CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 7 **CX/FH 10/42/7**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-second Session
Kampala, Uganda, 29 November – 3 December 2010

PROPOSED DRAFT REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS (At Step 3)

Prepared by the Australia, China, Denmark, European Union, Finland, France, Germany, Japan, New Zealand, Singapore, Thailand, United Kingdom, United States of America, FAO, WHO, CIAA, ICD, ICMSF, IDF and ISDI.

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft 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: 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 October 2010.**

BACKGROUND

The 41st Session of the Committee on Food Hygiene agreed to request the 33rd Session of the Commission to approve new work on the revision of *Principles for the Establishment and Application of Microbiological Criteria for foods* (CAC/GL 21-1997). The 33rd Session of the Commission approved this new work (N06-2010).

The Committee further agreed to establish a physical working group, led by Finland and co-chaired and co-hosted by Japan, to revise the principles for circulation for comments at Step 3 and consideration by the next session of the Committee.

The physical working group met on 25 – 28 May 2010 and prepared the revised principles (see Appendix I) for circulation at Step 3 for comments. The report of the working group is presented below.

Report of the Physical Working Group

1. The Physical Working Group (WG), co-chaired by Finland and Japan, met on 25-28 May 2010 in Tokyo, with the attendance of delegates from Australia, China, Denmark, European Union, Finland, France, Germany, Japan, New Zealand, Singapore, Thailand, United Kingdom and United States of America, representatives from FAO and WHO, and observers from CIAA, ICD, ICMSF, IDF and ISDI. A complete list of participants is provided in Appendix II to this report.

2. The WG recalled that its mandate was to update the existing document of the "*Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)*", by following the terms of reference of the WG as described in the Project Document in Appendix VI of ALINORM 13/33/13, aimed at reflecting the new risk management metrics namely Food Safety Objective (FSO), Performance Objective (PO) and Performance Criteria (PC) and other quantitative microbiological limits not currently dealt with in the original Microbiological Criteria (MC) document.

3. Prior to the substantive discussion, the WG had a general session, in which the following presentations were provided, in order to facilitate a better understanding of the new metrics among participants, linked to the establishment of MC, and to exchange views and information on either general or more particular aspects relating to MC:

   - A case-by-case risk assessment approach to compare the risk of a given batch to a defined base - line risk, and its application to domestic and imported foods in Denmark (by the Delegation of Denmark);

   - Implementation of the EU regulation (2073/2005) regarding microbiological criteria for foodstuffs and its application in Finland, including the use of National Guidance documents for government and industry (by the Delegation of Finland);

   - A general explanation about MC and the relationship(s) between MC and FSO/PO (by the observer from ICMSF), which addressed: i) assessing the performance of MC/compliance with FSO/PO; ii) assumption concerning pathogen distribution in the lot of food; iii) specifying the level of confidence in the rejection of non-conforming lots; iv) using appropriate analytical methods and v) other important relevant aspects.

4. The WG was informed of the JEMRA's ongoing work on the development of a web-based tool to study the performance of microbiological sampling plans and related documentation, which could be used to support the implementation of the revised Codex MC document.

5. The WG recalled the seven dash-points in Point 3 "Main aspects to be covered" of the Project Document and considered how these could be addressed in updating the original MC document. On the approach to revising the existing document, various opinions were shared among participants, as summarized below, but not limited to:
   i) The document should

   - clearly state its scope and use (i.e. for use by governments, industry and Codex);

   - provide practical guidance on how MC are established and applied in different circumstances and on actions to be taken where there are non-conforming lots;

   - be a more usable document for government and industry by looking at the reality of how MC are applied including their future application in the context of FSO/PO;

   - explain various purposes of MC in terms of sampling plans and limits (e.g. within-lot evaluation / between-lot testing for food product acceptability; verification of process hygiene control / validation of control measures in the context of HACCP);

   - not only look at MC alone, but address MC in the context of a food safety risk management system, as a whole;

   - cover both food safety and hygiene indicators;

   - explain the relationship between MC and new risk management metrics;

   - include a section on mathematical methods/approaches and risk management decisions to set MC for different purposes in a clear simple form, avoiding excessive technical detail;

   - address *"uncertainty"* and *"variability"* related to sampling in establishing microbial criteria for

testing end-products;

- describe a risk-based approach to setting a MC as a tool for good communication between governments and industry with a view to achieving a FSO set by a national competent authority; and
- address principles on setting of MC by Codex and the use of Codex-MC by governments in the context of their national food safety standards.

ii) The title of the document should be amended, where necessary, to reflect the context.

6. The WG took into account the written comments submitted in advance by Australia, Brazil, European Union, Finland, France, Germany, Ireland, United States of America, CIAA, ICMSF and IDF and comments made during the meeting.

7. The key points brought forward in revising the existing document are summarized as follows (proposed revised document is presented in Appendix I to this report):

Structure of the document

8. The WG re-structured the document to comprise: Section 1. Introduction; Section 2. Scope; Section 3. Definition; Section 4. Purpose of MC; Section 5. Components of MC; Section 6. Relationships between MC and other microbiological risk management metrics; and Section 7. Establishment and application of MC.

Title of the document

9. The WG agreed to change the original title to the following: "Guidelines for the Establishment and Application of Microbiological Criteria".

Scope

10. It was agreed that this document should be intended for use by government and industry to assist in the development of MC for both food safety and other aspects of food hygiene.

Section 3: Definition

11. The WG noted that the current definition for the term "MC" addressed only a product or a food lot but not processing and the process environment and therefore revised the definition to capture the multi-component nature of a MC and its utility to indicate the acceptability of a food, a process and/or a process environment.

12. Other relevant terms used in the document are also listed with respective references.

Section 4: Purpose of MC

13. The WG, while noting that the current MC document mainly addressed the use of MC for rejection of foods by government, agreed to highlight that "the design of a MC will depend on its purpose" and explain different purposes for MC when applied by government or industry, as examples.

Section 5: Components of MC

14. An indication of the performance of the sampling plan was added as a component of MC in Section 5.1.

Section 5.2: Microbiological aspects of Criteria

15. The WG refined the original Section 5 of the current MC document. With the addition of a new subsection (section 5.2.4), attention was drawn to "*variability*" and "*uncertainly*" of sampling when establishing and applying MC.

Section 5.2.3: Microbiological Limits

16. Paragraph 14 was elaborated by reproducing the second paragraph of Section 5.3.1 in the original principle document (CAC/GL 21-1997) and some modifications were made intended to pay attention to any changes of the target microorganisms only, but not microflora.

17. One delegation regretted that this modification lost the original intent on the need to look at increase or decrease of microflora in the establishment of the limits.

Section 5.2.5: Sampling plans

18. It was noted that the *Codex Guidelines on Sampling (CAC/GL 50 -2004),* referred to in this section,

specifically related to sampling where distribution of microorganisms in foods was homogeneous, but did not cover the control of non-homogeneous goods. It was observed that in many foods, the distribution of microorganisms was heterogeneous hence the WG agreed that additional guidance was necessary to account for such situations.

19. However, due to time constraints the WG did not elaborate the additional guidance, but agreed to develop it as an annex in the future, taking into account technical and scientific input, where necessary.

Section 6: Relationship between MC and other microbiological risk management metrics

20. The WG considered developing a bridge between the MC and the Microbiological Risk Management documents (CAC/GL 63-2007). In this regard, two observers expressed the view that guidance was necessary to adequately explain how to set MC from the output of risk assessments, including how to relate MC to other microbiological risk management metrics.

21. Most delegations had the general view that it was useful to address the relationship between different risk management metrics although this was not developed in detail during the meeting. The delegations suggested simply referring to relevant existing Codex documents, in particular the MRM document, which already stated the relationship between MC and the new metrics, with a view to avoiding any unnecessary repetition.

22. Some delegations insisted that MC was not the same as PO/PC because setting a MC required more scientific data particularly related to human health risks.

23. The WG noted that the relationship between MC and PO/PC was not yet universally acknowledged and that ICMSF was going to update their own work regarding these new metrics.

24. After some discussion, the WG elaborated only a general text addressing this issue. It was noted that the CCFH could elaborate a separate annex in future to provide more in-depth explanations and examples on this matter, if this would be helpful.

Section 7: Establishment and application of microbiological criteria

25. The WG elaborated this section in three parts to address the establishment, application and review/reporting of MC, respectively.

Sub-section 7.1.2, para. 36

26. The WG had some discussion on possible modification of the text dealing with number and size of analytical units, in relation to the following: “The number and size of analytical units should be [at least] those stated in the sampling plan [and should not be modified]”.

27. One view expressed was that if sample number was increased with an aim of rejecting a lot, then this practice was unfair to the producer. However, it was recognized that in some cases, sampling plans might need to be modified to address particular situations, i.e. an outbreak or suspicion of adulteration. Some delegations felt that a more correct way to deal with this kind of situation would be to increase the sampling frequency rather than the sample number. Food business operators may also choose to test more units than required in a sampling plan, e.g. to increase the likelihood of detecting contaminated batches before placing on the market. The text was left in square brackets for further discussion in the plenary of CCFH.

Subsection 7.2

28. This Section 7.2 is intended to provide nine illustrative examples of scenarios for the use of MC, which may apply to industry/government. The WG agreed that each example should contain the following elements:

    - *Purpose (what is intended to be achieved);*
    - *Who should establish and who should apply;*
    - *Food, process or environment; Point in food chain where the MC is applied;*
    - *Sampling plan (# of samples, sample size/units, sampling approach);*
    - *Organisms of concern;*
    - *Method(s)of analysis;*
    - *Interpretation of results; and*

- *(Nature of) actions in case of non-compliance.*

29. Due to time constraints, the WG was unable to complete the drafting of the examples and expressed its wishes to continue elaborating this section within the timeline of this work, taking into account the latest scientific and technical information available.

30. The WG agreed to **recommend** that the forthcoming 42nd Session of the Codex Committee on Food Hygiene (CCFH) should discuss this section, in particular, as to whether the structure/elements of the example section are sufficient , or needs to be rearranged, so that this part could be further elaborated in a desirable format in future.

31. The WG identified the following 9 matters that would link to its future work plan and agreed to recommend that the CCFH should discuss these points and provide direction and guidance on how to address them in the course of further elaborating the document:

    - Establishment of MC related to hygiene indicator microorganisms (in relation to paragraphs 11 -12 in Section 5.2.1);
    - "Uncertainty" and "variability" of sampling (in relation to Section 5.2.4);
    - Elaboration of the general process for establishing an MC and underlying statistical considerations (including elaboration of sampling plan using mathematical approaches as Annex I referred in paragraphs 17 and 20 of Section 5.2.5);
    - Further elaboration of practical examples for establishment of MC including a MC for a toxin (in Section 7.2);
    - Consideration of whether MC for animal feed should be covered ;
    - Consideration of a way forward to address MC for "processing" and "environment" ;
    - how to feature the aspect of "communication" (in paragraph 9, point 6 in Section 4 and in Section 7.2.6), by use of MC, in the context of FSO/PO/PC needs to be further addressed; and
    - New text relating to "frequency of applying a MC" needs to be elaborated (as Annex II referred in paragraph 23 of Section 7.1.2).

Conclusion

32. The WG **agreed** to submit the "Proposed Draft Guidelines for the Establishment and Application of Microbiological Criteria", which is presented in Appendix I to this report, for consideration at the forthcoming 42nd CCFH in November 2010.

APPENDIX I

PROPOSED DRAFT GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS AT STEP 3

INTRODUCTION

(1) Diseases caused by food-borne pathogens constitute a major public health concern and the prevention and control of these diseases are goals for industry and national governments. 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. 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. This has led to a series of additional food safety risk management metrics such as Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC), (see ref MRM doc). Where these metrics have been elaborated, they can allow the establishment of a direct relationship between microbiological criteria and public health outcomes.

(2) The microbiological safety of foods is principally assured by the effective implementation of validated control measures ideally ranging from adequate control at the source, through adequate product design and process control, and the application of Good Hygienic Practice (GHP), in conjunction with the application of HACCP. This preventive approach offers more advantages than reliance on microbiological testing of individual lots of the final product to be placed on the market.

(3) 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. The level of control should be based on risk and the performance should be verifiable.

SCOPE

(4) These Guidelines are intended to provide guidance on the establishment and application of microbiological criteria at a specific point(s) in the food chain by industry and governments in the context of a food safety control system. Codex Alimentarius also has a role in establishing microbiological criteria at the international level. National governments can adopt Codex microbiological criteria into their national standard systems or use them as a starting point for addressing their intended public health goals. Industry should apply microbiological criteria within the context of GHP/HACCP systems. This document is to be used in close conjunction with the Principles and Guidelines for the Conduct of MRM (CAC/CL 63-2007).

(5) These guidelines are applicable to microbiological criteria developed for both food safety and other aspects of food hygiene.

DEFINITIONS

(6) A microbiological criterion is a metric which indicates the acceptability of a food, a process or a process environment following the outcome of sampling and testing for microorganisms, parasites and/or their toxins/metabolites

(7) Other definitions relevant to these guidelines include:

- Appropriate Level of Protection (ALOP)[1]
- Food Safety Objective (FSO)[2]
- Performance Objective (PO) [2]
- Lot[3]
- Sample[4]
- Food safety control system[5]
- Validation[5]
- Verification [5]

[1]Guidelines for Food Import Control System (CAC/GL 47); [2] Codex Alimentarius Commission, Procedural Manual; [3]CAC/GL 63; [4]Guidelines on Sampling (CAC/GL 50); [5]Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008)

PURPOSE OF MICROBIOLOGICAL CRITERIA

(8) The design of the microbiological criterion will depend on its purpose.

(9) Different purposes of microbiological criteria include but are not limited to the following:

1. evaluating a specific lot to determine its acceptance or rejection;
2. evaluating the acceptability of a lot on the basis of the estimated public health outcome;
3. validating critical limits under consideration for CCPs prior to the implementation or modification of a HACCP plan;
4. verifying the performance of HACCP systems;
5. verifying the performance of all or part(s) of a food safety control systems;
6. communicating acceptance criteria between food business operators;
7. verifying the microbiological status of the processing and production environment;
8. validating that the selected control measures are capable of meeting quantified metrics such as POs and/or food safety objectives;
9. verifying hygienic conditions for the primary production environment; and.
10. providing advisory guidelines to inform food manufacturers on levels which can be achieved when applying best practices

COMPONENTS OF MICROBIOLOGICAL CRITERIA

A microbiological criterion should state all of the following components:

- the purpose of the microbiological criterion;
- the food, process or environment to which the criterion applies;
- the point in the food chain where the criterion applies;
- the microorganism, parasite, toxins or metabolites of concern and the reason for that concern
- a plan defining the number of samples to be taken and the size of the analytical unit-
- the microbiological limit(s)
- the number of analytical units that should conform to these limits;
- the analytical method(s) for detection and/or quantification
- an indication of the performance of the sampling plan; and
- the action to be taken when the criterion is not met.

Microbiological aspects of criteria

Microorganisms, parasites, toxins or metabolites of concern and the reason for that concern

(10) For the purpose of this document these include but are not limited to:

- bacteria, viruses, yeasts, moulds, and algae;
- parasitic protozoa and helminthes; and
- their toxins/metabolites.

(11) The microorganisms included in a microbiological criterion should be widely accepted as relevant - as pathogens, indicator organisms or spoilage organisms of significance in relation to the stated purpose. Organisms whose significance is doubtful should not be included

(12) Where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms.

Microbiological Methods

(13) Whenever possible, only methods should be used for which the reliability (accuracy, reproducibility, inter- and intra-laboratory variation) has been statistically established in comparative or collaborative studies in several laboratories or by single laboratory validation according to an internationally recognized protocol . Moreover, preference should be given to methods which have been validated for the stated purpose in relation to reference methods elaborated by international organizations. Although the methods used should be the most sensitive and reproducible for the purpose, in certain cases methods might sacrifice some degree of sensitivity and reproducibility in the interest of speed and simplicity.

Microbiological limits

(14) 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 or toxin/metabolite likely to occur after the point for which the microbiological criterion has been set should be taken into account.

(15) Microbiological limits should also take account of the actual or most likely distribution of microorganisms and the uncertainty and variability of the analytical procedures.

Variability and uncertainty

(16) An integral part of the development of food safety metrics, such as FSO, PO and PC from the view point of competent authorities and of PO and PC from the business operator's perspective, is a consideration of the variability inherent in food ingredients, control measures, and ultimately the food to be consumed that determine the range of results that can be expected when a food safety control system is functioning as intended. When establishing microbiological criteria for such metrics, this variability needs to be considered as well. Microbiological criteria should also be established with sampling variability in mind. Likewise, any uncertainties associated with the parameters affecting the food safety control system should be considered when establishing an integrated set of food safety risk management metrics and the microbiological criteria that is intended to operationalise such metrics.

Sampling Plans

(17) In the development of sampling plans where the distribution of the microorganism within the food is homogenous, the sampling plan should adhere to the Codex General Guidelines on sampling (CAC/GL 50-2004); where not, the sampling plan should adhere to the guidance provided in Annex I (to be developed).

(18) The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. Before specifying a sampling plan it is necessary to understand the underlying distribution/variability of the microorganism (or parasite, toxin/metabolite) in the food (ingredient, environment). Once the distribution has been determined or assumed the degree of stringency of the sampling plan should be determined. This will depend on the stated purpose of the microbiological criterion and can be expressed as a level of confidence in the result.

(19) Performance of a sampling plan is usually illustrated by its operational characteristics (OC) curve (see CAC/GL 50-2004). OC curves can be used to evaluate the influence of individual parameters of the sampling plan on the overall performance of the plan (i.e. number of samples (n); acceptability limit (m); maximum number of nonconforming items permitted in the sample (c); and/or the unacceptable level of contamination (M)).

(20) Tools for establishing the performance of sampling plans are being developed by FAO/WHO. (Ref: Annex I to be developed)

RELATIONSHIP BETWEEN MICROBIOLOGICAL CRITERIA AND OTHER MICROBIOLOGICAL RISK MANAGEMENT METRICS

(21) Where competent authorities have set an ALOP, and have derived an FSO and/or a PO as measures of the required stringency of hazard control in the farm-to-fork chain, microbiological criteria could be used to operationalise the FSO and/or PO. Notably, ALOP, FSO and PO are only set for pathogens with a demonstrated health concern regarding the context of these metrics. Where food business operators have established a PO, likewise, a microbiological criterion could be chosen as the operational metric.

(22) Before deriving a microbiological criterion from an ALOP, the need for such metrics should be clearly articulated. This is important since developing meaningful microbiological criteria in this way is a complex process that requires considerable effort, including a quantitative risk assessment and extensive mathematical modeling and computing power.

(23) FSOs should be given effect by actions at earlier stages in the food chain by the competent authority and/or the individual food business operator (e.g., food manufacturer). POs and PCs may be set by individual businesses and where POs and PCs are appropriately validated, microbiological criteria may not be needed. If used to verify that POs and PCs are being met, microbiological testing may be infrequent (Ref: Annex II to be developed).

ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

General Considerations

Establishment of microbiological criteria

(24) Microbiological criteria should be science-based, and developed using a structured and transparent approach.

(25) Microbiological criteria for pathogens should be developed, where data are available, based on the outcomes of microbiological risk assessment adhering to appropriate risk management and risk communication processes.

(26) A microbiological criterion should be established only when there is a need and when it can be shown to be effective and practical for the stated purpose. Microbiological criteria for food safety should be applied to the extent necessary to protect human life or health and set at a level that is not more trade restrictive than required to achieve an importing member's ALOP.

(27) Mandatory microbiological criteria (i.e., standards written into national law or other governmental regulations) should apply to those products and/or points of the food chain where no other effective tools are available, and where they are expected to improve the degree of protection offered to the consumer. Where these are appropriate they should be product-type specific and only applied at the point of the food chain as specified in the regulation.

(28) In keeping with the risk-based approach to more systematically relate the performance of a control measure, a series of control measures or even an entire food control system to the level of control needed to manage food safety problems, competent authorities may establish relevant microbiological criteria as one of the means to articulate the level of stringency required at different points in the farm-to-table continuum. In the governmental context, microbiological criteria are established to enable verification of compliance to an FSO, a PO or PC set by competent authorities.

(29) To fulfill the purposes of microbiological criteria for a food, consideration should be given to:

- the intended use of the food;
- the evidence of actual or potential hazards to health;
- the microbiological status 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, storage, preparation and use;
- the consumers concerned, including relevant vulnerable sub-populations, and consumption habits; and
- the cost/benefit ratio associated with the application of the criterion.

(30) To fulfill the purpose of microbiological criteria for a process or the processing environment monitoring, consideration should be given to:

- Type of product and process/operation;
- Type of samples;
- Target organisms;
- Sampling locations and number of samples;

- Frequency of sampling;
- Sampling tools and techniques;
- Analytical methods;
- Data management; and
- Action in case of positive results.

Application of microbiological criteria

(31) A microbiological criterion is based on the examination of foods or other samples at a specific point in the food chain to determine if the frequency and/or level of a microorganism, parasite or their toxins/metabolites exceed a pre-established limit. The effective use of a microbiological criterion is dependent on the selection of a sampling plan based on the above parameters to establish the appropriate level of stringency. Since the levels/prevalence of a microorganism, parasite or their toxins/metabolites can change over the course of manufacture, distribution, storage, marketing and preparation, a microbiological criterion is generally established at a specified point in the food chain and that particular microbiological criterion may not be pertinent at other points. Underlying a microbiological criterion should be a transparent articulation of the pre-determined limit and the rationale for the sampling plan chosen.

(32) The frequency with which sampling is conducted to verify compliance with a microbiological criterion should be based on risk.

(33) It is the responsibility of competent authorities to set FSOs, and articulate a risk-based limit that should be achieved operationally within the food chain, while providing flexibility for different production, manufacturing, distribution, marketing, and preparation approaches. Microbiological criteria can be used to assess compliance with the FSO and/or PO for a microorganism (Ref: Annex II to be developed).

(34) In situations of non-compliance with microbiological criteria, corrective actions will be based on an assessment of the risk to the consumer, the point in the food chain and the product-type specified. These may include sorting, reprocessing, withdrawal and/or recall, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken. Other actions by regulatory authorities or business operators taken in response to the discovery of non-compliance may include more frequent inspection and audits, fines, official suspension of operations, the loss of a contract with a large buyer, or de-certification by a private standard-setting body. In addition, a firm's compliance history may impact its liability exposure and insurance rates. These exposures to potential increased costs create economic incentives for food producing firms to limit the probability and degree of non-compliance.

(35) In addition to checking compliance with regulatory provisions, microbiological criteria may be applied by food business operators to formulate design requirements and to examine end-products as one of the measures to validate and/or verify the efficacy of the HACCP plan. Microbiological criteria may be applied in environmental monitoring to verify the efficacy of prerequisite programs.

(36) The number and size of analytical units should be [at least] those stated in the sampling plan [and should not be modified].

Documentation, reporting and review of microbiological criteria

Documentation and record keeping

(37) Documentation and records are essential to support the microbiological criteria, e.g. documentation on scientific evidence underpinning the microbiological criteria, records on application/ performance of the microbiological criteria.

(38) Refer to Section 5.7 of the General Principles of Food Hygiene (CAC/RCP 1-1969). In addition, it is important to understand that documentation and record keeping are implicit in food safety control systems and support the establishment and application of microbiological criteria.

Reporting

(39) Reporting against the microbiological criteria may be required by some National Governments. Assessment of the report including analysis of trends, should be carried out by a competent person (by

the food business operator and where appropriate, the competent authority) and appropriate action taken.

Review

(40) A review may be initiated by national governments, other governments, food businesses or consumers.

(41) A review may be carried out by government and/or food business.

(42) The risk management framework should be used to continuously improve, refine and adjust the component parts of the microbiological criterion in relation to improved scientific knowledge and the increasing knowledge of public health risk (FSO, PO, PC). This should take place whenever relevant information becomes available. The goal should ultimately be to achieve a more quantifiable estimation of the linkages between microbiological criteria and other metrics .

(43) Review should occur in response to changes in:

- a food safety control system
- a known pathogen (changes in prevalence and/or target distribution)
- the suitability of indicator organism
- a food
- a technology /process
- available methods/appropriateness of test (viable/viable non culturable/dead)
- a trait of microorganisms (pathogen/non-pathogen), e.g. anti-microbial resistance
- population dietary intake patterns; and/or
- understanding/knowledge of risk

(44) In a review and in response to an emerging issue, the following should be considered:

- food safety control system;
- whether it is with new and/or known pathogen/toxins/metabolites;
- food;
- process;
- problems with methods;
- population;
- understanding/knowledge of risk; and/or
- linkage to trade.

(45) The use of trend analyses should be considered by the food business operator and by the competent authority as well for verification purposes, e.g. to see if a non-conformity is an accident (by comparison with earlier results, e.g., consistency of conformity over the past years) or a shift (in a situation of insufficient hygiene control).

(46) Review should include a system to record the data and their evaluation, e.g. performing trend analyses. A long term review of the data is important to revise and adjust the review programme. It can also reveal adverse trends or low level intermittent issues.

Guidance on the establishment and application of microbiological criteria used for different purposes

(47) The following section contains illustrative examples of scenarios in which microbiological criteria are used.

Microbiological criteria for evaluating a specific lot to determine its acceptance or rejection

- lots with unknown hygienic history
- lots that otherwise have questionable microbiological status
- port of entry

- routine inspection

(48) A lot should not be subjected to repeat testing for the same microbiological criteria.

microbiological criteria for evaluating the acceptability of a lot on the basis of the estimated public health outcome

(49) In lot-by-lot testing based on quantitative risk assessment the acceptability of a lot may be defined as the acceptable relative public health risk of the lot as compared to the average risk of lots. This requires the use of quantitative risk assessment and the use of mathematical modeling in order to estimate the relative risk. The risk estimation may include a combination of several risk factors such as prevalence, concentration of microorganisms, subtypes and antimicrobial resistance pattern. This approach allows direct estimation of the impact on the public health outcome.

(50) If all components of a microbiological criterion are included then this approach is in accordance with the definition of a microbiological criterion.

Microbiological criteria for validating critical limits under consideration for CCPs prior to the implementation or modification of a HACCP plan

Examples of the application of a microbiological criterion for a pathogen (e.g.* Campylobacter*) in this context including:

- Pathogen reduction program for a commodity
- Verifying the efficacy of prerequisite programs

Microbiological criteria for verifying the performance of HACCP systems

- Trend analysis

Purpose: To determine if the HACCP system is working correctly.

Who: Industry establishes (may be guided by legal microbiological criteria). Industry applies primarily. CA may apply to support audit.

Organism(s): Pathogen that is most likely to be present and/or indicators.

Sampling plan: frequency depending on number of lines/production size/product types/probability of detection.

Method: Depends on limit and organism (absence/presence, MPN).

Action: Review monitoring system. Secondly, review system design.

Microbiological criteria for verifying the performance part(s) of a food safety control systems

Microbiological criteria for communicating acceptance criteria between food business operators (e.g. as part of a contract between suppliers and buyers)

Microbiological criteria for verifying the microbiological status of the processing and production environment

- performance of cleaning procedures
- *Listeria* spp. in food manufacturing facilities
- *Cronobacter* spp./*Entereobacteriaceae* in food manufacturing facilities

Microbiological criteria for validating that the selected control measures are capable of meeting quantified metrics such as POs and/or food safety objectives

- Water used for shellfish farming

Microbiological criteria for verifying hygienic conditions for the primary production environment

- Whether the control measures in place are capable of controlling the incoming level of a hazard (e.g. a H_0) to a degree that results in a specified hazard outcome (e.g. as expressed by a PO).

Microbiological criteria as microbiological advisory guidelines used to inform food manufacturers on levels which can be achieved when applying best practices

(51) Such criteria will be specific for the product and the stage in the food chain at which they will apply. They are microbiological advisory guidelines used to inform food manufacturers on levels which can be achieved when applying best practices. They may be stricter than the criteria used for regulatory purposes and should, as such, not be used for legal action.

APPENDIX II

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