

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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ALINORM 97/13A

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

*Twenty-Second Session*  
*Geneva, 23-28 June 1996*

### REPORT OF THE TWENTY-NINTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGEINE

*Washington, D.C., 21 - 25 October 1996*

**NOTE:** This report includes Codex Circular Letter CL 1996/40-FH

W3700

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CX 4/20.2

CL 1996/40 - FH  
5 December, 1996

TO: - Codex Contact Points  
- Interested International Organizations  
- Participants at the Twenty-Ninth Session of the Codex Committee on Food Hygiene

FROM: Secretary, Codex Alimentarius Commission  
Joint FAO/WHO Food Standards Programme  
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: Distribution of the Report of the Twenty-Ninth Session of the Codex Committee on Food Hygiene (ALINORM 97/13A)

The report of the Twenty-Ninth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-second Session of the Codex Alimentarius Commission, Geneva, 23-28 June 1997.

## MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

1. Draft Revised Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) System at Step 8; ALINORM 97/13A, paras. 16-19 and Appendix II.
2. Draft Revised Principles for the Establishment and Application of Microbiological Criteria for Foods at Step 8; ALINORM 97/13A, paras. 20-27 and Appendix III.
3. Amendment to the Procedural Manual: Guidance on revision of commodity-specific codes of practice; ALINORM 97/13A, paras.28-31<sup>1</sup>

Governments wishing to propose amendments to or comment on the above matters should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 of the Procedure for the Elaboration of Codex Standards Including Consideration of Any Statements Relating to Economic Impact (*Procedural Manual of the Codex Alimentarius Commission*, Ninth Edition, pages 33-35). Comments or proposed amendments should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39(6)5225.4593 or e-mail: [codex@fao.org](mailto:codex@fao.org)) not later than 1 April 1997.

## REQUEST FOR COMMENTS AND INFORMATION

1. Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment at Step 3; ALINORM 97/13A, paras. 35-39 and Appendix IV.

Governments and interested international organizations are invited to comment on the text cited above. Comments should be forwarded to the US Coordinator for Codex Alimentarius: U.S. Codex Contact Point, Food Safety and Inspection Service, US Department of Agriculture, Room 311, West End Court, Washington D.C. 20250-3700, U.S.A. (fax: +1(202)254 2530 or email: [uscodex@aol.com](mailto:uscodex@aol.com)) not later than 1 April 1997.

2. Implications for the broader application of the HACCP System; ALINORM 97/13A, paras. 61-63.

The Committee has invited governments to communicate their experience of implementing the HACCP system by sending a status report to Australia on the application of HACCP to the regulatory and the business sectors particularly in developing countries. This information is required in order to assist in the development of the Committee's further work in this area. Comments should be forwarded to the Codex Contact Point for Australia; Mr. Digby Gascoine, Director, Food Inspection Division, Australian Quarantine and Inspection Service, GPO Box 858, Canberra ACT 2601 AUSTRALIA (fax: +61(6)272 5226) not later than 1 April 1997.

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<sup>1</sup> This matter also referred to the Codex Committee on General Principles for information.

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## SUMMARY AND CONCLUSIONS

### MATTERS FOR CONSIDERATION BY THE CODEX ALIMENTARIUS COMMISSION:

- The following texts are submitted for adoption:
  - Draft Revised Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) System (paragraphs 16-19, Appendix II);
  - Draft Revised Principles for the Establishment and Application of Microbiological Criteria for Foods (paragraphs 20-27, Appendix III)
  - Guidance on revision of commodity-specific codes of practice (paragraphs 28-31)<sup>2</sup>.
- The following new work is proposed at Step 1 (see paragraph 66):
  - Code of Hygienic Practice for Milk and Milk Products;
  - Guidance on the hygienic recycling of processing water in food processing plants;
  - Guidance on the application of microbiological risk evaluation to international trade;
  - Revision of the standard wording for Food Hygiene Provisions;
  - Risk-based guidance for the use of HACCP-like systems in small businesses, with special reference to developing countries;
  - Recommendations for the management of microbiological hazards for foods in international trade.
- The Commission is invited to advise FAO and WHO to consider the establishment of an international advisory body addressing the microbiological aspects of food safety and provide scientific advice in the form of formal microbiological risk assessments (paragraph 53).
- The Committee endorsed food hygiene provisions in a number of draft Codex Standards, but not those for milk and milk products (paragraphs 8-15).

### MATTERS REFERRED TO OTHER CODEX COMMITTEES:

- The Committee requested a technical paper to be prepared by the Codex Committee on Fish and Fishery Products on residual chlorine in frozen shrimps and prawns (paragraph 11);

### OTHER MATTERS:

- The Committee suggested that of the Code of Hygienic Practice for the Collection, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) might require revision (paragraph 60);
- The Committee invited governments to communicate their experiences of implementing the HACCP system (paragraph 63);

The Committee decided to discontinue the work on consumer education in the application of HACCP, with the understanding that FAO, WHO and other relevant organizations should further develop materials for consumer education adapted to the need of different target groups and local situations (paragraphs 64-65).

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<sup>2</sup>

This matter also referred to the Codex Committee on General Principles for information.

**LIST OF ABBREVIATIONS**  
used in this Report

<b>CAC</b>	<b>Codex Alimentarius Commission</b>
<b>CCFFP</b>	<b>Codex Committee on Fish and Fishery Products</b>
<b>CCFH</b>	<b>Codex Committee on Food Hygiene</b>
<b>CCFICS</b>	<b>Codex Committee on Food Import and Export Inspection and Certification Systems</b>
<b>CCGP</b>	<b>Codex Committee on General Principles</b>
<b>CCMMP</b>	<b>Codex Committee on Milk and Milk Products</b>
<b>FAO</b>	<b>Food and Agriculture Organization of the United Nations</b>
<b>HACCP</b>	<b>Hazard Analysis/Critical Control Point</b>
<b>ICMSF</b>	<b>International Commission for Microbiological Specifications for Foods</b>
<b>IDF</b>	<b>International Dairy Federation</b>
<b>JECFA</b>	<b>Joint FAO/WHO Expert Committee on Food Additives</b>
<b>JMPR</b>	<b>Joint FAO/WHO Meeting on Pesticide Residues</b>
<b>SPS</b>	<b>Agreement on the Application of Sanitary and Phytosanitary Measures</b>
<b>TBT</b>	<b>Agreement on Technical Barriers to Trade</b>
<b>WHO</b>	<b>World Health Organization</b>

**REPORT OF THE TWENTY-NINTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE**

*Washington, D.C., 21 - 25 October 1996*

**INTRODUCTION**

1. The Codex Committee on Food Hygiene held its Twenty-Ninth Session in Washington, D.C., from 21 to 25 October 1996, at the kind invitation of the Government of the United States of America. The session was chaired by Dr. I. Kaye Wachsmuth, Assistant Deputy Administrator, Science and Technology, Food Safety and Inspection Service, United States Department of Agriculture. The session was attended by 203 delegates, advisors and observers representing 42 Member Countries and 13 international organizations. A complete list of participants, including the Secretariat, is provided in Appendix I to this report.

**OPENING OF THE SESSION (Agenda Item 1)**

2. The session was opened by Mr. Thomas J. Billy, Administrator, Food Safety and Inspection Service, United States Department of Agriculture, who welcomed participants on behalf of the Secretary of Agriculture, Mr. Dan Glickman.

3. The Committee was addressed by Dr. Robert L. Buchanan, Agricultural Research Service of the United States Department of Agriculture, on the subject of *Microbiological Risk Assessment*, which included an example of quantitative microbiological risk assessment.

**ADOPTION OF THE AGENDA<sup>3</sup> (Agenda Item 2)**

4. The Committee adopted the Provisional Agenda as the Agenda for the session, agreeing to rearrange the order of several items.

**REPORT BY THE SECRETARIAT ON MATTERS REFERRED TO THE COMMITTEE<sup>4</sup>  
(Agenda Item 3)****A) GENERAL MATTERS**

5. The Committee noted the on-going activities of FAO and WHO in providing expert scientific advice to governments and to the Codex Alimentarius Commission in areas relevant to the work of the Committee, specifically in biotechnology and food safety, the application of risk management to food safety, and on animal feeding and food safety.

6. The Committee further noted that the Executive Committee had advanced a number of texts to Step 5 at its previous session, noting that technical government comments on these texts would be taken into account at the Committee's present session. Furthermore, the Executive Committee had noted the Committee's initiative to consider consumer responsibilities in relation to food safety, in particular in regard to the application of HACCP principles. These matters are discussed under Items 4, 5, 7 and 13b of the present Agenda.

7. The Committee noted the work being undertaken by the Committee on General Principles in finalizing the Terms and Definitions used in Risk Analysis and in considering the status of Codex Guidelines, Codes of Practice and other advisory texts within the context of the SPS and TBT Agreements.

**B) ENDORSEMENT OF FOOD HYGIENE PROVISIONS IN CODEX STANDARDS*****Codex Regional Coordinating Committee for Asia***

8. The Committee endorsed the Hygiene Provisions contained in the following standards, as presented in Appendix I to CX/FH 96/2:

- Proposed Draft Standard for Canned Bamboo Shoots
- Proposed Draft Standard for Dried Salted Anchovies
- Proposed Draft Standard for Crackers made from Marine and Freshwater Fish, Crustacean and Molluscan Shellfish.

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<sup>3</sup> CX/FH 96/1

<sup>4</sup> CX/FH 96/2

9. The Committee did not endorse the proposal to include a microbiological test (incubation test) in the Standard for Canned Bamboo Shoots on the basis that using such a test would not provide any greater health protection than would adherence to the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* (CAC/RCP 23-1979, Rev.2 1993) already referenced in the document. Should spoilage occur, reference could also be made to the *Guideline Procedures to Establish Microbiological Causes of Spoilage in Low-Acid and Acidified Low-Acid Canned Foods*, which was an Appendix to the above-mentioned Code.

*Codex Committee on Fresh Fruits and Vegetables*

10. The Committee endorsed the use of the standard wording for the Food Hygiene Provisions in the Draft and Proposed Draft Standards for Banana, Mangosteen, Limes, Pummelos, Guavas and Chayotes.

*Codex Committee on Fish and Fishery Products*

11. The Committee considered that a technical paper should be prepared on the residual level of chlorine in products such as frozen shrimps and prawns when washed with chlorinated water and on recommended levels used in processing. It requested that such a paper be developed by the CCFPP.

*Codex Committee on Milk and Milk Products*

12. The Committee noted that the CCMMP had forwarded common hygiene provisions in standards for seven milk products for endorsement, and had asked for the Committee's consideration of two proposals in addition to the common provisions<sup>5</sup>. On the first proposal, to include microbiological criteria to the Revised Standard for Butter, the Committee agreed that such criteria did not provide health protection additional to that which would be achieved by the implementation of the General Principles of Food Hygiene, including the application of a HACCP plan to the product. It decided that the inclusion of such criteria would be inappropriate.

13. On the second proposal to modify the common hygiene provisions in these standards by including a specific reference to the use of pasteurization or an equivalent measure<sup>6</sup>, the Committee could not arrive at a consensus. Several delegations strongly resisted the specific reference to pasteurization, stating that the application of the revised General Principles of Food Hygiene and the Principles and Guidelines for the Application of the HACCP System negated the need to specify any one processing step as being necessary for health protection. Other delegations strongly supported the proposed inclusion stating that pasteurization provided a well-recognized level of protection against which other measures could be assessed.

14. There was discussion as to the meaning of the words "equivalent measure" to pasteurization and some delegations expressed the need for greater clarifications before coming to a decision on this point. Several Delegations emphasized the need to finalize the revisions of the milk and milk products standards, now at Step 8, because in their view they were not directly linked to the issue of pasteurization. However, the delegations disagreed. The Committee forwarded the common hygiene provisions to the CAC without making any additions to them.

15. The Delegation of the United States reserved its position in regard to the Committee's decision. In this reservation, the Delegation stated that the public health protection benefits that pasteurization provides had been scientifically established, internationally recognized, and were irrefutable. There were current alternative processes or technologies which might, under certain conditions, provide equivalent public health protection to pasteurization and more could be expected to evolve. The purpose of the Codex Alimentarius International Food Standards was to "protect consumers", while facilitating trade. The Delegation urged that the endorsement of standards for international trade in dairy products which did not provide the public health protection benefits of pasteurization or an equivalent process, be weighed carefully to assure that an appropriate balance between "protecting consumers" and "facilitating international trade", consistent with scientific principles, was provided. The Delegation of France reserved its position in regard to the decision of the Committee not to endorse the common hygiene provisions, being of the opinion that these provisions provided adequate health protection without any additional wording required, making reference as they did to the General Principles of Food Hygiene and related texts.

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<sup>5</sup> ALINORM 97/11, paragraphs 22 - 23, and 27 - 28.

<sup>6</sup> The exact wording of the proposal was: *Pasteurization, or an equivalent measure approved by the official agency having jurisdiction, shall be used in order to achieve the appropriate level of public health protection.*

## CONSIDERATION OF THE DRAFT REVISED GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM AT STEP 7<sup>7</sup> (Agenda Item 4)

16. The 43rd Session of the Executive Committee had adopted the Draft Revised Guidelines at Step 5. Comments were subsequently requested by CL 1996/24-FH. An *ad hoc* Working Group was convened under the direction of the United States to review the Guidelines in light of the received comments, with the understanding that substantial modifications at this stage would be kept to a minimum and that prescriptive expressions would be avoided in the text to the greatest extent possible.

17. In general, several delegations expressed their concern that difficulties might be encountered in applying the HACCP system in smaller businesses and in developing countries. It was pointed out that flexibility should be guaranteed in its application to primary production, whose situation may differ significantly from one country to another. The Committee noted that the Guidelines should be considered as providing an example of risk-based approaches to be employed in adhering to the Revised International Code of Practice - General Principles of Food Hygiene. The Committee also noted that FAO and WHO had been providing training opportunities to those countries in need and assistance should be continued to facilitate the application of the HACCP system in developing countries.

18. The Committee agreed to the revised text as presented by the Working Group with a number of modifications, mainly directed to addressing the question of flexibility and application to small businesses and developing countries.

### STATUS OF THE DRAFT REVISED GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

19. The Committee advanced the Draft Revised Guidelines for the Application of the HACCP System to Step 8 for the consideration of the 22nd Session of the Codex Alimentarius Commission as an integral part of the Revised General Principles of Food Hygiene. The Draft Revised Guidelines are attached to this report as Appendix II.

## CONSIDERATION OF DRAFT REVISED PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS AT STEP 7 (Agenda Item 5)<sup>8</sup>

20. The Committee reviewed the revised draft of the text prepared by a Working Group which had met under the Chairmanship of France. The revised draft had taken into account the comments submitted in writing prior to the session. The Committee accepted a large number of editorial changes proposed by the Working Group.

### DEFINITION OF MICROBIOLOGICAL CRITERION

21. The Committee agreed that microbiological criteria could be used to determine that processes were consistent with the General Principles of Food Hygiene, but that this need not be referred to explicitly in the definition. An appropriate statement was included in the section dealing with the Purposes and Application of Microbiological Criteria. It was noted that throughout the text reference to "design requirements" was a direct reference to the corresponding provisions of the General Principles of Food Hygiene.

### APPLICATION BY REGULATORY AUTHORITIES

22. The Committee agreed that criteria could be used both to define and to check compliance with regulatory provisions concerning hygiene. It further agreed that the use of microbiological criteria should be limited to situations where no more effective tools were available and where their use would improve the degree of protection offered to the consumer. The Committee agreed to provide more complete detail on approaches to be taken in cases where food was found not to be in compliance with microbiological criteria.

23. The Committee noted that a reference to the use of the microbiological criteria within the context of Codex standards or national regulations had been deleted as the principles enunciated in this paragraph were common to all Codex texts.

### APPLICATION BY A FOOD BUSINESS OPERATOR

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<sup>7</sup> ALINORM 97/13, Annex to Appendix II; CX/FH 96/3 comments by Denmark, New Zealand, Republic of South Africa, Spain, Switzerland, United Kingdom, United States, FAO and International Dairy Federation.

<sup>8</sup> ALINORM 97/13, Appendix III; CL 1996/24-FH; CX/FH 96/4 (Comments of The Netherlands, South Africa, United Kingdom, United States).



24. The Committee clarified that microbiological criteria should be specific for the product and for the specific stage in the food chain during the preparation and/or processing of the product to which they should apply.

#### MICROBIOLOGICAL ASPECTS OF CRITERIA

25. The Committee discussed at length the case of "presence-absence" tests and their relevance as indicators of public health. It confirmed that the finding of certain pathogenic organisms in such tests did not necessarily indicate a threat to public health. Because the same consideration applied to toxins, the Committee expanded the list of examples by making reference to *S. aureus*.

#### SAMPLING PLANS, METHODS AND HANDLING

26. The Committee decided to provide a more detailed description of the ability of sampling plans to detect organisms in a given food lot, and at the same time confirmed that sampling plans on their own could not ensure the absence of any of the specified organisms.

#### STATUS OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS

27. The Committee advanced the Draft Principles as attached in Appendix III to Step 8 for submission to the 22nd Session of the CAC.

#### CONSIDERATION OF APPROACHES FOR THE REVISION OF COMMODITY CODES<sup>9</sup> (Agenda Item 6)

28. At its previous session, the Committee had considered the nature of commodity-specific codes of hygienic practice which would need to be developed or revised as a result of the adoption of the Revised General Principles of Food Hygiene<sup>10</sup>. Of the alternatives considered, preference was given to an approach by which commodity-specific codes would contain guidance on food hygiene measures over and above the general guidance contained in the General Principles of Food Hygiene.

29. The Committee welcomed the opportunity to establish consistency in the revision of the commodity-specific codes and to base these revisions on the newly revised General Principles of Food Hygiene, including the Annex on HACCP, and the revised Principles for the Establishment and Application of Microbiological Criteria for Foods. However, the Committee noted that exclusive stress on food safety could limit the usefulness of Codex Codes of Hygienic Practice and that some flexibility had to be retained to provide guidance on certain non-safety factors such as decomposition or handling practices which could lead to spoilage. The Committee noted that the CCFPP had already begun the revision of the Codes of Practice within its mandate with this in mind. However, the Committee was of the opinion that the establishment of additional food hygiene requirements for specific food items or food groups should be limited to the extent necessary to meet the defined objectives of individual codes.

30. The Committee endorsed the following recommendations, referring them to the CCGP for information and submitting them to the CAC for adoption and inclusion in Section H of the Procedural Manual:

- a. Codex Codes of Hygienic Practice should serve the primary purpose of providing advice to governments on the application of food hygiene provisions within the framework of national and international requirements.
- b. The Revised Recommended International Code of Practice - General Principles of Food Hygiene (including the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System) and the Revised Principles for the Establishment and Application of Microbiological Criteria for Foods are the base documents in the field of food hygiene.
- c. All Codex Codes of Hygienic Practice applicable to specific food items or food groups shall refer to the General Principles of Food Hygiene and shall only contain material additional to the General Principles which is necessary to take into account the particular requirements of the specific food item or food group.
- d. Provisions in Codex Codes of Hygienic Practice should be drafted in a sufficiently clear and transparent manner such that extended explanatory material is not required for their interpretation.

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<sup>9</sup> CX/FH 96/5

<sup>10</sup> ALINORM 97/13, paragraphs 19-25.

- e. The above considerations should also apply to Codex Codes of Practice which contain provisions relating to food hygiene.

31. The Committee also agreed that consideration should be given to revision of the standard texts on food hygiene provisions recommended for use in commodity standards (contained in the Procedural Manual, Section K) as the existing texts had been developed well before the current revision of the General Principles of Food Hygiene or the development of HACCP and related principles.

**CONSIDERATION OF DRAFT CODE OF HYGIENIC PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF-LIFE AT STEP 7<sup>11</sup> (Agenda Item 7)**

32. The Delegation of Canada informed the Committee that an *ad hoc* Working Group which met under its chairmanship had not yet reached any consensus over a few issues such as refrigeration temperature, necessity for additional hurdles and the delineation of the Scope. The Committee felt that it was premature to conclude the Committee's discussion on this document at this stage.

33. The Committee agreed that the document should be revised to incorporate the comments received, particularly by making due reference to and avoiding replication with the General Principles of Food Hygiene.

**STATUS OF THE DRAFT CODE OF HYGIENIC PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF-LIFE**

34. The Committee agreed that the document would be revised by the government of Canada, with assistance provided by France, the United Kingdom and the United States, with potentially controversial parts high-lighted, and be circulated for comments by government at Step 6.

**GUIDELINES ON THE APPLICATION OF PRINCIPLES OF RISK ASSESSMENT AND RISK MANAGEMENT TO FOOD HYGIENE INCLUDING STRATEGIES FOR THEIR APPLICATION<sup>12</sup> (Agenda Item 8)**

35. The Committee recalled that the 21st Session of the CAC had requested its major subsidiary bodies dealing with risk analysis to consider guidelines for the application of risk assessment and risk management in their areas of competence<sup>13</sup>. The Committee had held a preliminary discussion on this subject at its previous session and had requested that a paper be prepared for discussion at its present session<sup>14</sup>.

36. In reviewing the document, the Committee decided that the statements on principles and application should be brought together, that the explanatory notes in the document be retained for the time being as notes at the end of the paper so as to allow for easier reading, and that the introduction should be made more concise and relevant to the objectives of the paper.

37. The Committee also agreed to clarify the Title of the document by referring to the conduct of risk assessments, and to simplify the Introduction and Scope of the document. It was pointed out that the Guidelines were intended to be used by governments, scientists and other interested parties in the preparation and presentation of scientific evaluations to risk managers and decision-making bodies such as the CAC in order to ensure that such assessments met the needs of decision-makers. It was agreed that the document should focus on microbiological hazards in all foods regardless of their origin. However, it was recognized that adequate flexibility should be provided where appropriate to meet any special needs of developing countries. The Committee made some technical amendments to the text.

38. The Committee also noted that the document contained a number of proposals for future discussion by the Committee. The Committee decided to circulate these proposals separately with a view to more complete discussion at its next session in the light of government comments.

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<sup>11</sup> ALINORM 97/13 Appendix IV; CX/FH 96/6

<sup>12</sup> CX/FH 96/10

<sup>13</sup> ALINORM 95/37, paragraphs 27-30

<sup>14</sup> ALINORM 97/13, paragraphs 51-58.

**STATUS OF THE PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT**

39. The Committee advanced the document to Step 3 of the Procedure. The Proposed Draft Principles and Guidelines are attached to the present report as Appendix IV.

**PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED/UNRIPENED CHEESE AND RIPENED SOFT CHEESE AT STEP 4<sup>15</sup> (Agenda Item 9)**

40. The Committee recalled that this matter had last been discussed in detail at its 27th Session (1994) when the CCMMP had been requested to provide technical review and comments on the code, including an annexed *Code of Hygienic Practice for Soft Cheese made with Raw Milk*. At the Committee's 28th Session (1995) it was agreed that comments would be requested on proposed guidelines for the production of cheeses from unpasteurized (raw) milk<sup>16</sup>. These proposals had also been reviewed by the CCMMP with input from the International Dairy Federation (IDF).

41. The Committee noted that the IDF had proposed *Draft Guidelines for the Production and Transport of Raw Milk, for the Purpose of the Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese*<sup>17</sup>. The CCMMP had recommended that these guidelines be applied to all milk products. Noting the serious concerns of the Delegations of India, Kenya, Egypt and Ghana concerning the implications of such a recommendation, the need to take into account the various production systems in different countries and for different milch animals, and the fact that such recommendations should be in the form of guidelines elaborated in full conformity with the Codex Procedures and with the participation of all Member countries, the Committee concluded that it would not be appropriate to accept the recommendation of the CCMMP in this regard. The Committee agreed, however, to consider the possibility of elaborating a Code of Hygienic Practice for Milk and Milk Products which would meet food safety needs and provide sufficient flexibility for application in all Member countries.

42. In reference to the Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese itself, the Committee agreed that it should be redrafted, taking into account all comments received since the 27th Session in 1994, the comments transmitted by the CCMMP, and the general guidance developed under Item 6 of the present Agenda. Support was expressed for the inclusion of the relevant provisions concerning the production, collection and transport of raw milk in the main text of the Code, using the IDF proposals to the CCMMP as a reference. The observer from the European Community spoke firmly in favour of including raw milk cheeses in the Code with specific provisions attached.

**STATUS OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED/UNRIPENED CHEESE AND RIPENED SOFT CHEESE**

43. It requested the Delegation of the United States, assisted by France and IDF, to redraft the present text as indicated above and to arrange for its circulation for Government comments at Step 3.

**PROPOSED DRAFT CODE OF PRACTICE FOR ALL FOODSTUFFS TRANSPORTED IN BULK<sup>18</sup> (Agenda Item 10)**

44. The elaboration of this Code had been originally assigned to the CCFAC. The Executive Committee subsequently recommended that this Committee should initiate the work and cooperate with the CCFAC and other interested Committees<sup>19</sup>. At its previous session, the Committee had asked the Delegation of the Netherlands to prepare a draft document, in cooperation with Canada and other countries.<sup>20</sup>

45. The Delegation of Canada introduced the draft that still was at its preparatory stage and asked for general comments and guidance from the delegations in order to proceed with its further elaboration.

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<sup>15</sup> ALINORM 95/13, Appendix V; CX/FH 96/7 (Comments of the CCMMP, incorporating comments from Canada, Denmark, The Netherlands, USA, European Association of Animal Production, International Dairy Federation).

<sup>16</sup> ALINORM 97/13, paragraphs 40-45.

<sup>17</sup> CX/FH 96/7, Annex 2.

<sup>18</sup> CX/FH 96/8

<sup>19</sup> ALINORM 93/13 Paragraph 103; ALINORM 95/4 Appendix

<sup>20</sup> ALINORM 97/13, paragraphs 61-64

46. The Committee recalled that the Code was intended to address hygienic concerns related to the transport of foodstuffs in bulk and agreed to modify the title accordingly. The Committee also agreed that live animals should not be included in the scope of the document, as such provisions might need to reflect epizootic and animal welfare considerations and were within the mandate of the OIE.

47. Some delegations stated that the Code should not include semi-packed foodstuffs in the scope of the document and that defining the term would not be necessary but the Committee made no decision in this matter. It was also recognized that the format of the General Principles of Food Hygiene, the decision of the Committee in Item 6 (above) and the linkage to the existing Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk should be taken into account when redrafting the text along with consideration of including positive and negative lists of previous cargoes.

48. With regard to the possible inclusion of generic HACCP plans in the document, many delegations were of a view that no such plan could be applicable to the wide variety of foodstuffs and the different situations in which they were transported and that it would be inappropriate to include generic HACCP plans in the document even as examples.

#### STATUS OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE TRANSPORT OF FOODS IN BULK

49. The Committee agreed that the document should be redrafted by the drafting group lead by the Netherlands and circulated at Step 3. It was agreed that Germany would be a member of the drafting group in addition to the members appointed at the Committee's previous Session.

#### CONSIDERATION OF ESTABLISHMENT OF SAMPLING PLANS FOR MICROBIOLOGICAL SAFETY CRITERIA FOR FOODS IN INTERNATIONAL TRADE<sup>21</sup> (Agenda Item 11)

50. The representative of ICMSF introduced the document which had been revised at the request of the Committee at its 28th Session, with contributions provided by the governments of the United Kingdom, the United States of America and Denmark. The revised document had been expanded to include recommendations on control of certain pathogens, viz. *Salmonella* with special reference to *S. enteritidis*, *Campylobacter* and enterohaemorrhagic *Escherichia coli*, in addition to *Listeria monocytogenes*. The scientific rationale for the determination of the microbiological criteria for *L. monocytogenes* was provided in the annex to the document. The Committee expressed its appreciation to the ICMSF for this highly interesting document.

51. The Committee noted that the document opened up the prospect of a new type of Codex recommendation in the area of food hygiene, namely recommendations on the control of specific organisms in food; such recommendations to be based on the results of comprehensive risk assessment and to include advice which could include as necessary sampling plans and microbiological criteria developed in accordance with the newly revised Principles for the Establishment and Application of Microbiological Criteria for Foods. It agreed to inform the Executive Committee and the CAC of its wish to undertake work in this field.

52. The Committee examined the ICMSF's recommendations and agreed that the text on *Listeria monocytogenes* should be elaborated separately from the rest of the document, although a reservation was expressed as to the appropriateness of the microbiological criteria for *L. monocytogenes* proposed in the document (<100/g). The Committee agreed to ask the governments of Germany, with assistance from Denmark and the United States, to finalize the Section of the document on *L. monocytogenes* by February 1997 and to circulate it, under an appropriate title, for comments by governments at Step 3. This document would provide a model format to be followed by future documents to be elaborated to address the other pathogens mentioned in the ICMSF's paper. Possible work on these other pathogens (*Campylobacter*, *Salmonella enteritidis* and enterohaemorrhagic *Escherichia coli*) would be considered at the next session of the Committee. The Committee noted the importance of taking into account different situations of countries when developing the texts for other specific pathogens in the future.

53. The Committee stressed that there was an increasing demand for the CCFH to receive scientific advice in the form of formal microbiological risk assessments, similar to the evaluations being carried out by the JECFA and the JMPR in their respective fields. The Committee hence agreed to invite the Commission to advise FAO and WHO to consider the establishment of an international advisory body addressing the microbiological aspects of food safety.

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<sup>21</sup>

CX/FH 96/9; CX/FH 96/9-ANNEX

**PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED WATER (OTHER THAN MINERAL WATER)<sup>22</sup> (Agenda Item 12)**

54. The Committee was informed that members of the Working Group established to develop this text had met during the period of the Fifth Session of the Codex Committee on Natural Mineral Waters, Thun (Switzerland), October 1996. The Working Group had considered the proposed draft code and the comments received, and had made a number of amendments based on these comments. The leader of the Working Group requested the Committee's advice on certain key issues which needed to be resolved in order for the Code to be developed further.
55. On the issue of whether to refer to "Bottled Water" or "Packaged Water", the Committee agreed to refer to both terms in the Title and Definition, but to refer simply to "Bottled Water" in the body of the Code for the sake of clarity and ease of reading.
56. The Committee debated the use of the term "Source water (supply water)" and the corresponding terms in French ("eau brute") and Spanish ("agua de origen"). As these terms had different nuances in the different languages and were difficult to translate into equivalent terms in other languages, it was proposed that it may not be necessary to define the expression, but instead to explain the meaning and use of the words in the appropriate context whenever they occurred. The Committee could not arrive at a conclusion on this matter. It was recommended that a clear distinction needed to be established between relatively-safe protected underground waters and other sources of water.
57. In relation to the provisions concerning treatment, it was agreed that the need for treatment should be determined on the basis of an appropriate risk analysis. Certain delegations drew attention of the Committee to the weaknesses of bacterial testing as an appropriate indicator for the presence of viruses and/or protozoa, whereas other delegations made reference to work which, in the case of naturally protected waters, established a link between these organisms and the presence of indicator bacteria. Reference was also made to the need to consider chemical contamination from elements such as fluorine, bromine and radon.
58. The Committee noted the proposals to include a separate section on labelling, especially in relation to claims directed toward special population groups, including the immuno-compromised. Consumers International expressed its strongly held view that information needed for consumers to make an informed safe choice of bottled water be provided on the label. The Committee agreed that labelling issues should be excluded from the Code unless they were immediately directed towards hygiene, and that the provisions of the General Standard for the Labelling of Pre-packaged Foods and related documents provided adequate guidance on labelling and claims.

**STATUS OF THE CODE OF HYGIENIC PRACTICE FOR BOTTLED WATER (OTHER THAN NATURAL MINERAL WATERS)**

59. The Committee agreed to return the draft to Step 2 for redrafting. It was agreed that Belgium would be a member of the drafting group in addition to the members appointed at the Committee's previous Session.
60. It was suggested that the drafting of the present Code might indicate the future need for a revision of the Code of Hygienic Practice for the Collection, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985).

**IMPLICATIONS FOR THE BROADER APPLICATION OF THE HACCP SYSTEM<sup>23</sup> (Agenda Item 13(a))**

61. The Delegation of Australia introduced the document it had prepared. In view of the comments received, many delegations felt that it was necessary to modify the title and scope of the document in order to better reflect the intended purpose of the document, which would be to provide guidance to governments in their efforts to implement the HACCP system.
62. Several delegations proposed to postpone the work under this Agenda Item for two years and wait until more experience had been obtained from different countries (especially from developing countries) and a better understanding would be available as to the format the document should follow. Other delegations were of the view that the current work should be continued in view of the immediate usefulness of providing governments

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<sup>22</sup> CX/FH 96/13; CX/FH 96/13 - Add.1 (Comments of Australia, Brazil, Czech Republic, Denmark, France, Malaysia, New Zealand, Switzerland, United Kingdom, Uruguay, Consumers International).

<sup>23</sup> CX/FH 96/11; CX/FH 96/11 Add.1 comments by Argentina, Australia, Brazil, New Zealand, United Kingdom, United States, Consumer International and World Health Organization.

with guidance on implementation of the HACCP system, regardless of the form in which the finalized document should be published. The Committee also noted a view of some delegations that this kind of work could more appropriately be addressed by CCFICS, since the issue of equivalence was involved.

63. The Committee agreed that a Circular Letter be prepared to invite governments to communicate their experience of implementing the HACCP system by sending a status report to Australia, which would prepare a redrafted document for presentation at the next session of the Committee. Delegations stressed the importance of training in the application of HACCP to the regulatory and the business sectors particularly in developing countries and called upon FAO and WHO to strengthen their efforts in this regard.

#### CONSUMER EDUCATION IN THE APPLICATION OF HACCP<sup>24</sup> (Agenda Item 13(b))

64. The Executive Committee, at its previous session, had invited the United States to prepare a discussion paper including an outline of guidance to be provided as to consumer education. During its drafting process, it was recognized that the application of the HACCP system in households would involve certain difficulties in terms of basic infrastructure available, that the nature of such guidance would need to be culture-specific, and that the direct application of the HACCP system might not be the only solution to achieve food safety at consumer level.

65. While recognizing the relevance of the HACCP concept applicable throughout the food chain and the usefulness of incorporating core elements of the HACCP system into training programmes of local health workers and teachers, the Committee decided to discontinue the work on this matter, with the understanding that FAO, WHO and other relevant organizations should further develop materials for consumer education adapted to the need of different target groups and local situations.

#### OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

66. The Committee decided to initiate work on the following matters, subject to confirmation by the CAC, was necessary:

- Code of Hygienic Practice for Milk and Milk Products, a discussion paper and outline to be prepared by the Delegation of the United States assisted by India, France and the IDF.
- Guidance on the hygienic recycling of processing water in food processing plants. The Committee noted that recycling of processing water was becoming more common in view of the necessity to conserve energy and water resources, but that there were significant food hygiene implications. A discussion paper is to be developed by the United States.
- Broader issues on the application of microbiological risk evaluation to international trade, especially taking into account trade in foods and animal feed between countries of differing microbiological status. A discussion paper which would consider the issue in light of countries' rights and obligations under the SPS Agreement and should take into account the outcome of the FAO Expert Consultation on Animal Feeding and Food Safety scheduled for early 1997 is to be prepared by Norway, with assistance from Sweden, Denmark and France).
- Revision of the standard wording for use by Codex Committees in relation to Food Hygiene Provisions currently contained in the Procedural Manual (Section K) to take into account revisions to the General Principles of Food Hygiene and the use of risk-based control systems (Codex Secretariat).
- Development of a discussion paper on risk-based guidance for the use of HACCP-like systems in small businesses, with special reference to developing countries (Netherlands).
- Recommendations for the management of microbiological hazards for foods in international trade (ICMSF).

67. The Committee noted that, in addition to the above, its Future Work would consist of the following items:

- Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-Life at Step 7
- Principles and Guidelines for the Conduct of Microbiological Risk Assessment at Step 4

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No document was made available for this agenda item.

- Recommendations for the Control of *Listeria monocytogenes* in Foods (Step 2/3)
- Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese (Step 2/3)
- Code of Hygienic Practice for the Transport of Foods in Bulk (Step 2/3)
- Code of Hygienic Practice for Bottled Waters (other than Mineral Water) (Step 2/3).
- Consideration of a technical paper (to be prepared by CCFFP) on residual chlorine in frozen shrimps and prawns

68. In response to a question from the Delegation of Canada, the Secretariat indicated that the publication of the Pictorial Manual on Can Defects, adopted by the Commission in 1993, had been delayed for technical and financial reasons. However, efforts were being made to determine how the manual could be published, possibly in relation to the second edition of the *Codex Alimentarius on CD-ROM*.

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 15)**

69. The Committee was advised that its 30th session was scheduled to be held in Washington D.C., from 20 - 24 October 1997, subject to confirmation by the CAC.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document
Draft Revised International Code of Hygienic Practice - General Principles of Food Hygiene	8	22nd CAC	ALINORM 97/13 Appendix II
Draft Revised Guidelines for the Application of the HACCP System	8	22nd CAC	ALINORM 97/13A Appendix II
Draft Revised Principles for the Application of Microbiological Criteria for Foods	8	22nd CAC	ALINORM 97/13A Appendix III
Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life	6	Canada, France, UK, USA Governments 30th CCFH	ALINORM 97/13A paras. 32-34
Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese	3	USA, France, IDF Governments 30th CCFH	ALINORM 97/13A paras. 40-43
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment	3	Governments 30th CCFH	ALINORM 97/13A paras. 35-39 Appendix IV
Proposed Draft Code of Hygienic Practice for the Transport of Foods in Bulk	3	The Netherlands, Canada, Indonesia, Malaysia, Philippines, South Africa, USA, Germany 30th CCFH	ALINORM 97/13A paras. 44-49
Recommendations on the control of Listeria monocytogenes in foods in international trade	3	Germany Governments 30th CCFH	ALINORM 97/13A paras. 50-53
Proposed Draft Code of Hygienic Practice for Bottled Waters (Other than Mineral Water)	2	USA, France, Indonesia, Japan, Spain, Switzerland, Belgium 30th CCFH	ALINORM 97/13A paras. 54-60
Implication of the Broader Application of the HACCP System	2	Australia 30th CCFH	ALINORM 97/13A paras. 61-63
Proposed Draft Code of Hygienic Practice for Milk and Milk Products	1	22nd CAC USA, India, France, IDF 30th CCFH	ALINORM 97/13A paras. 41
Hygienic recycling of processing water in food processing plants	1	USA 30th CCFH	ALINORM 97/13A para. 66
Application of microbiological risk evaluation in international trade	1	Norway, Sweden, Denmark, France	ALINORM 97/13A para. 66
Revision of the standard wording for Food Hygiene Provisions (Procedural Manual)	1	Secretariat 30th CCFH	ALINORM 97/13A para. 66
Use of HACCP-like systems in small businesses	1	Netherlands 30th CCFH	ALINORM 97/13A para. 66
Management of microbiological hazards for foods in international trade	1	ICMSF 30th CCFH	ALINORM 97/13A para. 66



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**DRAFT**  
**HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR**  
**ITS APPLICATION**  
*(At Step 8 of the Procedure)*

**PREAMBLE**

The first section of this document sets out the principles of the Hazard Analysis and Critical Control Point (HACCP) system adopted by the CAC. The second section provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.<sup>25</sup>

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from the primary producer to final consumer and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a multidisciplinary approach; this multidisciplined approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry, and engineering according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

**DEFINITIONS**

**Control (verb):** To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

**Control (noun):** The state wherein correct procedures are being followed and criteria are being met.

**Control Measure:** Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Corrective Action:** Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

**Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Critical Limit:** A criterion which separates acceptability from unacceptability.

**Deviation:** Failure to meet a critical limit.

**Flow diagram:** A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

**HACCP:** A system which identifies, evaluates, and controls hazards which are significant for food safety.

**HACCP Plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

**Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

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<sup>25</sup> The Principles of HACCP set the basis for the requirements for the application of HACCP, while the Guidelines provide general guidance for practical application.

**Hazard Analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

**Monitor:** The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

**Step:** A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

**Validation:** Obtaining evidence that the elements of the HACCP plan are effective.

**Verification:** The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

## **PRINCIPLES**

The HACCP system consists of the following seven principles:

### ***PRINCIPLE 1***

Conduct a hazard analysis.

### ***PRINCIPLE 2***

Determine the Critical Control Points (CCPs).

### ***PRINCIPLE 3***

Establish critical limit(s).

### ***PRINCIPLE 4***

Establish a system to monitor control of the CCP.

### ***PRINCIPLE 5***

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

### ***PRINCIPLE 6***

Establish procedures for verification to confirm that the HACCP system is working effectively.

### ***PRINCIPLE 7***

Establish documentation concerning all procedures and records appropriate to these principles and their application.

## **GUIDELINES FOR THE APPLICATION OF THE OF HACCP SYSTEM**

Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

### **Application**

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

#### **1. Assemble HACCP team**

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

#### **2. Describe product**

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including  $A_w$ , pH, etc.), microcidal/static treatments (e.g. heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution.

#### **3. Identify intended use**

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

#### **4. Construct flow diagram**

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

#### **5. On-site confirmation of flow diagram**

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

#### **6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (see Principle 1)**

The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and,
- conditions leading to the above.

The team must then consider what control measures, if any, exist which can be applied for each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

**7. Determine Critical Control Points (see Principle 2)<sup>26</sup>**

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree, e.g. Diagram 2, which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

**8. Establish Critical Limits for each CCP (see Principle 3)**

Critical limits must be specified and validated if possible for each critical control point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH,  $A_w$ , and available chlorine, and sensory parameters such as visual appearance and texture.

**9. Establish a Monitoring System for Each CCP (see Principle 4)**

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

**10. Establish Corrective Actions (see Principle 5)**

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

**11. Establish Verification Procedures (see Principle 6)**

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

Review of the HACCP system and its records.

Review of deviations and product dispositions.

Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

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Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

**12. Establish Documentation and Record Keeping (see Principle 7)**

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Documentation examples are:

- Hazard analysis
- CCP determination
- Critical limit determination

Record examples are:

- CCP monitoring activities
  - Deviations and associated corrective actions
  - Modifications to the HACCP system
- An example of a HACCP worksheet is attached as Diagram 3.

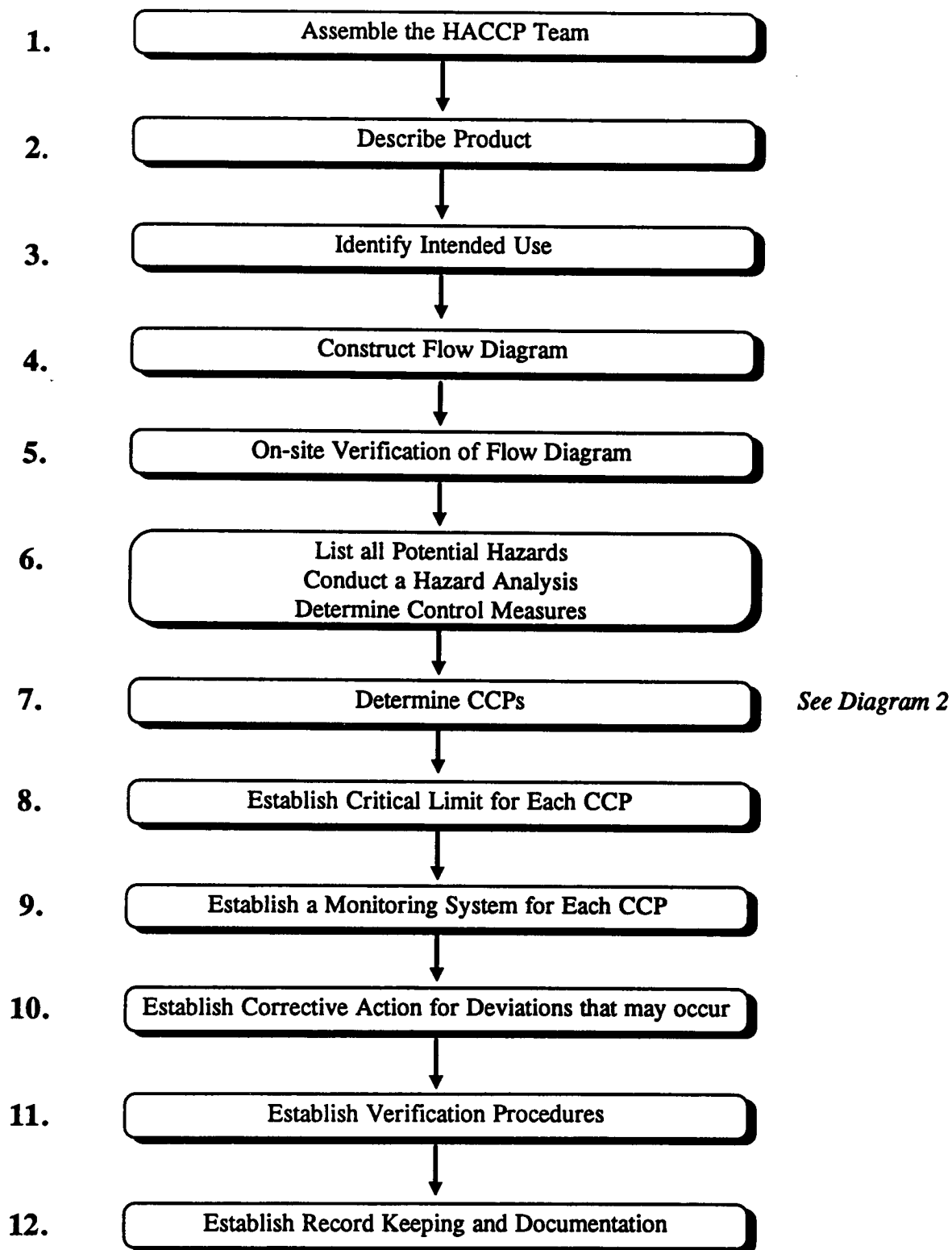
***TRAINING***

Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

Cooperation between primary producer, industry, trade groups, consumer organizations, and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

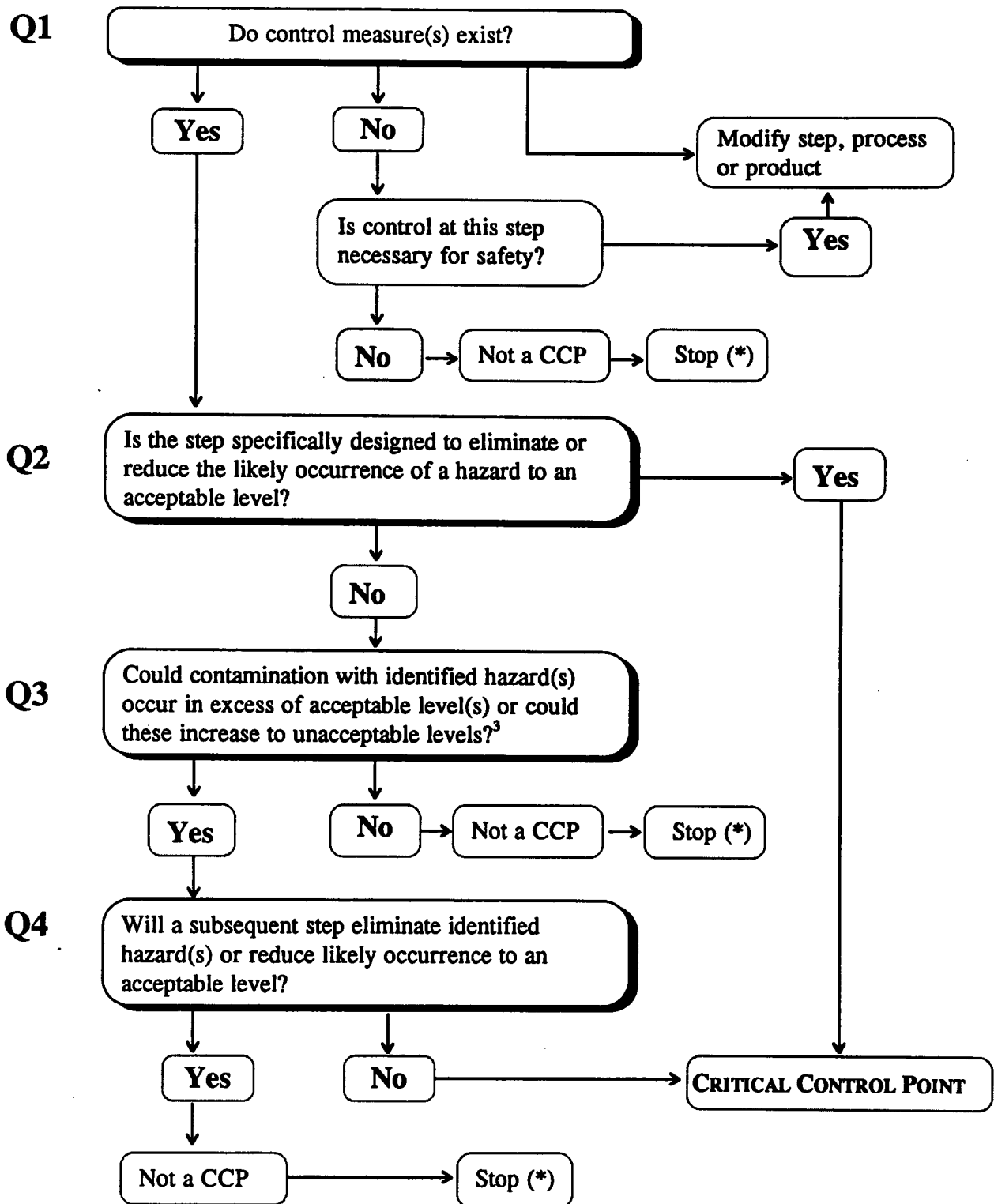
DIAGRAM 1

LOGIC SEQUENCE FOR APPLICATION OF HACCP





**DIAGRAM 2**  
**EXAMPLE OF DECISION TREE TO IDENTIFY CCPs**  
(answer questions in sequence)



<sup>(\*)</sup> Proceed to the next identified hazard in the described process.

<sup>3</sup> Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of HACCP plan.

**DIAGRAM 3**

**EXAMPLE OF A HACCP WORKSHEET**

1.

**Describe Product**

2.

**Diagram Process Flow**

3.

LIST							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4.

**Verification**

**DRAFT**  
**REVISED PRINCIPLES FOR THE ESTABLISHMENT**  
**AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS**  
*(At Step 8 of the Procedure)*

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### Introduction

These Principles are intended to give guidance on the establishment and application of microbiological criteria for foods at any point in the food chain from primary production to final consumption.

The safety of foods is principally assured by control at the source, product design and process control, and the application of Good Hygienic Practices during production, processing (including labelling), handling, distribution, storage, sale, preparation and use, in conjunction with the application of the HACCP system. This preventive approach offers more control than microbiological testing because the effectiveness of microbiological examination to assess the safety of foods is limited. Guidance for the establishment of HACCP based systems is detailed in *Hazard Analysis/Critical Control Point System and Guidelines for its Application*<sup>27</sup>. Microbiological criteria should be established according to these principles and be based on scientific analysis and advice, and where sufficient data are available, a risk analysis appropriate to the foodstuff and its use. Microbiological criteria should be developed in a transparent fashion and meet the requirements of fair trade. They should be reviewed periodically for relevance with respect to emerging pathogens, changing technologies, and new understandings of science.

### 1. Definition of Microbiological Criterion

A microbiological criterion for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.

### 2. Components of microbiological criteria for foods

2.1 A microbiological criterion consists of:

- a statement of the microorganisms of concern and/or their toxins/ metabolites and the reason for that concern. (see § 5.1);
- the analytical methods for their detection and/or quantification (see § 5.2);
- a plan defining the number of field samples to be taken and the size of the analytical unit (see § 6);
- microbiological limits considered appropriate to the food at the specified point(s) of the food chain (see § 5.3);
- the number of analytical units that should conform to these limits.

2.2 A microbiological criterion should also state:

- the food to which the criterion applies,

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- the point(s) in the food chain where the criterion applies,
  - any actions to be taken when the criterion is not met.
- 2.3 When applying a microbiological criterion for assessing products it is essential, in order to make the best use of money and manpower, that only appropriate tests be applied (see § 5) to those foods and at those points in the food chain that offer maximum benefit in providing the consumer with a food that is safe and suitable for consumption.
3. **Purposes and application of microbiological criteria for foods**
- 3.1 Microbiological criteria may be used to formulate design requirements and to indicate the required microbiological status of raw materials, ingredients and end-products at any stage of the food chain as appropriate. They may be relevant to the examination of foods, including raw materials and ingredients, of unknown or uncertain origin or when other means of verifying the efficacy of HACCP based systems and Good Hygienic Practices are not available. Generally, microbiological criteria may be applied to define the distinction between acceptable and unacceptable raw materials, ingredients, products, lots, by regulatory authorities and/or food business operators. Microbiological criteria may also be used to determine that processes are consistent with the General Principles of Food Hygiene.
- 3.1.1 **Application by regulatory authorities.**  
Microbiological criteria can be used to define and check compliance with the microbiological requirements.  
Mandatory microbiological criteria shall apply to those products and/or points of the food chain where no other more effective tools are available, and where they are expected to improve the degree of protection offered to the consumer. Where these are appropriate they shall be product-type specific and only applied at the point of the food chain as specified in the regulation.  
In situations of non-compliance with microbiological criteria, depending on the assessment of the risk to the consumer, the point in the food chain and the product-type specified, the regulatory control actions may be sorting, reprocessing, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken.
- 3.1.2 **Application by a food business operator.**  
In addition to checking compliance with regulatory provisions (see § 3.1.1) microbiological criteria may be applied by food business operators to formulate design requirements and to examine end-products as one of the measures to verify and/or validate the efficacy of the HACCP system.  
Such criteria will be specific for the product and the stage in the food chain at which they will apply. They may be stricter than the criteria used for regulatory purposes and should, as such, not be used for legal action.
- 3.2 Microbiological criteria are not normally suitable for monitoring Critical Limits as defined in Hazard Analysis/Critical Control Point System and Guidelines for its Application. Monitoring procedures must be able to detect loss of control at a Critical Control Point (CCP). Monitoring should provide this information in time for corrective actions to be taken to regain control before there is a need to reject the product. Consequently, on-line measurements of physical and chemical parameters are often preferred to microbiological testing because results are often available more rapidly and at the production site. Moreover, the establishment of Critical Limits may need other considerations than those described in this document.
4. **General considerations concerning principles for establishing and applying microbiological criteria .**
- 4.1 A microbiological criterion should be established and applied only where there is a definite need and where its application is practical. Such need is demonstrated, for example, by epidemiological evidence that the food under consideration may represent a public health hazard and that a criterion is meaningful for consumer protection, or as the result of a risk assessment. The criterion should be technically attainable by applying good manufacturing practices (codes of practice).
- 4.2 To fulfil the purposes of a microbiological criterion, consideration should be given to:
- 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 during subsequent handling, storage and use;
  - the category(s) of consumers concerned;
  - the cost/benefit ratio associated with the application of the criterion;
  - the intended use of the food.
- 4.3 The number and size of analytical units per lot tested should be as stated in the sampling plan and should not be modified. However, a lot should not be subjected to repeated testing in order to bring the lot into compliance.

## 5. Microbiological Aspects of Criteria.

### 5.1 *Microorganisms, parasites and their toxins/metabolites of importance in a particular food.*

#### 5.1.1 For the purpose of this document these include:

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

5.1.2 The microorganisms included in a criterion should be widely accepted as relevant - as pathogens, as indicator organisms or as spoilage organisms - to the particular food and technology. Organisms whose significance in the specified food is doubtful should not be included in a criterion.

5.1.3 The mere finding, with a presence-absence test, of certain organisms known to cause foodborne illness (e.g. *Clostridium perfringens*, *Staphylococcus aureus* and *Vibrio parahaemolyticus*) does not necessarily indicate a threat to public health.

5.1.4 Where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms. If a test for an indicator organism is applied, there should be a clear statement whether the test is used to indicate unsatisfactory hygienic practices or a health hazard.

### 5.2 *Microbiological methods.*

5.2.1 Whenever possible, only methods for which the reliability (accuracy, reproducibility, inter- and intra-laboratory variation) has been statistically established in comparative or collaborative studies in several laboratories should be used. Moreover, preference should be given to methods which have been validated for the commodity concerned preferably in relation to reference methods elaborated by international organizations. While methods should be the most sensitive and reproducible for the purpose, methods to be used for in-plant testing might often sacrifice to some degree sensitivity and reproducibility in the interest of speed and simplicity. They should, however, have been proved to give a sufficiently reliable estimate of the information needed.

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

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

### 5.3 *Microbiological limits.*

5.3.1 Limits used in criteria should be based on microbiological data appropriate to the food and should be applicable to a variety of similar products. They should therefore be based on data gathered at various production establishments operating under Good Hygienic Practices and applying the HACCP system. In the establishment of microbiological limits, any changes in the microflora likely to occur during storage and distribution (e.g. decrease or increase in numbers) should be taken into account.

5.3.2 Microbiological limits should take into consideration the risk associated with the microorganisms, and the conditions under which the food is expected to be handled and consumed. Microbiological limits should also take account of the likelihood of uneven distribution of microorganisms in the food and the inherent variability of the analytical procedure.

5.3.3 If a criterion requires the absence of a particular microorganism, the size and number of the analytical unit (as well as the number of analytical sample units) should be indicated.

## **6. Sampling plans, methods and handling**

6.1 A sampling plan includes the sampling procedure and the decision criteria to be applied to a lot, based on examination of a prescribed number of sample units and subsequent analytical units of a stated size by defined methods. A well-designed sampling plan defines the probability of detecting microorganisms in a lot, but it should be borne in mind that no sampling plan can ensure the absence of a particular organism.

Sampling plans should be administratively and economically feasible.

In particular, the choice of sampling plans should take into account:

- risks to public health associated with the hazard;
- the susceptibility of the target group of consumers; and
- the heterogeneity of distribution of microorganisms where variables sampling plans are employed.
- the acceptable quality level and the desired statistical probability of accepting a non-conforming lot. The Acceptable Quality Level (AQL) which is the percentage of non-conforming sample units in the entire lot for which the sampling plan will indicate lot acceptance for a prescribed probability (usually 95 per cent).

For many applications 2-or 3-class attribute plans may prove useful. (See Annex I or ICMSF, Microorganisms in Foods, 2. Sampling for Microbiological Analysis. Principles and Specific Applications, 2nd Edition, 1986 [Reference to be up-dated]).

6.2 The statistical performance characteristics or operating characteristics curve should be provided in the sampling plan. Performance characteristics provide specific information to estimate the probability of accepting a non-conforming lot. The sampling method should be defined in the sampling plan. The time between taking the field samples and analysis should be as short as reasonably possible, and during transport to the laboratory the conditions (e.g. temperature) should not allow increase or decrease of the numbers of the target organism, so that the results reflect - within the limitations given by the sampling plan - the microbiological conditions of the lot.

## **7. Reporting**

7.1 The test report shall give the information needed for complete identification of the sample, the sampling plan, the test method, the results and, if appropriate, their interpretation.

## PROPOSED DRAFT

## PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT

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**BACKGROUND**

Risks from microbiological hazards are of immediate and serious concern to human health. Risk Assessment will be a key element in assuring that sound science is used to establish standards, guidelines and other recommendations for food safety to ensure consumer protection and facilitate international trade. The Risk Assessment process should include quantitative information to the greatest extent possible in the estimation of risk. A Microbiological Risk Assessment should be conducted using a structured approach such as that described in this document. This document will be of primary interest to governments although other organizations, companies, and other interested parties who need to prepare a Microbiological Risk Assessment will find it valuable. Although Microbiological Risk Assessment is the primary focus of this document, the method can also be applied to certain other classes of biological hazards.

**SCOPE**

The scope of this document applies to Risk Assessment of microbiological hazards in food and water.

**DEFINITIONS**

The Committee did not discuss any definitions contained in the 1995 joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues Report since they are out for comment by governments. The working definitions cited here are to facilitate the understanding of certain words or phrases used in this document and should be subject to further discussion. The italicized references are for informational purposes only and will not appear in the final Codex document.

[Default - A type of assumption used in the absence of specific data, generally selected for conservative protection of public health in the current context.]

[Infection - Successful colonization of the host by a microorganism capable of causing damage to its host (modified from *Saylers and Whitt, 1994*).]

[Quantitative Risk Assessment - Emphasizes reliance on numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis)].

[Qualitative Risk Assessment - A systematic approach to data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.]

[Risk Estimate - Estimate of the likelihood, or statistical probability, that harm will occur as a result of exposure to a risk agent (*Cohrssen & Covello, 1989*).]

[Sensitivity analysis - A method used to examine the behavior of a model by measuring the variation in its outputs resulting from changes to its inputs (*Cohrssen & Covello, 1989*).]

[Structured approach - A framework for systematically addressing Risk Assessment.]

[Transparency - Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully stated, documented, and accessible for review.]

[Uncertainty analysis - A method used to estimate the uncertainty associated with model inputs, assumptions and structure/form.]

NOTE: The Codex Secretariat is to supply the agreed upon Codex Risk Analysis definitions.

#### GENERAL PRINCIPLES OF MICROBIOLOGICAL RISK ASSESSMENT

1. Microbiological Risk Assessment must be soundly based upon science.
2. There should be a functional separation between Risk Assessment and Risk Management.
3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.
4. A Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
5. A Risk Assessment should be transparent. This requires: full and systematic documentation, statement of assumptions and value judgements and rationale, and a formal record.
6. [Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.]
7. The Risk Estimate should contain a detailed description of uncertainty and where the uncertainty arose during the Risk Assessment process.
8. Data should be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized as far as possible.
9. Depending upon the purpose of the Risk Assessment, a Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human health data.
11. A Microbiological Risk Assessment may need reevaluation as new relevant information becomes available.

#### GUIDELINES FOR APPLICATION

These Guidelines provide an outline of the elements of a Microbiological Risk Assessment indicating the types of decisions that need to be considered at each step. In this outline the traditional steps in the Risk Assessment process developed by the 1983 NRC Committee as modified by the 1995 Joint FAO/WHO Expert Consultation have been used.

##### *Statement of Purpose of Risk Assessment*

At the beginning of a Risk Assessment the specific purpose of the particular Risk Assessment being carried out should be clearly stated. The output form and possible output alternatives of the Risk Assessment should be defined. Output might, for example, take the form of an estimate of an annual occurrence of illness, or an estimate of annual rate of illness per 100,000 population, or an estimate of the rate of human illness per eating occurrence.

##### *Hazard Identification*

Hazard identification has been defined as the identification of known or potential health effects associated with a particular agent. For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food. Hazard identification may be a qualitative process. Hazards can be identified from relevant data sources. Information on hazards can be obtained from scientific literature, from databases such as those in the food industry, and government agencies and through expert elicitations/consultations. Relevant information includes data in areas such as: clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous organisms and situations.



### *Exposure Assessment*

Exposure Assessment is the qualitative or quantitative evaluation of the degree of [hazard] intake likely to occur. This may include an assessment of the extent of actual or anticipated human exposure. For microbiological agents, Exposure Assessments might be based on the potential extent of food contamination by a particular agent, and on dietary information. Exposure assessment should specify the unit of food that is of interest, i.e., a single serving portion in most/all cases of acute illness.

Factors that must be considered for Exposure Assessment include the frequency of contamination of foods by the pathogenic agent and its level in those foods over time. These factors are influenced by the characteristics of the pathogenic agent, the microbiological ecology of the food, the initial contamination of the raw material, the level of sanitation and process controls, the methods of processing, packaging, distribution and storage of the foods, as well as any preparation steps such as cooking. Another factor that must be considered in the assessment is patterns of consumption. This relates to socioeconomic and cultural backgrounds, ethnicity, seasonality, age differences (population demographics), regional differences, and consumer preferences and behavior.

Microbial pathogen levels can be dynamic and while they may be kept low, for example, by proper time/temperature controls during food processing, they can substantially increase with abuse conditions (for example, improper food storage temperatures or cross contamination from other foods). Therefore, the Exposure Assessment should describe the pathway from production to consumption. Scenarios can be constructed to predict the range of possible exposures. The scenarios might reflect effects of processing, such as hygienic design, cleaning and disinfection, as well as the time/temperature history, and food handling and consumption patterns.

Exposure Assessment estimates the level, within various levels of uncertainty, of microbiological pathogens or microbiological toxins, and the likelihood of their occurrence in foods at the time of consumption. Qualitatively foods can be categorized according to the likelihood that the foodstuff will or will not be contaminated at its source; whether or not the food can support the growth of the pathogen of concern; whether there is substantial potential for abusive handling of the food; or whether the food will be subjected to a heat process. The presence, growth, survival, or death of microorganisms, including pathogens in foods, are influenced by processing, the storage environment, including the temperature of storage, the relative humidity of the environment, and the gaseous composition of the atmosphere. Other relevant factors include pH, moisture content or water activity ( $a_w$ ), nutrient content, the presence of antimicrobial substances, and competing microflora. Predictive microbiology can be a useful tool in an Exposure Assessment.

### *Hazard Characterization*

The purpose of this step is to provide a qualitative or quantitative estimate of the severity and duration of adverse effects that may result from the presence of a pathogen in food.

There are several important factors that need to be considered in Hazard Characterization. These are related to both the organism, and the human host. In relation to the organism the following are important: microorganisms are replicating; the virulence of organisms can change depending on their interaction with the host and the environment; genetic material can be transferred between organisms leading to the transfer of characteristics such as antibiotic resistance; organisms can be spread through secondary and tertiary transmission; the onset of clinical symptoms can be substantially delayed following exposure; organisms can persist in certain individuals leading to continued excretion of the organism and continued risk of spread of infection; low doses of some organisms can in some cases cause a severe effect; and the attributes of a food that may alter the microbial pathogenicity, e.g., high fat content of a food vehicle.

In relation to the host the following are important: genetic factors such as Human Leucocyte Antigen (HLA) type; increased susceptibility due to breakdowns of physiological barriers; individual host susceptibility characteristics such as age, poor health, concurrent infections, immune status and previous exposure history; population characteristics such as population immunity and population behavior; and persistence of the organism in the population.

A central feature of Hazard Characterization is establishing a dose-response relationship. In the absence of a known dose-response relationship, expert elicitation could be conducted to consider various factors, such as infectivity, necessary to describe Hazard Characterizations [until specific information is available]. Additionally, experts may be able to devise ranking systems so that they can be used to characterize severity and/or duration of disease.

### ***Risk Characterization***

Risk Characterization has been defined as the integration of the Hazard Identification, Hazard Characterization, and Exposure Assessment determinations previously described into qualitative or quantitative estimates of the likelihood and severity of the adverse effects which could occur in a given population, including a description of the uncertainties and variability. These estimates can be assessed by comparison with independent epidemiological data that relate hazards to disease prevalence.

Risk Characterization brings together all of the qualitative or quantitative information of the previous steps to provide a soundly based estimate of risk for a given population or subpopulation. The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk.

The degree of confidence in the final estimation of risk will depend on the variability, uncertainty, and assumptions identified in all previous steps. Uncertainty is associated with the data themselves, and with the choice of model. Data uncertainties include those that might arise in the evaluation and extrapolation of information obtained from epidemiological, microbiological, and laboratory animal studies. Uncertainties arise whenever attempts are made to use data concerning the occurrence of certain phenomena obtained under one set of conditions to make estimations or predictions about phenomena likely to occur under other sets of conditions for which data are not available. Biological variation includes the differences in virulence that exist in microbiological populations and variability in susceptibility within the human population and particular subpopulations. It is important to demonstrate the influence of the estimates and assumptions used in Risk Assessment; for quantitative Risk Assessment this can be done using sensitivity and uncertainty analyses.

### ***Documentation***

The Risk Assessment should be fully and systematically documented. To ensure transparency a formal record of the Risk Assessment, including a summary, should be prepared and made available to independent parties on request so that other risk assessors can duplicate and critique the work. The formal record and summary should indicate any constraints and assumptions relative to the Risk Assessment.

## ***EXPLANATORY END NOTES FOR THE GENERAL PRINCIPLES OF MICROBIOLOGICAL RISK ASSESSMENT***

It is anticipated that these end notes will not appear in the final Codex document. They are included in this document for informational purposes only.

1. Microbiological Risk Assessment must be soundly based upon science.
  - Microbiological Risk Assessments should be soundly based in science. However, it must be recognized that scientific data may be limited, incomplete or conflicting. In such cases, informed judgements will need to be made.
2. There should be a functional separation between Risk Assessment and Risk Management.
  - This Principle was lifted from the report of the 1995 joint FAO/WHO expert consultation “An important Principle is the functional separation of Risk Assessment from Risk Management. However, certain interactive elements are essential for a systematic Risk Assessment process. These elements may include ranking of hazards in the Hazard Identification step and Risk Assessment policy issues. Where Risk Management issues may intrude in Risk Assessment, the decision-making process should be transparent.” In some situations the risk manager will be the best qualified individual to assess the “science” of an issue. In such circumstances, it is more important to stress not who is the assessor and who is the manager, but the “unbiasedness” of the assessment.
3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.
4. A Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
5. A Risk Assessment should be transparent. This requires: full and systematic documentation, statement of assumptions and value judgements and rationale, and a formal record.

Understanding any limitations that influenced a Risk Assessment is essential for transparency of the process that is important in decision making. To ensure transparency a formal record on the Risk Assessment,

including a summary, should be prepared and made available to independent parties on request so that other risk assessors can duplicate and critique the work. With this in mind, the final Guidelines emphasize the importance of producing formal documentation.

6. [Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.]

The square brackets reflect the need for further discussion as to whether the consideration is adequately addressed in other Principles or whether the concept should stand alone as a Principle. It should be recognized that sufficient resources will not always be available and there will typically be constraints imposed on the Risk Assessment that will have an influence on the quality of the Risk Estimate. Where such resource constraints apply, it is important for transparency purposes that these constraints be described in the formal record. Where appropriate, the record should include an evaluation of the impact of the resource constraints on the Risk Assessment.

7. The Risk Estimate should contain a detailed description of uncertainty and where the uncertainty arose during the Risk Assessment process.

Understanding any limitations in the data or models that influenced a Risk Estimate is essential for transparency of the decision making process.

8. Data should be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized as far as possible.

This Principle is intended to emphasize the importance of using the best information available when conducting a Risk Assessment in order to reduce uncertainty and to increase the reliability of the Risk Estimate. It encourages the use of quantitative information to the extent possible but does not discount the value and utility of qualitative information.

9. Depending upon the purpose of the Risk Assessment, a Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.

10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human health data.

A major difference between Risk Assessment for chemical agents and microbiological agents is the availability of human health data related to the results of exposure. This factor may facilitate the opportunity to compare the Risk Estimate with resulting human disease for the purpose of gauging the reliability of the estimate. This may initiate a reevaluation of the Risk Assessment.

11. A Microbiological Risk Assessment may need reevaluation as new relevant information becomes available.