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World Health Organization

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Agenda Item 4 **CX/FH 12/44/6-Add.2**

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

(Comments at Step3 submitted byArgentina, Brazil, Colombia, Egypt, Japan, Mauritius, Mexico, New Zealand, Nicaragua, Norway, St. Lucia and United States of America)

ARGENTINA

GENERAL COMMENTS

Argentina appreciates the opportunity to provide these comments.

Firstly, Argentina would like to congratulate the Electronic Working Group for its work in this draft which is now more clear in its contents and understanding.

We want to express our concern in relation to the SPANISH TRANSLATION of the document, which does not contain the specific technical terminology and renders a confusion text hard to understand. On this regard, we have prepared a corrected version of the text for consideration by Spanish-speaking countries.

Finally, regarding where to place the examples, we understand that they should be both put in a webpage and as annexes of the main document, with a special statement that they are placed only for illustrative purposes on how CM could be used in different situations.

SPECIFIC COMMENTS

PARAGRAPH 8

Regarding the SCOPE, the framework defined in the first sentence is not clear and suggest the following wording:

8. These Principles and Guidelines are intended to provide a framework for national governments and food business operators on the establishment and application of MC that can be applied for food safety and**/or** ~~other aspects of~~ food hygiene**, process and food safety control system**. MC established for the monitoring of the food processing environment are not in the scope of this document.

PARRAFO 12

We suggest deleting first sentence as it is repeated in POINT 3, bullet 5 of previous paragraph.

12. ~~MC are established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain~~. When considering the establishment of MC, a variety of approaches can be used depending on the risk management objectives and the available level of knowledge and data. These approaches can range from developing MC based on empirical knowledge related to GHPs, to using scientific knowledge of control through a system such as HACCP, or conducting a risk assessment. The choice of the approach should be aligned with the risk management objectives and decisions relating to food safety and suitability.

PARRAFO 53

We suggest the following amendments to the text:

53. In the event of the non-conformance with an MC for a pathogen, **food business operators and national governments should manage the risk by taking specific actions** ~~actions may additionally include~~ **(e.g**

sorting, further processing, diversion to an alternate use, withdrawal and/or recall, rework, rejection or destruction of product**)** and/or further investigation to determine appropriate actions to be taken. Other actions taken may include more frequent sampling, inspection and audits, fines or official suspension of operations.

BRAZIL

GENERAL COMMENTS

Brazil supports moving the document forward and appreciates the opportunity to provide the following amendments in the items described below for improvement of the document.

SPECIFIC COMMENTS

4.2 Purpose (page 7)

Consider to replace in paragraph 16 "acceptance or rejection" by “appropriate destination” in bullet (i) and to insert “according to its intended use” in bullet (ii), as proposed below:

16. There may be multiple purposes for establishing and applying MC. The purposes of MC include, but are not limited to, the following:

i) Evaluating a specific lot of food to determine its acceptance or rejection **appropriate destination**, in particular if its history is unknown.

ii) Evaluating the acceptability of a specific lot of food**, according to its intended use** on the basis of the estimated public health outcome.

Rationale: Depending on the pathogen, the product could be submitted to a treatment that eliminates or mitigates the risk. As proposed in the last sentence on paragraph 19 “…estimate the reduction in public health risk as a result of applying corrective actions to lots or processes that do not conform to the MC”.

4.6 Microbiological and/or other limits (page 10)

Consider to remove “often zero” in paragraph 33, as proposed below:

33. In the case of a two-class attributes sampling plan, there is one upper microbiological limit on the acceptable concentration in the analytical unit, denoted by m, and the acceptance number c ~~(often zero)~~ is the maximum tolerable number of analytical units above the limit.

Rationale: Plans in which c=0 are not necessarily the most exacting. The adoption of such criteria alone may not increase the safety of the population. In addition, the concept of zero tolerance may provide consumers with a false sense of security, since in fact it does not actually mean "zero risk" for them*.

The indication of a specified C, even as an example, may induce the establishment of criteria that would not necessarily reflect the adequate stringency for a given situation.

*Adapted from Microorganims in foods 7. Microbiological testing in food safety management. ICMSF. Springer. 2001.

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**.

Here we focus on the Spanish version of document CX/FH 12/44/6.

I. 2.3 3. GENERAL PRINCIPLES – Paragraph 1

We propose to delete the word "or", as trade may override the health of the consumer, or vice versa. The Statutes of Codex Alimentarius Commission should be complied with.

*"An MC should be appropriate to protect the health of the consumer **and/or** ensure fair practices in food trade."*

Proposal: An MC should be appropriate to protect the health of the consumer and **/~~or~~** ensure fair practices in food trade.

II. 4.1 General Considerations – Paragraph 12

The internationally recognized food safety assurance system in Spanish is APPCC or HACCP (from its English name). In addition, the food safety assurance system cited in several Codex Alimentarius standards (in Spanish) is "APPCC" and in the text of this standard.

"(…) Los enfoques pueden ir desde el desarrollo de CMs basados en el conocimiento empírico relativo a las BPH, hasta el uso de los conocimientos científicos sobre el control a través de sistemas tales como el de ***análisis de riesgos*** *y puntos críticos de control (****AR****PCC) o la realización de una evaluación de riesgos."*

Proposal: (…) Los enfoques pueden ir desde el desarrollo de CMs basados en el conocimiento empírico relativo a las BPH, hasta el uso de los conocimientos científicos sobre el control a través de sistemas tales como el de **análisis de peligros y puntos de control crítico (APPCC)** o la realización de una evaluación de riesgos.

III. 4.7 Microbiological methods – Paragraph 36

The term "material" may refer to the sample, food, processed material, etc. Therefore, the scope of the term "material" should be specified.

"In general the methods used should be fit for purpose, meaning the method should give reliable results minimizing the risk of misclassification for ***material*** *around the microbiological limit."*

IV. 5. REVIEW OF MICROBIOLOGICAL CRITERIA FOR FOODS – Paragraph 58

It should clarify what type of metrics is referred to and which can relate to MCs.

"The goal should ultimately be to achieve a more quantifiable estimation of the linkages between MC, other metrics and public health outcomes".

V. 1. INTRODUCTION – Paragraph 1

The terminology should be consistent with other adopted Codex standards, such as the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007).

"(…) Advances in microbiological risk assessment (MRA) ***techniques****, and the use of the risk management framework are increasingly making possible a more quantifiable estimation of the public health risk and a determination of the effect of interventions (…)."*

Proposal: (…) Advances in microbiological risk assessment (MRA) ~~**techniques**~~, and the use of the risk management framework are increasingly making possible a more quantifiable estimation of the public health risk and a determination of the effect of interventions. (…)

VI. 1. INTRODUCTION – Paragraph 3

Comment on the Spanish wording.

"(…) Sin embargo, el establecimiento de CMs pudiera ser apropiado para verificar el sistema de inocuidad de los alimentos está siendo implementado correctamente."

Proposal: (…) Sin embargo, el establecimiento de CMs pudiera ser apropiado para verificar **que** el sistema de inocuidad de los alimentos está siendo implementado correctamente.

VII. 1. INTRODUCTION – Paragraph 4

Comment on the Spanish wording.

"A menudo los criterios de monitoreo del ambiente de procesamiento de los alimentos es considerado como una parte importante del sistema de control de la inocuidad de los alimentos."

Proposal: A menudo los criterios de monitoreo del ambiente de procesamiento de los alimentos ~~**es considerado**~~ **son considerados** como una parte importante del sistema de control de la inocuidad de los alimentos.

VIII. 4.1 General Considerations – Paragraph 14

Comment on the Spanish wording.

"(…) los CMs se establecen un punto específico en la cadena alimentaria."

Proposal: (…) los CMs se establecen **en** un punto específico en la cadena alimentaria.

IX. 4.1 General Considerations – Paragraph 14

Comment on the Spanish wording.

"(...) los CMs se establecen un punto específico en la cadena alimentaria."

Proposal: (…) los CMs se establecen **en** un punto específico en la cadena alimentaria.

X. 4.4 Components – Paragraph 23

Comment on the Spanish version, based on the English version.

*"(...) la posibilidad y consecuencias de la contaminación microbiológica y/o el crecimiento e inactivación durante el **manejo**, empaque, almacenamiento, preparación y uso subsecuentes;"*

Proposal: (…) la posibilidad y consecuencias de la contaminación microbiológica y/o el crecimiento e inactivación durante la ~~**manejo**~~ **manipulación**, empaque, almacenamiento, preparación y uso subsecuentes;

XI. 4.5 Sampling Plan – Paragraph 29

Comment on the Spanish wording.

"El número y tamaño de las unidades analíticas deberían ser el establecidas en el plan de muestreo (...)"

Proposal: El número y tamaño de las unidades analíticas deberían ser ~~**el**~~ **las** establecidas en el plan de muestreo (…)

XI. 4.11 Action to be taken when the MC is not met. – Paragraph 52

Comment on the Spanish version, based on the English version.

*"Éstas deberían basarse en una evaluación del riesgo **al** consumidor, **donde así corresponda;** (...)"*

Proposal: Éstas deberían basarse en una evaluación del riesgo **para el** consumidor **en su caso**; (…)

COSTA RICA (comments relate only to the Spanish and are included in the Appendix to this document)

EGYPT

The Draft of the *"Principles for the Establishment and Application of Microbiological Criteria for Foods" is very supportive, therefore:*

- Egypt greatly appreciates the efforts made by the Drafting Teams, Physical Working Group (PWG) and the first Comments submitted by countries.
- Egypt reassures the benefits and constructive experience of elaborating these practical examples, which contributed to improve the lucidity and understanding of the main document, "*the Principles…"*
- Egypt also accepts all the revised parts, added definitions, statements and texts done in the main Document, particularly, in Definitions, Purposes, the Moving Window Approach, and Trend Analysis Procedure, etc.
- Many important definitions are required such as *Appropriate Level of Protection (ALOP*), *Food Safety Objective (FSO), Performance Objective (PO), Performance Criterion (PC), Lot, Validation*, and *Verification*.
- Egypt also proposes to add an alternative term for metrics or to add a specific definition for this term to facilitate understanding it in line with various expression such as FSO, PO and PC
- In general, *Egypt found that "Draft of the Principles for the Establishment and Application of Microbiological Criteria for Foods*" is considered, indeed, more clear and applicable by countries, and can be easily utilized in many recent practices, situations, and even future usages.

Egypt desires to raise an important comment in "Purpose" section:

- *Application of Microbiological Criteria for Foods* should also cover or consider (in the following order): the Validation of Control Measures of HACCP Plans, Prerequisites, and the Operational Prerequisites during the Application of HACCP System or ISO 22000.

- Egypt also suggests to re – discussing CX/FH 12/44/6 how to use and where to locate the examples developed by the drafting team.

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 is a great improvement and become the fairly good shape than the last version. Japan wishes a fruitful discussion at the forthcoming 44th CCFH and, as a result, hopes the advancement of main document going forward for adoption by the Commission at Step 5/8. Having said that, Japan offers the following comments to provide additional clarity.

Specific Comments

2.2 Definitions

Paragraphs 10

Revise the 3rd bullet of paragraph 10 as follows:

- Their toxins/metabolites **(excluding toxins/metabolites that has/will been addressed by Codex Committees other than Committee on Food Hygine, e.g. mycotoxins, marine biotoxins)** ;and

Rational: Some natural toxins have already been addressed by other Codex Committee. For example, CCCF has established the maximum levels of mycotoxins which is toxic metabolites of certain microfungi.

4 General considerations

Paragraphs 15

Revise the second sentence as follows:

Such need could be demonstrated, e.g. by epidemiological evidence that the food under consideration may represent a **significant** public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment.

Rational: to clarify the intent of the sentense. Without this insertion, since most of food safety hazards may pose some levels of public health risk to consumers, thus MCs should be established almost all the hazards – commodity conbinations. But this is not the intention of the pWG.

MAURITIUS

In principle, Mauritius has no comments on the document, other than a general question regarding the definitions. Mauritius wishes to propose that the definitions be presented in the same way as they were in the Proposed Draft guidance for use by Government in prioritizing the national feed hazards (CX/AF 13/7/5) developed by the Task Force on Animal Feeding, which Mauritius believes are more user friendly that the one in CX/FH 12/44/6.

MEXICO

Specific Comments:

CX/FH 12/44/6	Comments	Rationale
Table of Contents 4.6 Microbiological and/or other limits	Microbiological and/or other ~~limits.~~ limits	It is unclear which "limits" they are referring to, because these could refer also to operational controls (e.g. time and temperature control in the peanut roasting process to meet the MC absence of *Salmonella* spp.)

CX/FH 12/44/6	Comments	Rationale
Paragraph 8 These principles and guidelines are intended to provide a framework for national governments and food business operators on the establishment and application of MC that can be applied for food safety and other aspects of food hygiene.	These principles and guidelines are intended to provide a framework for national governments and food business operators on the establishment and application of MC that can be applied for food safety (pathogenic microorganisms and/or its metabolites) and other aspects of food hygiene (indicator microorganisms like: mesophilic aerobic microorganisms, fungi and yeast, total coliforms, fecal coliforms, and others).	Contributes to clarify the text.
Paragraph 10 For the purpose of this document microorganisms include, but are not limited to, the following: • bacteria, viruses, moulds, yeasts, and algae; • protozoa and helminths; • 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) where/when linked to the presence of viable cells where appropiate.	For the purpose of this document microorganisms include, but are not limited to, the following: SAFETY - pathogenic bacteria (*Salmonella* spp., *Vibrio cholerae*, *E. coli 0157:H7*, *Listeria monocitogenes*, among others). - food-borne virus (hepatitis A virus, Norkwalk, rotavirus, among others). - Parasites (*Entamoeba histolytica*, *Ascaris lumbricoides*, helminths worms, among others). - 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) where/when linked to the presence of viable cells where appropriate. FOOD HYGIENE ASPECTS - Fungi and yeasts - anaerobic mesophilic microorganisms - total coliforms - fecal coliforms; amongst others that cause spoilage or unwanted defects in the product, but do not represent a threat to consumers' health	The purpose is to emphasize a clear distinction between safety aspects and hygiene aspects that do not necessarily lead to food safety issues, to prevent the user from using them interchangeably.
Paragraph 21 A MC consists of the following components: • the microbiological limits (m, M) and/or other limits considered appropriate to the food;	The term "other limits" is still very vague.	As suggested in our previous comment, consider clarifying whether “other limits” refers to process parameters associated to the CM (temperature, time, pH, Wa, among others).

CX/FH 12/44/6	Comments	Rationale
Chapter 4.6 Microbiological and/or other limits Paragraphs 30-35	Delete all paragraphs in this chapter and insert a reference to General Guidelines on Sampling CAC/GL 50-2004.	The guidelines provide an ample explanation of the sampling plans. This is a complex subject matter, and the way in which it has been summarized in this document seems to be aimed at statistical experts. Therefore, it is necessary to review chapter 4.6 to include the guidelines for a more in depth analysis, otherwise it becomes very difficult to understand.

NEW ZEALAND

New Zealand would like to thank Finland and Japan as Co-chairs, along with the members of the MC Working Group for preparing the draft document for comment at Step 3.

General comment

MC sometimes means "microbiological criterion" and at other times means "microbiological criteria".

New Zealand suggests that "MC" should always be elaborated in full so that this is not problematic throughout the document.

Specific comments

New Zealand would like to offer the following specific comments:

Section	**Proposed change**	**Rationale**
Section 1. Introduction Paragraph 1.	"Advances in microbiological risk assessment (MRA) techniques, and the use of the risk management framework are increasingly making ~~possible~~ a more quantifiable estimation of the public health risk and a determination of the effect of interventions <u>possible</u>."	Reason – improves readability
Section 3. General Principles	Change order and content of the bullet points to: • An MC should be appropriate to protect the health of the consumer and/or ensure fair practices in food trade • The purpose of establishing and applying an MC should be clearly articulated • The establishment of MC should be based on scientific advice and analysis and follow a structured and transparent approach • <u>An MC should be practical and feasible and established only when necessary</u> • ~~The required stringency of an MC used should be appropriate to its intended purpose~~ • MC should be established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain • ~~An MC should be practical and feasible and established only when necessary~~	There are some that would be considered before others

Section	Proposed change	Rationale
	• The required stringency of an MC used should be appropriate to its intended purpose • Periodic reviews of MC should be conducted, as appropriate, in order to ensure that MC continue to be relevant to the stated purpose under current conditions and practices.	
Section 3 General Principles New bullet point	• An MC should allow for measurement errors (e.g. rates of false positives and negatives) where this could noticeably affect its performance	Add new bullet point to capture measurement errors
Section 4. Establishment and application of MC 4.1 General considerations Paragraph 12	Amend to: "These approaches can range from developing MC based empirical knowledge related to GHPs, to using scientific knowledge of food safety control systems ~~through a system~~ such as through HACCP, or by conducting a risk assessment."	Food safety control systems includes GHP
Section 4.1		The text in section 4.1 repeats text or information elsewhere in the document e.g. Para 15 first sentence already covered in General Principles
Section 4.1 General considerations Para 13 and 14	~~The microorganism included in an MC should be accepted as relevant in relation to the stated purpose~~ ~~Since the levels/prevalence of a microorganism can change over the course of manufacture, distribution, storage, marketing and preparation, an MC is established at a specified point in the food chain.~~	Delete as these are covered under **Section 4.4 Components**
Paragraph 15	The need for an MC ~~should be practical and feasible and established only when necessary and practical for the stated purpose. Such need~~ should ~~could~~ be demonstrated, e.g. by epidemiological evidence that the food under consideration may represent a public health risk and that a criterion is meaningful for consumer protection, or as a result of a risk assessment.	Delete repetition of "practical and feasible" between the principles in section 3 and the General considerations in section 4.1.
4.2 Purpose Paragraph 16	There may be multiple ~~purposes~~ reasons for establishing and applying MC.	Improves readability
Paragraph 16 (iii)	Validating critical limits against ~~the maximum limit of~~ an MC when considering CCPs prior to implementation or modification of a HACCP plan	Simplifying the intent of 16 (iii)
4.2 Purpose Paragraph 17.	Amend to: "In addition, ~~an~~ MC is a valuable risk management metric when applied to ~~for~~ detect~~ing~~ potential unforeseen problems in the design and/or operation of a food safety control system, and for obtaining safety and	Improves readability

Section	Proposed change	Rationale
	suitability information that is not otherwise available."	
Paragraph 18	Ongoing efforts to reduce the complexity of risk assessment ~~can s~~should help facilitate the ~~development~~ use of risk-based MC	Adds clarity to the meaning of this sentence
Paragraph 19	One approach involves testing the acceptability of individual lots and evaluating the ~~acceptable~~ relative risk to public health of the lot as compared to the ALOP.	"Relative risk" commonly used, not "acceptable relative risk"
Section 4.4 **Components**	Change heading **Components and other considerations**	Section covers components and other considerations
Section 4.4 Paragraph 21	the microbiological limits (m, M) [1] and/or other limits considered appropriate to the food	Should footnote definitions for clarity
Section 4.5 Paragraph 28: Second sentence and last sentence	~~For these plans, to assess the probability of acceptance as a function of the level of the target microorganism, it is necessary to know or estimate the distribution of microorganisms.~~	Delete as leads to confusion. For attributes plans to be valid, all that is required (provided that measurement error is not considerable) is that some probability based technique (e.g. simple random sampling or stratified random sampling) is used to collect the sample units from the entire lot. However, the presence of considerable measurement error will affect the probabilities of acceptance, and needs to be allowed for.
Section 4.9 Moving Window Paragraph 43, 44	Amend to improve clarity and understanding of the concept of a moving window 43. For the ongoing verification of performance of food safety control systems, an MC can be applied across a series of sampling windows, each having a defined time frame and a specified sampling frequency ~~(window)~~. ~~While such a moving window approach may not identify particular lots as non-conforming, it provides a continuous metric for checking the acceptability of the performance of the food safety control system.~~ 44. Whilst the moving window approach may not identify particular lots as non-conforming it is a practical and cost beneficial way of checking continuous microbiological performance of a food safety control system ~~through generation of various inputs/data that enables a targeted analysis~~ and it allows	

[1] Two class attributes sampling plan – m denotes one upper microbiological limit on the acceptable concentration in the analytical unit
Three class attributes sampling plan - m separates conforming from marginally acceptable analytical units
Three class attributes sampling plan - M means non-conforming analytical units

Section	Proposed change	Rationale
	appropriate intervention in case of shifts in process control. 45. Single samples are taken at a specified frequency over a defined time frame (the sampling period)., ~~and~~ The results of the latest n samples are ~~continuously~~ compared with the microbiological limit(s) ~~and with~~ using the acceptance number c. Each time a new result or set of results from the sampling period is available, it is added to the window while the oldest result or set of results is removed. The window, always consisting of n results, moves one result or set of results forward in time.	
Paragraph 46	Move to **Section 4.5 Sampling Plan**: When designing the sampling frequency, consideration should be given to the following: • The number of processing lines subjected to the verification; • Sufficient production frequency (e.g. daily production); • Distribution of organisms in food; and • Probability of detection.	This paragraph relates to any type of plan not just moving windows
4.10 Trend Analysis	49. Trend analysis is a procedure to analyse results over time. It can be applied to many types of information including results of microbiological testing against an MC. 50. Trend analysis may show changes or patterns in the data that is a result of ~~, may reveal~~ unwanted shifts in the manufacturing process enabling the food business operator to take corrective actions before the food safety control system is out of control. The trends (or patterns) can be visualised ~~followed~~, e.g. by displaying the test results graphically on control charts.	Amend to more clearly state that trend analysis is about looking for changes or patterns and looks at data in an undefined time period and number of samples.
Section 4.11Action to be taken when MC is not met Paragraph 52	Amend first sentence. In situations of non-conformance with MC (unsatisfactory results), the first action ~~actions~~ to be applied should be to restore control. Further actions should relate to the purpose of the testing. These actions should be based on an assessment of the risk to the consumer where relevant; the point in the food chain, and the food specified and may consider history of conformance. Food business operators should re-evaluate their food safety control systems, including GHP and operational procedures, and/or further investigation to determine appropriate preventative actions to be taken.	The first action should be restoration of control. Further actions are usually preventative
Paragraph 53	In the event of the non-conformance with an MC for a pathogen, actions should include appropriate product disposition. This may ~~additionally~~ include:	Product disposition is a key component of corrective action and needs to be emphasised

Section	Proposed change	Rationale
	sorting, further processing, diversion to an alternate use, withdrawal and/or recall, rework, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken.	Clarity is required as to what is meant by "sorting"
Paragraph 59	When MC have been developed to address specific risk outcomes they should be reviewed against those outcomes and, if shown not to be effective, they should be amended or revoked	Amendment may suffice. MC may not always be revoked

NICARAGUA

Nicaragua commends the host countries that have organized and prepared this document, and suggests the following corrections to the aforementioned document:

General Comments The Spanish translation of the document needs to be thoroughly revised.
Specific Comments:

3. GENERAL PRINCIPLES

- An MC should be appropriate to protect the health of the consumer and **~~and/or~~** ensure fair practices in food trade.

Rationale: The word **or** is deleted because the health of the consumer cannot be separated from fair practices in food trade; they should go hand in hand.

- The purpose of establishing and applying an MC should be clearly ~~articulated~~ **justified.**

Rationale: The word **articulated** is deleted because it does not reflect the idea of the principle. We suggest the word **justified** because it defines the principles on which this criterion is based.

- The establishment of MC should be based on science and scientific ~~advice~~ analysis and follow a structured and transparent approach.

Rationale: We replace "advice" with "science", because CODEX decisions should be based on science.

- Periodic reviews of MC should be conducted, ~~as~~ **where** appropriate, in order to ensure that MC continue to be relevant to the stated purpose under current conditions and practices.

Rationale: We replace the word "as" with "where", because it provides guidance to undertake a criterion revision.

4. ESTABLECIMIENTO Y APLICACIÓN DE LOS CRITERIOS MICROBIOLÓGICOS (this comment applies to Spanish version)

4.1 Consideraciones generales

12. Los CMs se establecen con base en el conocimiento de los microorganismos y su ocurrencia y comportamiento a lo largo de la cadena alimentaria. Al considerar el establecimiento de CMs pueden usarse una gran cantidad de enfoques, dependiendo de los objetivos de gestión de riesgos y el nivel de conocimientos y datos disponibles. Los enfoques pueden ir desde el desarrollo de CMs basados en el conocimiento empírico relativo a las BPH, hasta el uso de los conocimientos científicos sobre el control a través de sistemas tales como el de análisis de **Peligro** ~~riesgo~~ y puntos críticos de control **(APPCC)** ~~(ARPCC)~~ o la realización de una evaluación de riesgos. La selección del enfoque debería estar alineada con los objetivos de gestión de riesgos y las decisiones relativas a la inocuidad y pertinencia de los alimentos.

Rationale: The word "riesgo" ("risk") is replaced with "peligro" ("hazard") because CODEX establishes guidelines for hazard analysis and critical control point (HACCP). Replace throughout the document.

4.4 Components

the microbiological limits (m, M) **and**~~/or~~ other limits considered appropriate to the food;

Rationale: To clearly define the limits to be considered. Delete **or**. .

22. Action to be taken when the MC is not met should be specified **in conformity with the national legislation of each country.**

Rationale: To include "in conformity with the national legislation of each country" after the word "specified", because each country has its national legislation.

NORWAY

Norway appreciates this opportunity to comment upon the proposed draft revision of the principles for the establishment and application of microbiological criteria for foods (CX/FH 12/44/6). We would like to congratulate Finland and Japan for the important progress made by the working group which took place in Parma, Italy in May 2012, but also thank Finland and Japan for all the effort that has been put into preparing this draft.

(i) General comments

Norway is of the opinion that structure and the clarity of the document has improved, compared with the previous version.

Furthermore, we suggest that priority should be given to finalize the main document as soon as possible, without waiting for the annex with examples to be completed.

We recommend the CCFH to continue the work on the annex with examples, because such an annex will contribute to improve the clarity and understanding of the main document.

(ii) Specific comments

SECTION 4 Establishment and application of microbiological criteria

4.1 General considerations

Insertion of a new para: "**During the establishment and application of an MC, the intrinsic differences seen between different food commodities in terms of challenging microorganism, should be taken into consideration."**

Rationale: Different food commodities have different microbiological challenging microorganisms, e.g. seafood has other microbiological challenges than food derived from terrestrial animals. Thus the proposed new paragraph to take care of these differences.

4.7 Microbiological methods

Insertion of new text: "**The microbiological methods used should preferably be validated in accordance with an internationally accepted protocol.**

Rationale: Consistency with other Codex documents.

ST. LUCIA

General Comments

St. Lucia would like to thank the working group for their efforts in revising the document. St. Lucia supports the overall revision of the document CAC/GL 21-1997 with inclusion of practical examples. The practical examples should be referenced as an annex to the Principles for establishment and application of microbiological criteria for foods.

St. Lucia supports the advancement for adoption of the revised P*rinciples and Guidelines for the Establishment and Application of Microbiological Criteria for Foods* to the 36th session of the Commission.

Specific Comments

St. Lucia would like to submit the following specific comments

Section 3 bullet 3

3. GENERAL PRINCIPLES

- An MC should be appropriate to protect the health of the consumer and/or ensure fair practices in food trade.

- The purpose of establishing and applying an MC should be clearly articulated.
- The establishment of MC ~~should~~ **needs to** be based on scientific ~~advice and~~ analysis **and evidence** and follow a structured and transparent approach.

Section 4.4, paragraph 22 and 23

"Action to be taken when the MC is not met should be specified. **See Clause 4.11."**

"To ~~fulfil~~ **fulfill** the establishment of an MC, some considerations are common to all MC. In addition to the components for an MC listed in section 4.4, these considerations include, but are not limited to, the following:"

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. We support moving this document forward with some minor changes indicated below.

SPECIFIC COMMENTS

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

SCOPE

Paragraph 8

Consider moving paragraph 10, revised as suggested below, to the end of the Scope. The Scope would thus read as follows:

8. These Principles and Guidelines are intended to provide a framework for national governments and food business operators on the establishment and application of MC that can be applied for food safety and other aspects of food hygiene. MC established for the monitoring of the food processing environment are not in the scope of this document. Microbiological criteria can be applied to the following:

- bacteria, viruses, moulds, yeasts, and algae;
- protozoa and helminths;
- 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) where/when linked to the presence of viable cells where appropriate.

Rationale: We believe that the list of entities for which an MC may apply would be more appropriate as part of the Scope. In addition, this would address our concerns noted below about including toxins, metabolites and markers associated with pathogenicity as "microorganisms."

DEFINITIONS

Paragraph 9

Insert the indicated text; delete the commas after "metric" and after "food" in the definition of a microbiological criterion:

A microbiological criterion is a risk management metric~~,~~ which indicates the acceptability of a food~~,~~ or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity at a specified point in the food chain.

Rationale: As noted with respect to paragraph 10, we have concerns about including toxins, metabolites and markers associated with pathogenicity as "microorganisms." Other changes are editorial.

Paragraph 10

We recommend revising the beginning of this paragraph as follows:

10. ~~For the purpose of this document microorganisms include, but are not limited to,~~ Microbiological criteria can be applied to the following: …

Moreover, we suggest that the revised paragraph 10 with its bullets may be more appropriate in the Scope of the document.

Rationale: We have concerns about including toxins, metabolites and markers associated with pathogenicity as "microorganisms." The list of entities for which an MC may apply would be more appropriate as part of the Scope.

GENERAL PRINCIPLES

Bullet 3

Revise as follows: The establishment of MC should be based on scientific ~~advice~~ information and analysis and follow a structured and transparent approach.

Rationale: It is not clear who should provide the scientific advice on which the MC is to be based. It is more appropriate to state that an MC be based on an analysis of scientific information.

Bullet 6

Move this bullet, which says "An MC should be practical and feasible and established only when necessary" to follow the first bullet.

Rationale: It is more logical to have this bullet follow the bullet about the MC being appropriate to protect public health and ensure fair practices in food trade and precede the one about clearly articulating the purpose of the MC.

ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

Paragraph 15

We recommend modifying the paragraph as follows:

15. ~~An MC should be practical and feasible and established only when necessary and practical for the stated purpose. Such~~ The need for an MC could be demonstrated, e.g. by epidemiological evidence that the food under consideration may represent a public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment.

Rationale: Modification to avoid redundancy: The first sentence of paragraph 15 is a repeat of two principles.

Section 4.4 Components

We recommend this be changed to "Components and Considerations"

Rationale: Only paragraph 21 lists components; paragraphs 22-24 in this section contain considerations.

Paragraph 22

Revise as follows:

Consideration should be given to the ~~A~~action to be taken when the MC is not met and the action should be specified.

Rationale: Emphasizes the need to consider what action should be taken before specifying what that action will be.

Paragraph 23

Revise the second sentence as follows:

In addition to the components for an MC ~~listed in section 4.4~~, these considerations include, but are not limited to, the following:

Rationale: Both the components and the considerations are found in section 4.4; the section would only be needed if the components were in a different section.

Paragraph 31

Insert a comma after "analytical unit."

Where the microbiological limits m and M are part of an attribute sampling plan further defined

through n, c, and the size of the analytical unit, they are expressed as presence/absence or concentration of the microorganism in one analytical unit.

Rationale: Editorial

Paragraph 44

Revise the last sentence:

It detects of a sudden deviation (significant change) from a microbiological limit, usually established from a baseline, and allows appropriate intervention in case of shifts in (i.e., a shift toward loss of) process control.

Rationale: Revision to help clarify the difference between a moving window approach and trend analysis and a clarification – interventions are generally taken when there is a loss of control or indication that a loss of control is likely in the absence of intervention.

Paragraph 47

Add the following at the end of the paragraph:

The length of the moving window may be based on a statistical probability of detecting c positives in n results that offers reasonable consumer protection with a low rate of "false positives," i.e., a chance occurrence rather than an indication of inadequate control.

Rationale: Revision to help clarify the difference between a moving window approach and trend analysis.

Paragraph 48

Revise as follows:

The moving window approach should not be confused with trend analysis, ~~which compares data over a longer period of time and~~ which is not a part ~~on~~ of an MC.

Rationale: Trend analysis does not necessarily compare data over a longer period of time than a moving window. For example, a decision criterion for a trend may be 3 observations in a row trending up or down.

Paragraph 49

Modify the paragraph as follows:

49. Trend analysis is a procedure to ~~analyse~~ detect a change in the pattern of results, such as a linear or nonlinear increase in some average value, over time. It can be applied to many types of information, including microbiological testing against an MC. Trend analysis can detect a gradual loss of control that might not be detected by a moving window approach, as well as a sudden loss of control.

Rationale: Revision to help clarify the difference between a moving window approach and trend analysis.

Paragraph 50

Revise the last sentence:

Trend analysis may reveal unwanted ~~shifts~~ changes in the manufacturing process, enabling the food business operator to take corrective actions before the food safety system is out of control.

Rationale: Editorial.