FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

Ministry of Health and Family Welfare, Government of India

Microbiological Criteria

International situation (Codex)

and ICMSF advice for commodities

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Codex Alimentarius

- Brief introduction to Codex Alimentarius
- Microbiological Criteria Guideline
  - Issued 1997, updated 2012/2013
  - Used by Codex in standards
  - Key principles
  - Key practices

Microbiological Criteria (MC)

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

- the food to which the criterion applies;
- the point in the food chain where the criterion applies;
- the microorganisms of concern and/or their toxins/metabolites and the reason for that concern;
- the analytical method for their detection and/or quantification;
- a plan defining the number of field samples to be taken and the size of the analytical unit;
- microbiological limits considered appropriate to the food at the specified point in the food chain;
- the number of analytical units that should conform to these limits;
- actions to be taken when the criterion is not met.

Practice since 2007: A microbiological criterion states:

- *the performance of the sampling plan*

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

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

- Based on risk assessment inputs (JEMRA for microbiological risks)

- National authorities can choose to implement Codex standards and guidelines in their regulation/law – only then it becomes mandatory

Microbiological Criteria (MC)

2007 – now: Use of microbiological criteria and sampling plans by Codex in guidelines and standards/codes:

- 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)

  Annex II: Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (RTE Foods)

  http://www.codexalimentarius.net/download/standards/10740/CXG_061e.pdf

- Code of Hygienic Practice for powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)

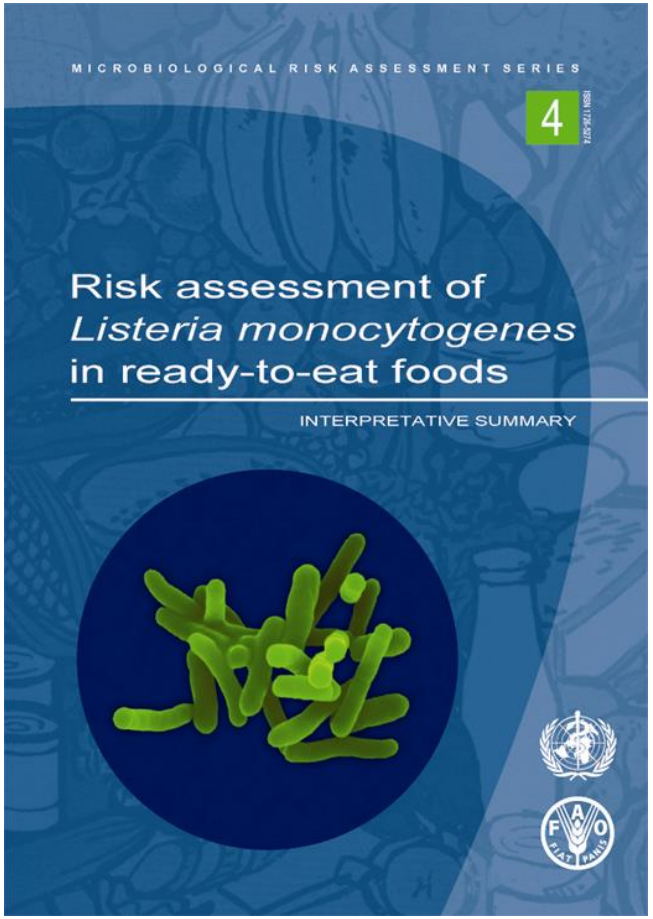
  Annex I: Microbiological criteria for Powdered Infant formula,…..

  Annex II: Microbiological criteria for follow-up formula,…..

  http://www.codexalimentarius.net/download/standards/11026/CXP_066e.pdf

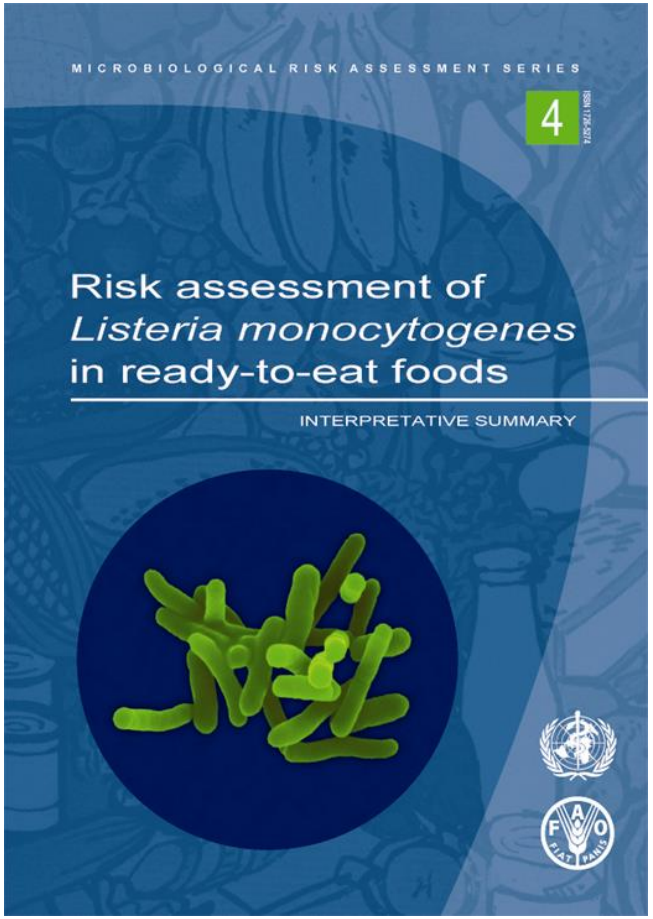
"*Listeria monocytogenes* in RTE food" MRA

- **Four model 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



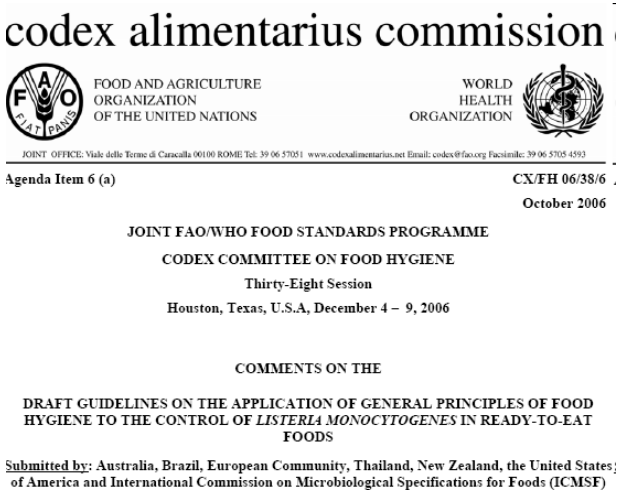
"*Listeria monocytogenes* in RTE food" MRA

- **Some insights:**
  - 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 result 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 the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods
(CAC/GL 61 – 2007)



codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6 (a) CX/FH 06/38/6

October 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-Eight Session

Houston, Texas, U.S.A, December 4 – 9, 2006

COMMENTS ON THE

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

Submitted by: Australia, Brazil, European Community, Thailand, New Zealand, the United States of America and International Commission on Microbiological Specifications for Foods (ICMSF)

- Annex II (Microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods)
  - Foods for which specific *L. monocytogenes* criteria are relevant:
    - foods not supporting growth of *L. monocytogenes,*
    - foods supporting growth of *L. monocytogenes*.

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* would very rarely be over 1000 CFU/g.
- Definitely generally unsafe levels occur very very infrequently ("defect" level considered in MRA was 10^6 *Lm* cfu/g)

Micro Criterion performance:

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

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.

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

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]

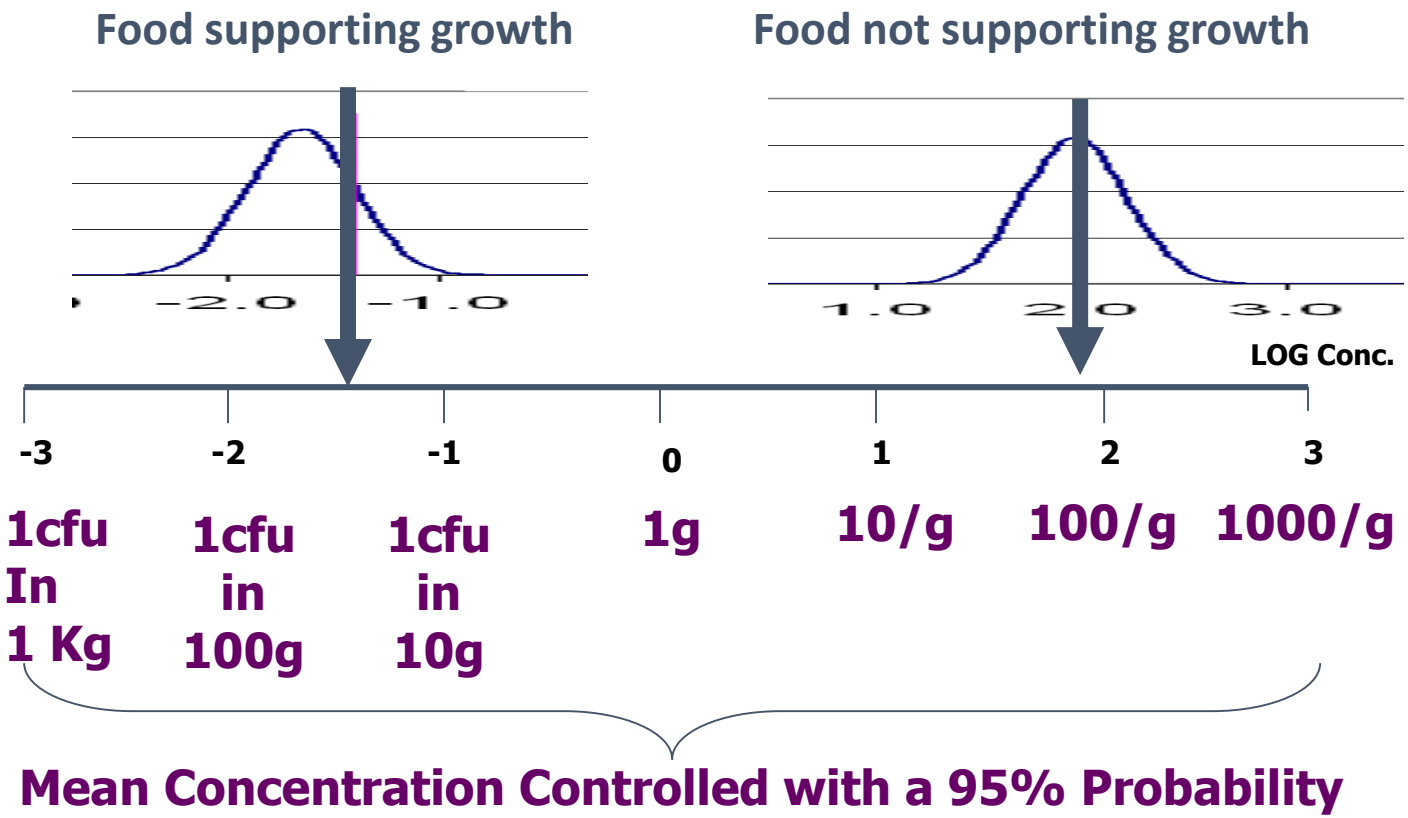
[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[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.

Listeria monocytogenes example



Criteria for pathogenic microorganisms

These are to be applied to the finished product (powder form) after primary packaging or anytime thereafter up to the point when the primary package is opened.

Microorganisms	n	c	m	Class Plan
Enterobacter sakazakii (Cronobacter species)*	30	0	0/10 g	2
*Salmonella***	60	0	0/25 g	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. m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality.

*The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

**The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%)[20].

The methods to be employed for *E. sakazakii(Cronobacter* species*)* and *Salmonella* should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

The criteria above are applied with the underlying assumption that the history of the lot is unknown, and the criteria are being used on a lot-by-lot basis. In those instances where the history of the product is known (e.g., the product is produced under a fully documented HACCP system), alternate sampling criteria involving between-lot process control testing may be feasible[21]. The typical action to be taken when there is a failure to meet the above criteria would be to (1) prevent the affected lot from being released for human consumption and (2) recall the product if it has been released for human consumption, and (3) determine and correct the root cause of the failure.

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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World Health Organization

http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/jp/

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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	✓	✓	✓	✓	⊘	⊘

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

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

Conclusions

For more information, see www.icmsf.org

- The latest Codex guidelines and standards advocate use of MC a more genuinely risk-based tool
- Should be established only when necessary and stringency should be appropriate to its intended purpose
- MC can be a very useful tool in public and private contexts
- Achieving MC should be evaluated as appropriate to the context
- Suitability of MC should be reviewed in a timely way

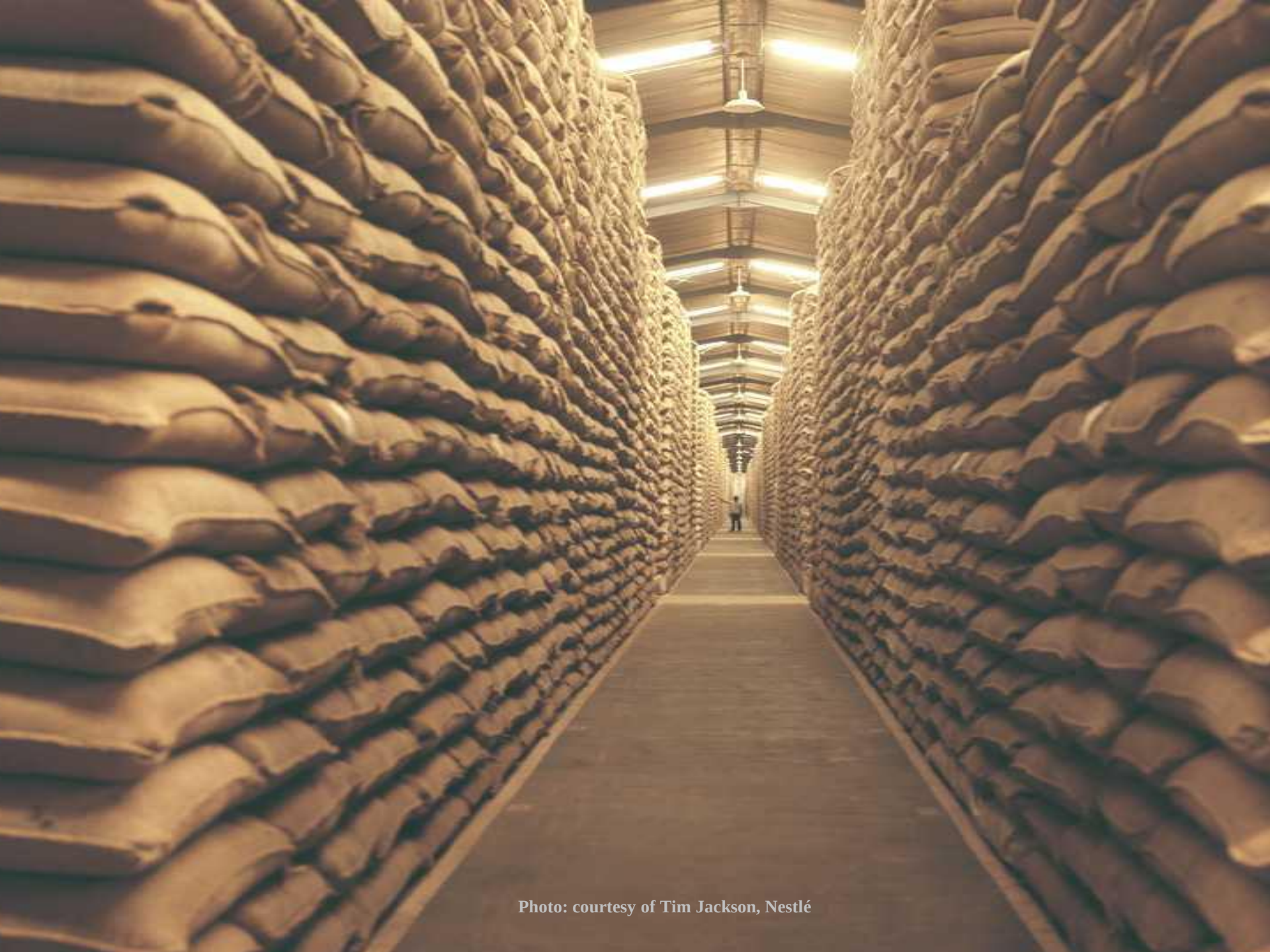


Photo: courtesy of Tim Jackson, Nestlé

List of MC components

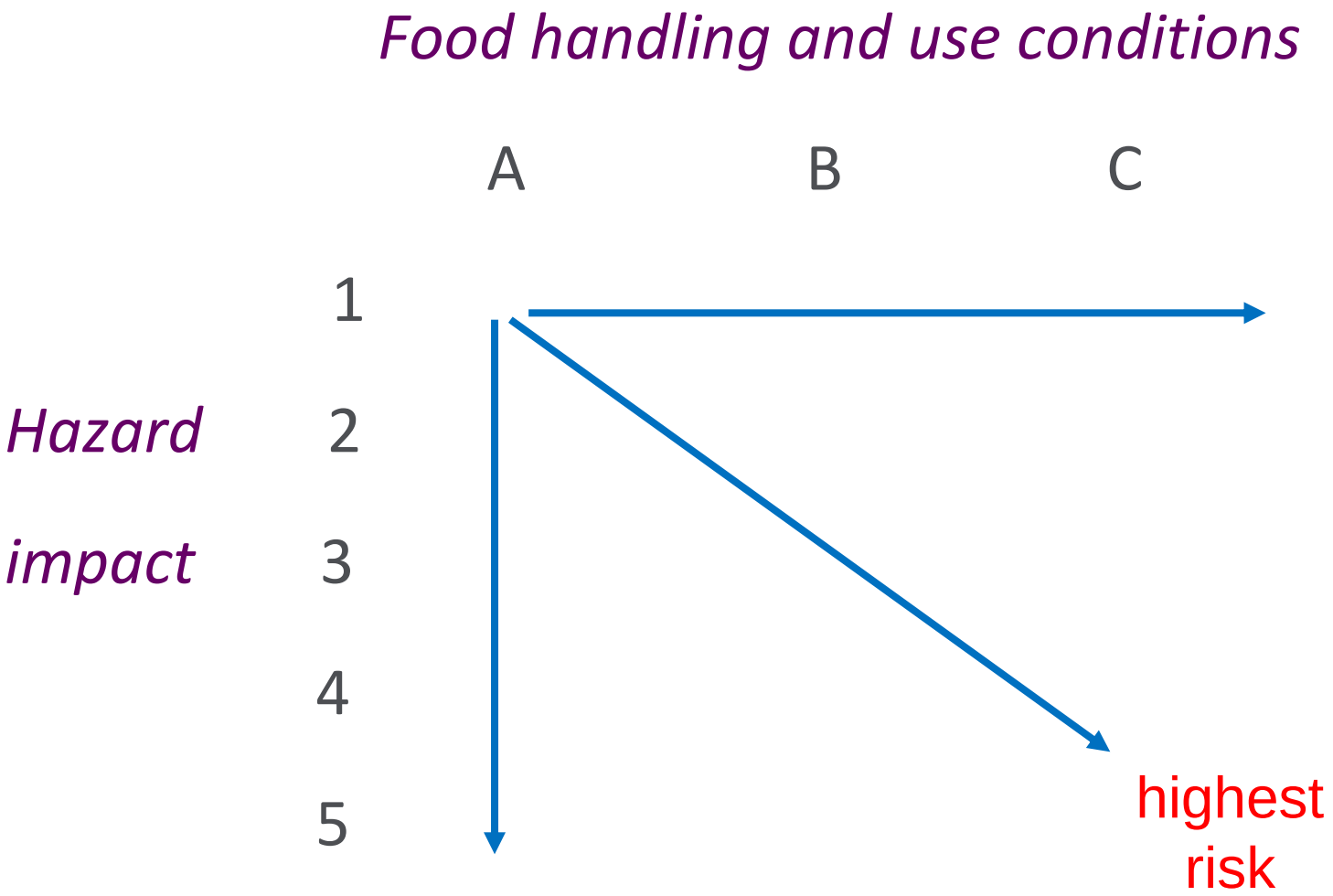
A MC consists of the following components:

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

ICMSF books


Book 1: Methods 1968
Book 2: Sampling Plans 1st ed 1974
Book 3: Microbial Ecology 1st ed 1980
Book 2: Sampling Plans 2nd Ed 1986
Book 4: HACCP 1988
Book 5: Pathogens 1996
Book 6: Microbial Ecology 1998
Book 7 MRM metrics/FSO 2002
Book 6: 2nd 2005
Book 8: Testing 2011
Book 7 2nd ed
1960
1970
1980
1990
2000
2010
2020
MICRO-ORGANISMS IN FOODS 1
Their significance and methods of enumeration
Second edition
ICMSF
MICRO-ORGANISMS IN FOODS 2
Sampling for microbiological analysis: Principles and specific applications
Second edition
ICMSF
MICROBIAL ECOLOGY OF FOODS
Volume 1
Factors Affecting Life and Death of Microorganisms
MICROBIAL ECOLOGY OF FOODS
Volume 2
Food Commodities
INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS
ICMSF
HACCP in Microbiological Safety and Quality
MICRO-ORGANISMS IN FOODS 5
MICROBIOLOGICAL SPECIFICATIONS OF FOOD PATHOGENS
MICRO-ORGANISMS IN FOODS 6
MICROBIAL ECOLOGY OF FOOD COMMODITIES
MICRO-ORGANISMS IN FOODS 7
MICROBIOLOGICAL TESTING IN FOOD SAFETY MANAGEMENT
Microorganisms in Foods 8
Use of Data for Assessing Process Control and Product Acceptance
Springer
微生物检验与食品安全控制
食品安全过程控制原理与实践

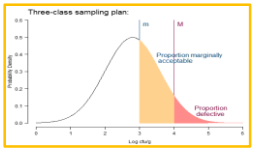
Risk Categorization Matrix

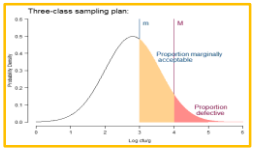


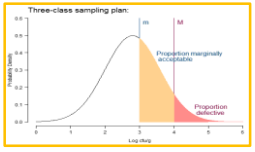
Relative performance values of ICMSF cases are illustrated in terms of the mean concentration that will be rejected with at least 95% probability, assuming hypothetical criteria and a standard deviation of 0.8. Calculations were performed with ICMSF Microbiological Sampling plan tool Version 2.08 (www.icmsf.org).

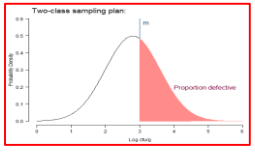
Analytical unit = 25g

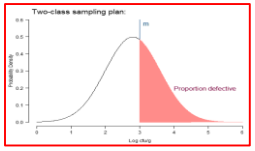
		Conditions under which food is expected to be handled and consumed after sampling in the usual course of events		
	Examples	**Reduce risk**	**No change in risk**	**May increase risk**
Utility	Aerobic colony count, yeasts and molds	Case 1 3-class: n = 5, c = 3, m = 1000/g, M= 10000/g **Mean conc.: 5105/g**	Case 2 3-class: n = 5, c = 2, m = 1000/g, M= 10000/g **Mean conc.: 3282/g**	Case 3 3-class: n = 5, c = 1, m = 1000/g, M= 10000/g **Mean conc.: 1829/g**
Indicator	Enterobacteriaceae, generic E. coli	Case 4 3-class: n = 5, c = 3, m = 100/g, M= 1000/g **Mean conc.: 511/g**	Case 5 3-class: n = 5, c = 2, m = 100/g, M= 10000/g **Mean conc.: 328/g**	Case 6 3-class: n = 5, c = 1, m = 100/g, M= 10000/g **Mean conc.: 183/g**
Moderate hazard	S. aureus, B. cereus, C. perfringens, V. parahaemolyticus	Case 7 3-class: n = 5, c = 2, m = 10/g, M= 100/g **Mean conc.: 33/g**	Case 8 3-class: n = 5, c = 1, m = 10/g, M= 100/g **Mean conc.: 18/g**	Case 9 3-class: n = 10, c = 1, m = 10/g, M= 100/g **Mean conc.: 6/g**
Serious hazard	Salmonella spp., L. monocytogenes	Case 10 2-class: n = 5, c = 0, m = 0/25g **Mean conc.: 1/55g**	Case 11 2-class: n = 10, c = 1, m = 0/25g **Mean conc.: 1/178g**	Case 12 2-class: n = 20, c = 1, m = 0/25g **Mean conc.: 1/495g**
Severe hazard	For the general population, E. coli O157:H7, C. botulinum neurotoxin; For restricted populations, Salmonella spp., Cronobacter spp.; L. monocytogenes	Case 10 2-class: n = 15, c = 0, m = 0/25g **Mean conc.: 1/328g**	Case 11 2-class: n = 30, c = 1, m = 0/25g **Mean conc.: 1/854g**	Case 12 2-class: n = 60, c = 1, m = 0/25g **Mean conc.: 1/2034g**





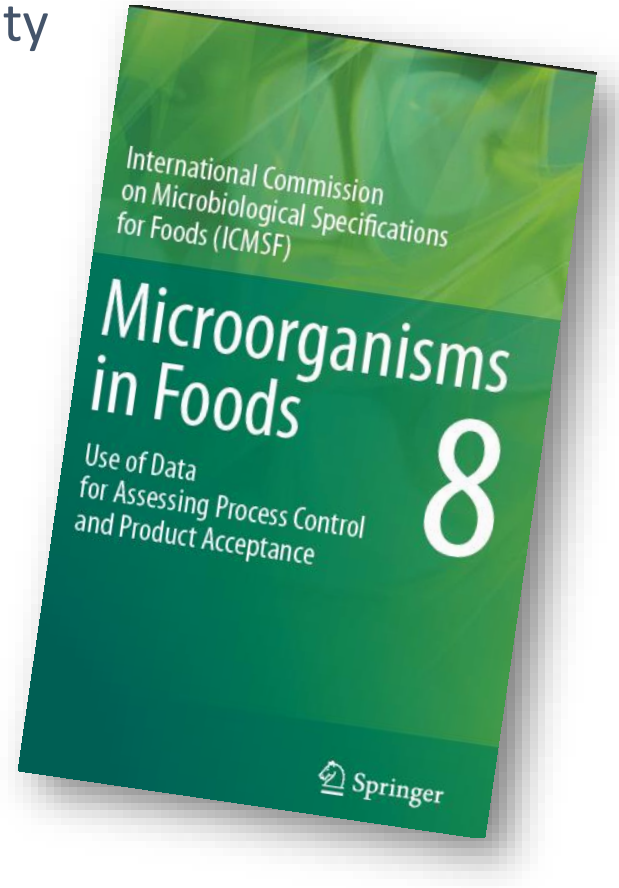






Book 8 – Part 1: Principles

- Utility of microbial testing for 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



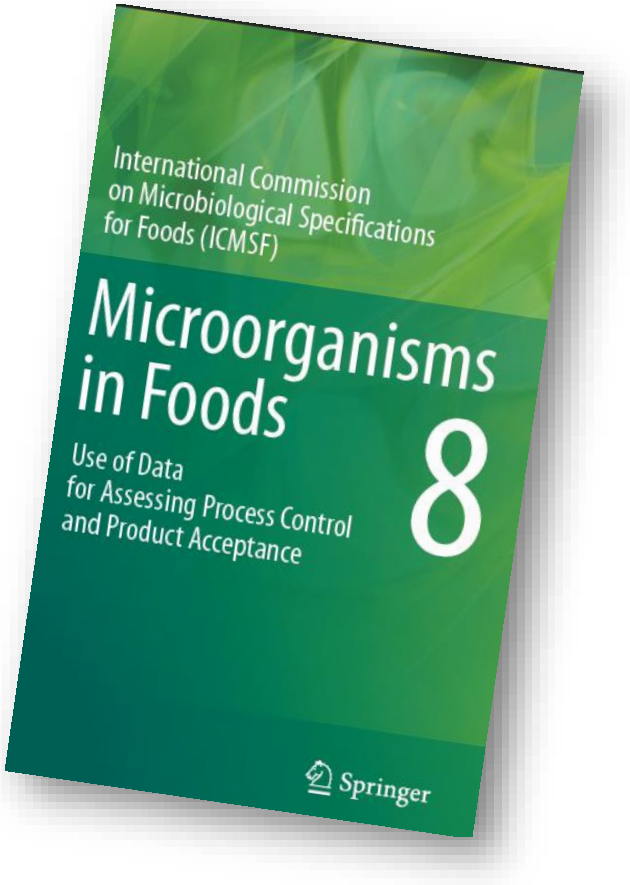
Book 8 – Part 2: Products

- Meats
- Poultry
- Seafood
- Feed & pet food
- Vegetables
- Fruits
- Spices, dried soups, flavorings
- Cereals
- Nuts, oilseeds, dried legumes
- Cocoa and confectionery
- Oil based foods
- Sugar, syrups, honey
- Beverages
- Water
- Dairy products
- Eggs
- Shelf stable, heat treated foods
- Dry foods for infants
- Combination foods




Testing Considerations

- Primary production
- Ingredients
- In-process
- Processing environment
- Shelf life
- End product



Primary Production

- Included when production conditions have a major influence on the microbial quality or safety
  - Fruits, vegetables, spices, meat, poultry and fish products

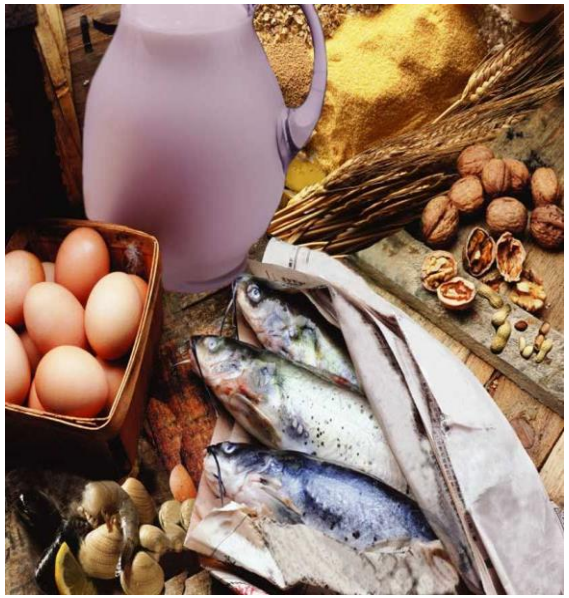
- Examples of samples to consider:
  - Irrigation water
  - Fertilizer
  - Feed
  - Other on-farm practices

E.g.: Agricultural Waters

Use	Impor-tance	Hazard or Indicator	Testing method / Analytical Unit	n	c	m	M
Irrigation, raw RTE	High	*E. coli*	ISO 9308-1 100 ml	3	1	10	10^2
Irrigation, cooked	Mediu m	*E. coli*	ISO 9308-1 100 ml	3	1	10^2	10^3
Pesticides, cleaning, etc.	High	*E. coli*	ISO 9308-1 100 ml	5	0	Absence in 100 ml	NA

Ingredient Testing

- May be useful for some applications and not others
- Example - cocoa powder:
  - ☑Dusted on chocolate, no heat treatment
  - ? Used in ice cream mix that is subsequently pasteurized
- Questions……..
  - Is control at the ingredient step necessary?
  - Is testing necessary to verify the acceptability of the ingredient?
- When yes, testing is recommended



In-Process Testing

- To verify a kill step or predict potential re-contamination
- Examples
  - Intermediate product, line residues, tailings, wash water.
  - Typically indicator organisms are monitored, giving quantitative results.
- Questions:……
  - Is the process needed to control a microbial concern?
  - Is there a location representing “loss of control”?
  - Is testing needed to verify:
    - that the process is functioning as intended or that
    - there is no contamination occurring in the process?
- When yes, testing is recommended

E.g. Chocolate Confectionary

Test	Impor-tance	Hazard or Indicator	Testing method	Typical limits encountered
Critical Ingredients: Cocoa powder, milk powder	High	• Salmonella	• ISO 6579	• absent
In-Process: cocoa powder product	Medium	• Salmonella • Enterobacteriaceae • ACC • Osmophilic yeasts and xerophilic moulds (a_w>0.6)	• ISO 6579 • ISO 21528-1 • ISO 4833 • ISO 21527-2	• absent • ≤10 cfu/g • FBO limits • ≤10 – 10^2 CFU/g
In Process: Product residues from contact surfaces	High	• Salmonella • Enterobacteriaceae • ACC	• ISO 6579 • ISO 21528-1 • ISO 4833	• absent • ≤10 cfu/g • FBO limits

Processing Environment Testing

- Use to verify that the environment is under appropriate hygienic control
- Examples
  - Swabs or sponges for equipment or in the environment
  - Rapid testing to verify cleaning & sanitation adequacy
- Considerations:
  - Identify harborage sites that can contaminate end product
  - Frequently, we can detect issues earlier than by end product testing and can take appropriate action
- Questions:…..
  - Does the environment need to be controlled to prevent contamination?
  - Will testing be beneficial to verify control?
- When yes, testing is recommended

E.g. Dried cereal products (ready to eat)

Test	Impor-tance	Hazard or Indicator	Testing method	Typical limits encountered
Process environment: line residues	High	Salmonella	ISO 6579	absent
Process environment: line residues	Medium	Enterobacteriaceae	ISO 21528-1	$\leq 10^2 - 10^3$ CFU/g

End-Product Testing

- Demonstrate successful application of controls or assess the status of a lot when no other information exists.
- Alternative sampling plans may be appropriate, for example:
  - Fewer samples for on-going surveillance activity
  - More samples when investigating significant process deviations or outbreaks.

- Questions considered:
  - Is end product testing necessary to verify the overall manufacturing process?
  - Is end product testing relied upon for ensuring the safety or quality of the lot?

E.g: Dried Cereal (Ready-to-Eat)

Relative importance		Useful testing							
End product	High	Testing for Enterobacteriaceae is recommended to verify process control (in addition to previously mentioned in-process and environmental testing)							
		Product	Microorganism	Analytical method	Sampling plan & limits/g				
					Case	n	c	m	M
		Dried Cereal	Enterobacteriaceae	ISO 21528-2	2	5	2	10	10^2
	Low	Testing for pathogens is not recommended during normal operation when GHP and HACCP are effective as confirmed by above tests. When above testing or process deviations indicate a possible safety issue, testing for Salmonella is recommended.							
		Product	Microorganism	Analytical method	Sampling plan & limits/25g*				
					Case	n	c	m	M
		Dried Cereal	*Salmonella*	ISO 6579	11	10[a]	0	0	NA

[a] individual 25g analytical units

E.g: Fresh cut vegetables (Ready-to-eat)

Relative importance		Useful testing							
End product	High	Routine microbiological testing is not recommended (Enterobacteriaceae, coliforms and fecal coliforms are part of the the normal microbiota of fresh cut produce produced under GAP) but periodic testing for specific indicators using internal standards or those below may be useful for verifying process control and trend analysis							
		Product	Microorganism	Analytical method	Sampling plan & limits/g				
					Case	n	c	m	M
		Fresh cut vegetables	*E. coli*	ISO 7251	6	5	1	10	10^2
	Low	Routine microbiological testing for pathogens is not recommended. Test for pathogens only when other data indicate potential for contamination.							
		Product	Microorganism	Analytical method	Sampling plan & limits/25g*				
					Case	n	c	m	M
		Fresh cut vegetables	*Salmonella*	ISO 6579	12	20[a]	0	0	NA
			E.coli O157:H7 (STEC)	ISO 16654 (ISO/TS 13136:2012)	15	60[a]	0	0	NA
			L. monocytogenes	ISO 11290-1	N/A	5[a]	0	0	NA

[a] individual 25g analytical units

Conclusions

For more information, see www.icmsf.org

- Testing safety “into” products usually does not work because of sampling probability
- Testing is recommended to generate meaningful data
  - Impact quality or safety
  - Verify appropriate controls or direct corrective action
- Focus on verification of process control preferred
  - Environmental monitoring
  - Selected sampling tailored to the line to verify control