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 Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-third Session

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COMMENTS ON

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

(At Step 3)

Comments Submitted By

Argentina, Australia, Brazil, Colombia, Costa Rica, Egypt, Jamaica, Japan, Kenya, Mexico, New Zealand, Peru, Philippines, Senegal, Uruguay, United States of America, Latin American Poultry Association (ALA), International Commission on Microbiological Specifications for Foods (ICMSF), International Dairy Federation (IDF), International Poultry Council (IPC)

ARGENTINA

Argentina appreciates the opportunity to provide the following comments BASED ON THE SPANISH VERSION OF THE DOCUMENT.

General Comments

Argentina believes that the development of the document is extensive and only specific changes to certain parts of the text will be proposed.

However, it should be noted that the use of terminology should be consistent throughout the text, switching the term “GERMS” by the term “MICROORGANISMS” in the ENTIRE text, since the latter is more widely used and is more current than the former.

Specific Comments

In PARAGRAPH 1, page 4, Argentina suggests that the word “mostrando” (showing/reflecting) be replaced with the word “reflejando” (reflecting) for a better understanding of the text. This change does not apply to the English version of the document, in which the word "reflecting" is already used. Specifically:

1. Las enfermedades causadas por gérmenes patógenos transmitidos por los alimentos constituyen una importante carga para los consumidores. Como tales, la prevención y el control de estas enfermedades se han convertido en objetivos internacionales de salud pública. El logro de estos objetivos se ha buscado tradicionalmente, en parte, a través del establecimiento de parámetros tales como el criterio microbiológico (CM), ~~mostrando~~ reflejando conocimiento y experiencia de las buenas prácticas de higiene (BPH) y el impacto de los posibles peligros en la salud del consumidor. […]

In PARAGRAPH 3, page 5, Argentina believes that the term “prácticas equitativas” is not appropriate and considers that it should be replaced with “prácticas leales” (fair practices). This change applies to the Spanish version of the document only.

3. El rigor requerido de los sistemas de control de la inocuidad de los alimentos, incluidos los criterios microbiológicos usados, debería ser adecuado para proteger la salud del consumidor y asegurar las prácticas ~~equitativas en el~~ leales de comercio de los alimentos. El rigor debería basarse en el riesgo cuando sea posible, y el funcionamiento debería ser verificable.

In the section on DEFINITIONS, page 5, an addition is proposed for the definition of MICROBIOLOGICAL CRITERION so that it considers food lots. Specifically:

A *microbiological criterion* is a parameter that indicates the acceptability of a food, a food lot, a process, or a food processing environment at a specific point of the food chain after obtaining sampling results and testing for the detection of microorganisms, parasites and/or their toxins or metabolites.

In PARAGRAPH 7, bullet point 9, Argentina proposes to specify that the concept of "levels" refers to microorganisms by adding the word "microbiological".

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

In PARAGRAPH 8, bullet point 6, the term "funcionamiento" should be replaced with the term "RENDIMIENTO" (performance) for a more specific technical reference associated to the text in the bullet point. This change applies to the Spanish version of the document only.

8. Dependiendo de su finalidad, un criterio microbiológico debería incluir los siguientes componentes:

- […]
- Una indicación del ~~funcionamiento~~ rendimiento estadístico del plan de muestreo;
- […]

In PARAGRAPH 18, Argentina considers that it is not appropriate to mention MICROFLORA within the scope of this document, so the term should be removed from the text.

In PARAGRAPH 19, Argentina considers that the text should be reorganized for a better interpretation. This does not apply to the English version. Specifically:

19. Los planes de muestreo también deberían tomar en cuenta la distribución real o más probable de microorganismos ~~real o más probable~~ y la incertidumbre y la variabilidad de los procedimientos analíticos.

In PARAGRAPH 21, Argentina believes that the text should be reorganized for a better interpretation. This does not apply to the English version. Specifically:

El tipo de plan de muestreo seleccionado para el criterio microbiológico dependerá de la naturaleza y finalidad del criterio microbiológico. En el caso de un criterio cuantitativo, se necesita información (conocida, estimada o supuesta) sobre la distribución subyacente del microorganismo, y especialmente su variabilidad (p. ej., desviación estándar), para determinar el rigor (probabilidad de la no conformidad) del plan de muestreo. No obstante, ~~para verificar la presencia o ausencia, la validez y el rendimiento del ensayo~~ para los ensayos de presencia/ausencia, la validez y rendimiento pueden caracterizarse suponiendo una distribución subyacente (esto es, lognormal) calculando o suponiendo la presencia o concentración por encima de un umbral. En la práctica, el rendimiento del plan de muestreo depende de la distribución de microorganismos, así como las características de los métodos analíticos de detección y/o cuantificación (p. ej., tasa de recuperación y sensibilidad).

The meaning of the term "MOVING WINDOW" in PARAGRAPH 22 is not clear to Argentina. We therefore request further clarification for its understanding.

In PARAGRAPH 27 there is a typographical error: the words "de la inocuidad" are repeated as follows:

27. If the food safety control system has been validated as being capable of meeting POs and PCs, microbiological criteria may not be needed. Si se usan para verificar que se está cumpliendo con los OR y CR, es posible que los ensayos microbiológicos no tengan que ser muy frecuentes. La frecuencia con la que se efectúa el muestreo debería basarse en el riesgo.

In PARAGRAPH 29, bullet point 1, Argentina believers that the use of MC based on GHP is useful for verifying the application of good hygienic practices rather than verifying hygienic conditions themselves. In this sense, the following change is proposed:

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~~ appropriate processing hygiene practices have been applied.

In PARAGRAPH 31, Argentina believes that the most appropriate term of those mentioned in square brackets is "MC should be science-based and developed using a structured and transparent approach." Therefore, the text should read as follows:

31. MCs should be science-based and developed using a structured and transparent approach. […]

In PARAGRAPH 33, in the main text, there is a word missing in the Spanish version (con); adding it would result in changing the word "fulfil" for the term "comply with" in English. Additionally, Argentina suggests that the last bullet point be removed, since record keeping is discussed later in the text.

Specifically, we suggest:

33. To ~~fulfil~~ comply with 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.~~

In PARAGRAPH 34, bullet point 3, Argentina believes that the term MICROBIOLOGICAL STATUS is not appropriate and thus suggests that it be replaced with MICROBIOLOGICAL LEVEL, which is a widely-known term. Specifically:

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~~ level of the raw material(s);
- […]

In PARAGRAPH 44, Argentina suggests that the word “examen” be replaced with “REVISION” (review). This change only affects the Spanish version of the document.

44. Los gobiernos nacionales y las empresas del sector alimentario pueden comenzar y llevar a cabo una ~~examen~~ revisión de los criterios microbiológicos. Los miembros del Codex podrán proponer ~~el examen~~ la revisión de los criterios microbiológicos presentes en los textos del Codex.

In PARAGRAPH 47, Argentina suggests that the text be removed from here and be merged with that of PARAGRAPH 49, as shown below:

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

[…]

49. Review should include a system to record the data and their evaluation, e.g. performing trend analyses, which includes a system to record, review and analyze laboratory results and routine testing results on a regular basis. 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.

AUSTRALIA

General Comments

Australia welcomes the opportunity to comment on the latest draft of this paper. We note that some structural changes and content changes have been made since the last version of the paper. However, we suggest the structure could be improved by reordering the text to aid in the readability and flow and also bring this document into alignment with other CCFH Principles and Guideline texts.

Australia suggests that the structure of the document should be as follows:

1. Introduction
2. Scope and Definition
   - 2.1 Scope
   - 2.2 Definitions
3. Components of Microbiological Criteria
4. General Principles for Establishing Microbiological Criteria
5. Guidelines for the Application of Microbiological Criteria
   - 5.1 Application and design of Microbiological Criteria
   - 5.2 Microbiological Methods
   - 5.3 Microbiological Limits
   - 5.4 Relationship between microbiological criteria and other microbiological risk management risk metrics
   - 5.5 Variability and uncertainty
   - 5.6 Sampling Plans
6. Documentation and record keeping
7. Reporting
8. Review of Microbiological Criteria for Foods
9. Annexes: Guidance on the establishment and application of microbiological criteria used for different purposes

Australia suggests that additional text be considered on the inclusion of markers particularly the limitations for application in regulatory frameworks.

Specific Comments

Introduction - Page 4

Paragraph (2)

Australia suggests retaining reference to GHP by the following amendment as control measures alone will not enhance the microbiological safety of food. We also consider that MC do not minimise contamination therefore we suggest deleting the word “minimise” and replacing it with “monitor”:

2. The microbiological safety of foods is enhanced by the effective implementation of validated control

~~M~~measures and the application of good hygienic Practice (GHP), often using MC throughout the food chain to ~~minimise~~ monitor 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.

Purposes of Microbiological Criteria - page 5

Australia suggests the text in paragraph 7 be moved to follow paragraph 6 (under Scope) as it elaborates on the scope. The heading could therefore be deleted.

Components of microbiological Criteria – page 6

The last dot point in paragraph 8 "the action to be taken when the criterion is not met" is an outcome not a component and should be a separate sentence.

Australia suggests deletion of the subtitle "Microbiological aspects of criteria" at the start of paragraph 9 as this is confusing.

Principles for Establishing and Applying Microbiological Criteria- Page 8

Paragraph 31

Australia supports the original wording in square brackets:

MC should be science-based, and developed using a structured and transparent approach.

Review and Revision – Page 10

Suggest that the title of this section be amended to "Review of Microbiological Criteria for Foods"

BRAZIL

Brazil congratulates the drafting group led by Finland and Japan for the advances obtained and the efforts to grant an objective approach to the document. Continuing the revision of the document, the alterations in the items described below are suggested.

SPECIFIC COMMENTS

Introduction

Consider transferring paragraph 4 and 5 to a new section entitle Use, as the proposed paragraphs are more applicable to that section.

USE

4. 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).

5. 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.

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

Consider to replace in the last bullet point in paragraph 9 the text "if applicable" to "on the context of the epidemiological status and when some relevant impact in human health is demanded", as the use of markers associated with pathogenicity and others traits should be related to an epidemiological context and importance of the microorganism to the public health.

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~~ on the context of the epidemiological status and when some relevant impact in human health is demanded;

Microbiological limits

Consider to clarify if the adding "and microflora" in paragraph 18 will reflect in the text proposed in paragraph 9, 14, 30 and 32.

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 nonconforming.

Sampling Plans

Consider to add a reference in this paragraph to the FAO/WHO web-based tool to assess performance of microbiological sampling plans.

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

Establishment of microbiological criteria

Brazil supports the original wording "MC should be science-based and developed using a structured and transparent approach" for consistency with the terminology used in other Codex documents.

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 .

Application of microbiological criteria

Consider to replace "normal conditions" to "standard parameters" in paragraph 40 for consistency with the terminology used in Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63/2007) and to improve its clarity.

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~~ standard parameters.

REVIEW AND REVISION

Consider to add "cells" in the end of the eighth bullet point of the paragraph 46 to complete the proposed text and improve its clarity.

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 cells);
- 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.

Consider to replace "Food" to "The intended use of food and its characteristics" in third bullet point paragraph 48 for consistency with the proposed text in paragraph 34 of this Proposed Draft Revision.

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/~~ The intended use of food and its characteristics;
- A technology /process;
- Problems with analytical methods/test;
- Population, especially a high risk subpopulation;
- Understanding/knowledge of risk; and/or
- Trend analysis results.

COLOMBIA

Colombia is pleased to submit the following comments on the "Proposed Draft Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods" at Step 3 of the Procedure, circulated by the Secretariat of the Codex Alimentarius Commission.

We herein refer to the document as it appears in Appendix I of CX/FH 11/43/5, based on the Spanish version.

I. INTRODUCTION– Paragraph 2

Food safety is not enhanced. There are different good practices set out that are intended to prevent food contamination, and therefore the safety of the product.

"(…) throughout the food chain to minimize contamination and improve food safety. (…)"

Proposal: (…) throughout the food chain to minimize contamination and ~~improve~~ ensure food safety. (…).

II. SCOPE – Paragraph 6

We suggest a change in the wording to make the text coherent in the Spanish version.

"(…) basados en los BPH, basados en los peligros y basados en el riesgo que han de aplicarse (…)"

Proposal: (…) basados en l~~o~~as BPH, ~~basados~~ en los peligros y ~~basados~~ en el riesgo que han de aplicarse (…).

III. PURPOSES OF MICROBIOLOGICAL CRITERIA – Bullet point vii

We suggest a change in the wording to make the text coherent in the Spanish version.

"(…) Verificar el estado microbiológico de los ambientes de producción primaria y de elaboración, cuando corresponda, (…)"

"(…) Verifying the microbiological status of the primary production and processing environments, where applicable, (…)"

Proposal: (…) Verificar el estado microbiológico de los ambientes de producción primaria y de elaboración, cuando corresponda, teniendo en cuenta los diferentes eslabones de la cadena (…).

(…) Verifying the microbiological status of the primary production and processing environments, where applicable, taking into account the various stages of the food chain (…).

IV. Microbiological aspects of criteria – Paragraph 10

The related phrase should be deleted, given that in the previous stages microorganisms whose significance is doubtful are excluded.

"(...) Organisms whose significance is doubtful should not be included.(…)"

Proposal: (...)~~Organisms whose significance is doubtful should not be included.".~~ (…).

V. General Considerations – Paragraph 29

There is not a level of understanding; the term used to describe characterization, life cycles, etc. of microorganisms is "knowledge".

"(…) MCs are established based on the level of understanding of the microorganisms, parasites and/or their toxins/metabolites (…)"

Proposal: (…) MCs are established based on the level of ~~understanding~~ knowledge of the microorganisms, parasites and/or their toxins/metabolites (…).

VI. General Considerations – Paragraph 34

The wording should be consistent with the English version.

"(…)Las pruebas de los peligros reales o posibles para la salud; (…)"

Proposal: (…)Las ~~pruebas~~ evidencias de los peligros reales o posibles para la salud; (…).

VII. REVIEW AND REVISION – Paragraph 44

The wording should be consistent with the English version.

"Los gobiernos nacionales y las empresas del sector alimentario pueden comenzar (…)"

Proposal: Los gobiernos nacionales y/o las empresas del sector alimentario pueden comenzar (…).

COSTA RICA

General Comments

Costa Rica would like to thank the Codex Committee on Food Hygiene for the opportunity to provide comments on the document prepared by the Physical Working Group led by Finland and Japan.

Specific Comments

In relation with paragraph 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.

Costa Rica believes that clarification is needed on the cases in which c is not 0, as, by definition, in two-class plans~~,~~ c=0 and a lot is accepted or rejected based on the value of m, specifically when a sample exceeds this value.

EGYPT

Egypt agrees on all the points mentioned in the report of the physical working group on the Revision of the principles for the Establishment and Application of microbiological criteria for foods

JAPAN

General Comments

Japan would like to express its gratitude to European Union (EU) for hosting the physical Working Group meeting and appreciate the efforts of the Physical Working Group to update the existing *Principles for the Establishment and Application of Microbiological Criteria for Foods*. Japan believes that this draft document has improved and become the fairly good shape. Japan wishes a fruitful discussion at the coming 43rd CCFH and, as a result, hopes the advancement of main document going forward for adoption by the Commission at Step 5. Having said that, Japan considers that the following points should be taken into account.

1. Paragraphs related to method of analysis and sampling, particularly paragraphs 12-13 (analytical methods), paragraphs 14-18 (microbiological limits) and Paragraphs 19-24 (sampling plans)

   Japan would like to propose CCFH to ask the view of Codex Committee on Methods of Analysis and Sampling (CCMAS), according to the procedure described in "terms of reference" of CCMAS, which serve as a coordinating body for Codex with other international groups working in methods of analysis and sampling. Though (d) of CCMAS's terms of reference exempts "the assessment of microbiological

quality and safety in food", the above mentioned paragraphs closely relate to or even overlap the General Guidelines on Sampling (CAC/GL 50-2004). The relevant paragraphs in the General Guidelines on Sampling are the following;

3.1 SAMPLING PROCEDURES FOR INSPECTION BY ATTRIBUTES: SAMPLING PLANS INDEXED BY LIMITING QUALITY (LQ) FOR ISOLATEDLOTINSPECTION (page 29);

3.1.1 Procedure A: Producer and consumer regard lot in isolation (page 30);

3.1.2 Procedure B: Producer regards lot as one of a continuing series: Consumer regards lot in isolation (page 30);

3.2 TWO AND THREE CLASS ATTRIBUTES PLANS FOR MICROBIOLOGICAL ASSESSMENTS

3.2.1 Two-class Attributes Plans (page 31);

3.2.2 Three-class Attributes Plans (page 32);

The Application of Two and Three-class Attributes Plans (page 33);

3.3 SINGLE SAMPLING PLANS FOR AVERAGE CONTROL (STANDARD DEVIATION UNKNOWN) (page 34)

2. Annex 1 – Guidance on the establishment and application of microbiological criteria used for different purposes:

While Japan recognizes the needs of the elaboration of the Annex I based on the comments made at the 42nd session of the CCFH and pWG in Ireland, Japan considers that the contents and procedure for the elaboration of this Annex needs to be discussed further in the coming session of the CCFH. Japan would like to propose two options.

The first option, which is a simple and less labor-intensive Annex is to list the relevant Codex texts (such as below).

Currently, following examples already exist in Codex;

1. Microbiological Criteria in the Framework of Microbiological Risk Assessment/Management

- Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969) and Annex Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application
- Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)
- Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007)

2. Sampling Plans for Determination of Microbiological Limits and Examples of Application

(1) General guidance on sampling plans

- General Guidelines on Sampling (CAC/GL 50-2004); Preamble; Section 1. Purpose of Codex Guidelines on Sampling; Section 2. Main Notions of Sampling

(2) Attribute sampling plans and their application examples

- General Guidelines on Sampling (CAC/GL 50-2004); Section 3. The Selection of sampling plans for single or isolated lots moving in international trade.
- Code of Hygiene Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008), Annex II, Microbiological Criteria for Powdered Follow-Up Formulae and Formulae for Special Purposes for Young Children and Annex
- Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria Monocytogenes* in Foods (CAC/GL 61-2007), Annex II: Microbiological Criteria for *Listeria Monocytogenes* in Ready-To-Eat Foods,

- Codex Sampling Plans for Prepackaged Foods (AQL 6.5)

(3) Variable sampling plans and their application examples

- General Guidelines on Sampling (CAC/GL 50-2004); Section 4.3 Sampling plans for inspection by variables for percent nonconforming; Section 5 The selection of sampling plans for the inspection by variables of bulk materials: known standard deviation. This provision is related to paragraph 27 dealing with trend analysis.

3. Examples of Application of Microbiological Criteria in Monitoring Program

- Code of Hygiene Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 662008), Annex III Guidance for the Establishment of Monitoring Programs for *Salmonella, Enterobacter Sakizakii* (*Cronobacter* species) and other Enterobacteriaceae in High Hygiene Processing Areas and in Powdered Formula Preparation Units

4. Examples of Application of Microbiological Criteria in HACCP

- Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria Monocytogenes* in Foods (CAC/GL 61-2007), Annex III: Recommendations for the Use of Microbiological Testing for Environmental Monitoring and Process Control Verification by Competent Authorities as a Means of Verifying the Effectiveness of HACCP and Prerequisite Programs for Control of *Listeria Monocytogenes*

The above list may not be exhaustive, and in future more will come up. These examples are, however, scattered in different Codex committees. Therefore, it will be useful for Members to have a list of texts using or useful for using microbiological criteria

Alternatively, if the CCFH wishes to elaborate several approaches to applying MC, Japan would like to suggest to reach the consensus on the following points at the next session of the CCFH;

- Structure of each example described in the section 2 of the current Annex
- The essential examples and purposes to be included in the Annex
- Lead drafting member state or observer to elaborate the draft examples

We believe that once CCFH agrees upon these points and confirms the strong needs for the elaboration of this Annex in an efficient manner, it could be worth investing resources to develop this Annex.

Specific Comments

Application of microbiological criteria

Paragraphs 40

To explain the trend analyses, paragraph 47 should be transferred here to a new foot note.

40. The use of trend analyses[6] 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.

Foot note 6

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

REVIEW and REVISION

Paragraphs 43, 46 and 48

Japan proposes that paragraphs 43, 46 and 48 should be combined to avoid repetitions.

Modified paragraph 43 as follows;

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, a review and revision of Microbiological Criteria should be considered ~~occur~~ in response to

revision of Microbiological Risk Management Metrics and also in response to changes and emerging issues 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;
- Food/ Technology /process of food production/ food safety control system;
- Population, especially a high risk subpopulation; ~~Sensitivity of subpopulation;~~
- Changes in dietary intake pattern of food concerned; ~~and~~
- Understanding/knowledge of risk; and/or
- Trend analysis results.

Paragraphs 47 This paragraph should be moved to paragraph 40 as a new foot note.

JAMAICA

General Comments

Jamaica has read this document and has no comment.

KENYA

General Comments

- The document is complicated and needs to be made user friendly.
- The document needs to provide practical examples to demonstrate applicability.
- The document when completed may be useful in the implementation of the Appropriate Level of Protection (ALOP) as provided for in WTO/SPS Agreement, and hence promoting public health and international trade.
- There is need for training on the concept of Microbiological Criteria to enable easy usage.

Justification:

1. The cross references should be made specific to the specific sections of the existing codex standard.
2. The standard should be **user friendly** to consumers, industry and regulators.

SPECIFIC COMMENTS

Conclusions & Recommendations

Par. 19.

Kenya proposes the first proposal ***'Microbiological criteria is a risk management measure and as such should take into account available science, and developed using a structured and transparent approach"***

Justification:

Establishment of Microbiological criteria (MC)should take into consideration the role of science in Risk Management.

Par .21.

Kenya supports the need to request FAO/WHO to provide technical support on the development of an annex which would address possible sampling plans for the implementation of various Microbiological Criteria as recommended by the p-WG.

Justification:

Kenya took note of the potential importance of MC in providing protection of public health and safety and promotion of fair trade in food if implemented

MEXICO

Mexico reiterates its commitment to Codex Alimentarius and appreciates the opportunity to comment on CX/FH 11/43/5 "Proposed Draft Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods".

General Comments

Risk management-based microbiological criteria include understanding, development and implementation of the concepts of Food Safety Objective (FSO), Performance Objective (PO) and Performance Criteria (PC), which, because of their complexity, have not been applied. We therefore support their inclusion, but for information purposes only; in a subsequent revision, as countries adopt them or implement them, their status can change from information to application.

SPECIFIC COMMENTS:

DOCUMENT	MEXICO'S COMMENTS:
Analytical Methods 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 **samples** should ensure that the results of testing will not be affected compared to individually analyzed sample units.	**13.** It should be specified that ", the procedure for pooling **samples** should ensure that the results of testing will not be affected compared to individually analyzed sample units".
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 **methods** ~~procedures~~.	**19.** For consistency of the terms used in the document, it should be redrafted as follows: "Sampling plans should also take account of the actual or most likely distribution of microorganisms and the uncertainty and variability of the analytical **methods** ~~procedures~~.
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 to base 10** ~~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).	**21.** Where it reads "(i.e., log normal)", we propose the words "(i.e., **log to base 10)"** as "lognormal" in Spanish is not considered a mathematical function.
22. [A sliding window is a sampling approach that allows analyzing data throughout a sliding period of time or with a certain number of sampling instances. When a set of new data is added, an equivalent amount of the oldest data is removed.].	**22.** There is a need to determine how many data constitute the sliding window and what the size is in terms of the time this sliding window can have. In addition, application of this sampling approach should be limited to lots only de frequent manufacturing lots.
RELATIONSHIP BETWEEN MICROBIOLOGICAL CRITERIA AND OTHER MICROBIOLOGICAL RISK MANAGEMENT RISK METRICS	
27. Si se ha validado la capacidad del sistema de control de la inocuidad ~~de la inocuidad~~ de los alimentos para alcanzar los OR y los CR, es posible que los criterios microbiológicos no	**27.** There seems to be a drafting error in the Spanish version; it should read as follows: "Si se ha validado la capacidad del sistema de control de la inocuidad

sean necesarios. Si se usan para verificar que se está cumpliendo con los OR y CR, es posible que los ensayos microbiológicos no tengan que ser muy frecuentes. La frecuencia con la que se efectúa el muestreo debería basarse en el riesgo.	~~de la inocuidad~~ de los alimentos para alcanzar los OR y los CR, …”.
PRINCIPLES FOR ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA	
General Considerations 31. ~~[LMC 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.	**31.** Risk management-based microbiological criteria include understanding, development and implementation of the concepts of Food Safety Objective (FSO), Performance Objective (PO) and Performance Criteria (PC), which, because of their complexity, have not been applied, so we believe that the second wording option is more feasible at this time: **"MC should be science-based and developed using a structured and transparent approach."**
Application of microbiological criteria 38. In situations of non-conformance with MCs, ~~corrective~~ actions **to be applied** should relate to the purpose of the testing. ~~Corrective~~ actions taken in response to non-conformance with microbiological criteria should be based on a risk assessment consumers are exposed to, the stage in the food chain and the type of specified product, and they may take into consideration conformance history. 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.	**38.** We propose the following wording: "In situations of non-conformance with MCs, ~~corrective~~ actions **to be applied** should relate to the purpose of the testing. ~~Corrective~~ actions taken in response to non-conformance with microbiological criteria should be based on a risk assessment consumers are exposed to, the stage in the food chain and the type of specified product, and they may take into consideration conformance history."
39. Asimismo, los criterios microbiológicos podrían ser aplicados por los empresarios del sector alimentario para formular requisitos de diseño y examinar los productos finales como una de las medidas para validar y/o verificar la eficacia del plan de ~~APPCC~~ **HACCP**. Los criterios microbiológicos pueden aplicarse en la vigilancia ambiental para verificar la eficacia de los programas de requisitos previos.	**39.** We propose to redraft the Spanish version as follows: “Asimismo, los criterios microbiológicos podrían ser aplicados por los empresarios del sector alimentario para formular requisitos de diseño y examinar los productos finales como una de las medidas para validar y/o verificar la eficacia del plan de ~~APPCC~~ **HACCP**”. This change is due to the fact that use of the acronym in English has been permitted because it is well-known.
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: • La prevalencia de ~~gérmenes~~ patógenos/toxinas; • 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.	**43.** In the first bullet point, we propose the following wording (in the Spanish version): • La prevalencia de ~~gérmenes~~ patógenos/toxinas; For consistency with the English version. In the seventh bullet point, we propose the following wording: • Changes in ~~dietary~~ intake pattern of food concerned; and; To avoid redundancy in the above phrase.

46. A review of microbiological criteria should be considered in response to changes or emerging issues in: • A food safety control system; • La prevalencia o distribución o cambios en las tendencias en los resultados de los ensayos de los ~~gérmenes~~ patógenos u organismos indicadores seleccionados; • 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); • Trait of (pathogenic/non pathogenic) microorganisms (e.g. anti-microbial resistance); • Consumer behavior and population dietary intake patterns; • Trend analysis; • Population, especially a high risk subpopulation; and/or • Understanding/knowledge of risk.	**46.** In the second bullet point, we propose the following wording (in the Spanish version): • La prevalencia o distribución o cambios en las tendencias en los resultados de los ensayos de los ~~gérmenes~~ patógenos u organismos indicadores seleccionados; For consistency with the English version.
48. In a review and in response to an emerging issue, the following should be considered: • Food safety control system; • Si se trata o no de ~~gérmenes~~ patógenos, toxinas o metabolitos nuevos y/o conocidos; • Food; • A technology /process; • Problems with analytical methods/test; • Population, especially a high risk subpopulation; • Understanding/knowledge of risk; and/or • Trend analysis results.	**48.** In the second bullet point, we propose the following wording (in the Spanish version): • Si se trata o no de ~~gérmenes~~ patógenos, toxinas o metabolitos nuevos y/o conocidos; For consistency with the English version.

NEW ZEALAND

New Zealand would like to thank Finland and Japan as Co-chairs, along with the members of the physical working group for preparing the Proposed Draft Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods.

General comments:

New Zealand would like to offer the following general comments on the draft text:

Section	Proposed change	Rationale
Overall document	Further in-depth plenary discussion is required. Continue drafting work to achieve outcomes proposed. Make more use of specific web-based tools to assist in application of MC in highly technical areas	This should be a practical hierarchical document that provides guidance to governments and industry on MCs their establishment and use with further elaboration in annexes as appropriate. As a whole, the document does not relate to the purposes currently selected (Para 7) and should, in a hierarchical manner, refine these purposes down to provide specific text about each within the document. Some sections (e.g. Paras 12-24) as drafted try to summarise a complex area only accomplished a level of confusion about what is meant.

		In order for the document to be of value, the document should focus clearly on the higher level of information about MCs and then decide whether to: 1) provide appropriate leads to more specific information found elsewhere, or 2) utilise an expert group to write the specific information for CCFH.

Specific comments:

New Zealand would like to offer the following specific comments on the draft text:

Section	Proposed change	Rationale
Introduction Para 2	The microbiological safety of foods is ~~enhanced~~ managed by the effective implementation of validated control measures ~~often using MC~~ throughout the food chain to minimise contamination and improve food safety……However, the establishment of an MC may be ~~useful~~ appropriate for verifying that food safety control systems are implemented correctly	Replace specific words with more relevant wording
Scope	These Principles and Guidelines are intended to provide a framework for governments and industry on the establishment and application of microbiological criteria in the context of a food safety control system, intended as a public health goal for consumer protection or to facilitate trade. MC may be GHP-based, hazard-based and risk-based~~ MC to be applied for food safety and other aspects of food hygiene~~. and may be applied for food safety and other aspects of food hygiene	Improves the clarity of the paragraph and articulates how an MC would be established and applied
Definitions	A microbiological criterion is a tool that facilitates risk management decisions about food control.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.~~	Suggest a more simple definition is needed. The definition needs to reflect that it applies to more than accept/reject situations. Using the word "acceptability" infers that this is the primary use of MC. Remove confusion as the MC should not be considered *following* sampling for the purposes of measuring *against* the MC.
Definitions	Metric – A system or standard of measurement; a criterion or set of criteria stated in quantifiable terms	(Oxford English Dictionary) Useful for users of this document to clearly understand what a metric is.
Purposes of Microbiological Criteria Para 7	The design of the microbiological criterion will depend on its purpose and the food safety outcome required iv~~) Verifying the performance of HACCP systems and/or pre-requisite programs~~ ~~v)~~ iv) Verifying the performance of ~~different parts of~~ a food safety control system or its parts, e.g. prerequisite programs and/or HACCP systems	Focuses the design in relation to the scope of the document Don't need two separate purposes here when one, further elaborated on, will suffice.
Components of microbiological criteria - Para 8 bullet point 2	The microorganism, parasite and/or toxin~~s~~, and/or metabolite, and the reason for selection	Included for consistency through the document
Microbiological aspects of criteria- Microorganisms,	For the purpose of this document these include but are not limited to: • Bacteria, viruses, mould, yeasts, and algae; • Parasitic protozoa and helminthes;	There are contexts within which pathogenicity (or other) genes are tested for: 1) where the organism is isolated and

Section	Proposed change	Rationale
parasites, toxins or metabolites and the reasons for selection Para 9.	• Their toxins/metabolites; and • Markers directly associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. anti-microbial resistance genes), or indicative of the potential presence of pathogenic organisms	subsequently probed for virulence genes to confirm that strains isolated are actually pathogenic (in this case, the organism is essentially undergoing more specific 'typing') 2) When genes are tested for independent of a test for the presence of the organism of concern, (the genes in this case are essentially indicators, because they may be carried by an unrelated organism that may not be a food safety concern).
Para 10	The microorganisms ~~included in a microbiological criterion~~ and/or markers of their presence/pathogenicity should be accepted as relevant ~~pathogens, indicator organisms or spoilage organisms of significance~~ in relation to the stated purpose. Organisms/indicators/surrogates of doubtful significance ~~whose significance is doubtful~~ should not be included	Content- refer to rationale for Para 9. Wording amended for clarity.
Para 11	In general, where pathogens and/or strains can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms.	Testing is frequently undertaken to identify species that contain pathogenic strains, rather than testing for the presence of the pathogenic strains themselves.
Para 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.~~ In general the methods used should be those that have the optimum combination of sensitivity and reproducibility for the organism and matrix in question. By "optimum combination" we mean the combination that minimises the risk of misclassification for material around the microbiological limit. However, pragmatic choices need to be made in the interests of speed and simplicity provided that the risks of misclassification remain satisfactory. This may require the modification of the criteria placed on the measured values.	The revised paragraph is proposed to improve clarity, the previous sentences were contradictory and were revised to improve the purpose. Further the most sensitive method may not be the most reproducible method, this has been addressed.
Analytical methods Para 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 analyses sample units~~ The results of testing may be impacted by compositing of samples prior to analysis. Compositing will affect the final concentration in the tested sample and is not appropriate for quantitative methods of analysis or	Pooling- or more accurately, compositing of samples, affects the final concentration of analyte in the tested sample. Whether this impacts the test result will depend on the sensitivity of the test and the level of contamination in the sample. There are a range of situations when it is generally considered inappropriate to composite samples, and a few when it is considered reasonable to take this approach. In addition to this, these

Section	Proposed change	Rationale
	within 3 class sampling plans. Compositing may be considered in the case of presence/absence testing within a 2 class sampling plan.	'rules of thumb' for compositing apply for all MCs (mandatory or not). The revised paragraph accommodates this.
Para 14	The microbiological limits, *m* and *M,* ~~define the level,~~ that separate conforming from nonconforming units (see *General Guidelines on Sampling* (CAC/GL 50-2004)), are expressed as absence/presence or concentration of the microorganism, parasite and/or toxin/metabolite in one analytical unit. ~~which separates conforming from nonconforming units (see *General Guidelines on Sampling* (CAC/GL 50-2004)).~~ In the case of a moving window, microbiological limits within a set timeframe are averaged to verify system performance.	Text added to account for moving window scenario. Additional minor text change made for clarity.
Para 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~~. The "acceptance number", *c*, is the maximum number of results permitted to be above *m* for the lot to be accepted.	The meaning of the number *c* needs to be expressed more clearly in standard terminology.
Para 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.~~ The "acceptance number", *c*, is the maximum number of results permitted to be between *m* and *M* for the lot to be accepted.	The meaning of the number *c* needs to be expressed more clearly in standard terminology.
New Para suggested between Para 16 and 17	In the case of a moving window plan, sequential results from single lots over a defined period are averaged to detect events that would not necessarily exceed microbiological limits for individual lots but cumulatively indicate unacceptable shifts in process control. Moving window limits include both the microbiological limit and the time period over which the individual lot results must be averaged.	Micro limits for Class 2 and Class 3 plans are described in 15 and 16. The proposed paragraph describes the nature of a 'moving window' micro limit.
Para 21	However, for presence/ absence ~~test~~ tests, performance ~~and validity~~ can be characterized by assuming an underlying distribution (i.e., log normal) and 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) and any uncertainty associated with estimates of the method performance parameters.	Punctuation and the conjunction "and" added to clarify the sentence. The evaluation of performance of sampling plan does not assess validity. The evaluation needs to take account of any uncertainty associated with estimates of the method performance parameters.
Para 22 [Place holder]	Moving window plans account for variability in the frequency and degree of microbiological contamination by averaging sequential results from single lots over a defined period. The window provides a continuous profile of microbiological performance of a process. Moving window plans can be used in isolation or adjunct to class 2/class 3 sampling plans. While individual lot results may not identify particular lots as non-conforming, they may cumulatively indicate shifts in process control and allow early intervention. The defined period of the window should	Microbiological contamination events in food processing are usually variable both in frequency of occurrence and degree. Microbiological monitoring for quality control (single lot testing) will detect events that exceed the microbiological limit but may not detect changes in process control that are manifest as a slow increase in contamination by a hazard over time but which at individual sampling points (between-lot) do not trigger non-

Section	Proposed change	Rationale
	reflect the anticipated defect rate.	compliance. Process quality assurance monitoring needs to identify trends in process control. The moving window approach uses sequential results from single lots over an extended period, e.g. three weeks for E. coli counts in, or 16 weeks for Salmonella detection on, meat, to cumulatively identify an increasing number of positive results over time. The window provides a continuous profile of the processes microbiological performance. As each new test result is obtained, the window is moved and the oldest result drops off. The length of the window depends on the expected defect rate. Use of a moving window in process assurance not only detects shifts in process control that would not be detected in single lot testing but it will do so early enough to trigger corrective action by the company before the critical limit is reached, and any trigger point will remain in the system until corrective actions have had a chance to improve process control.
Para 23	The statistical performance of a sampling plan is usually illustrated by its operating characteristics (OC) curve (see CAG/GL 50-2004), which describes the probability of ~~conformance~~ acceptance as a function of the actual proportion of non-conforming units. ~~OC curves can be used to evaluate the influence parameters of the sampling plan on the overall performance of the plan.~~ The OC curve can be used as a tool to design a suitable sampling plan.	Should be acceptance not conformance in first sentence. The last sentence as written was unclear – proposed new sentence to clarify.
Para 24	Web-based tools (http://www...) for estimating the ~~impact~~ performance of sampling plans …	The document needs to make more use of specific web-based tools where they are available to support highly technical areas.
Para 24 bis [new section proposed]	Variability and uncertainty Variability and uncertainty are factors that need to be taken into account when establishing and applying MC such as FSO, PO and PC.	A section that introduces the concepts of variability and uncertainty should be included in the revised document and elaborated on as appropriate in annexes. It is acknowledged that these concepts are still being debated in terms of their application but both factors need to be taken into account when establishing and applying MC.
Principles for Establishing and Applying Microbiological criteria Para 29	MCs are established based on the scientific knowledge ~~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. The evidence that informs the establishment of ~~Therefore~~ MCs can be broadly categorized as GHP-based, hazard-based or risk-based.	Adds clarity
Para 31	[MC ~~is a risk management measure and as such~~ should take into account …….	"is a risk management measure and as such" does not add anything to this

Section	Proposed change	Rationale
		paragraph. Suggest delete.
Para 36	Put under *Establishment of MC*	The paragraph relates to establishment to enable verification
Para 37	Put under *Establishment of MC*	The paragraph relates to establishment of MC where no other effective tools are available
Para 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.~~ In unusual circumstances (e.g. during a foodborne outbreak situation or when a food business operator wishes to increase the likelihood of detecting contaminated lots before placing them on the market), a sampling plan with increased stringency may become appropriate and it may become necessary to adopt an alternative microbiological criterion. 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.	The sampling plan is *a component of* the MC. Altering the sampling plan fundamentally changes the MC. This means rather than being a *modified* MC it becomes an *alternative* MC.
Review and Revision	Review ~~and revision~~	Superfluous words
Para 43	As establishing and implementing MC is a part of MRM activities, refer to …..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 the scientific knowledge underpinning the microbiological criterion • Change in prevalence of pathogens/toxins • Trait of microorganisms • 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 • Change in required level of assurance	These additional words are amongst the primary reasons for changing MCs and therefore need to be included.
Para 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;~~	Superfluous paragraph as have essentially been considered under Paras 43 and 46

Section	Proposed change	Rationale
	• ~~Understanding/knowledge of risk, and/or~~ • ~~Trend analysis results~~	

PERU

General Comments:

1. Include in the introduction:

✓ **The establishment and application of microbiological criteria should comply with these principles and be based on scientific advice and analysis. In addition, when sufficient data are available, a proper risk analysis may be conducted on foodstuffs and their use. The development of microbiological criteria should be transparent and meet fair trade requirements. Periodic reviews should be conducted on pathogens, technological changes and new scientific knowledge.**

Specific Comments:

The following wording is suggested for the definition:

1. A ***microbiological criterion*** is a parameter that indicates the acceptability of a food, a lot, a process, or a food processing environment at a specific point of the food chain after obtaining sampling results and testing for the detection of microorganisms, parasites and/or their toxins or metabolites, **per unit or units of mass, volume, area, or lot, as appropriate.**

The following is suggested for paragraph 12:

2. If possible, only methods whose performance parameters have been statistically determined based on benchmark studies or that have been carried out in collaboration among multiple laboratories or by validation of an only laboratory in accordance with an internationally accepted **and/or accredited** protocol should be used.

The following is suggested for paragraph 19:

3. Sampling plans should also consider the real or most likely distribution of microorganisms, **related criteria for determining the acceptability of the lot, acceptance and rejection number,** and the uncertainty and variability of analytic procedures.

4. As regards paragraph 22 *[A sliding window is a sampling approach that allows analyzing data throughout a sliding period of time or with a certain number of sampling instances. When a set of new data is added, an equivalent amount of the oldest data is removed.],* **we believe it is not clear. We therefore suggest that this paragraph be clarified or removed.**

PHILLIPINES

Specific Comments

The Philippines would like to propose revisions to the following items:

1. Introduction, page 5, paragraph 5.

From	To
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).	~~These~~ This document should be read~~ing~~ in 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).

2. Principles for Establishing and Applying Microbiological Criteria, General Considerations, establishment of microbiological criteria, page 8, paragraph 31

The sentence "MC should be science-based and developed using a structured and transparent approach." is preferred.

Rationale: To be consistent with the Codex principles to use a science-based approach in setting standards and consult with Codex-recognized scientific bodies in establishing international standards.

3. Review and Revision, page 10, paragraph 46

Add as additional bullets the following:

- the food chain
- public health policy

Rationale: To be consistent with the criteria for review of microbiological risk management metrics as indicated in Annex II (Guidance on Microbiological Risk Management Metrics), page 19 of the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).

SENEGAL

General Comments

- The document is comprehensive and well done, but it lacks practical examples to justify its applicability.
- There is a need to train Codex experts in the development of microbiological criteria.

UNITED STATES OF AMERICA

General Comments

The United States appreciates the efforts of the physical Working Group to revise the *Proposed Draft Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*, and progress has clearly been made. However, we have a number of concerns about the document that must be addressed before this document can move forward. We appreciate that this is a complicated subject, and we agree that breaking the complicated issue of the statistical and mathematical aspects of elaborating microbiological criteria (MC) into an annex is a logical approach. We also agree with the Working Group that an expert meeting should be convened to obtain technical support for such an annex.

With respect to the current document, much more work is needed to adequately address the three broad categories of GHP-based, hazard-based or risk-based MC to clarify the distinction. Moreover, the WG needs to reconsider how this document addresses the definition of MC – if MC are to apply to food, process and processing environment, then there should be discussion of how an MC applies in each case. It should be kept in mind that the General Guidelines on Sampling (CAC/GL 50-2004) apply only to lot acceptance sampling and provide no statistical guidance for process control or other proposed applications of microbiological criteria. As currently defined, a microbiological criterion is only suitable for attributes sampling for lot acceptance. The components and decision criteria would need to be substantially modified to permit application of microbiological criteria to process control or control of the processing environment. As this document has progressed, the discussions lead us to believe that there is confusion between the uses of MC and microbiological testing in general. If the WG cannot clearly demonstrate how an MC applies to a process or processing environment, then the document should be limited to MC for food, e.g., attributes sampling for lot acceptance.

We have some concern about statements on the use of MC in validation. Because validation is a non-recurrent decision, sampling and testing procedures (e.g., number of samples, sampling frequency) associated with routine process monitoring and lot acceptance sampling where microbiological testing is ongoing may not be suitable for validation purposes. The decision criteria for validation also may be more statistically complex. Validation studies should be based on experimental design criteria and the results should be based on statistical data analysis. This is not consistent with microbiological criteria as currently defined. The working group should provide additional discussion as to how an MC, as opposed to microbiological verification testing, is used in validating critical limits at CCPs or that control measures are capable of meeting POs or FSOs. The examples described in Annex 1 relate to verification but not to validation.

The document also has issues with respect to its discussion of sampling. There appears to be misunderstanding and confusion over the role played by underlying microorganism distributions in the valid application of attribute sampling plans in acceptance sampling. Paragraphs 19 and 21 continue to promote this misunderstanding and confusion. For valid application, variables sampling plans require underlying microorganism distributional form, but not attribute sampling plans. Generally, Codex sampling plans as

well as other sampling plans (e.g., Books 7 and 8 by the International Commission on Microbiological Specifications for Foods (ICMSF)) are attributes sampling plans, not variables sampling plans. What needs to be understood is that if, for example, the log normal distribution is assumed as an underlying distribution of a microorganism of interest, this assumption is not being made to validate the use of attributes sampling plans. Rather, this assumption is made to qualify other applications (e.g., probability of lot rejection based on a specified geometric mean concentration) based on sample information obtained from attributes 2- or 3-class sampling plans.

Further comments are provided with respect to specific paragraphs.

Specific Comments

In the comments below, text to be removed is indicated by strike outs and text to be added is underlined.

Introduction

Paragraph 1.

Revise the third sentence in the first paragraph to read as follows:

MCs have been used for many years and have contributed to improving ~~the~~ food hygiene in general, even when established ~~empirically~~ based on empirical observation of what is achieved under existing measures without any explicit linkage to specific level of public health protection.

Rationale: The meaning of "empirically" established microbiological criteria is not clear. Also, the term is used differently in the Codex General Guidelines on Sampling (CAC/GL 50-2004), which defines empirical sampling procedures as procedures that are not statistically-based. The common definition of empirical is information gathered by observation or experimentation as opposed to theory, but it can also mean information gained through practical experience. This paragraph does not seem to refer to criteria established experimentally, but rather to microbiological criteria that are based on observation of what is achieved under existing measures without linkage to any defined level of protection or public health risk.

In the 5th sentence, change "Performance Criteria" to "Performance Criterion."

Rationale: Grammatical change - The other metrics listed (Food Safety Objective and Performance Objective) are singular rather than plural.

Paragraph 2

Revise the first sentence in paragraph 2 as follows:

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.

Rationale: The sentence reads as if MC are used throughout the food chain to minimize contamination. This is contrary to the well-recognized understanding that microbiological testing is not a control measure. The role of microbiological testing, and the establishment of an MC, in verifying food control systems is stated at the end of the paragraph, so the deleted phrase is not needed.

Paragraph 3

Revise the last sentence of the 3rd paragraph to read:

The stringency should be based on risk where possible and the ~~compliance with the performance should be verifiable~~ MC used should be capable of verifying that the appropriate level of control is achieved.

Rationale: It is unclear as to what "the performance should be verifiable" refers.

Paragraph 5

Revise the beginning of paragraph 5.

~~These~~ This document should be ~~reading~~ read in conjunction with…

Rationale: Grammar and typographical errors.

DEFINITIONS

The definition of a microbiological criterion should be modified:

A microbiological criterion is a metric which can indicate the acceptability of a food, ~~a food lot,~~ a food 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.

Rationale: The distinction between a "food" and a "food lot" is unclear. We can accept use of either term (although "food" is the more general term) but do not see a need for both. Nothing in the rest of the document supports the need for both terms.

Change "Performance Criteria" to "Performance Criterion."

Rationale: Grammatical change - The other metrics listed (Food Safety Objective and Performance Objective) are singular rather than plural; the definition in the Procedural Manual is for Performance Criterion.

PURPOSES OF MICROBIOLOGICAL CRITERIA

Paragraph 7

Add the words "of food" following "lot" in bullets (i) and (ii) so they read as follows:

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

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

Rationale: Clarification

COMPONENTS OF MICROBIOLOGICAL CRITERIA

Paragraph 8

This paragraph contains a bulleted list of the components of a microbiological criterion, and is followed by paragraphs discussing some, but not all of the bullets. The purpose of the microbiological criterion was discussed in the previous section, but the last 3 bullets are not discussed. Some of this is touched on in the application of microbiological criteria. We suggest there be a subheader for each of the bullets where there is relevant discussion or reference to the section containing the relevant information.

Revise the second bullet to include "molecular markers"

The microorganism, parasite, toxin~~s, or~~, metabolites, or molecular markers and the reasons for selection

Rationale: New technologies are allowing detection of molecular markers such as combinations of virulence genes that present a concern. The Working Group anticipates that criteria based on such markers may be established in the future, and thus addressed this in the last bullet of paragraph 9, but did not include it in the components of a microbiological criterion.

Microbiological aspects of criteria

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

Revise the header to include "molecular markers"

Microorganisms, parasites, toxins, ~~or~~ metabolites, or molecular markers and the reasons for selection

Rationale: To include the concept in the last bullet related to virulence markers

Microbiological limits

General comments on paragraphs 14-18:

The definition of a microbiological limit as a level in a sample unit applies only to attributes sampling plans for lot acceptance and precludes the use of microbiological criteria for other applications that require a statistical form of decision rule or critical value. The document needs to either limit its scope to lot acceptance sampling plans for attributes or redefine the components of microbiological criteria so that they apply clearly and appropriately to all intended applications. A potential generalized approach could define "decision rules" and "critical values for microbiological criteria." If the decision is lot acceptance based on sampling plans for attributes, then the decision rule would be expressed in terms of the familiar microbiological limits (m, M), sample size (n), and acceptance number (c). For other decisions (e.g., lot acceptance based on inspection for variables, process control, performance criteria, etc.), the decision rule

would have to be based on different criteria and critical values. For example, for lot acceptance sampling plans for inspection by variables where the variance is unknown, the decision rule would be to reject the lot if the sample mean is > U - Ks (CAC/GL 50-2004). Note that the limit is not based on the level or presence in one analytical unit but on the mean of n sample units, and the critical value (U – Ks) has a statistical form that depends on U (upper limit analogous to m), K (analogous to a t-distribution value and depends on sample size and allowable error), and s (sample standard deviation). Similarly, in process control, the decision rule for a trend might be 5 observations in a row trending up or down. Here, the decision rule is based on a sequential pattern of sample values, not the level in any one sample, and the critical value is that the probability of the observed pattern occurring by chance absent a trend is less than 5%. (Five observations in a row trending up or down would occur with probability = $0.06 = 2*0.5^5$.)

Paragraph 14

Modify paragraph 14 as follows:

For lot acceptance sampling for attributes, t~~T~~he 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)).

Rationale: The parameters m and M are applicable to attributes sampling plans.

Paragraph 15

Modify paragraph 15 as follows:

In the case of a two-class lot acceptance sampling plan for attributes, there is one microbiological limit, denoted by m, and ~~there can be a certain~~ the acceptance number c (often 0)~~, that~~ is the maximum allowable number of sample units ~~accepted~~ above the limit.

Rationale: Unclear as written -- *c* refers to a number of samples. The Codex General Guidelines on Sampling defines *c* as the acceptance number. A two-class plan is specific to lot acceptance sampling for attributes.

Paragraph 16

Modify paragraph 16 as follows:

For a three-class lot acceptance sampling plan for attributes 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.

Rationale: A three-class plan is specific to lot acceptance sampling for attributes.

Paragraph 17

Modify paragraph 17 as follows:

The microbiological limits (*m* and *M*) are part of a sampling plan (defined by *n*, *c*, *m*, *M*) that constitute part of a microbiological criterion for lot acceptance sampling for attributes.

Rationale: For clarification. As currently defined, microbiological limits (m and M) are specific to lot acceptance sampling for attributes.

Paragraph 18

In paragraph 18 remove the phrase in square brackets and revise the last sentence or delete it.

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, parasite~~s~~, or toxin/metabolite/molecular markers ~~[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 unit, or to the average, or to the proportion nonconforming.

Rationale: The point of this paragraph is that in setting a microbiological limit it must be recognized that numbers of the target microorganism may change after the point in the food chain where the limit is applied. There are many factors (which also may be changing) that impact such a change in the target microorganism,

including microflora, package atmosphere, pH, a_w, etc. Although changes in competing microflora may be the most important of these, when establishing the limit it is the changes that may occur with respect to the target microorganism/parasite/toxin/metabolite/molecular marker that is considered.

The phrase "representativeness of that sample result" makes the sentence unclear. The wording above is based on the Codex Procedure Manual, 20th ed. (p. 79).

Sampling Plans

We propose the following revisions to paragraphs 19-21:

Begin with the first sentence of paragraph 21. Follow this with the sentence in paragraph 20. Complete the paragraph with a modified version of the original paragraph 19. Add a new paragraph 20 and a revised paragraph 21 describing attributes and variables sampling plans and their requirements for a known or assumed distribution. The revised paragraphs would read as follows:

~~20~~. 19. The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. 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). ~~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. Most microbiological sampling plans designed for lot inspection are attributes sampling plans, including those based on presence-absence tests and two- and three-class plans based on quantitative criteria (CAC/GL 50-2004). (In the latter case, the microbiological attribute is whether the estimated concentration in a sample unit is above or below a microbiological limit (m or M).) For attributes sampling plans, no knowledge or assumption about the underlying distribution of the microorganism is required. For attributes sampling plans to be valid, all that is required is that some probability sampling technique (e.g., simple random sampling or stratified random sampling) is used to collect the sample units from the entire lot. Sampling plans for inspection by variables evaluate quantitative data without grouping into classes, require information about the distribution of microorganisms, and typically assume that the inspected variables follow a normal or lognormal distribution.

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.~~ Under ideal conditions of negligible measurement error, attributes sampling plans depend only on the proportion of non-conforming sample units and not on the distribution of microorganisms (CAC/GL 50-2004). However, for microbiological analyses, measurement error is typically appreciable. Therefore, i~~I~~n practice, both variables and attributes 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).

Rationale: To clarify the differences between attributes and variables sampling plans and improve the flow of the paragraphs.

Paragraph 22

We support the inclusion of discussion on a moving window approach. However, we think this would be better covered in a different section of the document, perhaps in the application section with the discussion of trend analysis. Depending on the depth the Working Group would like to include, the moving window approach could also be discussed in a section of the document, or an annex, on the application of microbiological criteria to process control, which is not adequately addressed in this document.

Paragraph 23

Revise the first sentence as follows:

The statistical performance of a lot acceptance sampling plan is usually illustrated by its operating characteristic~~s~~ (OC) curve (see CAC/GL 50-2004), which describes the probability of ~~conformance~~

acceptance as a function of the actual proportion of non-conforming units.

Rationale: This definition of an OC curve is specific to lot acceptance sampling plans. "Operating characteristic" is singular. The y-axis is probability of lot acceptance, not the probability of conformance. OC curves for process control would differ from this definition. For example, the x-axis of an OC curve for an $\bar{x}$ chart is the process mean, and an OC curve for an $\bar{x}$ chart would describe the probability of a Type II error (β = probability of not detecting a shift of the process mean by kσ in the first sample mean following the shift).

RELATIONSHIP BETWEEN MICROBIOLOGICAL CRITERIA AND OTHER MICROBIOLOGICAL RISK MANAGEMENT METRICS

Paragraph 25

Revise paragraph 25 to delete the indicated text:

Where competent authorities have set an ALOP, FSO and/or a PO for a pathogen~~s 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.

Rationale: It is unclear what is meant by the phrase. ALOP, FSO and PO relate to hazards, therefore the "demonstrated health concern" is implicit.

Paragraph 26

Delete this paragraph, or clarify it and show how it could be applied.

~~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.~~

Rationale: It is unclear how this concept would be applied. Moreover, the point of acceptance sampling is to ensure that acceptance of a lot with a certain level of defects is unlikely. If all of the lots are uniformly bad, this statement implies that since an individual lot is not worse then the average of all lots, it would be accepted. Clearly all of the lots from such a process should be rejected.

PRINCIPLES FOR ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA

Delete the subheader

~~General Considerations~~

Rationale: This subheader is not needed, only the two subheaders on Establishment of microbiological criteria and Application of microbiological criteria.

Paragraph 30

Revise the first sentence to read as follows:

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~~ probability of rejection at unacceptable levels of contamination.

Rationale: We recognize that this paragraph comes directly from Annex II (Guidance on Microbiological Risk Management Metrics) of the *Principles and Guidelines for the Conduct of Microbiological Risk Management*. However, the revision is needed to distinguish between stringency of a sampling plan (the probability of rejection) and the stringency of the acceptable level of contamination.

Paragraph 31

Delete the text in square brackets, so the paragraph reads as follows:

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.]~~ An 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. The MC should be ~~and~~ set at a level that is not more trade restrictive than required to achieve an importing member's ALOP.

Rationale: Both sentences in square brackets are true (although MC should be referred to as a "risk management metric" rather than a "risk management measure.") However, we believe that neither statement is needed, as these reflect the risk management principles in *Principles and Guidelines for the Conduct of Microbiological Risk Management*. Moreover, the issue of transparency is addressed at the end of paragraph 30. The key point in this paragraph is that an MC should only be established when there is a need, a point that is emphasized by having the paragraph lead with this statement. Breaking the sentence in two separates the two different points and makes the paragraph more readable.

Paragraphs 33-35

If microbiological criteria are to be defined as applying to a food, a food process and a food processing environment, all three should be addressed here. If the document cannot clearly elaborate considerations for MC for a food process, the definition should not include it.

Paragraph 34

Delete the 7th bullet.

~~The cost/benefit ratio associated with the application of the criterion;~~

Rationale: Cost/benefit clearly falls under the purview of risk management. It is reasonable to suggest that the cost-benefit ratio should be considered, but this would apply to any microbiological criterion, not just to one for a food.

Paragraph 40

Modify the paragraph to incorporate paragraph 47, as indicated below. Also, consider a separate section on trend analysis, which would include paragraph 49 as well. A discussion of trend analysis could come at the beginning of the section on REVIEW AND REVISION or in a section preceding it.

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

Rationale: The added sentence comes from late in the section on REVIEW AND REVISION, which we interpret to be review and revision of the MC. This sentence is more appropriate as part of the discussion on trend analysis itself, e.g. the review of data to determine if they identify issues that warrant changes.

Paragraph 41

Revise the paragraph as follows.

However, there may be ~~unusual~~ situations in which sample numbers (or samplinge frequency) may be justifiably modified; e.g., during a foodborne outbreak investigation, when a supplier has a history of nonconformance, 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. Unless the sampling scheme specifies a multi-stage or sequential sampling plan (e.g., to resolve inconclusive test results, a ~~A~~ lot should not be subjected to

repeat testing for the same MC.

Rationale: The situations in which sample numbers or sample frequency may be modified need not be unusual, but they should be justifiable and transparent. Also, care needs to be taken to ensure that the microbiological criteria guidelines do not contradict other Codex guidelines. The General Guidelines on Sampling (CAC/GL 50-2004) allow for normal, reduced, or tightened inspection levels with defined switching rules. The Guidelines for Food Import Control Systems (CAC/GL 47-2003) indicate that the frequency of inspection should take into account the likelihood of non-compliance. As noted in paragraph 27 of this document, the frequency of sampling should be risk-based. The key is to assure that sampling is not modified in an arbitrary or discriminatory fashion. Although not covered by the General Guidelines on Sampling due to their complexity, some sampling plans (e.g., multi-stage or sequential) call for repeat

testing. For example, ISO 10576-1 recommends a formal two-stage procedure to resolve inconclusive test results. Sequential sampling plans may be applied when the specified limit seeks to control the average so that additional samples may be drawn to reduce uncertainty about the mean if, based on an initial sample, the confidence interval about the mean contains the limit.

Paragraphs 43-46

These paragraphs use both "MC" and "microbiological criteria." The acronym has been defined and should be used in all places subsequent to that.

Paragraph 43

Revise the second sentence as follows, and revise the bulleted list to include bullets from paragraph 46 that were not included:

In addition, revision of M~~icrobiological C~~riteria should ~~occur~~ be considered in response to revision of other Microbiological Risk Management Metrics and also in response to emerging issues or other changes, including ~~in~~ the following:

- ~~Change in p~~Prevalence or distribution of pathogens/toxins;
- The incidence of disease
- Trait of microorganisms (e.g. anti-microbial resistance, virulence);
- The suitability of an indicator organism;
- Analytical methods/tests;
- Technology /process of food production/ food safety control system;
- Sensitivity of a subpopulation;
- Changes in consumer behavior or dietary intake pattern of the food concerned;
- Understanding/knowledge of risk; and
- Trend analysis results e.g., changing trends in the results of testing for selected pathogens or indicator organisms.

Rationale: MC may not need revision in all cases, but consideration of the need to revise MC is appropriate for the indicated circumstances. Most of the bullets in paragraph 46 repeated those in paragraph 43. Other changes are editorial.

Paragraph 46

Combine this list with the one in paragraph 43 as indicated above.

Rationale: Avoid duplication.

Paragraph 47

Move to the end of paragraph 40. As indicated previously, a discussion of trend analysis could come at the beginning of the section on REVIEW AND REVISION or in a section preceding it.

Rationale: the text relates to review of data, not to the review of the MC. Paragraph 43 adequately addresses consideration for changes in an MC based on the results of trend analysis.

Paragraph 48

Delete.

~~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.~~

Rationale: It is unclear what purpose is served by this list, as the issues are considered in paragraph 43 with respect to changes in MC.

Paragraph 49

This paragraph appears to be related to review of microbiological testing data and conducting trend analysis. This should be included with other text on trend analysis, e.g., paragraphs 40, 47 and 49. As indicated previously, discussion of trend analysis could come at the beginning of the section on REVIEW AND REVISION or in a section preceding it.

URUGUAY

Uruguay appreciates the work conducted by the Physical Working Group (WG) co-chaired by Finland and Japan and sponsored by the European Union (EU).

General Considerations:

Uruguay supports the document as it believes it is in line with the concepts set out by the ICMSF. In regards to Annex I, its development is essential, and examples should be introduced to clarify the application of microbiological criteria throughout the food chain.

Specific Considerations:

Report of the physical working group

(Spanish version)

13. Después de algunos debates, el Grupo de trabajo acordó que, como regla general, el número y tamaño de las unidades analíticas deberían ser los que se estipulan en el plan de muestreo. El plan de muestreo **del** criterio microbiológico solo podría modificarse en circunstancias especiales, como las investigaciones sobre los brotes de enfermedades trasmitidas por los alimentos. En tales situaciones, la autoridad competente debe establecer con claridad el motivo y la justificación para hacerlo.

(Spanish version)

~~Mezcla de muestras~~ **"Pool de muestras "**

17. El Grupo de trabajo observó que ~~la mezcla~~ **el "Pool de muestras"** no es un componente del criterio microbiológico. Por consiguiente, no se incluyó en la sección de Componentes de los criterios microbiológicos. No obstante, el Grupo de trabajo consideró importante abordar esta cuestión en el contexto de los métodos analíticos, ya que ~~la mezcla~~ **el "Pool de muestras"** podría incidir en la sensibilidad del método. Se elaboró un párrafo independiente sobre ~~mezcla de muestras~~ **el "Pool de muestras"** y se lo incluyó en la sección sobre métodos analíticos.

We suggest that the concept of "pooling of samples" be defined as the sample obtained from mixing different sample units.

Proposed Draft Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods

1. Diseases caused by food-borne pathogens ~~constitute a major burden to~~ **significantly affect** consumers. ~~As such~~ **Therefore**, the prevention and control of these diseases have become international public health goals.

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 samples** of the final product to be placed on the market **as a criterion for lot release.**

(Spanish version)

3. ~~El rigor requerido de~~ **La exigencia requerida por** los sistemas de control de la inocuidad de los alimentos, incluidos los criterios microbiológicos usados, debería ser adecuado para proteger la salud del consumidor y asegurar las prácticas equitativas en el comercio de los alimentos. ~~El rigor~~ **Esta exigencia** debería basarse en el riesgo cuando sea posible, y el funcionamiento debería ser verificable.

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

ii) Evaluating the acceptability of a lot on the basis of ~~the estimated public health outcome~~ **the possible public health consequences**;

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

iv) Verifying the performance of HACCP systems and/or prerequisite programs (~~requisitos previos~~ **de Prerrequisitos;** Spanish version)

ix) Providing guidance (~~Ofrecer directrices~~ **Orientar** suggested in the Spanish version) to food business operators ~~on levels~~ **on the results** which can be achieved when applying best practices (~~las~~, Spanish version).

(Spanish version)

8. Dependiendo de su finalidad, un criterio microbiológico debería incluir los siguientes componentes: (fourth bullet point)

- El/los límite(s) microbiológico(s) considerado(s) adecuado(s) **para el alimento** en el/los punto(s) específico(s) de la cadena alimentaria;

(Spanish version)

11. En general, en los casos en que los gérmenes patógenos puedan detectarse de manera directa y fiable, debería ~~examinarse~~ **considerarse** la posibilidad de realizar ensayos para ~~detectar los~~ ~~gérmenes~~ **detectarlos** en lugar de realizar ensayos ~~para detectar los~~ **de** organismos indicadores.

(Spanish version)

13. Cuando los criterios microbiológicos son obligatorios, es decir, son normas que se han incorporado en la legislación nacional u otras reglamentaciones gubernamentales y cuando el método analítico permite ~~la mezcla de unidades de muestreo~~ **realizar un "Pool de muestras"**, el procedimiento debería asegurar que los resultados de los ensayos no se verán afectados en comparación con el análisis de unidades de muestreo por separado.

25. Where competent authorities have set an ALOP, FSO and/or a PO for pathogens ~~with a demonstrated health concern~~ **importance to health** ~~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.

(Spanish version)

27. Si se ha validado la capacidad del sistema de control de la inocuidad ~~de la inocuidad~~ de los alimentos para alcanzar los OR y los CR, es posible que los criterios microbiológicos no sean necesarios. Si se usan para verificar que se está cumpliendo con los OR y CR, es posible que los ensayos microbiológicos no tengan que ser muy frecuentes. La frecuencia con la que se efectúa el muestreo debería basarse en el riesgo.

29. Second bullet point

- **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 (~~alimentos~~ **peligros** Spanish version). There is an ~~expectation~~ **intention** of consumer protection but the actual degree of protection will be unknown. They are for example used for the verification of the ~~performance~~ **effectiveness** of HACCP systems and for lot-by-lot acceptance.

31. We support the second phrase of the options in square brackets.

Rationale: This phrase is broader; microbiological criteria are not only a risk management measure but also allow monitoring, control or verification of hazards within Good Practices and HACCP.

33. Fourth bullet point.

- ~~Sampling locations~~ **Sampling points** and sampling plan;

34. Second bullet point.

(Spanish version)

- ~~Las pruebas~~ **La evidencia** de los peligros reales o posibles para la salud.

35. Third bullet point.

(Spanish version)

- El ~~calendario~~ **cronograma** de muestreo.

(Spanish version)

38. En las situaciones en las que no se cumpla con los criterios microbiológicos, las medidas correctivas deberían estar relacionadas con la finalidad de los ensayos. Las medidas correctivas adoptadas como respuesta a la falta de conformidad con los criterios microbiológicos **vinculados a los patógenos,** se deberían basar en una evaluación del riesgo a que esté expuesto el consumidor, el punto de la cadena alimentaria y el tipo de producto especificado y podrán tomar en consideración la historia de conformidad. Estas podrían incluir un proceso de selección, la reelaboración, la retirada y/o el retiro del producto del mercado, el rechazo o la destrucción del producto, y/o una nueva investigación para determinar las medidas apropiadas que han de tomarse.

(Spanish version)

39. Asimismo, los criterios microbiológicos podrían ser aplicados por los empresarios del sector alimentario para formular requisitos de diseño y examinar los productos finales como una de las medidas para validar y/o verificar la eficacia del plan de APPCC. Los criterios microbiológicos pueden aplicarse en ~~la vigilancia~~ **el monitoreo** ambiental para verificar la eficacia de los programas de ~~requisitos previos~~ **prerrequisitos**.

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 **working** conditions.

(Spanish version)

44. Los gobiernos nacionales y las empresas del sector alimentario pueden comenzar y llevar a cabo ~~un examen~~ **una revisión** de los criterios microbiológicos. Los miembros del Codex podrán proponer ~~el examen~~ **la revisión** de los criterios microbiológicos presentes en los textos del Codex.

(Spanish version)

46. Debería considerarse ~~un examen~~ **una revisión** de los criterios microbiológicos en respuesta a cambios o cuestiones de reciente aparición en:

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

(Spanish version)

48. En ~~un examen~~ **una revisión** y en respuesta a un asunto emergente, es preciso tener en cuenta lo siguiente:

(Spanish version)

49. ~~El examen~~ **La revisión** debería incluir un sistema de registro de los datos y su evaluación, p. ej., la realización de análisis de tendencias.

LATIN AMERICAN POULTRY ASSOCIATION (ALA)

The Latin American Poultry Association wishes to congratulate Finland and Japan by the good and productive meeting held in Merge and puts forward the following comments for consideration.

Specific comments (ii):

Text	Proposal	Rational
7. vii) Verifying the microbiological status of the primary production and processing environments,where applicable;	Refer to the OIE standards	The responsibility and competence belongs to OIE
9. Their markers associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. anti-microbial resistance genes), if applicable;	Complete the sentence	Their markers associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. anti-microbial resistance genes), ~~if applicable~~; on the context of the epidemiological status and when some relevant impact in human health is demanded.
24. Web-based tools for estimating the impact of sampling plans can be utilized to evaluate the performance of sampling plans under consideration.	Change the sentence	24. Web-based tools developed by International Reference Organisms for estimating the impact of sampling plans can be utilized to evaluate the performance of sampling plans under consideration.
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.].	The original text follow the codex principles and should be kept. Other reference than science base can be used in commercial forum but not in Codex.	We support the original sentence: "Microbiological criteria should be science-based, and developed using a structured and transparent approach"
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.	Change the sentence	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.~~ hygiene programs applied (eg: PPHO)
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.	Change the sentence	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.~~ standard parameters.
46. Available analytical methods/appropriateness of test (viable/viable non- culturable/dead);	Complete sentence	46. Available analytical methods/appropriateness of test (viable/viable non- culturable/dead cells);
47. Trend analysis includes a system to record, review and analyze laboratory results and routine testing results on a regular basis.	Change the sentence	47. Trend analysis includes a system to record, review and analyze the historic of laboratory ~~results and~~ routine testing results on a regular basis.

For a practical example of establishment of a Microbiological Criterion (MC) for batch-wise verification, based on a quantitative risk assessment suggested from Denmark, we would like to express our objection to use "Poultry Meat" like a reference.

ALA supports the structure of this model and recognizes the importance of the Campylobacteriosis for the Public Health, however we understand that this example must be harmonic and compatible with CAC/GL 78-2011: "GUIDELINES FOR THE CONTROL OF CAMPYLOBACTER AND SALMONELLA IN CHICKEN MEAT", published this year. These guidelines have a clear objective and focus restrict to "Prevention, Control and Monitoring", as we support widely.

The document don´t offer references to apply microbiological criteria for poultry meat. This question was discussed for four years without consensus for many issues. It´s not means that it´s not important, it means that is not feasible yet recommend one international reference for risk base microbiological criteria for *Campylobacter* in poultry meat that can be used in developed and developing countries.

ALA support that the model suggested by Denmark could be applied for a generic example. One second option could be use like a example *Listeria Monocytogenes* in Read to Eat Foods. The annex I and II of the CAC/GL 61 – 2007: "GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS, can be used as a reference data.

INTERNATIONAL COMMISSION ON MICOBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF)

General Comment:

The ICMSF appreciates the progress made regarding the revision of this principles document and would like to use the opportunity to provide further comments for consideration by the Committee. As a general comment, ICMSF would request clarification on an apparent restriction to the scope of the document, such that it would focus on the use of microbiological criteria (MCs) in "food and food processing environments", as may be concluded from the statement in paragraph 10 of the report of the physical working group, where it reads "10. Furthermore, it was decided that the procedure elaborated in the document should mainly focus on food and food processing environments". ICMSF recommends that the document considers possible MC uses broadly and along the complete farm-to-fork continuum, so including for instance primary production and food service operations.

Paragraph 2.

ICMSF proposes to delete the phrase "often using MC" in the first sentence. MCs may be considered as control measures, but (1) many other control measures are more often used than MCs and (2) to refer to MCs as "validated control measures" is not making reference to what is common practice for MCs; the first sentence is equally valuable and more correct without this phrase.

Paragraph2.

ICMSF proposes to delete "However," at the start of the third sentence, such that it reads: "The establishment of an MC may be useful for verifying that food control systems are implemented correctly". "However" does not seem to refer to any other statement in the paragraph.

Paragraph 6 (Scope)

Paragraph 6 refers to "…the application of microbiological criteria such as GHP-based, hazard-based and riskbased MC". ICMSF believes that currently there is no clear distinction between these 3 apparently different types of MCs. They have not been described clearly at an earlier point in the document, so it would be confusing to mention them under scope. We suggest to delete this language and have the scope read "These Principles and Guidelines are intended to provide a framework for governments and industry on the establishment and application of microbiological criteria to be applied for food safety and other aspects of food hygiene."

Paragraph 6 - Definition of microbiological criterion.

In the phrase "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", ICMSF proposes to delete the text ", a process " in accordance with the decisions at the pWG meeting (paragraph 10 of the report of the pWG).

The following rationale of ICMSF provides further substantiation to leave out "the process" from the definition of MC: An MC gives the status of the product or environment and does not give insight in how this status was achieved, so it cannot define the acceptability of a process or any other form of handling that contributed to the prevailing food or environment status; for example, when after a treatment no survivors are found this can mean that either the initial hazard level was very low or the process was effective but when contaminants are found this can equally mean that the raw material was either unfit or that the process was not acceptable; whatever scenario is more pertinent can't be derived from the MC and thus the MC can't provide evidence/information on the acceptability of a process.

ICMSF furthermore proposes to delete the text ", parasites", as parasites are examples of microorganisms and it is not clear why they would need to be mentioned specifically rather than other microorganisms.

For the bullet "Performance Criteria (PC)[3]", ICMSF suggests to replace " criteria" by "criterion" as this is the language used in the cited procedural manual regarding PC

Paragraph 7, bullet vi

"Communicating acceptance criteria between food business operators;". ICMSF suggests that this is not really a common or possible purpose of an MC and requests changing this bullet to: "Verifying the microbiological status in relation to acceptance criteria between food business operators"

Paragraph 8. "Components of microbiological criteria".

ICMSF recommends to add to the list of components "- the number of analytical units that should conform to these limits." as this has been a integral part of an MC also in the original Codex guideline and important to retain.

Paragraph 8. "Components of microbiological criteria".

ICMSF recommends to add a new component to the list of components which reads "- an expression of the performance of the sampling plan used in the microbiological criterion".

In recent guidelines in which MCs were established such as Annex I of the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66 – 2008), such an expression was used as shown below for *Enterobacter sakazakii* (*Cronobacter* sp.) and *Salmonella* as indicated with astrixes. ICMSF believes this additional information should be included as a component of the MC, as it is useful for communicating the performance of the MC as it relates to the stringency of hazard control as well as allows assessment of alternative sampling plans with equal performance.

Taken from Annex I of the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66 – 2008)

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].

Paragraph 10.

Paragraph 10 mentions that "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. ICMSF would recommend qualification of the expression "accepted as relevant" in terms of the basis for acceptance and the basis of relevance.

Paragraph 14.

ICMSF recommends to change the text "The microbiological limits, m and M,…." to "The microbiological limits, e.g. m and M,…." As m and M are examples of limits; other limits exists in statistical process control approaches such as the moving window sampling approach.

Paragraph 14.

Paragraph 14 reads "….define the level…..of the microorganism, parasites and/or toxins/metabolites ……".. ICMSF proposes to delete the text ", parasites", as parasites are examples of microorganisms and to use the singular form for "toxin/metabolite".

Paragraph 17.

Paragraph 17 seems to infer that a sampling plan consists of the components *n*, *c*, *m*, and *M*. ICMSF recommends adding also "the weight of the analytical unit" to these components, as this parameter influences the statistical performance of the sampling plan. The paragraph would then read: "The microbiological limits (*m* and *M*) are part of a sampling plan (*n*, *c*, *m*, *M* and the weight of the analytical unit) that constitutes part of a microbiological criterion"

Paragraph 18.

ICMSF proposes to delete ", parasites" from the first sentence of paragraph 18 as these are an example of a type of microorganism, and to delete the text in square brackets as the "microflora" referred to between brackets is not the target of the MC and therefore there is no need to consider it in setting microbiological limits.

Paragraph 18.

The second sentence of paragraph 18 is not optimally clear; also to be able to judge the nonconformity of samples some form of limit must have been set, which leads to circular reasoning. ICMSF therefore recommends rephrasing the sentence to: In establishing microbiological limits, it should be clearly stated in the MC whether the limits apply to every sample, to the average, or to another specific method of calculation."

Paragraph 21.

The second sentence of paragraph 21 starts "For a quantitative criterion, information….". As all microbiological criteria are inherently quantitative and qualitative criteria are not defined, ICMSF suggests to change this wording. One option is to replace "quantitative" by "microbiological". Another option for improvement is to rephrase to "For an MC based on concentration measurements, information…..," as this complements the following sentence better.

Paragraph 21.

In the 3rd sentence replace "However" by "Also" and "by" with "for": Also for presence/ absence test performance and validity can be characterized by assuming an underlying distribution (i.e., log normal) for estimating or assuming the presence or concentration above a threshold.

Paragraph 23.

As an additional sentence to the end of paragraph 23, ICMSF recommends adding "The OC curve can also be represented as function of the quality of the lot, for example characterised by the average concentration."

Header before paragraph 25.

ICMSF recommends to remove "other" from the header such that it reads: "RELATIONSHIP BETWEEN MICROBIOLOGICAL CRITERIA AND MICROBIOLOGICAL RISK MANAGEMENT METRICS".

Using "other" in the header infers that MCs are microbiological risk management metrics, whilst they are qualified as "traditional metrics" or "food safety metrics" in annex II to the MRM document (*Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007); whereas the

"emerging metrics" FSO, PO and PC in several places of the MRM document are collectively referred to as "risk management metrics".

Paragraph 27.

ICMSF recommends that in paragraph 27, the text "and PCs" occurring twice is deleted in both instances. MCs can be used only to verify a status or an outcome, not a process or the performance criterion required to meet an outcome. To verify meeting a PC, two MCs would need to be established and verified. One before the step (to assess the status of the incoming hazard level) and one at the end of the step (to assess the status of the hazard in the product at that point), which would be the PO for that step anyway.

Paragraph 28.

ICMSF suggests to reword the first sentence to: "The need for deriving a risk based microbiological criterion ~~directly~~ from an ALOP and the need for other MRM metrics should be clearly articulated."; it is suggested to delete "directly" as an MC likely cannot be derived directly from ALOP, but either follows the hierarchy from ALOP over FSO to PO and the MC is set to verify the PO or else uses a quantitative risk assessment to link ALOP to PO levels for which an MC could be used for verification.

Paragraph 29.

ICMSF proposes to delete the following text from paragraph 29: ", parasites", ", process" and "Therefore, ".

Paragraph 29.

ICMSF is concerned that the current descriptions of the three types of MCs does not sufficiently clarify the intended description of the differences between the MC types. It is suggested to consider the following rewording in which also an illustrative example is given for each type of MC:

- *GHP-based* criteria may be used to verify that hygienic practices have been properly applied and are based on scientific knowledge and experience related to basic hygiene. Examples of GHP-based criteria may be *Enterobacteriaceae* counts in refrigerated, pasteurized milk products or *Campylobacter* counts on raw poultry products.
- *Hazard-based* criteria may be used to verify the performance of a HACCP system or for lot acceptance. These criteria are based on scientific knowledge of the system, the hazards that may be encountered in the specific type of product, and validation of controls that are being applied. While a level of consumer protection is implied, the level of protection typically cannot be quantified. An example may be microbiological criteria for *Salmonella* species in dried milk products.
- *Risk-based* criteria are based on risk assessment or other quantitative data that allow for an estimate of the level of consumer protection. Risk-based criteria may be employed to verify compliance with an established PO or to demonstrate that an ALOP is achieved. An example is criteria for *Cronobacter* species in powdered infant formula.

Paragraph 31.

In the first sentence of paragraph 31, giving the choice between two phrases in brackets, ICMSF suggests adopting the phrase "MC should be science-based and developed using a structured and transparent approach."

Paragraph 33

Several bullets in this paragraph repeat components that are already included in the description of an MC (see paragraph 8) and these can be omitted when the introductory sentence would read:

"To fulfill the establishment of a MC, some considerations are common to food and the food processing environment. In addition to the components for an MC listed under paragraph 8, these considerations include, but are not limited to:

- Sampling tools and techniques;

- Frequency of sampling;

- Record keeping."

By deleting bullets 1, 2, 4 and 6

ICMSF proposes to additionally introduce back from the original guideline (CAC/GL 21) into the list of general considerations the consideration of the:

- administrative and economical feasibility, in particular in the choice of sampling plan;

Paragraph 36

ICMSF requests to delete "or PC" from paragraph 36 and rephrase "In the governmental context, MCs may be established to enable verification of compliance to an FSO or a PO set by competent authorities." Competent authorities don't set PC values; The metric PC covers the whole change required in a step from the incoming hazard level to the PO so it includes any processing and handling in a step. Competent authorities may, however, set PO (for which industry then sets a PC needed to meet the PO given the incoming hazard level) or default process standards/process criteria, but the latter are only a part of a PC.

Paragraph 41.

In the course of the revision, the last sentence of paragraph 41 lost an important thought included in the original guideline (CAC/GL 21) which ICMSF would like to bring back into the revised document by deleting the 4th sentence of paragraph 41 ("A lot should not be subjected to repeat testing for the same MC.") and replacing it by "However, a lot should not be subjected to repeated testing in order to bring the lot into compliance." It actually would be important to repeat testing for the same MC and not to retest with an MC that is less relevant or stringent. The results of retesting with the same MC should however be interpreted as a whole and not as individual findings.

textual comments

33 an MC

INTERNATIONAL DAIRY FEDERATION (IDF)

General Comments

IDF wishes to congratulate the co-chairmen (Finland and Japan) and the Ad Hoc Working Group with the provision of a considerably improved draft document. IDF supports the development of the two annexes proposed by the working group. However, we wish to emphasize that it is important that the annex on statistical analyses and mathematical considerations not only address MC for lot-by-lot testing but also MC for the other purposes, in particular "moving windows".

SPECIFIC COMMENTS

Par. 22 – Moving windows

IDF recommends that the square brackets be removed and the phrase "sampling occasions" be replaced by "analytical units", For clarification and to avoid confusion between the moving window approach and trend analysis, we also recommend the addition of text that relates moving windows with trend analysis (see for example, Simulation-based assessment of Microbiological Criteria on Salmonella in poultry meat. EFSA Journal 2011; 9(2):1986).

Suggested revised text:

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 analytical units ~~sampling occasions~~. When the latest data are added, a similar amount of the

oldest data is removed. ├ . Trends can be assessed by dividing the sum of the number of times a moving window meets (or exceeds) the microbiological criterion by the total number of moving windows during a period.

Par. 28 – MC directly from an ALOP

The current text in the 2nd sentence gives the impression that the development of risk based MC is too complex to consider in practice. The complexity depends on the scope of the MC (e.g. single food/plant combination versus all ready-to-eat foods/all manufacturers combination) We consider that text discouraging the use of risk-based approaches should be avoided. Risk based approaches need not be over-complex (see

also the approach developed by Schothorst, Zwietering, Ross, Buchanan and Cole - Food Control 20 (2009) 967–979)

We recommend deletion of the last sentence of paragraph 28, alternatively, we suggest that the par. 28 be rephrased as follows:

Suggested revised text:

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~~ While 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, there are simple risk-based approaches available.

Par. 40 – Trend analysis

We recommend that additional guidance be included in the text, as follows:

Suggested revised text:

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~~. Trends in results may reveal unwanted shifts in the manufacturing process enabling the food business operator to take corrective actions before the process is out of control. The trends can be followed, for example, by displaying the test results graphically on control charts.

Par. 47 – Trend analysis records

We suggest that the text be relocated after para. 42, as it relates to documentation and record keeping.

Annex I – Guidance on establishment and application of MC used for different purposes

We have attached recommended text for example no. 4

Example: Microbiological criteria for verifying the performance of a HACCP system

Purpose:

To verify the intended performance over time of the food safety control system, particularly the hazard plan, through use of the moving window approach.

Who should establish and who should apply:

MC, other than those established by regulation (competent authorities), are primarily established by industry.

It is the industry that applies the MC. However, competent authorities may apply to support audit.

Food or food process environment:

The MC is applied for verification of the process food safety control system, based on analysis of food samples.

Point in the food chain where the MC is applied:

End products prior to release to the market.

Sampling plan:

A sample is made of a defined number of analytical units, taken at a specified frequency over a specified or defined time period or over a defined volume of production.

Adequate frequency depends on:

1. *The number of lines subjected to the verification.*

   Two or more processing lines can be pooled provided that they do not differ in terms of level of pathogen control and that they process similar products.

2. *Sufficient production frequency.*

This approach is intended for frequent (e.g. daily) production; it is not adequate if production frequency is too low (e.g. once a month).

3. *Distribution of organisms in food.*

   Food products with relatively higher standard deviation should be tested more frequently (e.g. portioned solid products).

4. *Probability of detection and analytical method.*

   The probability of detection and the analytical method level of detection must be accounted for when establishing the frequency of taking analytical units and the length of the moving window:

In the case of class 2 criteria tested using detection methods, samples can be pooled (several processing lines, sampling spots, product types, etc), provided that actual detection is followed by appropriate actions such as a review of this approach.

Organism(s) of concern:

Pathogen(s) that is(are) intended to be controlled by the HACCP plan and/or indicators for the pathogen(s) as well as indicators relating to specific or general hygiene control.

Method(s) of analysis:

The appropriate analytical method to use will depend on the chosen type of limit, (absence/presence, MPN or direct colony counting) and the organism. The analytical method must correspond with the verification need and planned corrective action.

Interpretation of results:

A criterion for conformity or non conformity with the planned performance of the food safety control system are typically established as:

- a specified maximum frequency of exceeding a level during a specified period, but never above an absolute maximum level (e.g. the number "c" samples out of "n" samples taken during a month that may exceed the limit "m", but not the limit "M"), and/or
- a specified maximum average of results obtained during a period.

Actions in case of non-compliance:

The MC typically includes an action limit for individual results as well as action limit(s) for results obtained over time.

Actions on results over time may be based on one limit or, in the case of enumeration, more action limits that each triggers different corrective actions on the food safety control system.

Actions include a review of the HACCP system. A higher frequency of verification should be considered for a short period to verify the effect of corrective action.

INTERNATIONAL POULTRY COUNCIL (IPC)

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 please find below the (ii)specific comments which we would like to be considered in the final draft:

(ii)Specific Comments:

§ 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.

Microbiological Criteria should be science-based and developed using a structured and transparent approach.
2