CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 **CX/FH 12/44/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-fourth Session

New Orleans, United States of America, 12 – 16 November 2012

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

(At Step 3)

Prepared by the Physical Working Group led by Finland and Japan

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Principles and Guidelines at Step 3 (*see* Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Ms Barbara McNiff, US Department of Agriculture, Food Safety and Inspection Service, US Codex Office, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720 3157, or email Barbara.McNiff@fsis.usda.gov with a copy **to**: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 September 2012.**

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

Report of the Physical Working group on the

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

Introduction

1. The Physical Working Group (pWG), co-chaired by Finland and Japan and hosted by the European Union, met on 29 May - 1 June 2012 in Parma, Italy, with the attendance of delegates from Argentina, Australia, Belgium, Bolivia, Brazil, Cameroon, Canada, China, Colombia, Costa Rica, Denmark, Egypt, European Union, Finland (co-Chair), France, Germany, Ghana, India, Ireland, Italy, Japan (co-Chair), Kenya, the Netherlands, New Zealand, Norway, Panama, Poland, Samoa, Spain, Sweden, Switzerland, Thailand, United Kingdom, United States of America and Uruguay and observers from ALA, CLITRAVI, ICMSF and IDF and respective representatives from FAO, WHO and the Codex Secretariat. A complete list of participants is given in Appendix II to this report.

2. The pWG recalled the mandate assigned by the 43rd Session of the Committee on Food Hygiene (CCFH) to:

- elaborate an Annex with practical examples on the establishment and application of microbiological criteria for different purposes through electronic means by teams of two or more countries;
- finalize these practical examples; and
- review and complete the main document, i.e. revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997), based on the examples and the comments received before and during the current session (ref. REP 12/FH, para. 56).

3. A revised version of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (Main document), prepared by the co-Chairs of the pWG, along with a document compiling the practical examples (Annex document) was circulated in advance of the meeting to Codex members and observers with a request to: (i) identify missing / inappropriate parts, or areas which needed to be modified in the Main document, in light of the seven examples; and (ii) comment on the practical examples.

4. Comments submitted by Argentina, Belgium, European Union, France, New Zealand, Peru, Switzerland and United States of America, were considered in a further revised document, which was distributed to the pWG members prior to the meeting.

5. The pWG agreed to discuss first the Annex document and secondly the main document.

Discussion on the Annex Document

6. The lead countries of each drafting team gave a presentation on the key features of the seven examples: namely:

- Example 1: A GHP-based approach, prepared by European Union (lead), Benin, Cameroon, Ghana and Panama;
- Example 2: Microbiological Criterion to Assess the Acceptability of a Food Lot, prepared by the United States of America (lead), Argentina, Thailand and Uruguay;
- Example 3a: Microbiological Criterion for verifying the performance of a HACCP system by the FBO, prepared by: IDF (lead), Bolivia, Gambia, and Nigeria;
- Example 3b: Microbiological Criterion for verifying the performance of a food safety control system, prepared by New Zealand (lead), Costa Rica, Kenya, Kiribati and Samoa;
- Example 4: Risk-based Microbiological Criterion for food/pathogen with a high prevalent pathogen, prepared by Denmark (lead), Colombia, Costa Rica, Senegal and ALA.
- Example 5a: Operationalising a Performance Objective with a Microbiological Criterion for a Risk-Based Approach, prepared by Canada (lead), Brazil, France, India and ICMSF;
- Example 5b: Operationalising a Performance Objective with a Microbiological Criterion for a Risk-Based Approach, prepared by the United States of America (lead), Brazil and Thailand.

7. Members of the drafting teams highlighted the benefits and positive experience of elaborating the practical examples. The pWG noted that all examples contributed to improve the clarity and understanding of the main document, that the level of complexity of the examples varied and that the structure and terminology of all examples needed to be harmonised. It was suggested to extract the more complex statistical and mathematical texts and tables of some examples (e.g. Example 2), which could be further considered by FAO/WHO.

8. The pWG also noted that the examples illustrated useful approaches to the establishment and application of MC, e.g. the Moving Window (MW) approach in Example 3a, which could be incorporated in the main document. In the further discussion of Example 3a, the relationship between the MW approach and trend analysis was also considered, and it was suggested to further clarify the relation between these two approaches in the main document.

9. With regard to Example 3b, the pWG noted that this illustrated the usefulness of a hazard-based MC when aiming at improving public health. On the issue of cost-benefits of using such an approach it was suggested that, while this kind of application could be very effective in a situation of a high pathogen prevalence and concentration, it might become less so in a situation where public health had improved because of the MC. In addition, it was noted that in a situation of improved compliance with the MC, efforts could target food business operators with poor compliance. The pWG discussed the need to clarify the actions to be taken by the Competent Authority (CA) in case of MW failure.

Discussion on the Main Document

10. The key points brought forward in the discussion of the pWG are summarised in the following paragraphs.

11. The pWG recalled that the last session of CCFH decided not to address food processing environment at this time. Therefore, the term "process environment" was deleted from the main document; the following new sentence was inserted in section *2.1 Scope*:

> "MC established for the monitoring of the food processing environment are not in the scope of this document."

12. The pWG agreed that for the purpose of the document, "microorganisms" included not only bacteria, viruses, moulds, yeasts, algae, protozoa and helminths, but also their toxins/metabolites and their markers or other traits. Consequently, relevant parts of the main document were modified accordingly.

13. The pWG agreed not to define Metrics, because in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007) (MRM document) this term is not defined either.

14. The pWG re-structured the main document and (a) created a new Section 3 on general principles; (b) combined Sections 4 and 5 into a Section entitled "Establishment and application of MC"; and (c) created in Section 4 a new sub-section "Purpose" to highlight the multiple purposes of MC.

15. The pWG decided that the various purposes listed in the new sub-section would not be listed in a hierarchical order.

16. The pWG agreed to include in Section 4.1 "general considerations" a new paragraph, which stated that "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." The 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. Consequently, the pWG agreed to delete the three categories of MC, i.e. GHP-; hazard- and risk-based MC, from the draft document.

17. The pWG recalled that for establishing an MC from the ALOP, it was traditionally proposed that it should be done using FSO and PO. The pWG, based on some of the examples, concluded that an MC could also be derived directly from the ALOP. The draft title of the subsection 4.3, "Relationship between MC and other MRM metrics", was subsequently re-titled accordingly.

18. The pWG revised sub-section 4.3 on the basis of the statistical considerations and experience gained in developing examples 5A and 5B.

19. In sub-section 4.5 "Sampling Plan", the pWG distinguished between variables and attributes sampling plans, and reduced the technical complexity in order to make the document easier to understand.

20. In sub-section 4.6 "Microbiological Limits and/or other limits", a new paragraph was inserted to take into account that an alternative to microbiological limit (m and M) might be used in applying MC to other microbiological risk management metrics or the ALOP.

21. The pWG re-wrote texts on the sub-section 4.9 "Moving Window" and 4.10 "Trend Analysis", based on the experiences gained during the preparation of the examples. The pWG decided to keep the two sub-sections separate, as trend analysis is not part of an MC and should preferably be described in a stand-alone section in order to avoid confusion.

22. The pWG agreed to: develop a new sub-section entitled 4.11. "Action to be taken when MC is not met", to highlight general actions and specific actions for non-conforming against MC for a pathogen. Section 5 on "Documentation and record keeping" was moved into Section 4, as a new sub-section 4.12.

Conclusions and recommendations

23. The pWG concluded that all examples, prepared by the drafting teams had been useful to revise the main document, which was now ready to be considered by the 44th Session of the CCFH for finalisation and to be forwarded to the Commission for adoption.

24. Therefore, the pWG recommended that the 44th CCFH consider and finalise the revised *Principles and Guidelines for Establishment and Application of Microbiological Criteria for Foods*, as presented in Appendix I, and forward it to the 36th Session of the Commission for adoption.

25. The pWG agreed to request the drafting teams to undertake some additional work on the practical examples to ensure that they have a harmonized structure; use consistent language and, where possible, are consistent with the main document. The pWG also asked the drafting teams to include in each example: (i) a

brief introduction; (ii) a detailed indication of the type of food covered by the example; and (iii) a sentence to indicate that the examples were not peer-reviewed.

26. The pWG agreed that the compilation of examples would be circulated as a separate document for the 44th CCFH, and that the CCFH discuss how the examples should be made available. In this regard, the pWG requested the Codex Secretariat, in collaboration with FAO/WHO, to include in the document a list of potential options for making the examples available, and to renumber the examples from 1 to 7.

27. The pWG requested the drafting teams to complete the additional work on the examples by 15 August 2012, in order to have the document finalised and distributed by beginning of September 2012.

28. The pWG recommended the 44th CCFH discuss how to use and where to locate the examples developed by the drafting teams.

Appendix I

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

(at Step 3)

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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, 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. 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 and other aspects of food hygiene. MC established for the monitoring of the food processing environment are not in the scope of this document.

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 at a specified point of the food chain.

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 appropriate.

11. Other definitions relevant to these guidelines include:

- *Appropriate Level of Protection (ALOP*)[1]
- *Food Safety Objective (FSO)*[2]
- *Performance Objective (PO)*[2]

[1] *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007)
[2] Codex Alimentarius Commission, *Procedural Manual*

- *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.
- 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.
- 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.
- 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.

4. ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

4.1 General considerations

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.

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.

15. An MC should be practical and feasible and established only when necessary and practical for the stated purpose. Such need 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.

4.2 Purpose

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, in particular if its history is unknown.

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

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[3] *General Guidelines on Sampling* (CAC/GL 50-2004)
[4] *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008)

iii) Validating critical limits against the maximum limit of 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.

17. In addition, an MC is a valuable risk management metric applied 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.

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 help facilitate the development 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 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

21. An MC consists of the following components:

- the purpose of the MC;
- the food or process 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) and/or other limits considered appropriate to the food;
- 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. Action to be taken when the MC is not met should be specified.

23. To fulfil 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:

- type of sample;
- sampling tools and techniques;
- frequency and timing of sampling;
- type of sampling (randomized, stratified etc.);
- economic 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.

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 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

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.

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 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 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.

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[5] 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 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.

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

44. The moving window approach 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. It allows appropriate intervention in case of shifts in process control.

45. Single samples are taken at a specified frequency, and the results of the latest n samples are continuously compared with the microbiological limit(s) and with the acceptance number c. Each time a new result is available, it is added to the window while the oldest result is removed. The window, always consisting of n results, moves one result forward in time.

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.

47. The length of the moving window should be appropriate to enable corrective action to be taken in a timely manner.

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 an MC

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 microbiological testing against an MC.

50. Trend analysis may reveal unwanted shifts in the manufacturing process enabling the food business operator to take corrective actions before the food safety system is out of control. The trends can be followed, e.g. by displaying the test results graphically on control charts.

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), actions to be applied 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 actions to be taken.

53. In the event of the non-conformance with an MC for a pathogen, actions may additionally include 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).

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.

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 revoked.

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Annex

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

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

(i) General Comments

(ii) Specific Comments

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

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

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

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