Using the ICMSF Sampling Plan Tool to assess the performance of Microbiological Criteria

Part 1: MCs for *Listeria monocytogenes* in Ready to Eat Foods

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Global authority for international standards, codes of practice and guidelines on food safety

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

Outline

- The Codex Alimentarius standard for *Listeria monocytogenes* (*Lm*) in Foods
- Details of the Microbiological Criterion (MC) included in this Codex Standard for Ready-to-Eat (RTE) foods
- Comparison of control stringencies associated to the two MCs proposed for different groups of RTE foods

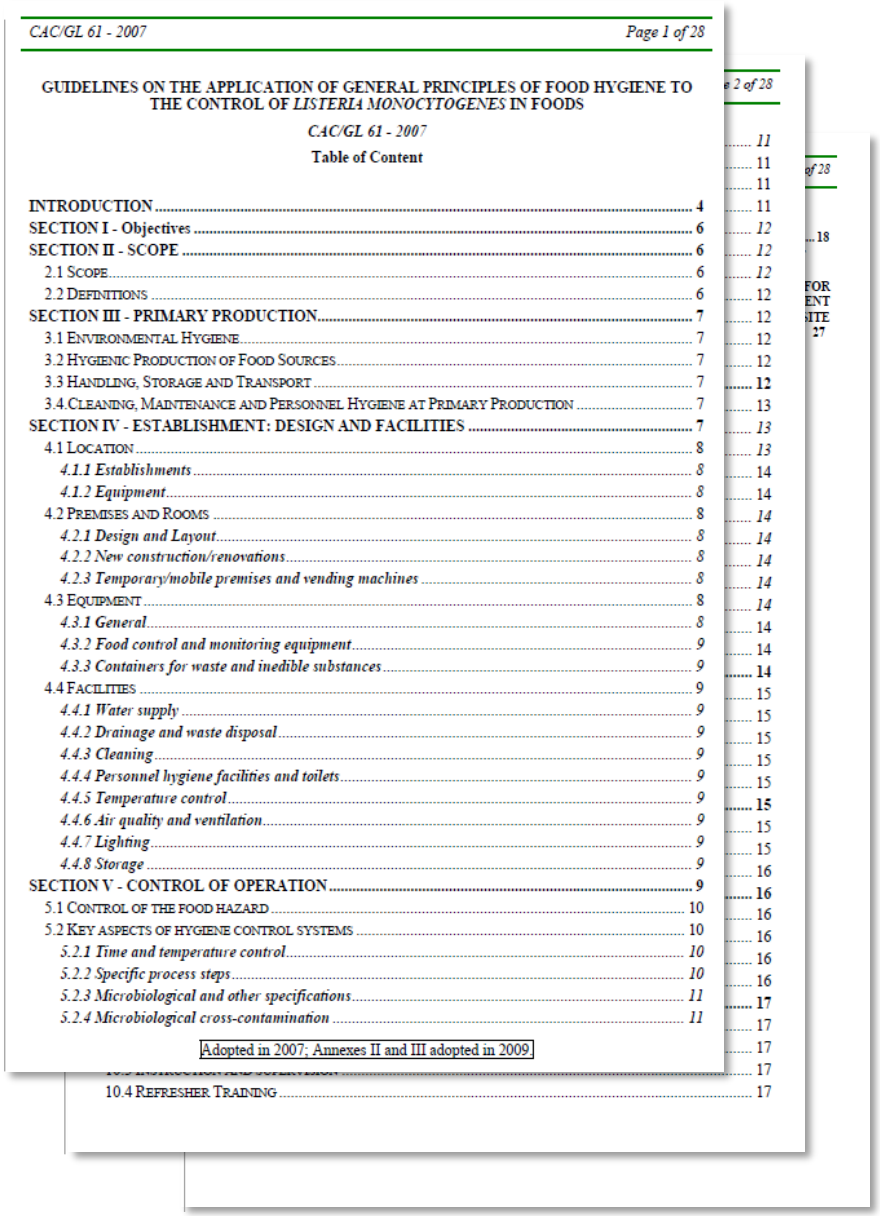
Note: Check the ICMSF playlist for clips showing how to use our Sampling plan tool to assess the performance of the sampling plans for this MCs

Lm = Listeria monocytogenes MC = Microbiological Criterion RTE = Ready to Eat

The Codex guideline

CAC/GL 61 – 2007

Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods



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

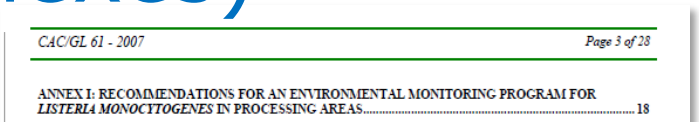
CAC/GL 61 - 2007

Table of Content

Adopted in 2007; Annexes II and III adopted in 2009

[1] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B61-2007%252FCXG_061e.pdf

The Codex guideline (Annexes)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ANNEX I: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING PROGRAM FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS..... 18

[1] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B61-2007%252FCXG_061e.pdf

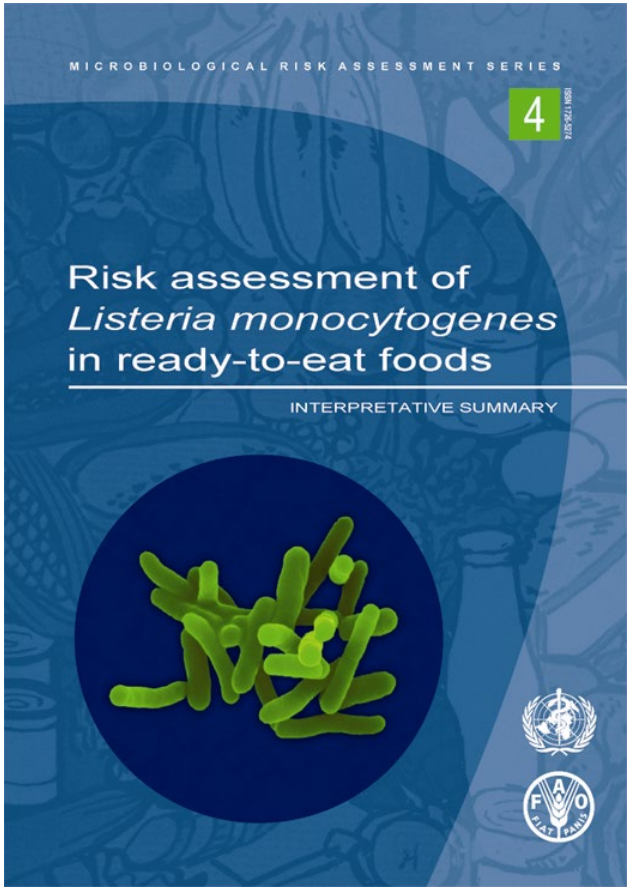
Microbiological Criterion (MC) concept

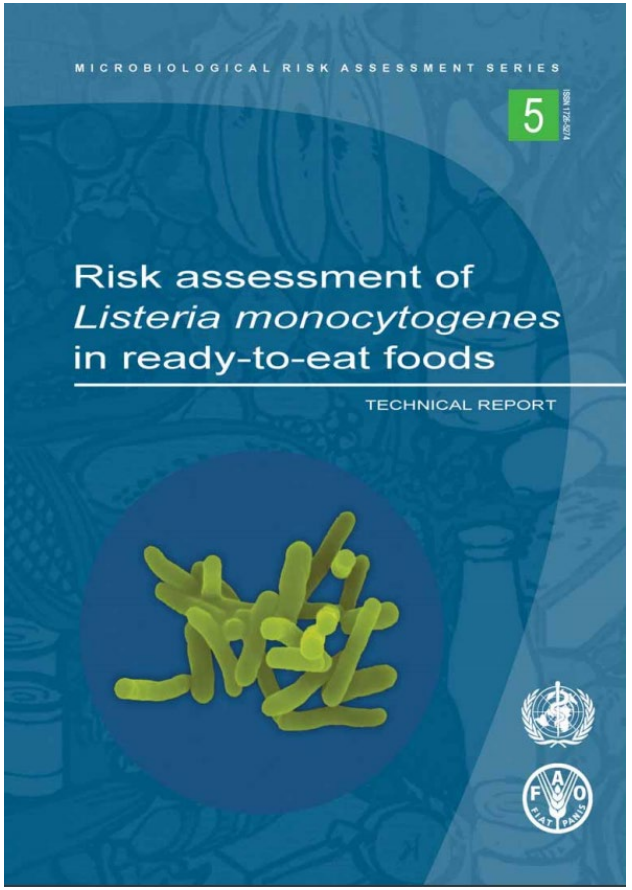
Ideally, a *MC consists of the following components* [1]*:*

- The food, process or food safety control system to which the MC applies;
- The specified point in the food chain where the MC applies;
- The microorganism(s) and the reason for its selection;
- The microbiological limits (*m*, *M*) or other limits (e.g. a level of risk);
- 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*);
- …., an indication of the statistical performance of the sampling plan;
- Analytical methods and their performance parameters;
- Actions to be taken when the criterion is not met

[1] CXG 21-1997: Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods

JEMRA Risk Assessment to inform Codex setting Microbiological Criterion

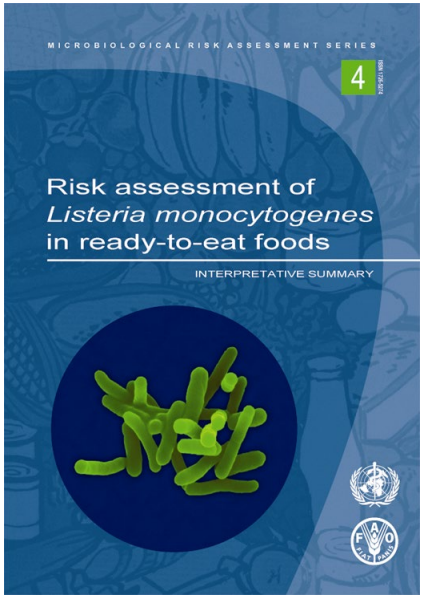




http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/listeria0/en/

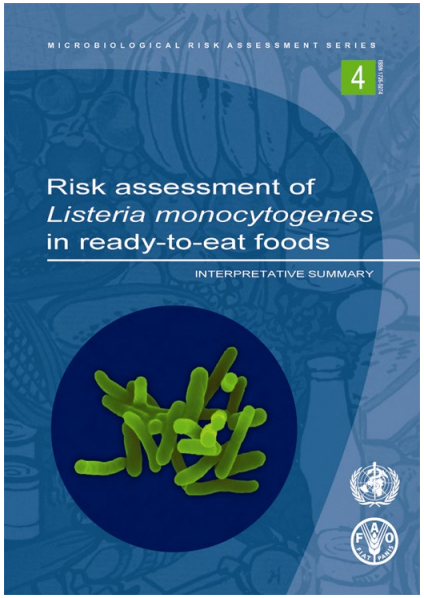
JEMRA Risk Assessment to inform Codex setting Microbiological Criterion

MRA considered four model RTE foods :



- Milk: pasteurized, low *Lm* level, supports *Lm* growth, very high consumption
- Ice-cream: *Lm* level low, as for milk, but does not support growth
- Fermented meat: frequently contaminated, no "Listeria kill step" during production, no growth (even some decrease), low consumption
- Cold smoked fish: as for fermented meat, but supports growth

JEMRA Risk Assessment to inform Codex setting Microbiological Criterion



Some insights:

1) Vast majority of listeriosis cases results from ingestion of very high numbers of pathogen cells

2) Consumption of low numbers of pathogen cells has a very low probability of causing illness for generally healthy consumers

3) RTE food products differ in
   a) the relative presence of the pathogen and
   b) their ability to support growth of the pathogen

JEMRA Risk Assessment to inform Codex setting Microbiological Criterion

Annex II: Microbiological Criteria for two RTE food types

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

MC: RTE foods **not supporting** Lm growth

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.

MC: RTE foods **not supporting** Lm growth

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

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Sampling plan

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Method

Performance

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Actions

MC: RTE foods **not supporting** Lm growth

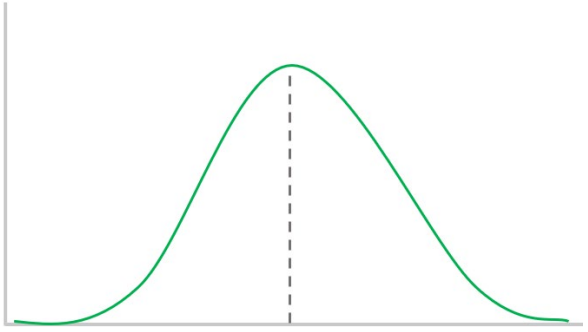
Rationale:

- There is a (low) level of *Lm* that can be considered as "tolerable" for generally healthy consumers
- Unsafe *Lm* levels for generally healthy consumers occur very, very infrequently
- Levels of *Lm* in RTE foods very rarely over 1000 CFU/g

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

Status of food lot just meeting MC:

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



MC: RTE foods **supporting** Lm growth

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.

MC: RTE foods **supporting** Lm growth

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Actions

MC: RTE foods **supporting** Lm growth

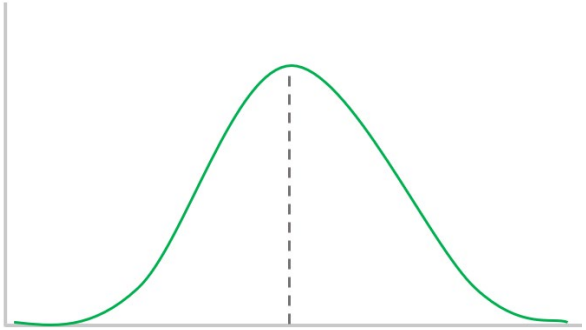
Rationale:

- Per default, *Lm* growth is not controlled
- A large safety margin is needed from *Lm* levels that are considered unsafe for generally healthy consumers

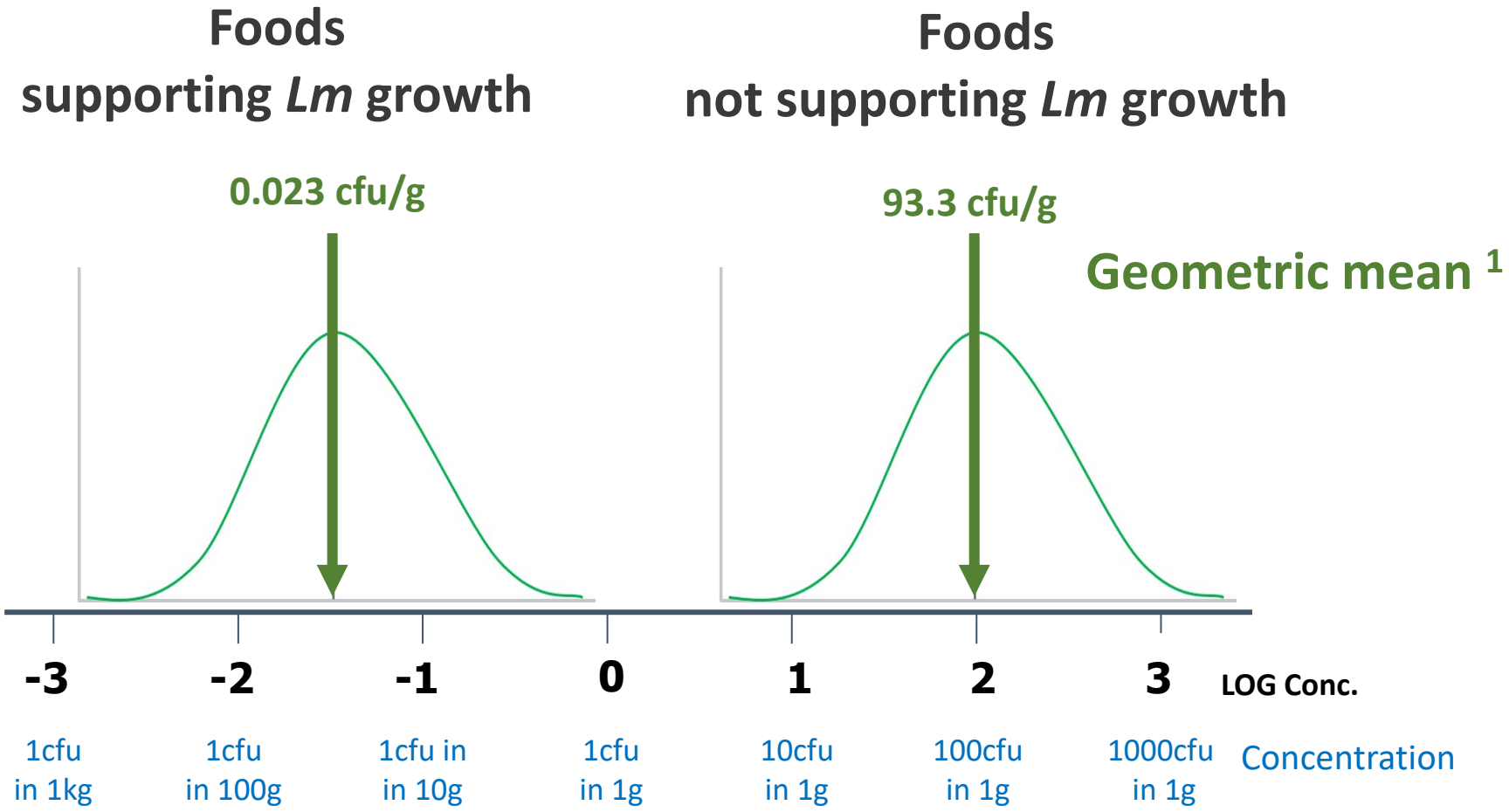
n	*c*	*m*	Class Plan
5 [a]	0	Absence in 25 g (< 0.04 cfu/g) [b]	2 [c]

Status of food lot just meeting MC:

- 55 % of samples ***negative*** for *Lm*
- 45 % of sample ***positive*** for *Lm*
- 0.5 % could be ***above*** 0.1 cfu/g

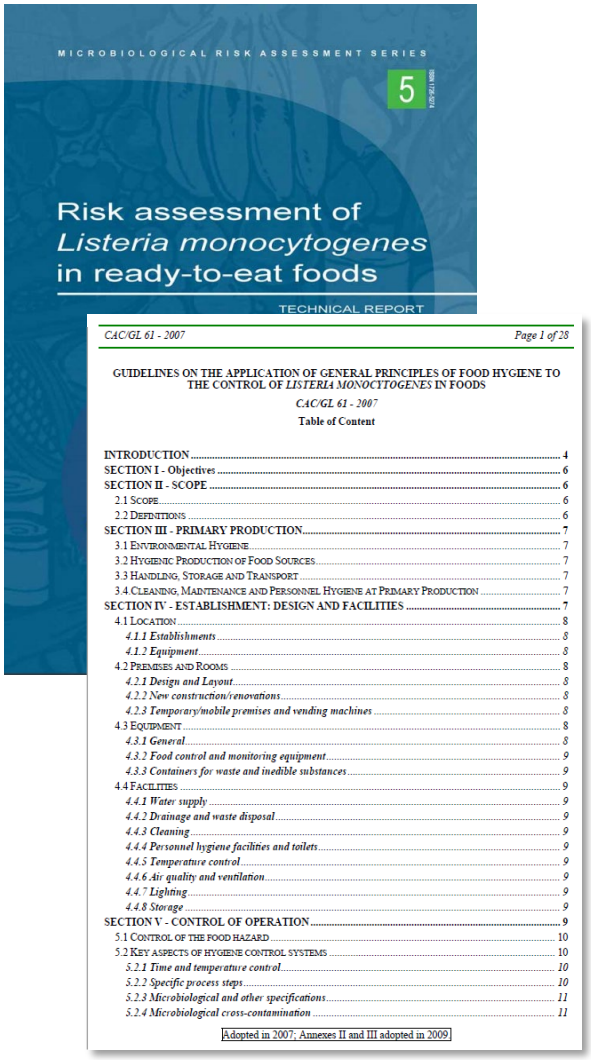


Comparing performance stringencies of the MCs



[1] assuming a Standard Deviation of 0.25 log cfu/g and a rejection confidence of 95%

Summary



- The Microbiological Criteria that Codex Alimentarius proposes for the control of *Listeria monocytogenes* in Ready-to-Eat Foods are risk-based
- Separate MCs, with stringencies proportional to the consumer risk, have been established for those foods that either **do** or that **do not** support growth of *L. monocytogenes*
- See our other clips to understand how the ICMSF Sampling plan tool can be used to assess and interpret the performance of these MCs

For more information, see www.icmsf.org