CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 5** **CX/FH 11/43/5**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD HYGIENE**

**Forty-third Session**

**Miami, United States of America, 5 - 9 December 2011**

# PROPOSED DRAFT REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS

**(At Step 3)**

Prepared by the Physical Working Group led by Finland and Japan

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Principles and Guidelines at Step 3 (*see* Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Ms Barbara McNiff, US Department of Agriculture, Food Safety and Inspection Service, US Codex Office, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720 3157, or email Barbara.McNiff@fsis.usda.gov with a copy **to**: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 October 2011.**

**Format for submitting comments:** In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

## Report of the physical working group on the

## Revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods*

1. The Physical Working Group (p-WG), co-chaired by Finland and Japan and hosted by the EU, met on 11 - 13 July 2011 in Grange, Ireland, with the attendance of delegates from Argentina, Australia, Belgium, Brazil, Canada, China, Denmark, European Union, Finland, France, Ireland, Japan, New Zealand, Norway, Poland, Spain, Switzerland, Sweden, Thailand, The Netherlands, United Kingdom and United States of America, respective representatives from FAO and WHO, and observers from ALA, CLIMTRAVI, ICMSF and IDF. A complete list of participants is given in Appendix II to this report.
2. The p-WG recalled that its mandate was to update the existing *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997). The p-WG was working with the following terms of references (see REP 11/FH, para. 124):

   - Further consider the main document taking into account the comments received before and during the current session;
   - Elaborate an Annex with practical examples on the establishment and application of MC for different purposes; and
   - Initiate the development of an Annex to address the statistical and mathematical aspect of elaborating.

3. A draft document was circulated for comments in advance of the meeting and comments submitted by Argentina, Australia, Canada, Columbia, Denmark, France, Japan, New Zealand, Spain and ICMSF were compiled in a document and distributed in advance to the p-WG members

4. The meeting took into account the compilation of comments and the written comments of the Netherlands and IDF, which were made available at the meeting.

5. The p-WG used as a starting point for its discussion the proposal of Japan, which took into account written comments, as included in the compilation document.

6. After a general discussion, the p-WG agreed that the Principles and Guidelines should be practical, easy to understand and to apply. It was agreed that the document should take into account already existing Codex texts. It was also agreed that assistance from FAO/WHO would be required for the elaboration of the Annex on statistical and mathematical considerations.

7. The p-WG considered in detail the draft proposal prepared by Japan taking into account all comments received prior to the meeting. In doing so, the p-WG took into account the specific recommendations of the 42nd CCFH (see REP 11/FH para. 121).

8. The key points brought forward in revising the document are summarised as follows:

The categorisation of the establishment of microbiological criteria

9. The p-WG agreed that MCs could be broadly categorized as GHP-based, hazard-based or risk-based. It was agreed that this categorization should be introduced at the beginning of Section Principles for Establishing and Applying Microbiological Criteria. The p-WG refined the proposal by illustrating the development of each category and gave examples of use of these microbiological criteria. As regards the third category (microbiological criteria based on risk) the p-WG came to the conclusion that this type of microbiological criteria can be used for example to verify that the PO is met or to show that the ALOP has been achieved. It was recognised that there is still little experience regarding the use of FSO.

10. Furthermore, it was decided that the procedure elaborated in the document should mainly focus on food and food processing environments. Consequently, the term “process” was deleted for clarity and only retained in the definition of MC.

Definition of a microbiological limit

11. The p-WG, while noting that no clear definition for a microbiological limit exists, found it necessary to better clarify the concept of a microbiological limit in the relevant subsection. It was generally agreed that a microbiological limit illustrates a value in one sample unit separating conforming from non-conforming units. Together with the sampling plan, the microbiological limit constitutes the core components of the microbiological criterion.

Markers of pathogenicity

12. The p-WG concluded that genetic markers or other traits might be useful as targets when applying microbiological criteria but should be used appropriately.

Adjusting the sampling plan

13. After some discussion, the p-WG agreed that as a general rule the number and size of analytical units should be those stated in the sampling plan. Only under special circumstances, such as food borne outbreak investigations, the sampling plan of a microbiological criterion could be modified. In such situations, the reason and justification for doing so should be clearly stated by the competent authority.

Trend analysis and moving windows

14. The p-WG added a paragraph on trend analysis to verify the production process under the heading Application of microbiological criteria.

15. The p-WG made a proposal to incorporate a paragraph on the concept of moving windows, as an alternative approach to the more traditional but limited application of a microbiological criterion to a specific lot at a defined point or period in time. The paragraph was put in square brackets for further consideration by the CCFH. The p-WG noted that New Zealand would provide additional language regarding moving windows in their written comments.

Establishing risk based microbiological criteria

16. On establishing risk-based microbiological criteria, the p-WG noted that the proposed text was overly discouraging. It was agreed that, although setting a risk based microbiological criterion is intellectually demanding, it does not necessarily require extensive mathematical modelling and computing power. The text was modified accordingly.

Pooling of samples

17. The p-WG noted that pooling is not a component of a microbiological criterion. Therefore, it was not included in the section of Components of Microbiological Criteria. However, the p-WG found it important to deal with this issue in the context of analytical methods as pooling might have influence on the sensitivity of the method. A separate paragraph on pooling of samples was elaborated and included in the section on analytical methods.

**Conclusions and recommendations**

18. The p-WG did not have time to consider the communication issue and the rearrangement/structure of the draft document. These issues could be considered by the 43rd CCFH.

19. In the section on Establishment of MC, the p-WG could not agree on whether ["Microbiological criteria is a risk management measure and as such should take into account available science, and developed using a structured and transparent approach" or "Microbiological criteria should be science-based, and developed using a structured and transparent approach"]. Therefore it agreed to include both proposals in square brackets for further consideration by the 43rd CCFH.

20. With regard to Annex I "Guidance on the establishment and application of microbiological criteria used for different purposes", the p-WG agreed that the practical examples regarding the application of microbiological criteria should be put into a separate Annex. A preliminary structure to this Annex was elaborated by the p-WG, and has been added to the end of the main document. The p-WG foresees that the completion of the Annex could be done in the future, pending the agreement of the CCFH on the proposed structure and scope of the examples, as presented in Annex I.

21. With regard to the Annex on statistical and mathematical considerations for elaborating MC, the p-WG recommended that CCFH requests FAO/WHO to provide technical support on the development of the Annex by addressing possible sampling plans for the implementation of various microbiological criteria. In particular, CCFH should consider the following terms of reference for such a request to FAO/WHO:

    i) Prepare a Call for Data and collect from appropriate sources any relevant guidance regarding sampling plans, approaches and paradigms that could be applicable for Annex on statistical and mathematical considerations for elaborating MC;

    ii) Convene an expert meeting to peer review the collected materials for the suitability of developing the Annex on statistical and mathematical considerations for elaborating MC; and

    iii) Prepare a report to be considered by CCFH for the elaboration of the Annex on statistical and mathematical considerations for elaborating MC.

22. The p-WG agreed to submit the draft document, as presented in Appendix 1 to this document, for consideration at the 43rd CCFH in December 2011.

**Appendix I**

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

(at Step 3)

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## INTRODUCTION

1. Diseases caused by food-borne pathogens constitute a major burden to consumers. As such, the prevention and control of these diseases have become international public health goals. These goals have traditionally been pursued, in part, through the establishment of metrics such as the microbiological criterion (MC), reflecting knowledge and experience of Good Hygienic Practice (GHP) and the impact of potential hazards on consumer health. MCs have been used for many years and have contributed to improving the food hygiene in general, even when established empirically**.** Advances in microbiological risk assessment (MRA) techniques, and the use of the risk management framework are increasingly making possible a more quantifiable estimation of the public health risk. This has led to a series of additional food safety risk management metrics such as Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC), (*see Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)). Where these metrics have been elaborated, they can allow the establishment of a direct relationship between microbiological criteria and public health outcomes.

2. The microbiological safety of foods is enhanced by the effective implementation of validated control measures often using MC throughout the food chain to minimise contamination and improve food safety. This preventive 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 an MC may be useful for verifying that food control systems are implemented correctly.

3. The required stringency of food safety control systems, including the microbiological criteria used, should be appropriate to protect the health of the consumer and ensure fair practices in food trade. The stringency should be based on risk where possible and the performance should be verifiable.

4. Codex Alimentarius has a role in establishing microbiological criteria at the international level. National governments can adopt Codex microbiological criteria into their national standard systems or use them as a starting point for addressing their intended public health goals. Industry also can establish and apply microbiological criteria within the context of their food safety control systems.

5. These document should be reading conjunction with the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007); and the *General Guidelines on Sampling* (CAC/GL 50-2004).

**SCOPE**

6. These Principles and Guidelines are intended to provide a framework for governments and industry on the establishment and application of microbiological criteria such as GHP-based, hazard-based and risk-based MC to be applied for food safety and other aspects of food hygiene.

**DEFINITIONS**

A ***microbiological criterion*** is a metric which can indicate the acceptability of a food, a food lot, a process or a food process environment at a specific point in the food chain following the outcome of sampling and testing for microorganisms, parasites and/or their toxins/metabolites.

Other definitions relevant to these guidelines include:

- ***Appropriate Level of Protection (ALOP)***[1,2]
- ***Food Safety Objective (FSO)***[3]
- ***Performance Objective (PO)***[3]
- ***Performance Criteria (PC)***[3]
- ***Lot***[4]
- ***Sample***[4]
- ***Food safety control system***[5]
- ***Validation***[5]
- ***Verification***[5]

**PURPOSES OF MICROBIOLOGICAL CRITERIA**

7. The design of the microbiological criterion will depend on its purpose. Different purposes of microbiological criteria include but are not limited to the following:

i) Evaluating a specific lot to determine its acceptance or rejection;

ii) Evaluating the acceptability of a lot on the basis of the estimated public health outcome;

iii) Validating critical limits under consideration for CCPs prior to the implementation or modification of a HACCP plan;

iv) Verifying the performance of HACCP systems and/or prerequisite programs;

v) Verifying the performance of different parts of a food safety control system;

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[1] *Guidelines for Food Import Control System* (CAC/GL 47-2003)
[2] *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)
[3] Codex Alimentarius Commission, Procedural Manual
[4] *General Guidelines on Sampling* (CAC/GL 50-2004)
[5] *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008)

vi) Communicating acceptance criteria between food business operators;

vii) Verifying the microbiological status of the primary production and processing environments, where applicable;

viii) Validating that the selected control measures are capable of meeting quantified metrics such as POs and/or FSOs; and

ix) Providing guidance to food business operators on levels which can be achieved when applying best practices.

## COMPONENTS OF MICROBIOLOGICAL CRITERIA

8. A microbiological criterion, depending on its purpose, should include the following components:

- The purpose of the microbiological criterion;
- The microorganism, parasite, toxins or metabolite and the reason for selection;
- Analytical methods and their performance parameters;
- The microbiological limit(s) considered appropriate to the food at the specified point(s) of the food chain;
- A sampling plan defining the number of samples to be taken and the size of the analytical unit;
- An indication of the statistical performance of the sampling plan;
- The food, process or environment to which the criterion applies;
- The point in the food chain where the criterion applies; and
- The action to be taken when the criterion is not met.

### Microbiological aspects of criteria

#### *Microorganisms, parasites, toxins, or metabolites and the reasons for selection*

9. For the purpose of this document these include but are not limited to:

- Bacteria, viruses, mould, yeasts, and algae;
- Parasitic protozoa and helminthes;
- Their toxins/metabolites; and
- Their markers associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. anti-microbial resistance genes), if applicable;

10. The microorganisms included in a microbiological criterion should be accepted as relevant - pathogens, indicator organisms or spoilage organisms of significance in relation to the stated purpose. Organisms whose significance is doubtful should not be included.

11. In general, where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms.

#### *Analytical Methods*

12. Whenever possible, only methods should be used for which the performance parameters have been statistically established in comparative or collaborative studies in several laboratories or by single laboratory validation according to an internationally recognized protocol. Preference should be given to methods which have been validated for the stated purpose in relation to reference methods. Although the methods used should be the most sensitive and reproducible for the purpose, in certain cases methods might sacrifice some degree of sensitivity and reproducibility in the interest of speed and simplicity.

13. Where MCs are mandatory i.e. standards written into national law or other governmental regulations and where the analytical method allows pooling of individual sample units before analysis, the procedure for pooling should ensure that the results of testing will not be affected compared to individually analysed

sample units.

***Microbiological limits***

14. The microbiological limits, *m* and *M*, define the level, expressed as absence/presence or concentration of the microorganism, parasites and/or toxins/metabolites in one analytical unit, which separates conforming from nonconforming units (*see General Guidelines on Sampling* (CAC/GL 50-2004)).

15. In case of a two-class plan, there is one microbiological limit, denoted by *m*, and there can be a certain number *c* (often 0), that is accepted above the limit.

16. For a three-class plan the microbiological limit *m* separates conforming from marginally conforming, and a limit *M* defines non-conforming samples. Here a certain number of samples, *c* (>0), with results between *m* and *M* are accepted.

17. The microbiological limits (*m* and *M*) are part of a sampling plan (*n*, *c*, *m*, *M*) that constitute part of a microbiological criterion.

18. In the establishment of microbiological limits in the context of microbiological criteria, any changes (e.g. decrease or increase in numbers) in the levels of the target microorganism, parasites or toxin/metabolite [and microflora] likely to occur after the point for which the microbiological criterion has been set should be taken into account. In establishing microbiological limits, it should be clearly stated the representativeness of that sample result whether the MC applies to every sample, or to the average, or to the proportion non-conforming.

***Sampling Plans***

19. Sampling plans should also take account of the actual or most likely distribution of microorganisms and the uncertainty and variability of the analytical procedures.

20. In the development and selection of sampling plans consideration should be given to the principles in the *General Guidelines on Sampling* (CAC/GL 50-2004).

21. The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. For a quantitative criterion, information (known, estimated, or assumed) about the underlying distribution of the microorganism, and especially its variability (e.g., standard deviation), is required to determine the stringency (probability of non-conformance) of the sampling plan. However, for presence/ absence test performance and validity can be characterized by assuming an underlying distribution (i.e., log normal) by estimating or assuming the presence or concentration above a threshold. In practice, sampling plan performance depends on the distribution of microorganisms as well as the performance characteristics of the analytical methods for detection and/or quantification (e.g., sensitivity and recovery rate).

22. [A moving window is a sampling approach which allows for the review of data over a moving period of time or defined number of sampling occasions. When the latest data are added, a similar amount of the oldest data is removed.]

23. The statistical performance of a sampling plan is usually illustrated by its operating characteristics (OC) curve (*see* CAC/GL 50-2004), which describes the probability of conformance as a function of the actual proportion of non-conforming units. OC curves can be used to evaluate the influence of individual parameters of the sampling plan on the overall performance of the plan.

24. Web-based tools for estimating the impact of sampling plans can be utilized to evaluate the performance of sampling plans under consideration.

**RELATIONSHIP BETWEEN MICROBIOLOGICAL CRITERIA AND OTHER MICROBIOLOGICAL RISK MANAGEMENT METRICS**

25. Where competent authorities have set an ALOP, FSO and/or a PO for pathogens with a demonstrated health concern regarding the context of these metrics, microbiological criteria could be used by competent authorities or food business operators to operationalise the PO. Where food business operators have established a PO, likewise, a microbiological criterion could be chosen as the operational metric.

26. In lot-by-lot testing the acceptability of a lot may be defined as the acceptable relative risk to public health of the lot as compared to the average risk of lots. This requires the use of quantitative risk assessment

and the use of mathematical modelling in order to estimate the relative risk. The risk estimation may include a combination of several risk factors such as prevalence, concentration of microorganisms, subtypes and antimicrobial resistance pattern. This approach allows direct estimation of the impact on the public health outcome.

27. If the food safety control system has been validated as being capable of meeting POs and PCs, microbiological criteria may not be needed. If used to verify that POs and PCs are being met, microbiological testing may be infrequent. The frequency with which sampling is conducted should be based on risk.

28. Deriving a risk based microbiological criterion directly from an ALOP and the need for other MRM metrics should be clearly articulated. This is important since developing risk based microbiological criteria can be a complex process that requires considerable effort, including a quantitative risk assessment and may require extensive mathematical modelling and computing power.

## PRINCIPLES FOR ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA

### General Considerations

***Establishment of microbiological criteria***

29. MCs are established based on the level of understanding of the microorganisms, parasites and/or their toxins/metabolites and their relationship to the food, process, process environment or the public health outcome. Therefore MCs can be broadly categorized as GHP-based, hazard-based or risk-based.

- **Good hygienic practice (GHP)-based.** They are generally developed from empirical scientific knowledge and experience and relate to food hygiene. They are for example used for verification that hygienic conditions have been applied
- **Hazard-based**. They are developed from scientific knowledge of a likely level of control of a microbiological hazard at a step or series of steps in a food chain and can be validated as to their efficacy in hazard control. There is an expectation of consumer protection but the actual degree of protection will be unknown. They are for example used for the verification of the performance of HACCP systems and for lot-by-lot acceptance.
- **Risk-based**: They are developed from risk assessment or other information on risk e.g. surveillance data, on the basis of specific knowledge of the likely levels of consumer protection that will result. They have a quantitative base and should be able to be validated against a level of consumer protection**.** They can for example be used for verification that a PO has been met or by the use of an appropriate risk assessment model to show that the ALOP has been achieved.

30. The effective use of a microbiological criterion is dependent on the selection of a sampling plan based on the above parameters to establish the appropriate level of stringency. Since the levels/prevalence of a microorganism, parasite or their toxins/metabolites can change over the course of manufacture, distribution, storage, marketing and preparation, a microbiological criterion is generally established at a specified point in the food chain and that particular microbiological criterion may not be pertinent at other points. Underlying a microbiological criterion should be a transparent articulation of the pre-determined limit and the rationale for the sampling plan chosen.

31. [MC is a risk management measure and as such should take into account available science, and developed using a structured and transparent approach. / MC should be science-based and developed using a structured and transparent approach.]. A MC should be established only when there is a need and when it can be shown to be effective and practical for the stated purpose and set at a level that is not more trade restrictive than required to achieve an importing member's ALOP.

32. MCs for pathogens should be developed, where data are available, based on the outcomes of microbiological risk assessment adhering to appropriate risk management and risk communication processes (see *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)).

33. To fulfil the establishment of a MC, some considerations are common to food and the food processing environment. These considerations include, but are not limited to:

- Target microorganisms, parasites or their toxins/metabolites;

- Analytical methods;
- Sampling tools and techniques;
- Sampling locations and sampling plan;
- Frequency of sampling;
- Action to be taken when the criteria is not met; and
- Record keeping.

34. In addition, for microbiological criteria for a food, consideration should be given to:

- The intended use of the food;
- The evidence of actual or potential hazards to health;
- The microbiological status of the raw material(s);
- The effect of processing on the microbiological status of the food;
- The likelihood and consequences of microbial contamination and/or growth and inactivation during subsequent handling, storage, preparation and use;
- The consumers concerned, including relevant vulnerable sub-populations, and consumption habits;
- The cost/benefit ratio associated with the application of the criterion; and
- The likelihood of detection.

35. In addition, for MCs for a process environment, consideration should be given to:

- Type of product and process/operation;
- Type of samples; and
- Timing of sampling.

***Application of microbiological criteria***

36. In the governmental context, MCs may be established to enable verification of compliance to an FSO, a PO or PC set by competent authorities.

37. Mandatory MCs (i.e. standards written into national law or other governmental regulations) should apply to those products and/or points of the food chain where no other effective tools are available, and where they are expected to improve the degree of protection offered to the consumer. Where these are appropriate they should be product-type specific and only applied at the point of the food chain as specified in the regulation.

38. In situations of non-conformance with MCs, corrective actions should relate to the purpose of the testing. Corrective actions undertaken as a response to non-conformity to MC relating to pathogens should be based on an assessment of the risk to the consumer, the point in the food chain and the product-type specified and may consider history of conformance. These may include sorting, reprocessing, withdrawal and/or recall, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken.

39. MCs may also be applied by food business operators to formulate design requirements and to examine end-products as one of the measures to validate and/or verify the efficacy of the HACCP plan. MCs may be applied in environmental monitoring to verify the efficacy of prerequisite programs.

40. The use of trend analyses on routine testing results should be considered by the food business operator and by the competent authority for verification purposes, e.g. to see if the observed results are related to a transient or recurrent change in normal conditions.

41. The number and size of analytical units should be those stated in the sampling plan and should not be modified where the criterion has been established for regulatory compliance. However, there may be unusual situations in which sample numbers (or sample frequency) may be modified; e.g., during a foodborne outbreak investigation or when a food business operator wishes to increase the likelihood of detecting contaminated lots before placing them on the market. The rules and procedures for switching from one sampling plan to another should be clearly stated in the sampling approach. A lot should not be subjected to repeat testing for the same MC.

**DOCUMENTATION AND RECORD KEEPING**

42. Documentation and records are essential to support the microbiological criteria, e.g. documentation on scientific evidence underpinning the microbiological criteria, records on application/ performance of the microbiological criteria. Records such as test reports should give the information needed for complete identification of the sample, the sampling plan, the test method, the results and, if appropriate, their interpretation. Reporting against the microbiological criteria may be required by some National Governments. *See* also Section 5.7 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 2.3.7 of the *General Guidelines on Sampling* (CAC/GL50-2004).

**REVIEW AND REVISION**

43. As establishing and implementing MC is a part of MRM activities, refer to the section 8.2 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007). In addition, revision of Microbiological Criteria should occur in response to revision of Microbiological Risk Management Metrics and also in response to change in the following:

- Change in prevalence of pathogens/toxins;
- Trait of microorganisms (e.g. anti-microbial resistance, virulence);
- The suitability of indicator organism;
- Analytical methods/tests;
- Technology /process of food production/ food safety control system;
- Sensitivity of subpopulation;
- Changes in dietary intake pattern of food concerned; and
- Trend analysis results.

44. A review of Microbiological Criteria may be initiated and carried out by national governments and/or food businesses. Codex members may propose review of microbiological criteria in Codex texts.

45. The risk management framework should be used to continuously improve, refine and adjust the component parts of the MC in relation to improved scientific knowledge and the increasing knowledge of public health risk and related food safety risk management metrics (FSO, PO, and PC). The goal should ultimately be to achieve a more quantifiable estimation of the linkages between microbiological criteria, other metrics and public health outcomes.

46. A review of microbiological criteria should be considered in response to changes or emerging issues in:

- A food safety control system
- The prevalence or distribution or changing trends in the results of testing for selected pathogen or indicator organisms;
- The incidence of disease;
- The suitability of indicator organism;
- A food/ingredients;
- A technology /process;

- Available analytical methods/appropriateness of test (viable/viable non- culturable/dead);
- A trait of microorganisms (pathogen/non-pathogen), e.g. anti-microbial resistance;
- Consumer behaviour and population dietary intake patterns;
- Trend analysis;
- Population, especially a high risk subpopulation; and/or
- Understanding/knowledge of risk.

47. Trend analysis includes a system to record, review and analyze laboratory results and routine testing results on a regular basis.

48. In a review and in response to an emerging issue, the following should be considered:

- Food safety control system;
- Whether it is with new and/or known pathogen/toxins/metabolites;
- Food;
- A technology /process;
- Problems with analytical methods/test;
- Population, especially a high risk subpopulation;
- Understanding/knowledge of risk; and/or
- Trend analysis results.

49. Review should include a system to record the data and their evaluation, e.g. performing trend analyses. A long-term review of the data is important to revise and adjust the review program. It can also reveal adverse trends or low-level intermittent issues.

## ANNEX 1 - GUIDANCE ON THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA USED FOR DIFFERENT PURPOSES

*(for further development)*

1. This Annex contains examples of several approaches to applying MC. All of the examples described below are for purposes of illustration only, do not represent actual scenarios in a global sense and should not be replicated as presented. Also, the examples below are presented in a specific format only for consistency and this format is not intended to be a general model for application of MC.

2. The following six examples provide a representative demonstration of implementing MC for different purposes. These examples will follow the following structure:

- *Purpose (what is intended to be achieved);*

- *Who should establish and who should apply;*

- *Food or food process environment; Point in food chain where the MC is applied;*

- *Sampling plan (# of samples, sample size/units, sampling approach);*

- *Organisms of concern;*

- *Method(s) of analysis;*

- *Interpretation of results; and*

- *(Nature of) actions in case of non-compliance.*

Example 1 *Title to be decided*

*Purpose* a GHP-based approach is needed

Example 2 *Title to be decided*

*Purpose* MC is established for food to assess the acceptability of a food lot

Example 3 *Title to be decided*

*Purpose* MC is established to verify the processing environment under a HACCP system for a hazard-based approach

Example 4 *Title to be decided*

*Purpose* MC is established for the food to verify the performance of a HACCP system

Example 5 *Title to be decided*

*Purpose* MC is established for a food high prevalence pathogen for a risk-based approach

Example 6 *Title to be decided*

*Purpose* Operationalising a PO with an MC for a risk-based approach

## Appendix II

**List of participants**

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Annex

## GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in underlined/bold font and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.