmsf.org

IMPORTANCE OF SAMPLING AND TESTING, ESPECIALLY MICROBIOLOGICAL CRITERIA SET IN A REGULATORY CONTEXT

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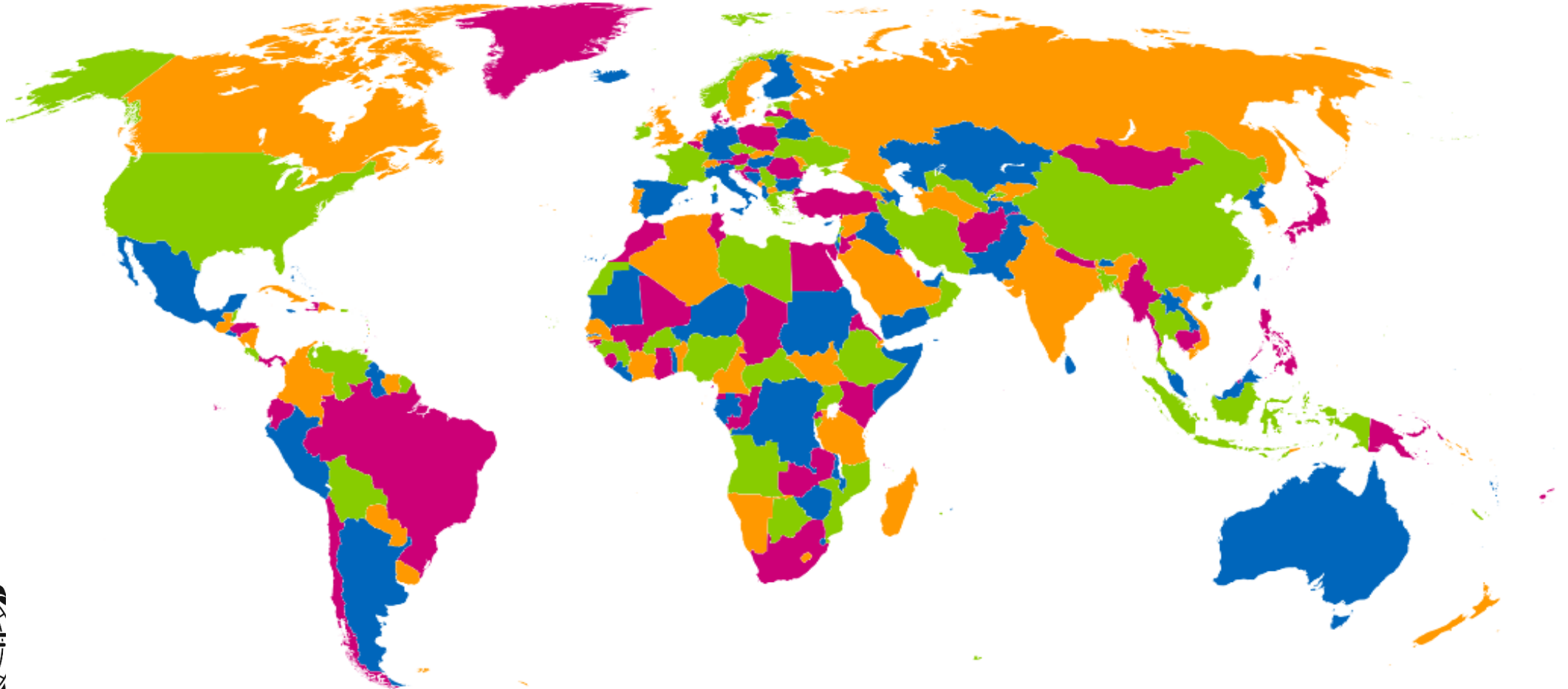


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Food safety regulations around the world

“6000+ years of local regulation development and 60 years of harmonization”



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Codex Alimentarius facilitates harmonization

C O D E X
A L I M E N T A R I U S
International Food Standards

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

*The global authority for
international standards,
codes of practice and
guidelines on food safety*



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Role Codex Alimentarius vs Governments

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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;
- **Note: 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/ and regulatory systems
 - Without change
 - Adapted as they consider necessary, supported by a rationale



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Codex Alimentarius – Risk Management role



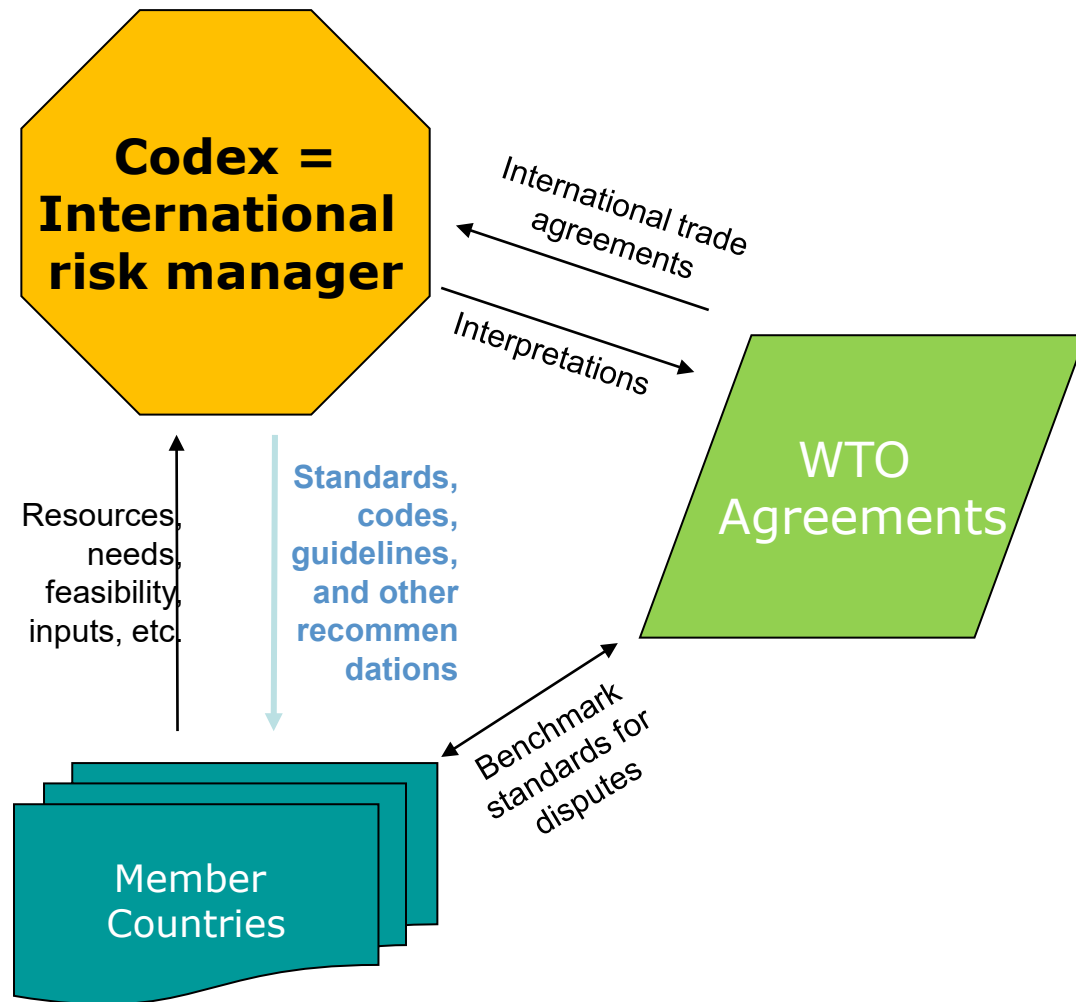
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The Risk Management

*process within Codex
Alimentarius*



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Codex Alimentarius – Risk Assessment (1)

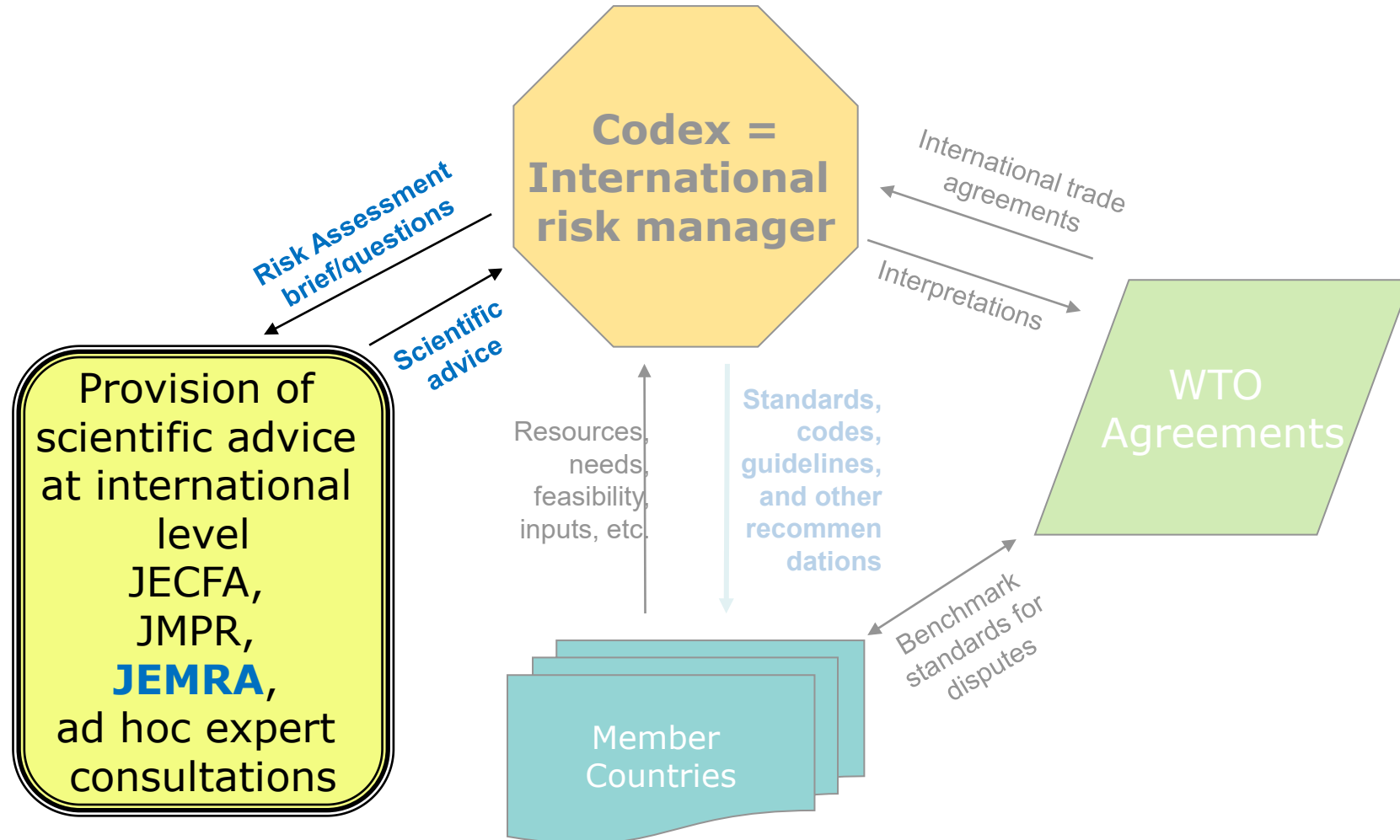


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The Risk Management and Risk Assessment processes within Codex Alimentarius

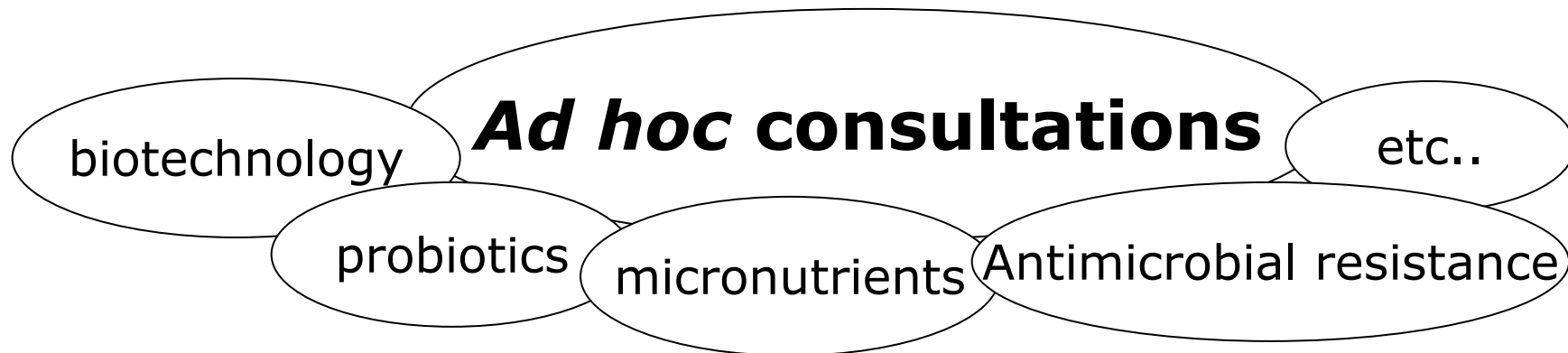
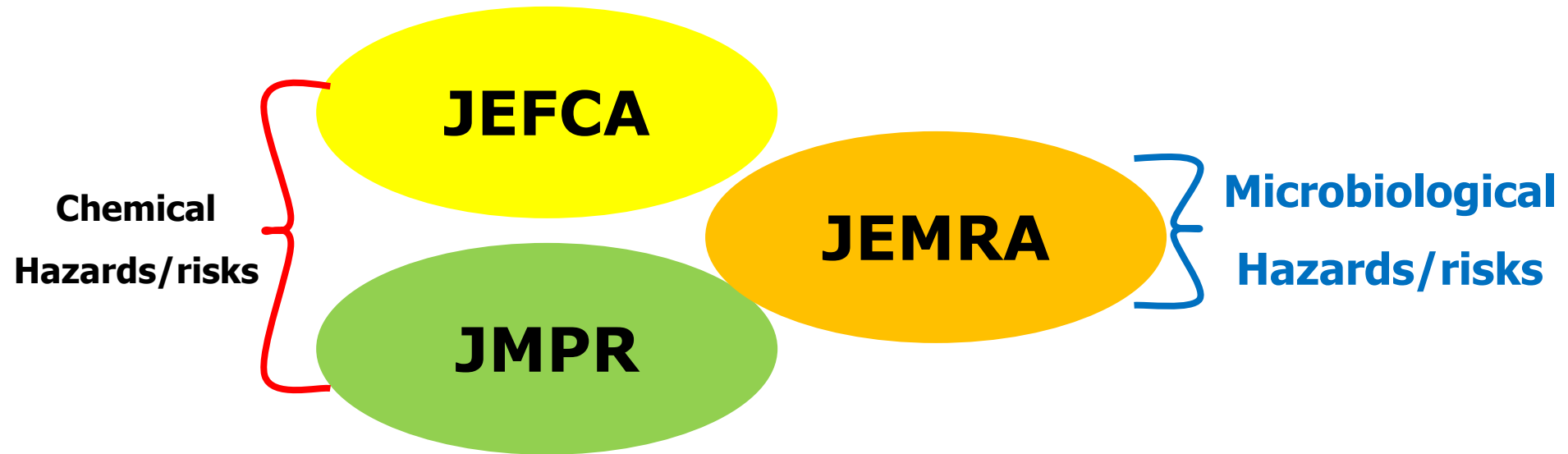


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Codex Alimentarius – Risk Assessment (2)





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

Relevant 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
- Principles and Guidelines for the Conduct of **Microbiological Risk Assessment**
- Principles for the Establishment and Application of **Microbiological Criteria** for Foods



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CODEX guidelines on Microbiological Criteria

http://www.codexalimentarius.org/download/standards/394/CXG_021e.pdf

PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS

CAC/GL 21 - 1997 Last modified: 2013

1. INTRODUCTION

1. Diseases caused by foodborne pathogens constitute a major burden to consumers, food business operators and national governments. Therefore, the prevention and control of these diseases are international public health goals. These goals have traditionally been pursued, in part, through the establishment of metrics such as the microbiological criterion, reflecting knowledge and experience of Good Hygienic Practice (GHP) and the impact of potential hazards on consumer health. Microbiological criteria have been used for many years and have contributed to improving food hygiene in general, even when established based on empirical observation of what is achieved under existing measures without any explicit linkage to specific levels of public health protection. Advances in microbiological risk assessment (MRA), and the use of the risk management framework are increasingly making a more quantifiable estimation of the public health risk and a determination of the effect of interventions possible. This has led to a series of additional food safety risk management metrics: Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC) (see Annex II of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)). Where MRA models are available or these metrics have been elaborated, they can allow the establishment of a more direct relationship between microbiological criteria and public health outcomes.

2. The establishment and application of microbiological criteria should comply with the principles outlined in this document and should be based on scientific information and analysis. When sufficient data are available, a risk assessment may be conducted on foodstuffs and their use.

3. The microbiological safety of foods is managed by the effective implementation of control measures that have been validated, where appropriate, throughout the food chain to minimise contamination and improve food safety. This preventative approach offers more advantages than sole reliance on microbiological testing through acceptance sampling of individual lots of the final product to be placed on the market. However, the establishment of microbiological criteria may be appropriate for verifying that food safety control systems are implemented correctly.



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CODEX guidelines on Microbiological Criteria

http://www.codexalimentarius.org/download/standards/394/CXG_021e.pdf

2. The **establishment and application** of **microbiological criteria** should comply with the principles outlined in this document

and should be based on **scientific information and analysis**.

When sufficient data are available, a **risk assessment** may be conducted on foodstuffs and their use.



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CODEX guidelines on Microbiological Criteria

http://www.codexalimentarius.org/download/standards/394/CXG_021e.pdf

3. The **microbiological safety of foods** is managed by the **effective implementation of control measures that have been validated**, where appropriate, throughout the food chain to minimise contamination and improve food safety.

This **preventative approach** offers more advantages than **sole reliance on microbiological testing** through acceptance sampling of individual lots of the final product to be placed on the market.

However, the establishment of **microbiological criteria** may be appropriate for **verifying that food safety control systems** are implemented correctly.



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CODEX guidelines on Microbiological Criteria

http://www.codexalimentarius.org/download/standards/394/CXG_021e.pdf

A microbiological criterion is a **risk management metric** that indicates the **acceptability of a food**, or the **performance of either a process or a food safety control system** following the outcome of sampling and testing for microorganisms at a specified point of the food chain

<i>n</i> and <i>c</i> parameters		limit	sampling plan class
5^a	0	Absence in 25 g (< 0.04 cfu/g) ^b	2^c



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Microbiological Criteria are not just numbers

http://www.codexalimentarius.org/download/standards/394/CXG_021e.pdf

An MC consists of the following components:

- 1) The **purpose** of the MC
- 2) The **food, process or food safety control system** to which the MC applies
- 3) The **specified point in the food chain** where the MC applies
- 4) The **microorganism(s)** and the reason for its selection
- 5) Analytical **methods** and **their performance parameters**
- 6) The **microbiological limits** (m, M) or other limits (e.g., a level of risk);
- 7) A **sampling plan** defining the number of sample units to be taken (n), the size of the analytical unit and where appropriate, the acceptance number (c)
- 8) An indication of the **typical (mitigation) measures** to taken in case a microbiological criterion is not met



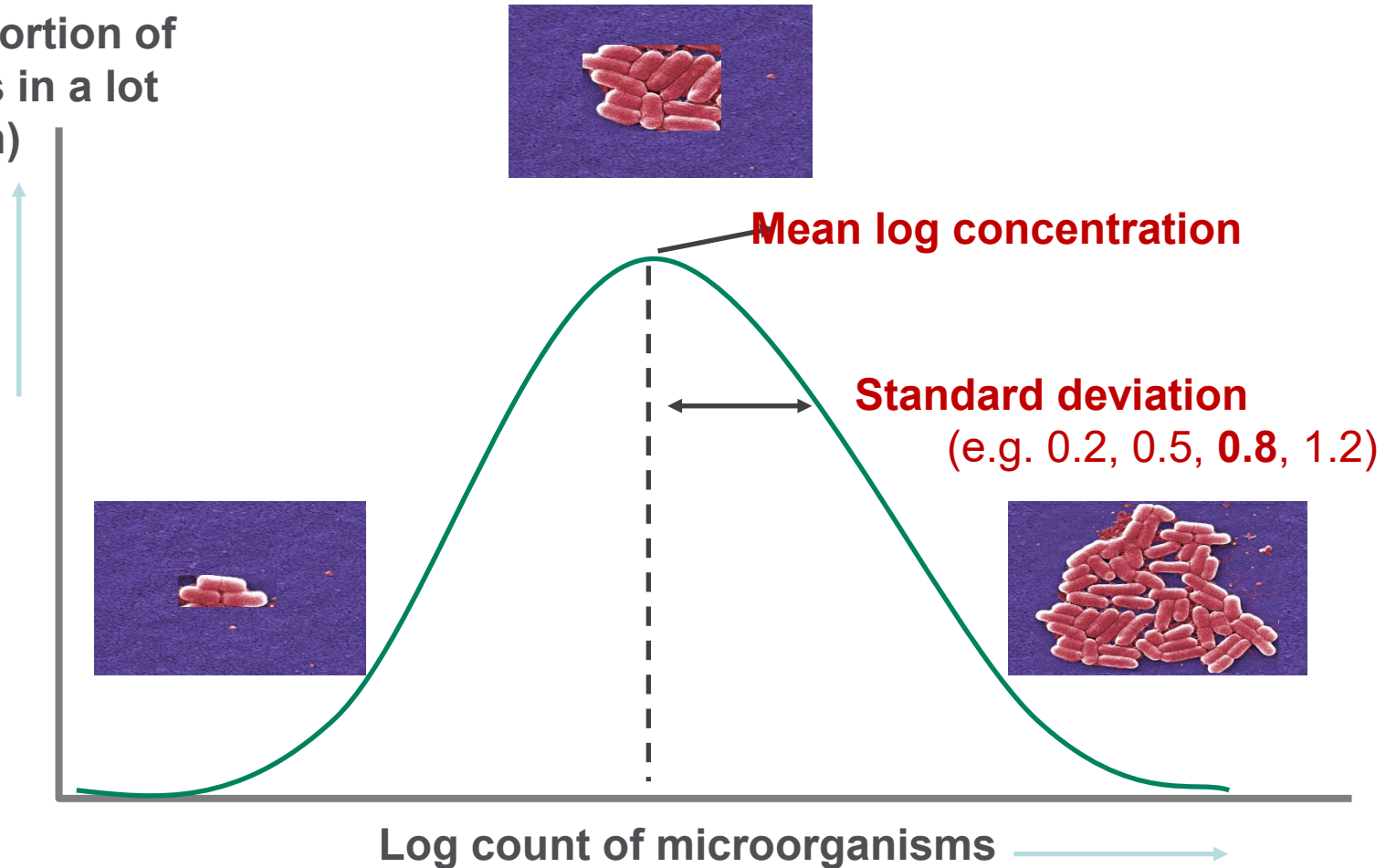
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Parameters relate to the distribution of microorganisms in a food lot/batch

Statistical representation of the variation in concentrations of microorganisms in sample units analysed of a food lot/batch

Relative proportion of sample units in a lot (batch)



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The Codex standard for *Listeria monocytogenes* in (Ready to Eat) Foods

Guidelines 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 II (Microbiological Criteria for *Listeria monocytogenes* in **Ready-To-Eat Foods**)



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GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS

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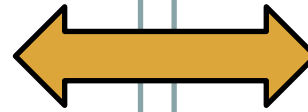
Codex Alimentarius – CCFH and JEMRA

CCFH asks JEMRA for MRAs that CCFH then consider when establishing risk management standards

JEMRA

SCIENCE

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



C O D E X
A L I M E N T A R I U S
International Food Standards

STANDARDS

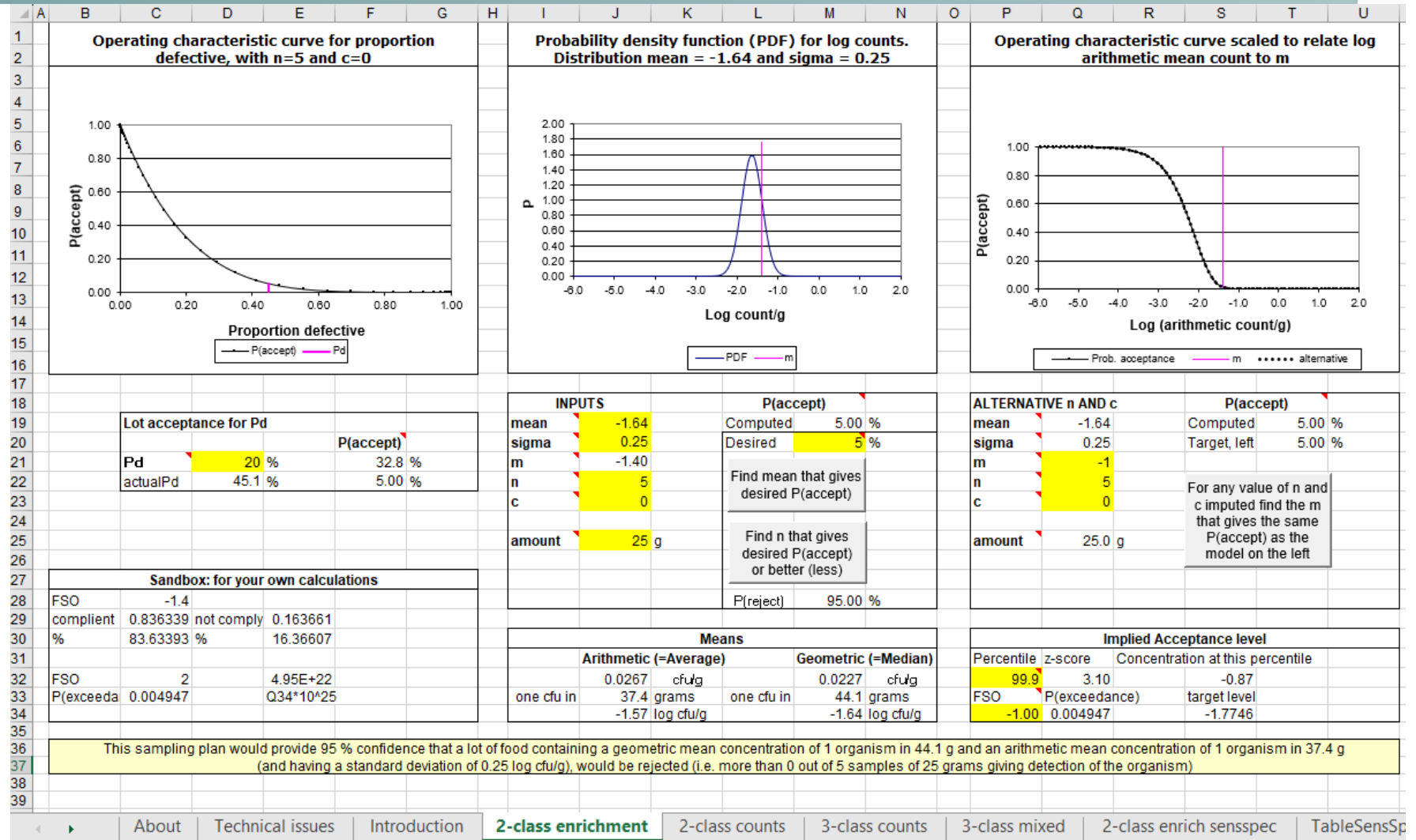
- Risk management strategies for *Salmonella* spp. in poultry
- **General principles of food hygiene for management of *L. monocytogenes***
- Risk management strategies for *Campylobacter* spp. in poultry
- Risk management strategies for *Vibrio* spp. in seafood
- Code of hygienic practices for powdered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



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The ICMSF sampling plan - dashboard

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

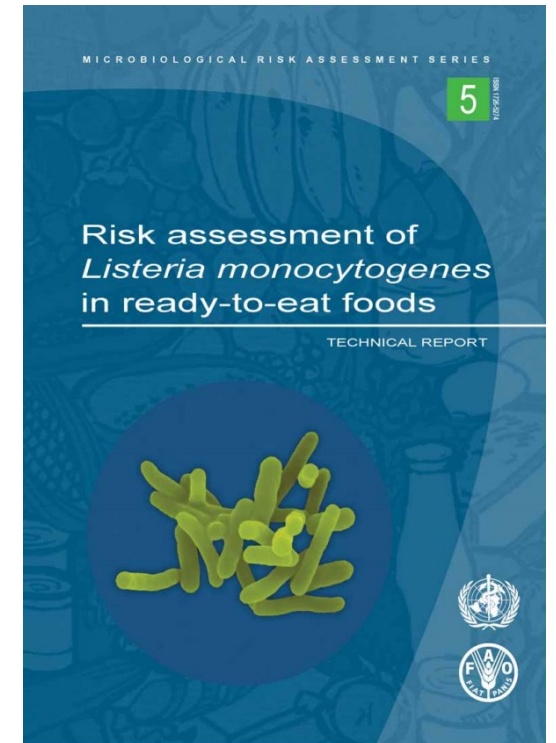
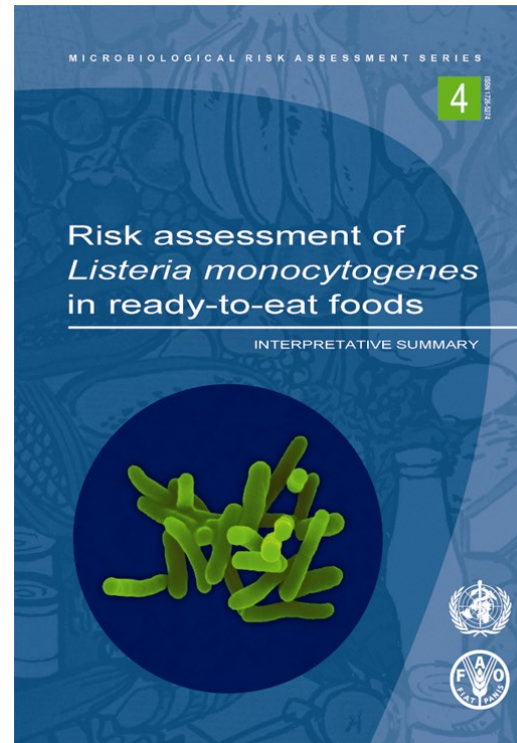




Codex Alimentarius – CCFH and JEMRA

JEMRA MRA reports

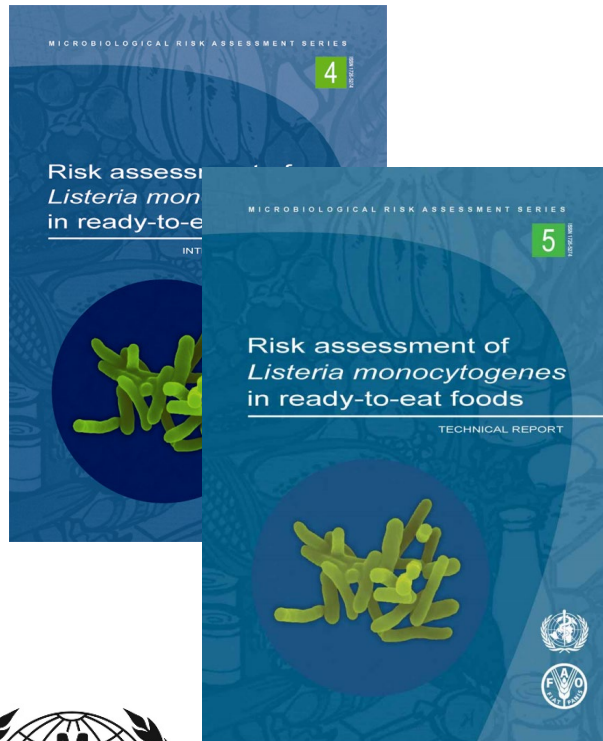
- [#4. Interpretative summary](#) (48 pgs)
- [#5. Technical report](#) (270 pgs)



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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 very 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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Key CCFH decisions regarding *L. monocytogenes* in RTE foods

To establish different Microbiological Criteria for the two RTE food types that are different in supporting the growth of *L. monocytogenes* (*Annex II*)

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

Rationale:

- There is a (low) level of *L. monocytogenes* that is “tolerable” for generally healthy consumers
- Unsafe *Lm* levels for generally healthy consumers occur very infrequently

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

Rationale:

- In these foods, there is no intrinsic/extrinsic control over *L. monocytogenes* growth
- Thus, a relatively large safety margin is needed from *Lm* levels that are considered unsafe for generally healthy consumers

MC for RTE foods not supporting *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

*MCs in regulatory standards:
compliant lots are "legally
acceptable to place on market"*



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 the samples being above 100 cfu/g, whereas
- 0.002% of all the samples from this lot could be above 1000 cfu/g.



MC for RTE foods supporting *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

*MCs in regulatory standards:
compliant lots are "legally
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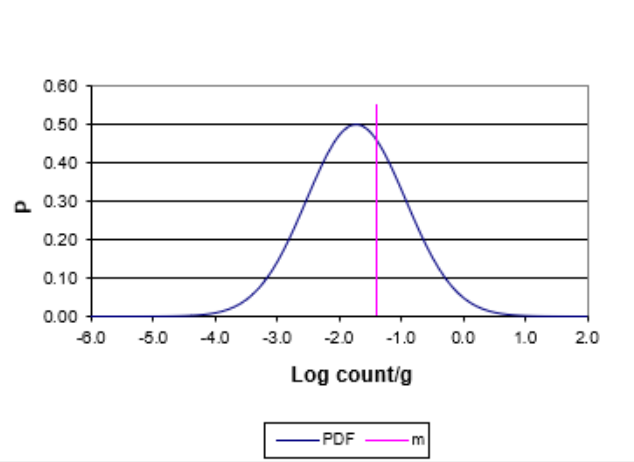
Status of a "just compliant" lot as described by Codex:

- Such a lot may consist of 55% of the 25g samples being negative and
- up to 45% of the 25 g samples being positive.
- 0.5 % of this lot could harbour concentrations above 0.1 cfu/g



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

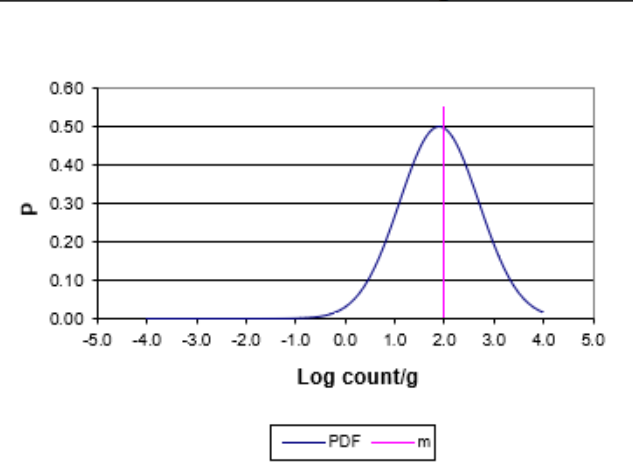
Probability density function (PDF) for log counts.
Distribution mean = -1.74 and sigma = 0.80



INPUTS		P(accept)	
mean	-1.74	Computed	5.00 %
sigma	0.80	Desired	5 %
m	-1.40	Find mean that gives desired P(accept)	
n	5	Find n that gives desired P(accept) or better (less)	
c	0		
amount	25 g		
		P(reject)	95.00 %

Means			
Arithmetic (=Average)		Geometric (=Median)	
	0.0997 cfu/g		0.0183 cfu/g
one cfu in	10.0 grams	one cfu in	54.7 grams
	-1.00 log cfu/g		-1.74 log cfu/g

Probability density function (PDF) for log counts.
Distribution mean = 1.90 and sigma = 0.80



INPUTS		P(accept)	
mean	1.90	Computed	5.00 %
sigma	0.80	Desired	5 %
m	2	Find mean that gives desired P(accept)	
n	5	Find n that gives desired P(accept) or better (less)	
c	0		
		P(reject)	95.00 %

Means			
Arithmetic (=Average)		Geometric (=Median)	
	434.3 cfu/g		79.6 cfu/g
	2.64 log cfu/g		1.90 log cfu/g

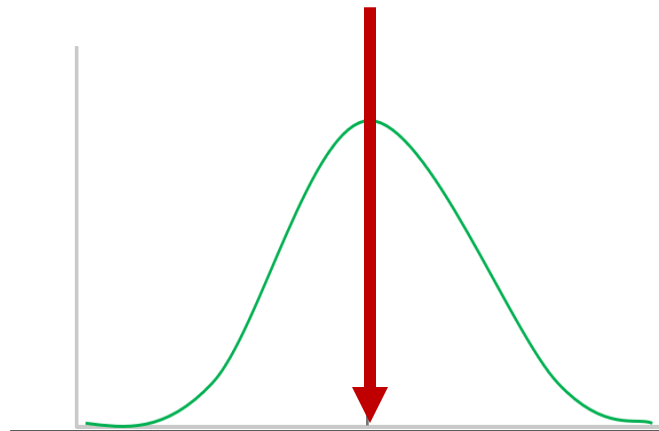




Performance of the two Codex MCs for *L. monocytogenes* in different RTE foods

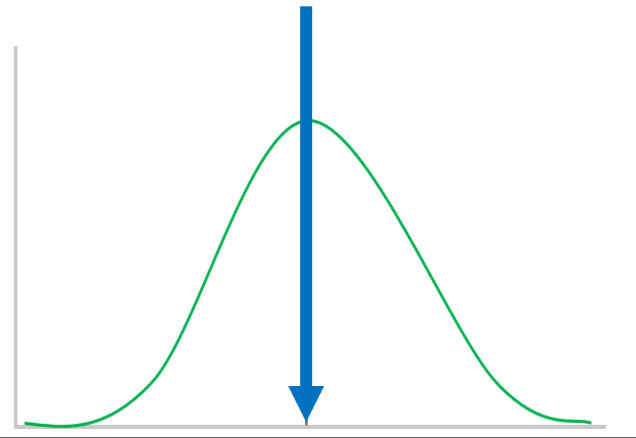
Foods supporting *Lm* growth

0.018 CFU/g
(- 1.74 Log CFU/g)



Foods not supporting *Lm* growth

80 CFU/g
(1.9 Log CFU/g)



Geometric mean
L. monocytogenes

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

* For Standard deviation:
0.8 and Confidence Level:
95%





Summary

- A MC is a **statistical** testing tool to verify the **acceptability** of a lot (batch) of food product or to **verify control** over production of a lot
- Governments may establish MCs as **regulatory limits** in food safety standards, thereby articulating the **stringency** of control over microbiological hazards needed for appropriate consumer protection, or the “acceptable risk” to society
- The ICMSF sampling plan tool can be used to **interpret** the **stringency** of control of microbiological criteria included in food safety standards

