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

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1. INTRODUCTION

1. Diseases caused by foodborne 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, reflecting knowledge and experience of Good Hygienic Practice (GHP) and the impact of potential hazards on consumer health. Microbiological criteria 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), and the use of the risk management framework are increasingly making a more quantifiable estimation of the public health risk and a determination of the effect of interventions possible. This has led to a series of additional food safety risk management metrics: Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC) (*see* Annex II of the *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 microbiological criteria and public health outcomes.

2. The establishment and application of microbiological criteria should comply with the principles outlined in this document and should be based on scientific information 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 preventative 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 microbiological criteria 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 microbiological criteria 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 microbiological criteria used, should be appropriate to protect the health of the consumer and ensure fair practices in food trade. Microbiological criteria used should be capable of verifying that the appropriate level of control is achieved.

6. Codex Alimentarius has a role in recommending microbiological criteria at the international level. National governments may choose to adopt Codex microbiological criteria 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 microbiological criteria. Food business operators may establish and apply microbiological criteria 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 microbiological criteria that can be applied for food safety and other aspects of food hygiene. Microbiological criteria established for the monitoring of the food processing environment are not in the scope of this document. Microbiological criteria can be applied, but are not limited to, 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.

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 or other traits at a specified point of the food chain.

10. 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]
- *Attributes sampling plans*[3]
- *Variables sampling plans*[3]

3. GENERAL PRINCIPLES

- A microbiological criterion should be appropriate to protect the health of the consumer and where appropriate, also ensure fair practices in food trade.
- A microbiological criterion should be practical and feasible and established only when necessary.
- The purpose of establishing and applying a microbiological criterion should be clearly articulated.
- The establishment of microbiological criteria should be based on scientific information and analysis and follow a structured and transparent approach.
- Microbiological criteria should be established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain.
- The intended as well as the actual use of the final product by consumers needs to be considered when setting a microbiological criterion.
- The required stringency of a microbiological criterion used should be appropriate to its intended purpose.
- Periodic reviews of microbiological criteria should be conducted, as appropriate, in order to ensure that microbiological criteria continue to be relevant to the stated purpose under current conditions and practices.

4. ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

4.1 GENERAL CONSIDERATIONS

11. When considering the establishment of microbiological criteria, 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 microbiological criteria based on empirical knowledge related to GHPs, to using scientific knowledge of food safety control systems 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.

12. Since the levels/prevalence of a microorganism can change over the course of manufacture, distribution, storage, marketing and preparation, a microbiological criterion is established at a specified point in the food chain.

13. The need for a microbiological criterion should 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.

4.2 PURPOSE

14. There may be multiple reasons for establishing and applying microbiological criteria. The purposes of microbiological criteria 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) Verifying the performance of a food safety control system or its elements along the food chain, e.g. prerequisite programs and/or HACCP systems.

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

iv) Verifying that the selected control measures are meeting POs and/or FSOs.

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

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[1] *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)
[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)

15. In addition, a microbiological criterion is a valuable risk management metric when applied to detect 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, other Microbiological Risk Management Metrics and ALOP

16. Microbiological criteria 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 microbiological criterion 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 should help facilitate the development and use of risk-based microbiological criteria.

17. A microbiological criterion 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 relative risk to public health of the lot as compared to the ALOP. Another approach is to link a microbiological criterion 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 microbiological criterion.

18. Statistical models can be used to translate a PO or FSO to a microbiological criterion. The link between the PO or the FSO and the ALOP should also be demonstrated. To establish such a microbiological criterion 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.

4. 4 Components and other considerations

19. A microbiological criterion consists of the following components:

- The purpose of the microbiological criterion;
- The food, process or food safety control system to which the microbiological criterion applies;
- The specified point in the food chain where the microbiological criterion applies;
- The microorganism(s) and the reason for its selection;
- The microbiological limits (*m*, *M*; see Section 4.6) or other limits (e.g. a level of risk);
- A sampling plan defining the number of sample units 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.

20. Consideration should be given to the action to be taken when the microbiological criterion is not met and the action should be specified (see Section 4.11).

21. Other considerations could include, but are not limited to, the following:

- Type of sample (e.g. type of food matrix, raw materials, finished product);
- Sampling tools and techniques;
- Prevalence and concentration data for the organism of concern (e.g. baseline data)
- Frequency and timing of sampling;
- Type of sampling (randomized, stratified etc.);
- Methodology used and, when appropriate, suitable conditions for pooling of samples;
- Economic and administrative 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.

22. In addition, for a microbiological criterion targeting a foodborne pathogen, consideration should be given to:

- The evidence of actual or potential risks to health; and
- The population at risk and consumption habits.

4.5 SAMPLING PLAN

23. 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).

24. The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. 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. For microbiological criteria based on quantitative levels, where information is available on within lot and between lot variability, variables sampling plans can be tailored for the specific condition of a particular production process, resulting in a more informative interpretation of results.

25. 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.

26. The number and size of analytical units should be those stated in the sampling plan and should not be modified where the microbiological criterion has been established for regulatory compliance. In unusual circumstances (e.g. during a foodborne outbreak situation or when a food business operator wishes to increase the likelihood of detecting contaminated lots before placing them on the market) a sampling plan with increased stringency may become appropriate and it may become necessary to adopt an alternative microbiological criterion. The rules and procedures for switching from one sampling plan to another should be clearly stated in the sampling approach. Unless the sampling plan specifies otherwise, a lot should not be subjected to repeat testing.

4.6 MICROBIOLOGICAL AND/OR OTHER LIMITS

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

28. Where the microbiological limits *m* and *M* are part of an attributes 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.

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

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* is the maximum tolerable number of analytical units above the limit.

31. 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.

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

4.7 ANALYTICAL METHODS

33. Depending on the microbiological limit (e.g. presence/absence of a specific foodborne pathogen), an appropriate analytical method should be selected. The methods used should be fit for purpose, meaning the method has been validated for relevant performance characteristics (e.g. limit of detection, repeatability, reproducibility, inclusivity, exclusivity). 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.

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

35. The results of testing may be impacted by compositing (i.e. pooling) of sample units 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

36. 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.

37. Web-based tools for evaluation of sampling plans developed by FAO and WHO through JEMRA[5] or by others can be utilised to evaluate sampling plans under consideration.

[5] http://www.mramodels.org/sampling/

4.9 MOVING WINDOW

38. In a moving window approach a sufficient number of sample units (*n*) is collected for a defined period of time (the "window"). The results of the latest *n* sample units are compared with the microbiological limit(s) (*m, M*) using the acceptance number *c*. Each time a new result from the sampling period is available, it is added to the window while the oldest result is removed, creating the "moving window". This approach can also be applied to a set of results, e.g. results obtained during a week. The window, always consisting of *n* results, moves one result or set of results forward in time. In determining the size of the moving window consideration should be given to the combination of the production frequency and sample frequency necessary to obtain a sufficient number of results that enables appropriate verification of performance of a process or a food safety control system.

39. The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a process or a food safety control system. As in the traditional point-in-time approach commonly used in connection with microbiological criteria, the moving window determines the acceptability of the performance so that appropriate interventions can be made in case of unacceptable shifts in control.

40. The length of the moving window should be appropriate to enable corrective action to be taken in a timely manner. If more than *c* out of *n* results is above the limit *m*, or the limit *M* is exceeded, then corrective action is required.

41. The moving window approach should not be confused with trend analysis, which is described in the following section.

4.10 TREND ANALYSIS

42. Trend analysis is a procedure to detect a change in the patterns of observations over a period of time (usually over a relatively long period of time, often not predefined). It can be applied to many types of information including results of microbiological testing against a microbiological criterion. Trend analysis can detect a gradual loss of control that might not be detected by a moving window approach, as well as a more sudden loss of control.

43. Trend analysis may show changes or patterns in the data that are a result of unwanted 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, e.g. by displaying the test results graphically.

4.11 ACTION TO BE TAKEN WHEN THE MICROBIOLOGICAL CRITERION IS NOT MET

44. In situations of non-conformance with the microbiological criterion (unsatisfactory results), actions to be applied should include corrective actions related 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.

45. In the event of a non-conformance with a microbiological criterion for a foodborne pathogen, actions should include appropriate product containment and disposition. This may include 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

46. Documentation and records are essential to support the microbiological criterion, e.g. documentation on scientific evidence underpinning the microbiological criterion, records on application/performance of the microbiological criterion. Records such as test reports should give the information needed for complete identification of the sample, the sampling plan, the analytical method, the results and, if appropriate, their interpretation. Reporting against the microbiological criterion 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).

47. Records should be maintained documenting all instances of non-conformance with the microbiological criterion, together with records of the corrective actions taken, both to manage food safety risks and to prevent further instances of non-conformance.

5. REVIEW OF MICROBIOLOGICAL CRITERIA FOR FOODS

48. As establishing and implementing microbiological criteria 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 microbiological criteria 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.

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

50. A review will result in retention, adjustment or revocation of a microbiological criterion, as appropriate.

51. The risk management framework should be used to continuously improve, refine and adjust the relevant components of the microbiological criterion 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 microbiological criteria, other metrics and public health outcomes.

52. When microbiological criteria 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 adjusted or revoked.