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

(at Step 3)

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<MEXICO: 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.)>

4.12 Documentation and Record Keeping

5.   Review of Microbiological criteria for Foods

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1.   INTRODUCTION

1.   Diseases caused by food-borne pathogens constitute a major burden to consumers, food business operators and national governments. Therefore, the prevention and control of these diseases are international public health goals. These goals have traditionally been pursued, in part, through the establishment of metrics such as the microbiological criterion (MC), reflecting knowledge and experience of Good Hygienic Practice (GHP) and the impact of potential hazards on consumer health. MC have been used for many years and have contributed to improving food hygiene in general, even when established based on empirical observation of what is achieved under existing measures without any explicit linkage to specific levels of public health protection. Advances in microbiological risk assessment (MRA) techniques<COLOMBIA: 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). >, 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 possible<NZ>. This has led to a series of additional food safety risk management metrics such as Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC) (*see Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)). Where MRA models are available or these metrics have been elaborated, they can allow the establishment of a more direct relationship between MC and public health outcomes.

2.   The establishment and application of MC should comply with the principles outlined in this document and should be based on scientific advice and analysis. When sufficient data are available, a risk assessment may be conducted on foodstuffs and their use.

3.   The microbiological safety of foods is managed by the effective implementation of control measures that have been validated, where appropriate, throughout the food chain to minimise contamination and improve food safety. This 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 MC may be appropriate for verifying that food safety control systems are implemented correctly.

4.   Criteria for monitoring of the food-processing environment are often considered important parts of the food safety control system. Since they cannot be defined as specifically as MC for food they generally are not used in defining the acceptability of food, and therefore they are not in the

scope of the document, despite their utility in managing food safety.

5. The required stringency of food safety control systems, including the MC used, should be appropriate to protect the health of the consumer and ensure fair practices in food trade. MC used should be capable of verifying that the appropriate level of control is achieved.

6. Codex Alimentarius has a role in recommending MC at the international level. National governments may choose to adopt Codex MC into their national systems or use them as a starting point for addressing their intended public health goals. National governments also may establish and apply their own MC. Food business operators may establish and apply MC within the context of their food safety control systems.

7. This document should be read in conjunction with the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007), the *General Guidelines on Sampling* (CAC/GL 50-2004) and the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).

2. SCOPE AND DEFINITIONS

2.1 Scope

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 (pathogenic microorganisms and/or its metabolites) and/or other aspects of food hygiene (indicator microorganisms like: mesophilic aerobic microorganisms, fungi and yeast, total coliforms, fecal coliforms, and others) <MEXCO: Contributes to clarify the text.> , process and food safety control system.< ARGENTINA: Regarding the SCOPE, the framework defined in the first sentence is not clear and suggest the revised wording.> 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.

<USA: Consider moving paragraph 10, revised as suggested below, to the end of the Scope.
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.">

2.2 Definitions

9.   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 of the food chain. <USA: 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.>

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

<JAPAN 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.>

- 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.

<MEXCO: replace bullet points with following.

Rationale: 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. >

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,* helminthes 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

<USA: 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.>

11. Other definitions relevant to these guidelines include:

- *Appropriate Level of Protection (ALOP)*[1]

- *Food Safety Objective (FSO)*[2]

- *Performance Objective (PO)*[2]

- *Performance Criterion (PC)*[2]

- *Lot*[3]

- *Sample*[3]

- *Food safety control system*[4]

- *Validation*[4]

- *Verification*[4]

3. GENERAL PRINCIPLES

- An MC should be appropriate to protect the health of the consumer and/or ensure fair practices in food trade.<COLOMBIA: 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.> <NICARAGUA: 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. <NICARAGUA: 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.>/ stated <KENYA>]

- The establishment of MC should need to be based on [scientific advice and analysis and evidence <ST.

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

LUCIA>/ scientific ~~advice~~ information and analysis <USA: 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.>] and follow a structured and transparent approach. <NICARAGUA: We replace "advice" with "science", because CODEX decisions should be based on science.>

- An MC should be practical and feasible and established only when necessary.
  <USA: Move this bullet 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.>

- ~~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.~~

- The required stringency of an MC used should be appropriate to its intended purpose.
  <NZ: There are some that would be considered before others>

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

- An MC should allow for measurement errors (e.g. rates of false positives and negatives) where this could noticeably affect its performance. <NZ: Add new bullet point to capture measurement errors>

4. ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

4.1 General considerations
<NZ: 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>

12. ~~MC are established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain.~~ < ARGENTINA: We suggest deleting first sentence as it is repeated in POINT 3, bullet 5 of previous paragraph.> 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 food safety control systems ~~through a system~~ <KENYA> such as through HACCP, or by 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. <NZ: Food safety control systems includes GHP>

13.   The microorganisms included in an MC should be accepted as relevant in relation to the stated purpose.

14.   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. <NZ: Delete as these are covered under Section 4.4 Components>

15.   The need for Aan MC [should<NZ>/could<USA>] be practical and feasible and established only when necessary and practical for the stated purpose. Such need could <NZ: Delete repetition of "practical and feasible" between the principles in section 3 and the General considerations in section 4.1.> <USA: Modification to avoid redundancy: The first sentence of paragraph 15 is a repeat of two principles.> <PHILLIPINES: replace the term "practical" with "appropriate". Rationale: to avoid redundancy in the statement.> 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. <JAPAN 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 combinations. But this is not the intention of the pWG.>

15-bis. 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.
<NORWAY *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.* >

4.2   Purpose

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

<KENYA: There is need to reorganize the order of the points due to their weight.>

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.
<BRAZIL 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".>

iii) Validating critical limits against ~~the maximum limit of~~ <NZ> an MC when considering CCPs prior to the implementation or modification of a HACCP plan.

iv) Verifying the performance of a food safety control system or its elements along the food chain, e.g. prerequisite programs and/or HACCP systems.

v) Verifying the microbiological status of foods in relation to acceptance criteria specified between food business operators.

vi) Validating and/or verifying that the selected control measures are capable of meeting POs, FSOs and/or ALOPs.

vii) Providing information to food business operators on microbiological levels, which should be achieved when applying best practices.

<EGYPT: 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.>

17. In addition, ~~an~~ MC is a valuable risk management metric when applied to ~~for detecting~~ potential unforeseen problems in the design and/or operation of a food safety control system, and for obtaining safety and suitability information that is not otherwise available. <NZ>

4.3 Relationship between Microbiological Criteria, ALOP and other Microbiological Risk Management Metrics

18. MC may be used by competent authorities and food business operators, to operationalize the ALOP either directly or through other microbiological risk management metrics (e.g. PO, FSO). This requires the use of quantitative risk assessment. The risk estimation should include a combination of several factors such as the prevalence and concentration distribution of target microorganisms, as well as any changes in these after the step for which the MC has been set. The risk assessment should include a characterization of the variability inherent to the food production system and express the uncertainty in the risk estimate. Ongoing efforts to reduce the complexity of risk assessment ~~can~~ should help facilitate the ~~development~~ use <NZ> of risk-based MC.

19. An MC can be linked directly to the ALOP, without explicit articulation of an FSO or a PO. One approach involves testing the acceptability of individual lots and evaluating the ~~acceptable~~ <NZ> relative risk to public health of the lot as compared to the ALOP. Another approach is to link an MC directly to an ALOP, using a risk assessment model to 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.

20.   Statistical models can be used to translate a PO or FSO to an MC. To establish such an MC for a food, an assumption needs to be made regarding the distribution of the target microorganism in the food. A log-normal distribution is often assumed and a default value for the standard deviation applied. Furthermore, the maximum frequency and/or concentration of the hazard needs to be defined in the FSO or PO. If a concentration is used as a limit, also the proportion (e.g. 95%, 99%) of the distribution of possible concentrations that satisfies this limit should be defined. Other statistical considerations may need to be applied for other situations, e.g. an MC similarly established for a food process.

4. 4   Components and other consideration <NZ: Section covers components and other considerations> <USA: Only paragraph 21 lists components; paragraphs 22-24 in this section contain considerations.>

21.   An MC consists of the following components:

- the purpose of the MC;

- the food or process or food control system <KENYA: to be in-line with the definition of an MC> to which the MC applies;

- the specified point in the food chain where the MC applies;

- the microorganism(s) and the reason for their selection;

- the microbiological limits (m, M) [5] and/or other limits considered appropriate to the food; <NICARAGUA: To clearly define the limits to be considered. Delete "or".> <MEXCO: 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 MC (temperature, time, pH, Wa, among others).>

- a sampling plan defining the number of samples to be taken (n), the size of the analytical unit and where appropriate, the acceptance number (c). Depending on its purpose, an indication of the statistical performance of the sampling plan; and

- analytical methods and their performance parameters.

22.   Consideration should be given to the Aaction to be taken when the MC is not met and the action <USA: Emphasizes the need to consider what action should be taken before specifying what that action will be. > should be specified [in conformity with the national legislation of each country. <NICARAGUA: To

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[5] 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 <NZ>

include "in conformity with the national legislation of each country" after the word "specified", because each country has its national legislation.>/ See Clause 4.11. <St. LUCIA>]

23.   To 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: <USA: 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.>

- type of sample;

- sampling tools and techniques;

- frequency and timing of sampling;

- type of sampling (randomized, stratified etc.);

- economic <u>and administrative</u> <KENYA: an important component which is best included in this document> feasibility, in particular in the choice of sampling plan;

- interpretation of results;

- record keeping;

- the intended and actual use of the food;

- the microbiological status of the raw material(s);

- the effect of processing on the microbiological status of the food;

- the likelihood and consequences of microbial contamination and/or growth and inactivation during subsequent handling, packaging, storage, preparation and use; and

- the likelihood of detection.

24.   In addition, for MC targeting a pathogen, consideration should be given to:

- the evidence of actual or potential hazards to health; and

- the population at risk and consumption habits.

4.5   Sampling plan

25.   The effective use of an MC is dependent on the selection of a sampling plan to establish the appropriate probability of detecting non-conformance.

26.   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).

27.   The type of sampling plan selected for the MC will depend on the nature and purpose of the

MC. Variables sampling plans for inspection evaluate quantitative data without grouping it into classes. Variables sampling plans require information about the distribution of microorganisms, and typically assume that the inspected variables follow a normal or log-normal distribution. Variables sampling plans are seldom used, in part because they are not applicable to presence/absence testing.

28.   In practice, most microbiological sampling plans designed for lot acceptance are attributes sampling plans. For these, to assess the probability of acceptance as a function of the percentage of non-conforming units, 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 based sampling technique (e.g. simple random sampling or stratified random sampling) is used to collect the sample units from the entire lot. ~~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.~~ <NZ: 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.>

29.   The number and size of analytical units should be those stated in the sampling plan and should not be modified where the MC has been established for regulatory compliance. In unusual circumstances (e.g. during a food-borne 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~~ <KENYA> necessary to adopt an alternative MC. 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 otherwise, a lot should not be subjected to repeat testing.

4.6   Microbiological and/or other limits

<MEXCO: Delete all paragraphs in this chapter and insert a reference to General Guidelines on Sampling CAC/GL 50-2004.

Rationale: 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.>

30.   Microbiological limits separate conforming from non-conforming analytical units.

31.   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.

32.   In the establishment of microbiological limits in the context of MC, any changes (e.g. decrease or increase in numbers) in the levels of the target microorganism, likely to occur after the point for which the MC has been set should be taken into account, where appropriate. It should also be clearly stated in the MC whether the limits apply to every analytical unit, to the average, or to another specific method of calculation.

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.

<BRAZIL 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.>

34.   For a three-class attributes sampling plan the microbiological limit m separates conforming from marginally acceptable, and a limit M defines non-conforming analytical units. In this case, the acceptance number c refers to the maximum allowable number of marginally acceptable analytical units.

35.   Alternatives to microbiological limits m and M may be used in applying MC to other risk management metrics or the ALOP.

4.7   Microbiological methods

36.   The appropriate analytical microbiological <PHILLIPINES: For purposes of consistency with the title of the Section and to be specific on the method.> method (e.g. presence/absence, Most Probable Number (MPN) or colony counting) used to assess conformance with the MC will depend on the type of limit specified, the organism and the food. In general the methods used should be fit for purpose, meaning the method should give reliable results minimising the risk of misclassification for material<COLOMBIA: The term "material" may refer to the sample, food, processed material, etc. Therefore, the scope of the term "material" should be specified.> around the microbiological limit. Preference should be given to methods whose performance characteristics have been statistically determined based on benchmark studies or in collaborative method performance studies in accordance with an internationally accepted procedure. The microbiological methods used should

preferably be validated in accordance with an internationally accepted protocol. <NORWAY *Rationale: Consistency with other Codex documents.* >

37.   For many food-borne pathogens, particularly those causing illness by infection, presence/absence test methods are often specified, because they generally have a lower limit of detection than direct plating methods and thus may increase confidence that even if a pathogen is present at low levels, it will be detected.

38.   Where methods are used to determine the suitability for consumption of highly perishable foods, or foods with a short shelf-life, these should be chosen wherever possible so that the results of microbiological examinations are available before the foods are consumed or exceed their shelf-life.

39.   The microbiological methods specified should be reasonable with regard to complexity, availability of media, equipment, ease of interpretation, time required and costs.

40.   The results of testing may be impacted by compositing (i.e. pooling) of samples prior to analysis. Compositing will affect the final concentration in the tested sample and is not appropriate for enumeration methods of analysis or within three-class sampling plans. Compositing may be considered in the case of presence/absence testing within a two-class sampling plan, as long as it is ensured that the result of testing will not be affected when compared to testing of individual analytical units.

4.8   Statistical performance

41.   The statistical performance of a sampling plan is usually illustrated by its operating characteristic (OC) curve, which describes the probability of acceptance as a function of the actual proportion of non-conforming analytical units or concentration of the microorganisms in the food. An OC curve can be used to evaluate the influence of individual parameters of the sampling plan on the overall performance of the plan.

42.   Web-based tools developed by FAO/WHO through JEMRA[6] for estimating the performance of sampling plans can be utilised to evaluate sampling plans under consideration.

4.9   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 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.

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[6] http://www.who.int/foodsafety/micro/jemra/en/index.html

44. Whilst Tthe 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 Iit 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. <USA: 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.>

45. Single samples are taken at a specified frequency over a defined time frame (the sampling period). and tThe 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. <NZ: Amend to improve clarity and understanding of the concept of a moving window>

46. 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.

<NZ: Move to Section 4.5 Sampling Plan.

Rationale: This paragraph relates to any type of plan not just moving windows>

47. The length of the moving window should be appropriate to enable corrective action to be taken in a timely manner. 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. <USA: Revision to help clarify the difference between a moving window approach and trend analysis.>

48. 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. <USA: 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.>

4.10 Trend Analysis

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 results of 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. <USA: Revision to help clarify the difference between a moving window approach and trend analysis.>

50.　Trend analysis may show changes or patterns in the data that is a result of reveal unwanted shifts changes 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 visualized followed, e.g. by displaying the test results graphically on control charts. <NZ: 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.>

51.　Action should be taken on patterns or trends that indicate periodic or potential loss of control. Competent authorities may use trend analyses to assess the performance over time as a means to evaluate of a particular food sector.

4.11 Action to be taken when the MC is not met

52.　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. <NZ: The first action should be restoration of control. Further actions are usually preventative>

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 (e.g. <ARGENTINA>/ actions should include appropriate product disposition. This may additionally<NZ: Product disposition is a key component of corrective action and needs to be emphasised>] include sorting<NZ: Clarity is required as to what is meant by "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.

4.12 Documentation and Record Keeping

54.　Documentation and records are essential to support the MC, e.g. documentation on scientific evidence underpinning the MC, records on application/performance of the MC. Records such as test reports should give the information needed for complete identification of the sample, the

sampling plan, the test method, the results and, if appropriate, their interpretation. Reporting against the MC may be required by some national governments. See also Section 5.7 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 2.3.7 of the *General Guidelines on Sampling* (CAC/GL 50-2004).

54-bis. Records should be maintained documenting all instances of non-conformance with the MC, together with records of the corrective actions taken, both to manage food safety risks and to prevent further instances of non-conformance. <IACFO>

5. REVIEW OF MICROBIOLOGICAL CRITERIA FOR FOODS

55.   As establishing and implementing MC is a part of Microbiological Risk Management (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 MC should be considered in response to revision of other MRM Metrics and also in response to emerging issues or changes in the following, but not limited to:

- Taxonomy, prevalence or distribution for selected microorganisms;

- The incidence of disease including attribution to specific foods;

- Traits of microorganisms (e.g. anti-microbial resistance, virulence);

- The suitability of an indicator organism;

- Available analytical methods/tests/appropriateness of test;

- Food/ingredients/technology/process of food production;

- Food safety control system;

- Population(s) at risk;

- Consumer behaviour or dietary intake pattern of the food concerned;

- Understanding/knowledge of risk;

- Trend analysis results; and

- Required level of assurance.

56.   A review of the MC may be initiated and carried out by national governments and/or food business operators. Codex members may propose review of MC in Codex texts.

57.   A review will result in retention, adjustment or revocation of an MC, as appropriate.

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

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

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. <NZ:

Amendment may suffice. MC may not always be revoked>

Section 4.2 Purpose

36 妥当性確認のためにMCを使用するというブレットポイントは制御措置の妥当性確認にMCを滅多に使用しないので削除した。

Section 4.3 Relationship between microbiological criteria, other microbiological risk management metrics and ALOP

37. パラグラフ 20 （最終的には18）の最後の文（Other statistical considerations may need to be applied for other situations[, e.g. an MC similarly established for a food process].が意味が不明確なので削除した。

Section 4.4 Components and other considerations

パラグラフ 23 （最終的には21）の頭の部分のテキストをより一般的にするために修正し、また、6番目の ブレットポイント において、明確にするため "suitable conditions for pooling of samples" の前に "when appropriate" を追加した。パラグラフ 24 （最終的には22）の・第1ブレットポイント "the evidence of actual or potential hazards to health; の"hazard" を "risks" に訂正した。

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Section 4.5 Sampling plan

パラ26 （最終的には24）のvariables sampling plansに関するテキストをより正確な記述に変更

"Variables sampling plans for inspection evaluate quantitative data without grouping it into classes. Variables sampling plans require information about the distribution of microorganisms and typically assume that the inspected variables follow a normal or log-normal distribution."

すでに他のセクションでカバーされているため旧パラグラフ 28とその下の３つのブレットポイント（以下）を削除

[When designing the sampling frequency, consideration should be given to the following:

- The number of processing lines subjected to the verification;
- Distribution of organisms in food; and
- Probability of detection]

Section 4.6 Microbiological and/or other limits

パラグラフ　32(最終的には30)

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.の"(often zero)" は不要なので削除した。

Section 4.7 Analytical methods
パラグラフ　36(最終的には33), inter-laboratory study ができない場合、は標準化されたプロトコルに従ってinter-laboratory validation はできうると明確にした。
　"The validation study should be based on internationally accepted protocols and include an interlaboratory study. If not available, a validation should be done by the laboratory applying the method, according to a standardised protocol."

Section 4.9 Moving window
コンセプト、目的、MWアプローチをどのように適用するかについて、よりわかりやすく説明するため、テキストを書き換え
これらの変化に伴い, Section 10 "Trend analysis"は前日 p WGで改定されたテキストを再修正する必要はなくなった。

Moving window
　通常のサンプリング計画では同一ロットから決められたサンプル数（n）を採取して検査し、その中で基準値（m）を超えるものが（c）個以内であれば合格と判定するが（2階級法）、Moving windowでは、比較的大きな数のサンプル数n個を一定の期間、決められた頻度で採取して検査し、最新の結果が加わるたびに最古の検査結果をn個の枠から削除し、そのn個のなかで、基準値（m）を超えるものが（c）個以内であればその工程または食品安全管理システムは適切に管理されていると判断する手法であり、サンプル日ごとの検査結果を表に表した場合、n個の枠が検査結果が加わる度に日々移動するように見えるので、Moving windowと呼ばれている。
the moving window のサイズを考えるとき、

- 　　　製品の製造頻度
- 　　　必要なサンプリング頻度　　　組み合わせを考慮すべき