Relevance of Microbiological Sampling and Testing in Codex Food Safety Standards

Delivered by

Leon Gorris

Regulatory Affairs Director Global Food Safety

Unilever, The Netherlands

Outline

- Brief introduction to Codex Alimentarius
- The *testing for food safety* challenge
- Microbiological Criteria concept
- Codex guidance on Microbiological Criteria

- International food standards organization, established in 1963 by FAO and WHO
- Codex Secretariat located in Rome, hosted by FAO
- Codex standards formally recognized by WTO (SPS and TBT Agreements, 1994)
- 186 member States plus European Union.
- Active participation of >200 IGO/NGOs without voting rights

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

Codex Alimentarius

- Establishes international food safety standards to:
  - protect the health of consumers
  - ensure fair practices in trade

- Issues food safety management “principles” through its standards and guidelines that are….

- …. based on risk assessment inputs (JEMRA for microbiological risks)

- National authorities can choose to implement Codex standards and guidelines in their regulations/laws – only then these become mandatory

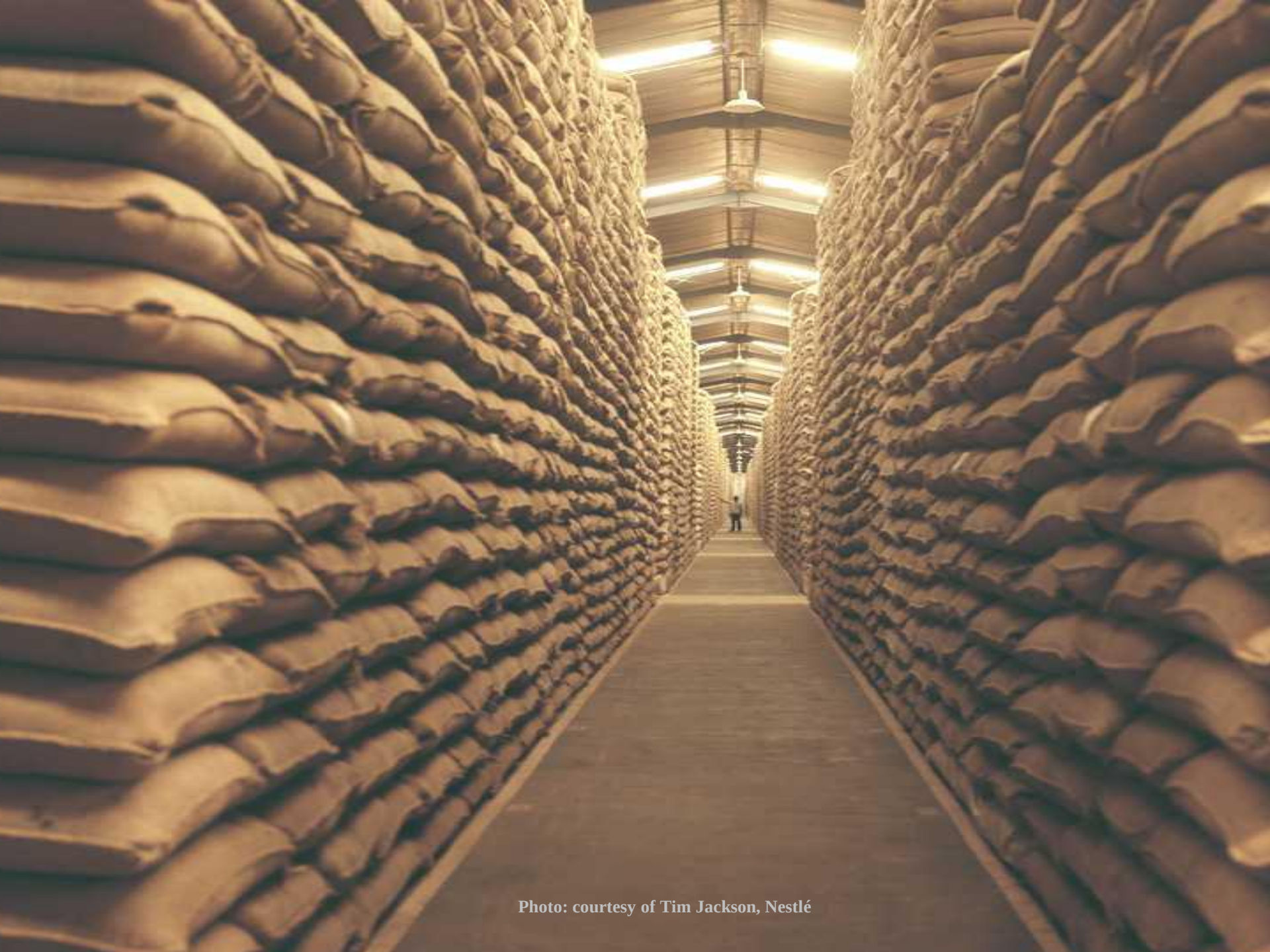

Photo: courtesy of Tim Jackson, Nestlé

Microbiological Criterion (MC) concept

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	100 cfu/g [b]	2 [c]

First Codex guideline[1]: a microbiological criterion should state:

- the food and point in value chain the criterion applies;
- the target microorganisms and analytical method
- a sample plan and the size of the analytical unit;
- microbiological limits considered appropriate
- the number of analytical units that should conform to these limits;
- actions to be taken when the criterion is not met.

[1] Principles for the Establishment and Application of Microbiological Criteria for Foods, CAC/GL 21, 1997, Food Hygiene Basic Texts

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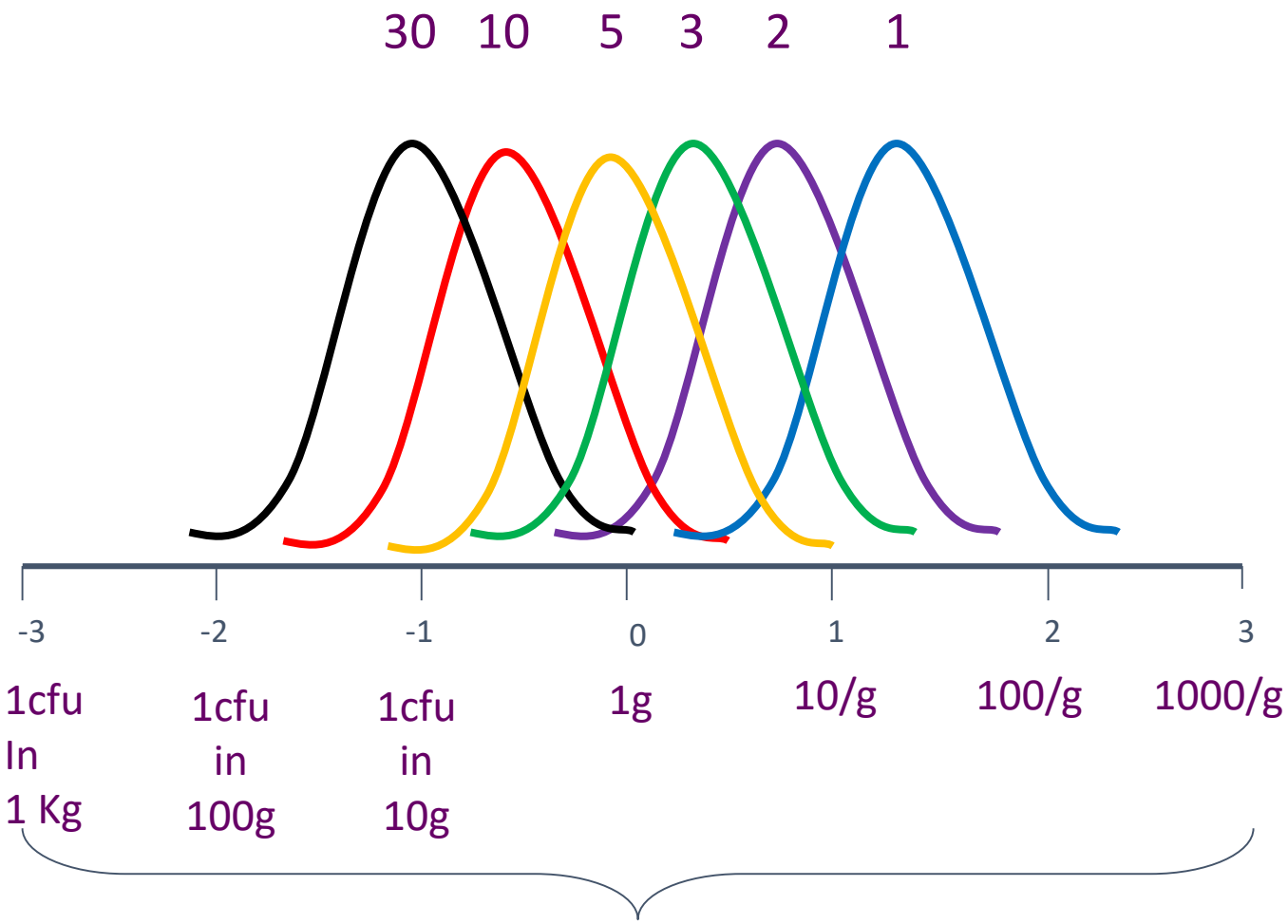
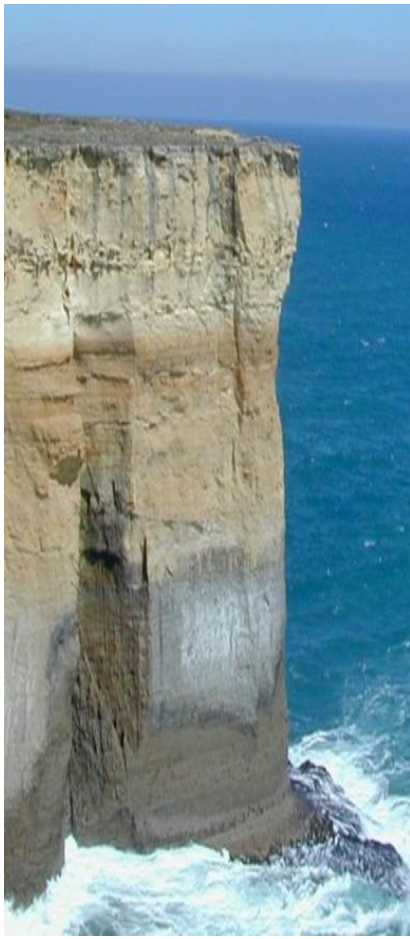
- Microbiological Criteria are meant to be a risk-based management tool, founded on sound science, to verify that production/processing is under control and that thus the is product safe
- Scrutiny of food batches (stringency of the MC) is proportional to the possible consumer risk
- Microbiological Criteria can be set by competent authorities (mostly mandatory) and food industry (mostly guidelines/contract specifications)

Sampling Plans for Food Lot Acceptance

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

Stringency: effect of number of samples
(m=1/g, s.d. =0.8)





List of MC components

A 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) Depending on its purpose, an indication of the statistical performance of the sampling plan

Risk Assessments & setting MCs

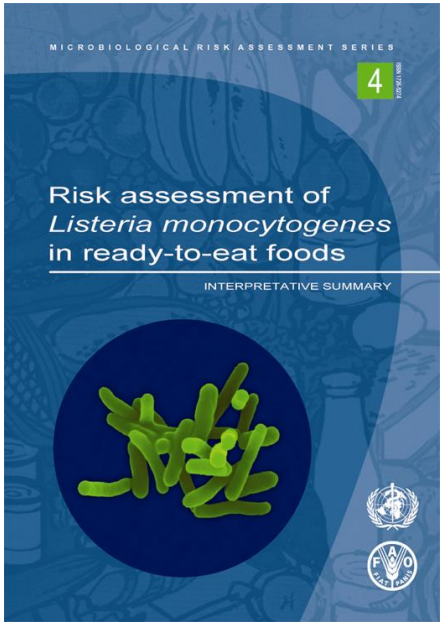
Since 2007 : Microbiological criteria and sampling plans are proposed by Codex in guidelines and standards/codes, e.g.:

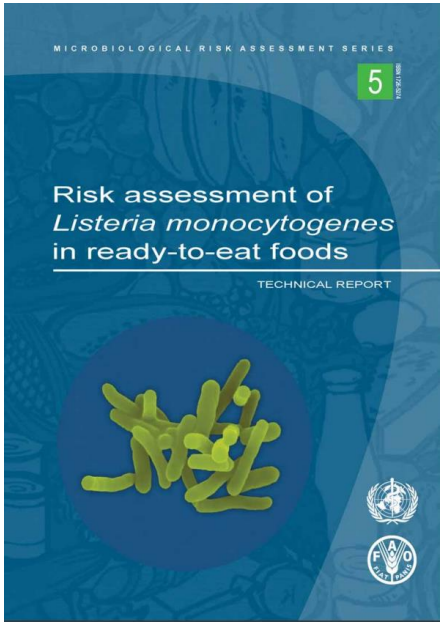
- **Codex document**
  - Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods (CAC/GL 61-2007)
    http://www.codexalimentarius.net/download/standards/10740/CXG_061e.pdf

- **JEMRA risk assessment**

http://www.fao.org/fileadmin/templates/agns/pdf/jemra/mra4_en.pdf

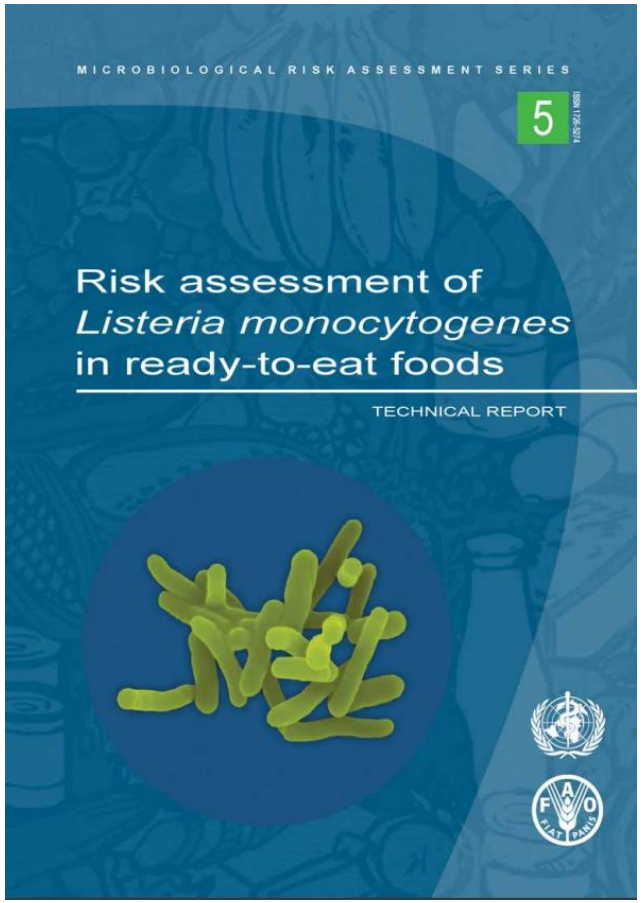
http://www.fao.org/3/a-y5394e.pdf





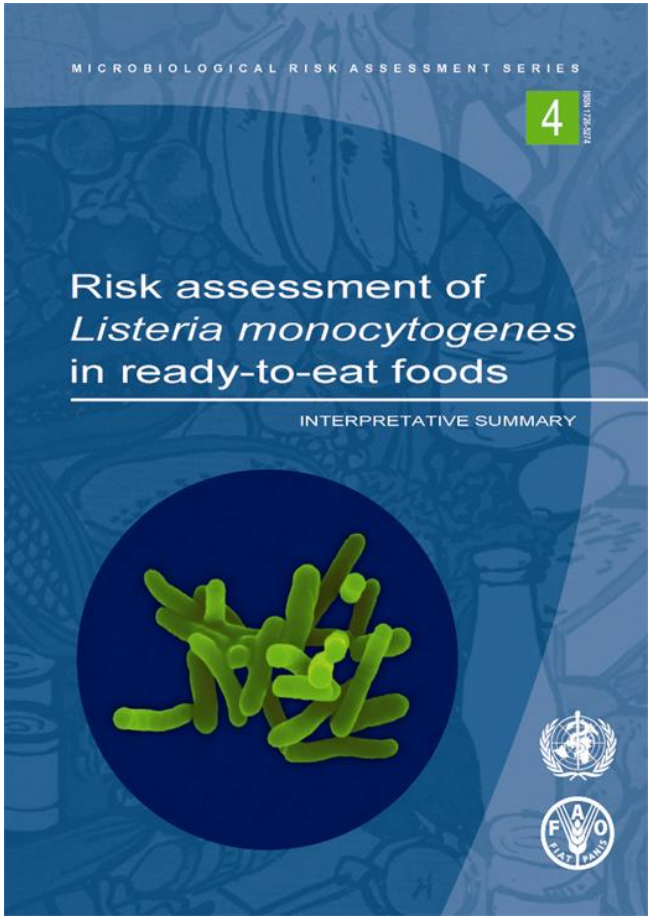
"*Listeria monocytogenes* in RTE food" MRA

- **Four model Ready To Eat products considered:**
  - **Milk:** pasteurized, low contamination level, supports growth, high consumption
  - **Ice-cream:** as for milk, but does not support growth
  - **Fermented meat:** frequently contaminated, no "killing step" during production, no growth (even some decrease), low consumption
  - **Cold smoked fish:** as for fermented meat, but supports growth



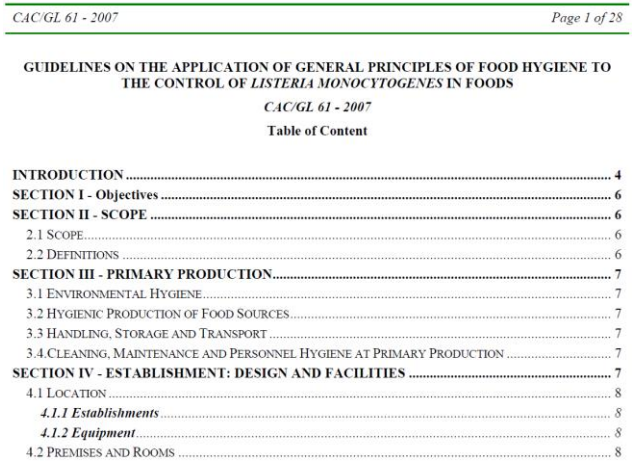
"*Listeria monocytogenes* in RTE food" MRA

- **Some insights from MRA study:**
  - Impact of control measures on *Lm* in foods
  - Existence of different groups / categories of RTE foods relative to *Lm* presence and growth
  - Vast majority of listeriosis cases results from ingestion of very high numbers
  - Consumption of low numbers has a very low probability of causing illness
  - Level of hazard that is tolerable at the point of consumption is in the order of 100 CFU/g for generally healthy consumers
  - Vulnerable subgroups may be much more vulnerable than generally healthy



"Listeria monocytogenes in RTE food Codex guidelines"

Guidelines on application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods (CAC/GL 61 – 2007)



CAC/GL 61 - 2007 Page 1 of 28

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

CAC/GL 61 - 2007

Table of Content

- Annex II (MCs for *L. monocytogenes* in RTE foods)

– Foods for which specific *L. monocytogenes* MCs are relevant:

  A. foods in which growth of *L. monocytogenes* **will not occur**,

  B. Foods in which growth of *L. monocytogenes* **can occur**

A. Foods not supporting growth of *L. monocytogenes*

Microbiological criterion for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	100 cfu/g [b]	2 [c]

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan;. m=a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots.

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] This criterion is based on the use of the ISO 11290-2 method.

Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 93.3 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected based on any of the five samples exceeding 100 cfu/g *L. monocytogenes*. 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. The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

A. Foods not supporting growth of *L. monocytogenes*

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

Rationale:

- There is a level of *Lm* that can be considered as "generally safe"*.
- Levels of *Lm* very rarely over 1000 CFU/g.
- Definitely generally unsafe levels occur very very infrequently

("defect" level considered in MRA was 10^6 cfu/g)

Micro Criterion performance:

- 55% of samples below 100 cfu/g
- 45% of samples above 100 cfu/g.
- 0.002% could be above 1000 cfu/g.

Note: *e.g. 100 cfu/g is far below risk level and may still be tolerable for particular risk groups, except extremely vulnerable.

B. Foods supporting growth of *L. monocytogenes*

Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	Absence in 25 g (< 0.04 cfu/g) [b]	2 [c]

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] Absence in a 25-g analytical unit. This criterion is based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 0.023 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected if any of the five samples are positive for *L. monocytogenes*. 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.

The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

B. Foods supporting growth of *L. monocytogenes*

Rationale:

- Per default, growth is not controlled to any "safe level".
- A large safety margin is needed from those generally unsafe levels that occur very very infrequently

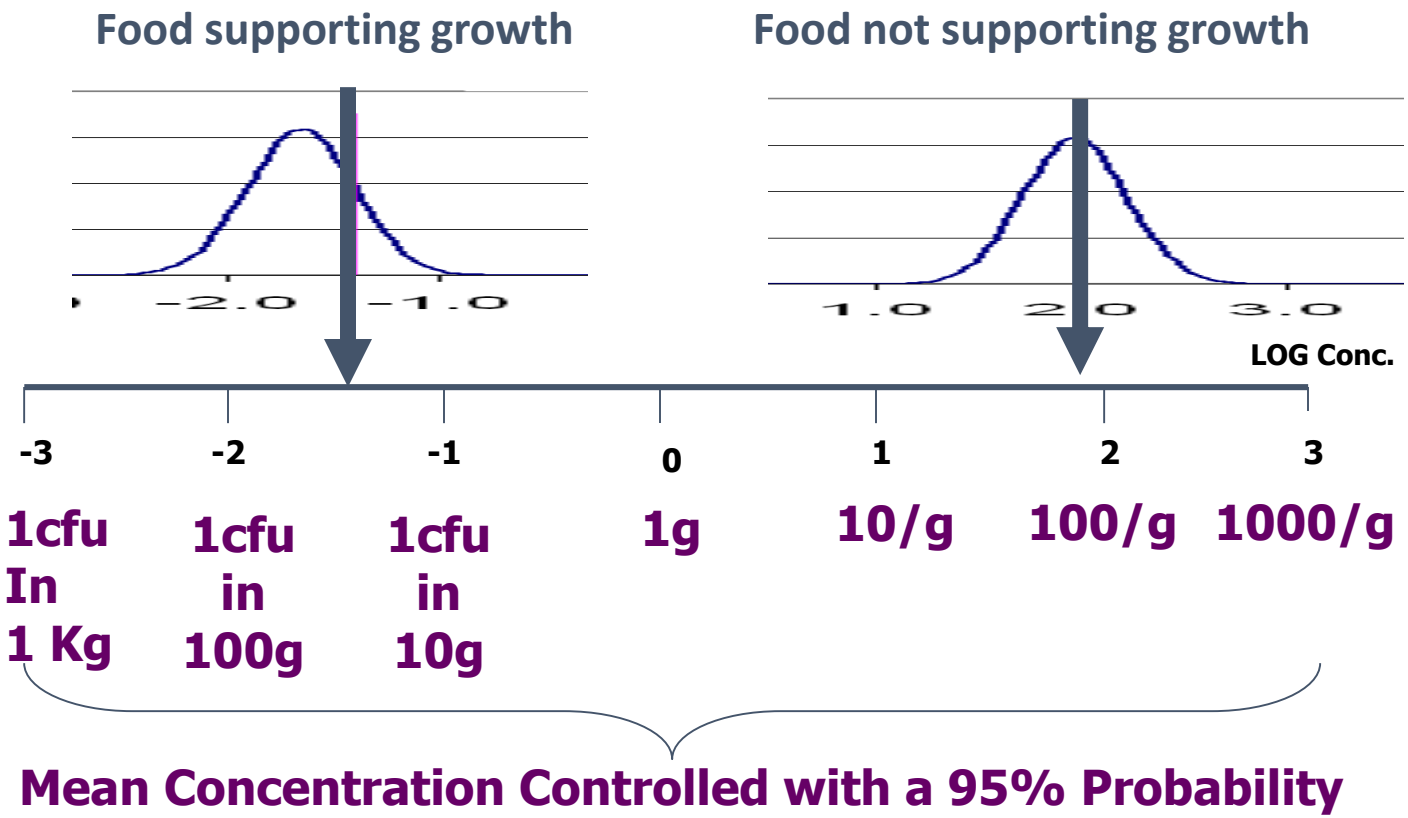
("defect" level considered in MRA was 10^6 *Lm* cfu/g)

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

Micro Criterion performance:

- 55 % of samples negative
- up to 45 % being positive.
- 0.5 % could be above 0.1 cfu/g.

Listeria monocytogenes example



Criteria for process hygiene

These are to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of the verification.

The safe production of these products is dependent on maintaining a high level of hygienic control. The following additional microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs, and not by the competent authority. As such these tests are not intended to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs.

Microorganisms	n	c	m	M	Class Plan
Mesophilic Aerobic Bacteria*	5	2	500/g	5000/g	3
Enterobacteriaceae**	10	2^{22}	0/10 g	Not applicable	2

Where n = number of samples that must conform to the criteria: c = the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan: m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality: M = a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality.

* The proposed criteria for mesophilic aerobic bacteria are reflective of Good Manufacturing Practices and do not include microorganisms that may be intentionally added such as probiotics. Mesophilic aerobic counts provide useful indications on the hygienic status of wet processing steps. Increases beyond the recommended limits are indicative of the build-up of bacteria in equipment such as evaporators or contamination due to leaks in plate-heat exchangers (refer to Annex III).

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS

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codexalimentarius > Codex Texts > Guidelines

Guidelines

Codex Guidelines provide evidence based information and advice together with recommended procedures to ensure that food is safe, of good quality and can be traded.

Reference	Title	Committee	Last modified	EN	FR	ES	AR	ZH	RU
CAC/GL 1-1979	General Guidelines on Claims	CCFL	2009	✓	✓	✓	✓	✓	✓
CAC/GL 2-1985	Guidelines on Nutrition Labelling	CCFL	2017	✓	✓	✓	✓	✓	✓
CAC/GL 3-1989	Guidelines for Simple Evaluation of Dietary Exposure to Food Additives	CCFA	2014	✓	✓	✓	⊘	⊘	⊘
CAC/GL 4-1989	General Guidelines for the Utilization of Vegetable Protein Products (VPP) in Foods	CCVP	1989	✓	✓	✓	✓	✓	✓
CAC/GL 8-1991	Guidelines on Formulated Complementary Foods for Older Infants and Young Children	CCNFSDU	2017	✓	✓	✓	✓	✓	⊘
CAC/GL 9-1987	General Principles for the Addition of Essential Nutrients to Foods	CCNFSDU	2015	✓	✓	✓	✓	✓	✓
CAC/GL 10-1979	Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intented for Infants and Young Children	CCNFSDU	2015	✓	✓	✓	✓	✓	✓
CAC/GL 13-1991	Guidelines for the Preservation of Raw Milk by Use of the Lactoperoxidase System	CCMMP	1991	✓	✓	✓	⊘	⊘	⊘
CAC/GL 14-1991	Guide for the Microbiological Quality of Spices and Herbs Used in Processed Meat and Poultry Products	CCPMPP	1991	✓	✓	✓	⊘	✓	⊘
CAC/GL 17-1993	Guidelines Procedures for the Visual Inspection of Lots of Canned Foods for Unacceptable Defects	CCPFV	1993	✓	✓	✓	✓	✓	✓
CAC/GL 19-1995	Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations	CCFICS	2016	✓	✓	✓	✓	✓	✓
CAC/GL 20-1995	Principles for Food Import and Export Inspection and Certification	CCFICS	1995	✓	✓	✓	✓	⊘	✓
CAC/GL 21-1997	Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods	CCFH	2013	✓	✓	✓	✓	✓	⊘
CAC/GL 22R-1997	Regional Guidelines for the Design of Control Measures for Street-Vended Foods (Africa)	CCAFRICA	1999	✓	✓	✓	✓	✓	⊘
CAC/GL 23-1997	Guidelines for Use of Nutrition and Health Claims	CCFL	2013	✓	✓	✓	✓	✓	⊘
CAC/GL 24-1997	General Guidelines for Use of the Term "Halal"	CCFL	1997	✓	✓	✓	✓	✓	✓
CAC/GL 25-1997	Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods	CCFICS	2016	✓	✓	✓	✓	✓	✓
CAC/GL 26-1997	Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems	CCFICS	2010	✓	✓	✓	✓	⊘	⊘

New scope of latest MC guidelines

A microbiological criterion is a risk management metric, which 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

Latest Codex MC guidelines

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

CAC/GL 21 - 1997

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.

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

Latest Codex MC guidelines

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

CAC/GL 21 - 1997

1. INTRODUCTION

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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Latest Codex MC guidelines

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CAC/GL 21 - 1997

1. INTRODUCTION

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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Summary: MCs in public and private contexts

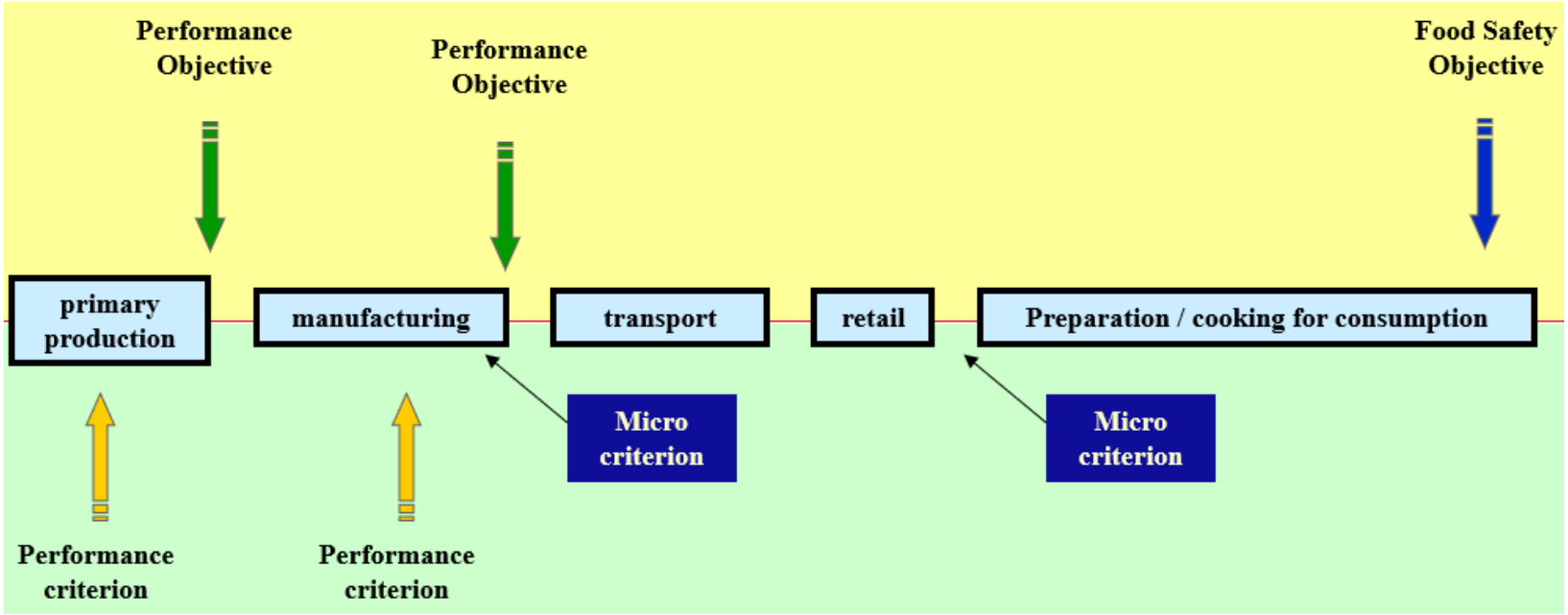
Public

- **Codex Alimentarius** recommends MCs at the international level. JEMRA (through FAO/WHO) provides science, i.e.:
  - The risk assessment to inform Codex risk-managers;
  - Guidance for stakeholders on establishing Microbiological Criteria.

- **National and local governments**
  - National governments may choose to adopt Codex MCs into their national Food Law/Regulatory systems.
  - National governments also may establish and apply their own MC, best on a sound science approach.

Private

- **Food Businesses**
  - Food business operators may establish and apply MCs within the context of their food safety control systems.



Conclusions

For more information, see www.icmsf.org

- The latest Codex guidelines and standards advocate use of MCs as a genuinely risk-based tool
- An MC should be established only when necessary and its stringency should be appropriate for its intended purpose
- The suitability of an MC should be reviewed in a timely way