

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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ALINORM 99/13

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

*Twenty-Third Session*

*Rome, 1999*

### **REPORT OF THE THIRTIETH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE**

*Washington, D.C., 20 - 24 October 1997*

*Please note that due to differences in available fonts, the page numbering of this report in PDF format may have changed.*

**NOTE:** This report includes Codex Circular Letter CL 1997/41-FH



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CX 4/20.2

CL 1997/41 - FH

**TO:** Codex Contact Points  
Interested International Organizations

**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 Thirtieth Session of the Codex Committee on Food Hygiene (ALINORM 99/13)

The report of the Thirtieth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Forty-fifth Session of the Executive Committee, Rome, 1998, and by the Twenty-Third Session of the Codex Alimentarius Commission, Rome, 1999.

## **MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:**

1. Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life at Step 8; ALINORM 99/13, paras. 11-20 and Appendix III.
2. Hygiene Provisions of Certain Milk and Milk Products Standards at Step 8; ALINORM 99/13, paras. 54-61 and Appendix VII.<sup>1</sup>
3. Amendment to the Procedural Manual: Food Hygiene Provisions in "Relations between Commodity Committees and General Committees", ALINORM 99/13, paras. 49-53 and Appendix VI.

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)570.54593 or E-mail: [codex@fao.org](mailto:codex@fao.org)) **before 1 April 1998**.

## **REQUEST FOR COMMENTS AND INFORMATION**

1. **Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment at Step 5/6;** ALINORM 99/13, paras. 21-27 and Appendix IV.
2. **Proposed Draft Code of Hygienic Practice for Packaged (Bottled) Drinking Waters (other than Natural Mineral Water) at Step 5/6;** ALINORM 99/13, paras. 32-48 and Appendix V.
3. **Proposed Draft Amendment to the General Principles of Food Hygiene at Step 3;** ALINORM 99/13, paras. 8-10 and Appendix II.

Governments and interested international organizations are invited to comment on the texts 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)) with a copy to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by Fax: +39(6) 570.54593 or E-mail: [Codex@fao.org](mailto:Codex@fao.org) **before 1 April 1998**.

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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 at Step 8:

- Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life (paras. 11-20, Appendix III);
- Revised Standard Wording for Food Hygiene Provisions, Section K of the Procedural Manual for endorsement, pending the advice from the Committee on General Principles (paras. 49-53, Appendix VI);
- Hygiene Provisions of Certain Milk and Milk Products Standards (paras. 54-61, Appendix VII).

### MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE:

#### • The following new work is proposed at Step 1 (see paragraph 108):

- Discussion paper on the Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce, to be prepared by the drafting group lead by Canada, with assistance from Argentina, Chile, Denmark, Guatemala, Honduras, Japan, Mexico (as the host government of the Committee on Fresh Fruits and Vegetables), United Kingdom and United States. The Proposed Draft Code should also address the issue of the use of manure in the production of sprout seeds;
- Discussion paper on the Proposed Draft Code of Hygienic Practice for Pre-cut Vegetables, to be prepared by the drafting group lead by France, with assistance from Mexico (as the host government of the Committee on Fresh Fruits and Vegetables), Netherlands, United Kingdom and United States;
- Discussion paper on the Proposed Draft Annex on "Cleaning and Disinfection" to the Recommended International Code of Practice - General Principles of Food Hygiene, to be prepared by the United States, with assistance from the United Kingdom.

#### • The Executive Committee advice is also sought for:

- the use of the Accelerated Procedure for the amendment of Section 6.1.2 of the General Principles of Food Hygiene (para. 10, Appendix II);
- the proposal to conduct a Regular Survey of Member countries on the implementation of HACCP and related systems (para. 83).

### MATTERS REFERRED TO OTHER CODEX COMMITTEES:

- The Committee agreed that a Circular Letter be prepared to invite additional government comments to the Proposed Draft Code of Practice of Good Animal Feeding and that comments, including those already received, be referred to the Committee on Residues of Veterinary Drugs in Foods for consideration (paras. 96-99).
- The Committee decided to inform the Committee on General Principles of the proposal to amend the Food hygiene Provisions in "Relation Between Commodity Committees and General Committees" of the Procedural Manual (para. 53).

### OTHER MATTERS:

- The Committee agreed to discontinue development of the Proposed Draft Code of Hygienic Practice for Uncured/Unripened and Ripened Soft Cheese as an independent Code, with the understanding that the work would continue as part of the elaboration of the more general Proposed Draft Code of Hygienic Practice for Milk and Milk Products (para. 67);

- The Committee agreed to circulate the working document on Recommendations for the Management of Microbiological Hazards for Foods in International Trade for government comments (paras. 68-73);
- The Committee agreed to circulate working document on Broader Issues on the Application of Microbiological Risk Evaluation in International Food and Feed Trade for government comments in the light of Article 6 of the SPS Agreement (paras. 74-79);
- The Committee decided to circulate the conclusions of an *ad hoc* working group on priorities for the Revision of Codex Codes for government comments and recommended that CCFH formally assumes responsibility for work done under the Codex Committees on Meat hygiene and other Codes of hygienic practice which are currently the responsibility of Commodity Committees (para. 106).

**LIST OF ABBREVIATIONS**  
**used in this Report**

CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CRD	Conference Room Document
EU	European Union
EXEC	Executive Committee of the CAC
FAO	Food and Agriculture Organization of the United Nations
HACCP	Hazard Analysis and Critical Control Point
IAEA	International Atomic Energy Agency
ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
OIE	Office international des epizooties
PAHO	Pan American Health Organization
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
UK	United Kingdom
US	United States of America
WHO	World Health Organization
WTO	World Trade Organization



**REPORT OF THE THIRTIETH SESSION OF THE CODEX COMMITTEE  
ON FOOD HYGIENE**

*Washington, D. C., 20 - 24 October 1997*

## **INTRODUCTION**

1. The Codex Committee on Food Hygiene held its Thirtieth Session in Washington, D.C., from 20 to 24 October 1997, by courtesy of the Government of the United States of America. The Session was chaired by Dr. I. Kaye Wachsmuth, Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA). The Session was attended by 266 delegates, advisors and observers representing 55 Member Countries, 1 Observer Country and 19 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. Mr. Thomas J. Billy, Vice-Chairperson of the Codex Alimentarius Commission, introduced Dr. Catherine Woteki, Under-Secretary for Food Safety, USDA, who welcomed the participants and stressed the importance of the work being carried out by the Codex Committee on Food Hygiene in furthering international harmonization of food standards, particularly in the context of the SPS Agreement of WTO.

The Committee was addressed by Mr. Michael R. Taylor, formerly U.S. Food and Drug Administration and USDA, and currently a visiting scholar in the Center for Risk Management at Resources for the Future. He gave a speech entitled "Trade, Food Safety, and the Role of Codex", stressing that scientifically sound and public-health oriented food safety standards were crucial in promoting the welfare of consumers.

4. The Committee appointed Mr. Peter Pauker, Canada, as rapporteur.

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

5. The Committee adopted the Provisional Agenda as the Agenda for the session, with deletion of Item 10, for which no working paper had been prepared. It agreed to rearrange the order of several items, the agreed order of the items being 1, 2, 3, 4, 5, 8, 9, 18, 6, 14, 7, 11, 16, 12, 13, 15, 17, 19, 20 and 21. For the ease of reference, the item numbers referred to in this report follow those in the Provisional Agenda.

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

### **APPLICATION OF RISK ANALYSIS PRINCIPLES IN CODEX: MICROBIOLOGICAL HAZARDS**

6. The Committee expressed its strong support for and stressed urgency of the establishment of an expert group to conduct risk assessments on microbiological hazards, as suggested by the 22nd Session of the Commission. Its role would be similar to that of JECFA and JMPR. The Committee noted that consultations were ongoing between FAO and WHO on the establishment of such a body, including the form it would take, and the working procedures and the selection of experts. The Committee noted that some governments might wish to inform FAO and WHO of the availability of potential experts in their countries, while recalling that the final decision on this matter rested with the Directors-General of FAO and WHO.

### **REVISION OF THE CODES OF PRACTICE**

7. The Committee noted the recommendations of the Commission concerning the Codes of Practice, and recognizing the urgent need to revise the Codes, agreed to establish an *ad hoc* working group, chaired

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<sup>2</sup> CX/FH 97/1  
<sup>3</sup> CX/FH 97/2

by Australia, to discuss priorities. The Committee agreed to consider the proposals for the revision of the codes under Agenda 19 - Other Business and Future Work.

#### **GENERAL PRINCIPLES OF FOOD HYGIENE**

8. The Committee noted that the Commission, while adopting the General Principles of Food Hygiene, had requested the Committee to consider proposals for the amendment of Sections 4.4.4. Personnel Hygiene Facilities and Toilets and Section 6 - Establishment: Maintenance and Sanitation.

9. With reference to Section 4.4.4., the Committee recognized that it was not always necessary for facilities to include a supply of both hot and cold water, an important issue in developing countries and small businesses. It also confirmed that, according to the current text, hot water was not required in all cases but only "where appropriate", and that it was left to competent authorities to make the relevant decision, based on an assessment of the risk.

#### **STATUS OF GENERAL PRINCIPLES OF FOOD HYGIENE**

10. The Committee decided to include an amendment at the end of Section 6.1.2 on the need for sufficient rinsing after chemical disinfection. In view of the non-controversial nature of the proposal, the Committee agreed to circulate the Proposed Draft Amendment to the General Principles of Food Hygiene at Step 3 of the Accelerated Procedure, subject to confirmation by the Executive Committee (see Appendix II).

#### **DRAFT CODE OF HYGIENIC PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF LIFE<sup>4</sup> (Agenda Item 4)**

11. The Delegation of Canada presented the draft code, which had been revised following the recommendations of the last session of the Committee, and in the light of the comments received. In particular, the Scope was clarified; the provisions already covered in the General Principles of Food Hygiene were identified and included by reference only, or retained when necessary; more flexibility was introduced in the selection of refrigeration temperatures; and the use of the hurdles was emphasized. The Committee expressed its appreciation to the Delegation of Canada and to the Drafting Group for their comprehensive work in order to provide a final version of the Code taking into account all comments received. The Committee reviewed the text section by section and made the following amendments.

12. The Committee had an exchange of views on the use of refrigeration temperatures, as some delegations felt that reference to a specific temperature, even as an example, might be interpreted as too prescriptive. The Committee agreed that no numeric value would appear for temperature, with an exception of an example which appears in the Objective, and that reference would be made to "the specified temperature" throughout the text.

13. The Scope was amended to specify more precisely the characteristics of the foods covered by the Code, such as shelf-life and type of processing, and the examples of such foods were retained.

14. The Committee agreed to introduce definitions for "hurdles" and "hurdle technology" as their use represented an essential aspect of the code. The definition of Good Manufacturing Practice was deleted as it was not used in the text of the code.

15. After an extensive exchange of views on the definitions related to packaging, the Committee confirmed that, for the purposes of the code, a container corresponded to primary package and clarified the definition of packaging; the text was amended where necessary to make it consistent with these definitions.

16. The Committee confirmed that the requirements corresponding to the High Risk Areas in each section were essential in certain cases as identified by the HACCP plan to ensure the safety of the products covered by the Code.

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<sup>4</sup> CX/FH 97/3, CX/FH 97/3-Add.1 (Denmark, Finland, UK, USA), CRDs 17 and 21 (amended and annotated versions of draft).

17. In sections 5.2.1.2 and 5.2.1.3, it was clarified that the use of the word “monitoring” was justified where it applied to equipment used to control a hazard.

18. In Section 6.2 Cleaning Programmes, HR areas, the wording was amended to make it more general and include all types of cleaning procedure which might cause cross-contamination, such as high-pressure spray cleaning.

19. The Committee agreed to delete Table 1 - Pathogenic Microorganisms, Growth Limits as it was only included for information and it would not be practical to update it in the future for the purpose of the Code.

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

20. The Committee agreed to advance the Draft Code to Step 8 for consideration by the 23rd Session of the Codex Alimentarius Commission (see Appendix III).

#### **CONSIDERATION OF THE PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT AT STEP 4<sup>5</sup> (Agenda Item 5)**

21. The Committee recalled that at its 29<sup>th</sup> Session it had agreed to modify the title, introduction and scope of the document originally contained in the discussion paper prepared by the United States.<sup>6</sup> It also noted that the definitions adopted at the 22nd Session of the Commission had been incorporated in its Definition Section. The Delegation of the United States introduced the proposed draft text<sup>7</sup> incorporating further amendments agreed to by the *Ad Hoc* working group that had met prior to the Plenary Session and had considered the government comments received.

22. The Committee agreed that definitions for common medical terms such as infection, clinical infection, pathogenicity and virulence need not to appear in the document. The Committee also agreed to the clarification of the definitions for Hazard Characterization and Risk Estimate and agreed that the definition for "default" was moved to the Explanatory End Notes.

23. Regarding the General Principles of Microbiological Risk Assessment, it was agreed that Principles 7 and 9 be slightly amended and Principle 8 further expanded and that Principles 7 and 8 be inverted.

24. With regard to the Guidelines for Application, the Committee agreed to make several amendments for clarification and add reference to regulatory control and surveillance systems in the section on Exposure Assessment. Further explanation on the establishment of a dose-response relationship was added in the section on Hazard Characterization.

25. While noting the usefulness of the document, the Delegation of India, supported by several delegations, stated that microbiological risk assessment was an emerging discipline that still required certain flexibility in its implementation and that technical assistance in the area of training would be crucial in promoting microbiological risk assessment in developing countries. The Committee was reminded that FAO and WHO were offering technical assistance to those countries in need.

26. The Committee also noted that the Explanatory End Notes contained some useful information which might well be moved to the body of the document and agreed that this should be considered at a later stage.

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

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<sup>5</sup> CX/FH 97/4; CX/FH 97/4 Add. 1 (comments from Denmark, Finland and the United States); CRD 13. (comments from France); CRD 16 (Report of the *Ad Hoc* Working Group held on 18 October 1997).

<sup>6</sup> ALINORM 97/13A, paragraphs 35-39.

<sup>7</sup> CRD 16.

27. The Committee advanced the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment to Step 5. The Proposed Draft Principles and Guidelines are attached to this report as Appendix IV.

**PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE TRANSPORT OF FOODSTUFFS IN BULK AND SEMI-PACKED FOODSTUFFS<sup>8</sup> (Agenda Item 8)**

28. At its 29th Session, the Committee had agreed that the Proposed Draft Code should be redrafted by the Netherlands and circulated for comments at Step 3.<sup>9</sup>

29. The Delegation of the Netherlands introduced the proposed draft, highlighting improvements made by the drafting group in view of government comments received and asked for guidance from the Committee to proceed with its further elaboration.

30. The Committee noted that significant improvement had been made by the redrafting group. Despite the usefulness of the document, the Committee noted that a number of editorial and other comments received still needed to be considered and incorporated in the document. Such comments included the consistency of the definition for "semi-packed food" between different Codex texts, and the need to further consider the decision tree in the Table. As regards the list of previous cargoes, the Committee noted the proposal of the drafting group to record two previous cargoes. The Delegation of India indicated that it would be difficult to apply strict requirements at the farm level in developing countries. In view of these issues to be addressed, the Committee felt that additional time was needed to further improve the document and that government comments should be particularly sought to specify the Scope of the Code.

**STATUS OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE TRANSPORT OF FOODSTUFFS IN BULK AND SEMI-PACKED FOODSTUFFS**

31. The Committee agreed that the document should be redrafted by the drafting group lead by the Netherlands with assistance from Brazil, Canada, Germany, France, Indonesia, Malaysia, Philippines and the United States, and circulated for government comments at Step 3 prior to the next session of the Committee.

**PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PACKAGED (BOTTLED) DRINKING WATERS (OTHER THAN NATURAL MINERAL WATER)<sup>10</sup> (Agenda item 9)**

32. The Delegation of the United States presented the proposed draft which had been revised in the light of the comments received. The Committee expressed its appreciation to the United States and the countries involved in the redrafting for their constructive work, and after reviewing the text section by section, agreed on the following amendments.

33. The Committee agreed to the proposal of the Delegation of India to amend the title to refer to Packaged (Bottled) Waters to better reflect various packaging materials being used.

34. In the Introduction, a reference to "physical and chemical safety" was added to microbiological safety, in order to cover all classes of hazards.

35. In Section 2.1 Scope, the Committee agreed that reference to labelling should be placed in square brackets for the time being, subject to deletion of the term at a later stage.

36. In Section 2.3 Definitions, the Committee agreed that some clarification would be needed regarding "Ingredient" to avoid any possible confusion. The Delegation of Uruguay suggested the deletion of the word "Ingredient" or that the reference be made to the definition of packaged (bottled) potable water.

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<sup>8</sup> CX/FH 97/7; CX/FH 97/7 Add. 1 (comments from Brazil, Denmark, Finland, Singapore, UK, USA; CRD 6 (comments from Costa-Rica)

<sup>9</sup> ALINORM 97/13A, paragraphs 40-49.

<sup>10</sup> CX/FH 97/8, CX/FH 97/8-Add. 1 (comments of Canada, UK, USA, Consumers International, UNESEM/GISEM, CRD 6 (Costa Rica)

37. In Section 3.3.1, the wording was amended to make it clear that the text covered surface water as well as underground water, especially by referring to "extraction and collection". In Section 3.3.1.3, the Committee agreed to replace the reference to "coliforms" with "indicator organisms".
38. In Section 3.3.2, the Delegation of France, supported by some delegations, proposed to indicate that bottling at the source should be encouraged in order to minimize risks of contamination. The Delegation of the United States, supported by other delegations pointed out that when it was not possible to bottle water at the source, other preventive measures could be applied, that physical distance between the point of origin and the bottling point did not constitute a risk in itself, and that the code should not be too prescriptive in this respect. The Committee however agreed to refer to a directly connected piping system of water supply as one of the means of avoiding contamination from bulk transport. The Committee agreed that the important consideration was adherence to hygienic practices through all stages.
39. The Committee agreed to the proposal from the Delegation of Brazil to include a new section on Protection of Surface Water Supply (3.2.2) and Criteria for Surface Water Supplies (3.2.2.1), with specific wording to be included at a later stage.
40. The title of Section 5.1.1 was amended to refer to "Preventive measures", to reflect that other measures than treatments were included. The Committee further agreed to delete the reference to glacier water in the third paragraph and to specify that surface water should be treated where necessary.
41. The Committee noted a proposal to delete the entire Section 5.4 Packaging as reference to the General Principles of Food Hygiene might be sufficient, and agreed to consider this possibility at a later date.
42. The Committee noted that the sections corresponding to matters covered by the General Principles of Food Hygiene were omitted, whereas an explicit reference was included in other codes and it was noted that consistency should be sought in the format of the codes. The Delegation of Canada preferred the approach being used in the Draft Code considered under Agenda Item 4 (see Appendix III).
43. In Section 9, the Committee recalled its decision at the 29<sup>th</sup> Session that labelling provisions should not be included unless they related to food hygiene matters, and the opportunity of including the requirements intended for infants (9.3.1) and immunocompromised persons (9.3.2) was discussed extensively. Some delegations and the Observer from Consumers International pointed out that the section addressed essential health concerns and should be included in the code, especially as no standard existed as yet for bottled waters.
44. Other delegations supported the deletion of Section 9 as labelling provisions should not be addressed in a code of hygienic practice; it was also noted that recommendations on the ingestion of water by infants (9.3.1) were more closely related to nutrition aspects than to food safety. Moreover, such labelling might imply that treated waters were safer than other similar products and therefore mislead the consumers. Information for specific population groups should preferably be provided through consumer information and education programmes.
45. The Delegations of the United States and the United Kingdom stressed that, although the current text (9.3.2) referred to immunocompromised persons, the contamination of underground water with parasitic protozoa was a serious concern affecting all consumers, and this issue would need to be addressed in further discussions.
46. The Committee agreed that Section 9 should be deleted at a later stage and that related issues might be addressed in some way by the time the corresponding commodity standard was developed in the future. However, as the need for further consideration of these important issues was recognized, both sub-sections were left in square brackets, in order to invite governments to provide additional comments on how to address these issues for consideration by the next session.
47. It was suggested by the Delegation of India, supported by other delegations, that end-product specifications should be reflected in the Product Standard as has been done in the case of the Standard for Natural Mineral Waters. The Committee noted that the development of Appendix 1 (Application of the

HACCP System) would proceed with the questions and guidelines and not give HACCP examples. Appendix 2 (Microbiological, Chemical and Physical Criteria) would be considered at the next session on the basis of the comments received.

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

48. The Committee, recognizing that substantial progress had been made on the text, agreed to advance the Proposed Draft Code to Step 5 of the Procedure (see Appendix V).

**REVISION OF THE STANDARD WORDING FOR FOOD HYGIENE PROVISIONS , SECTION K OF THE PROCEDURAL MANUAL <sup>11</sup> (Agenda Item 18)**

49. At the 29th Session of the Committee, it was proposed to initiate the revision of the standard wording for use by Codex Committees in relation to Food Hygiene Provisions currently contained in the Procedural Manual to take into account revisions to the General Principles of Food Hygiene and the use of risk-based control systems.<sup>12</sup> This proposal was subsequently approved by the 22nd Session of the Commission as new work.<sup>13</sup>

50. The Codex Secretariat introduced a document containing an analysis of the current wording of the Section and proposals for revision, consisting of three options.<sup>14</sup> Noting the vital role of the General Principles of Food Hygiene as the basic Codex guiding document in food hygiene, a majority of countries supported Option 3, which implied that distinctive wordings according to the nature of the product be removed; the reference to the General Principles of Food Hygiene be updated; and the provision on product examination and sampling plans be replaced by the reference to the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

51. After closely examining the wording of Option 3, the Committee felt that the second bullet point requiring the product to be free from objectionable matters was covered by the reference to the Revised General Principles of Food Hygiene in the first bullet point. The Committee also agreed to delete the phrase "(A list may follow)" in the first bullet point and simplify the wording of the last bullet point. It was also agreed to remove the footnote indicated by an asterisk in the last bullet point, because the issue was covered by the reference to the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

52. The Committee considered the proposal from the Delegation of France to include a reference to the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems but agreed not to include it in the provision. The Committee also felt that an additional provision on the working relationship between Codex Committees, as proposed by the United States, was not necessary.

**STATUS OF THE DRAFT AMENDMENT TO THE FOOD HYGIENE PROVISIONS IN "RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES"**

53. The Committee decided to submit the wording in Option 3 as amended in the Draft Amendment to the Food Hygiene Provisions in "Relations Between Commodity Committees and General Committees" in the Procedural Manual to the Commission, for endorsement at its 23rd Session, while informing the Committee on General Principles accordingly. The Draft Amendment is attached to this report as Appendix VI.

**CONSIDERATION OF HYGIENE PROVISIONS OF CERTAIN MILK AND MILK PRODUCTS STANDARDS<sup>15</sup> (Agenda Item 6)**

<sup>11</sup> CX/FH 97/17; CRD 9 (comments from France); CRD 19 (Comments from the USA).

<sup>12</sup> ALINORM 97/13A, paragraphs 31 and 66.

<sup>13</sup> ALINORM 97/37, Appendix IV.

<sup>14</sup> CX/FH 97/17

<sup>15</sup> CX/FH 97/5, CRD 5 (comments of France), CRD 10 (International Dairy Federation), CRD 12 (New Zealand, CRD 15 (Report of the Working Group).

54. The Committee recalled that its 29<sup>th</sup> Session had not been able to endorse the hygiene provisions in the draft standards for certain milk and milk products. In the light of widely divergent opinions expressed at the 22nd Session of the Commission, the question of including a reference to pasteurization or alternative measures in the milk products standards was referred back to the Committee on Food Hygiene with request to address this issue as a matter of high priority.

55. The Committee was informed that the Working Group which had met prior to the Session had not been able to reach consensus and that three proposals made by Denmark, France and IDF had been put forward as possible interim language, in order to facilitate the adoption of the standards. The proposals from Denmark and IDF referred to pasteurization or alternative combined measures to achieve the appropriate level of public health protection, while the proposal from France referred only to the relevant codes of practice.

56. The Committee had an extensive discussion on the need to add further requirements over and above the new common hygiene provisions agreed upon under Agenda Item 18. The Delegation of France, supported by several delegations, expressed the view that the standard should contain only general hygiene provisions, as defined in Section K of the Procedural Manual, and that matters concerning food safety should be addressed in the relevant Codes of Hygienic Practice.

57. The Delegation of the United States, supported by other delegations, pointed out that no reference should be made to documents which were still under development; as no code of practice existed as yet for the milk products under consideration, it was necessary to include appropriate hygiene requirements in the standards. The Delegation also stressed that the hygiene requirements should not focus on pasteurization as such but on the appropriate level of health protection.

58. The Delegation of Canada proposed to mention pasteurization as an example of the sanitary measures to be applied and to use the current wording of the general hygiene provisions to specify the outcome of such measures. Although some delegations supported this proposal, the Committee agreed that no reference should be made to the hygiene provisions of the current standards, as it had been decided to revise them thoroughly under Agenda Item 18 (see paragraphs 49-53).

59. Several delegations expressed the view that the whole process of production should be taken into consideration and that pasteurization should not be presented as the essential reference measure; a combination of control measures should be applied to ensure the safety of the final product. After an extensive exchange of views, the Committee agreed to stress the importance of control measures at all stages of the food chain, from primary production to consumption, and to mention pasteurization as an example of the measures that could be taken.

60. In order to reflect this consensus, the Committee agreed to the following wording, as proposed by the Delegation of the United Kingdom:

From raw material production to the point of consumption, the products covered by this standard should be subject to a combination of control measures, which may include, for example, pasteurization, and these should be shown to achieve the appropriate level of public health protection.

#### **STATUS OF THE CONSIDERATION OF HYGIENE PROVISIONS OF CERTAIN MILK, AND MILK PRODUCTS STANDARDS**

61. The Committee agreed that the food hygiene provisions in the draft standards for milk and milk products under consideration should include 1) the first paragraph of the revised general Food Hygiene Provisions, 2) the above paragraph and 3) the second paragraph of the general Provisions. The Committee noted that the draft standards for milk and milk products under consideration would be submitted to the 23rd Session of the Commission for adoption. The complete Hygiene Provisions are attached as Appendix VII.

## **CONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS<sup>16</sup> (Agenda Item 14)**

62. The Delegation of the United States introduced the document on behalf of the drafting group. It was noted that the Proposed Draft Code had been formatted in accordance with the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3-1997).

63. Several delegations commended the work done by the working group and stated that a high priority should be given to the development of this Code. The Delegation of the Netherlands, speaking on behalf of the Members of the EU, indicated that the HACCP principles, mentioned only in the Scope, needed to be further emphasized. The Delegation of the United Kingdom noted that the reference to pasteurization in Section 5.1 might need modification. The Observer from the International Dairy Federation stated that the Code of Practice for Dried Milk<sup>17</sup> could be taken into account in the elaboration of the Code. In relation to Section 9, the Delegation of Sweden indicated a need for labelling provisions for products made from raw milk. The Delegation of France stated that products from raw milk should not be considered as more risky than other products.

64. The Delegations of India and Kenya stressed the need to take into consideration various production systems in different countries, especially small dairy holdings. It was also stated that different milch animal products of importance to international trade should be taken into account during the elaboration of this Code.

### **STATUS OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS**

65. The Committee agreed to convert the outline into a proposed draft code and circulate it for government comments at Step 3. The Committee confirmed that the drafting group would be lead by the United States with assistance from Argentina, Australia, India, France, the Netherlands, New Zealand, the United Kingdom, Uruguay and IDF.

### **PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE MANUFACTURE OF UNCURED/UNRIPENED AND RIPENED SOFT CHEESES AT STEP 4<sup>18</sup> (Agenda Item 7)**

66. The Delegation of the United States, who had lead the drafting group, proposed that the Draft Code of Hygienic Practice for the Manufacture of Uncured/Unripened and Ripened Soft Cheeses be incorporated into the Proposed Draft Code of Hygienic Practice for Milk and Milk Products under elaboration (see Agenda Item 14). A number of delegations supported this proposal. The Committee noted that the drafting group envisaged under Agenda Item 14 (see paragraph 65) should take into account the work already done in the past regarding the cheese code as well as all the comments received on the latest document when developing the Proposed Draft Code of Hygienic Practice for Milk and Milk Products.

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

67. The Committee agreed to discontinue development of the document as an independent code, with the understanding that the work would continue as part of the elaboration of the Proposed Draft Code of Hygienic Practice for Milk and Milk Products.

### **RECOMMENDATIONS FOR THE MANAGEMENT OF MICROBIOLOGICAL HAZARDS FOR FOODS IN INTERNATIONAL TRADE<sup>19</sup> (Agenda Item 11)**

68. The Committee was reminded that the document included two inter-related annexes: Annex 1 originally from the discussion paper prepared by ICMSF and Annex 2 from the paper prepared by the United States on microbiological risk assessment, which had been discussed at the 29th Session of the Committee.

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<sup>16</sup> CX/FH 97/13; CRD 4 (comments from France); CRD 14 (comments from India)

<sup>17</sup> CAC/RCP 31-1983

<sup>18</sup> CX/FH 96/6, CX/FH 97/6-Add.1 (comments from Canada, Denmark, France, the Netherlands, New Zealand, Switzerland, United Kingdom, the USA and International Dairy Federation), CRD 1.

<sup>19</sup> CX/FH 97/10; CRD 7 (France).



69. The Observer from ICMSF indicated that the intention was intended to provide guidance on the establishment of sampling plans adapted to the appropriate level of public health protection, since this area had not been covered by any of Codex texts. The document also aimed at providing a starting point in the on-going efforts of integrating the existing and future Codex documents into a coherent overall structure of risk analysis by using the key concept of "food safety objectives". Annex 2, on the other hand, provided useful reflection as to the way to further improve risk assessment practices within Codex and its parent organizations.

70. Some delegations supported the working framework proposed by ICMSF. Many delegations expressed the view that the Committee should not proceed its work too quickly in view of the paramount importance of the issue in the Codex-wide context of risk analysis. It was also noted that the risk analysis was a developing science and flexibility was needed in its application.

71. Many delegations noted that the step-wise approach suggested in Annex 1 needed to be brought in line with the risk management principles recommended by the FAO/WHO consultation on risk management (1997). It was also pointed out that both risk assessment and management components contained in Annex 1 had been formulated in a narrow context of risk analysis.

72. The Committee also noted that the Committee on General Principles had undertaken the work to provide Codex-wide policies in risk analysis, including several horizontal definitions and principles, while the Committee had the mandate to implement the risk analysis in its field of competence. It was stressed that the discussion paper addressed the very subjects which the Commission at its 22nd Session had requested the relevant Codex Committees to elaborate. It was stressed that the work in this area should be co-ordinated between the Codex Committees involved and in the meantime governments should further be invited to comment on Annexes 1 and 2 in the broadest context of the Codex risk assessment and management, including the concepts expressed in the FAO/WHO consultation on risk management (1997).

#### **STATUS OF THE RECOMMENDATIONS FOR THE MANAGEMENT OF MICROBIOLOGICAL HAZARDS FOR FOODS IN INTERNATIONAL TRADE**

73. The Committee agreed to circulate the working document and invite governments to provide their comments by May 1998, in the light of the outcome of the FAO/WHO Consultations on risk assessment (1995) and on risk management (1997). The Committee requested that these government comments be compiled by the Delegation of France, in consultation with Italy, Argentina, Australia, Canada, Denmark, Germany, India, Japan, New Zealand, the Netherlands, Norway, United Kingdom, the United States and ICMSF, and the discussion paper be revised for consideration at the next session of the Committee.

#### **BROADER ISSUES ON THE APPLICATION OF MICROBIOLOGICAL RISK EVALUATION IN INTERNATIONAL FOOD AND FEED TRADE<sup>20</sup> (Agenda Item 16)**

74. The Delegation of Norway, on behalf of the drafting group, introduced the document. The Delegation stated that international trade between regions with difference in prevalence of foodborne pathogens has important public health implications and should be taken into account, as was the case for animal trade in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

75. The Delegation of the Netherlands, on behalf of the Members of the EU, supported by some delegations, expressed the view that the countries or regions, which naturally or through control measures enjoyed a lower prevalence of certain foodborne pathogen, should be recognized when applying microbiological risk assessment in relation to food and feed trade.

76. Other delegations were of the opinion that the SPS Agreement readily provided a framework for such recognition of certain areas and that Codex needed not to play a role in the area where the Office international des epizooties provided an appropriate forum for implementing control measures for zoonotic

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disease. A number of delegations pointed out that epidemiological and other scientific data currently available did not allow for an objective comparison between different countries or regions to determine such disease free or low prevalence areas although such an exercise might become possible in the future. Under these circumstances, this initiative might lead to the creation of unintentional trade barriers. Several delegations stressed the importance of risk prevention as a goal of further work in this area.

77. The Delegation of the Netherlands stated that this new exercise could start by making use of data available at present. The Delegation of Sweden indicated that his country had successfully controlled Salmonella in foods through the measures at the source and that its level of public health protection should be respected.

78. The Committee felt that this issue deserved further discussion. Although some delegations indicated that this issue was related to the issue discussed under Agenda Item 11, it was agreed that government comments should be sought by a separate Circular Letter to avoid confusion, however the relationship between the two documents should be stressed.

79. The Committee agreed to circulate the working document for government comments in the light of Article 6 of the SPS Agreement (Adaptation to Regional Conditions, Including Pest- or Disease Free Areas and Areas of Low Pest or Disease Prevalence). The Committee agreed that the Delegation of Norway, with assistance from Denmark, France, India, Sweden and the United States prepare a revised discussion paper, taking government comments into consideration, for discussion at the next session of the Committee. Government comments received by Norway should be made available to France to be used in the paper on management of microbiological hazard for foods in international trade (see paragraph 73).

#### **IMPLICATIONS FOR THE BROADER APPLICATION OF THE HACCP SYSTEM<sup>21</sup> (Agenda Item 12)**

80. The Delegation of Australia recalled that the 29th Session of the Committee had agreed to ask for comments on the experience of governments in the implementation of the HACCP system, in order to obtain guidance on how to proceed in this area. In view of limited comments received, it was proposed to conduct an annual survey on the development and implementation of HACCP systems and the draft outline of a questionnaire was presented in the Appendix to the working paper.

81. The Delegation of India referred to its experience in the introduction of the HACCP system in certain sectors of the industry and stressed the need for information on both training needs and training resources and expertise available in other countries. The Delegation of Indonesia supported this view and indicated that the HACCP system had been introduced in some large-scale industry, especially fisheries, but that problems still existed for large and small-scale businesses in that country. The Committee agreed that the survey should include specific questions concerning training resources and training needs. The Delegation of the United Kingdom mentioned that its research on the application HACCP principles in small businesses was nearing completion and offered to share the results with the Committee.

82. The Delegation of Peru indicated that the HACCP system had been implemented in that country in the fisheries industry with the support of the private sector and that other training programmes were being developed. The Delegation of Argentina suggested that the questionnaire should refer more specifically to the strategies applied and the articulation between official agencies and the private sector. Many delegations felt that the draft questionnaire should be further expanded in order to collect information pertinent and useful to the countries intending to promote HACCP and related food safety systems. It was also noted that it would be too early to obligate the Committee to an annual survey.

#### **STATUS OF THE IMPLICATIONS FOR THE BROADER APPLICATION OF THE HACCP SYSTEM**

83. The Committee agreed to inform the Executive Committee of the proposal to conduct a regular survey of Member countries on the implementation of HACCP and related systems. It was further agreed that the document would be circulated for government comments and revised by Australia with the

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<sup>21</sup> CX/FH 97/11, CRD 2 (comments of Australia, Canada, Ireland, New Zealand), CRD 11 (Japan)

assistance of Finland, India, Indonesia, Peru, the United Kingdom and the United States, for consideration at the next session of the Committee.

**DISCUSSION PAPER ON THE DEVELOPMENT OF RISK-BASED GUIDANCE FOR THE USE OF HACCP-LIKE SYSTEMS IN SMALL BUSINESSES, WITH SPECIAL REFERENCE TO DEVELOPING COUNTRIES<sup>22</sup> (Agenda Item 13)**

84. The Delegation of the Netherlands introduced the discussion paper, viewing the difficulties that small businesses encounter, especially in developing countries when dealing with the HACCP system. In particular, Hazard Analysis, Documentation and Verification were difficult to handle. Furthermore, the approach followed in the European Community in the application of the HACCP system was highlighted.

85. The Committee was reminded that there were two issues on which the Committee was invited to express its view on: (1) the applicability of HACCP in small businesses and (2) the need for Codex guidance for food businesses operating mainly domestically.

86. The Delegation of Japan supported the general application of the HACCP system in small businesses. Though they might encounter difficulties in implementing Hazard Analysis and Documentation, government and other scientific support and appropriate training were useful in resolving the problems. The Delegation indicated that the government had developed an extensive training programme to facilitate the implementation of the HACCP system, especially at the level of small businesses.

87. The Delegation of India highlighted the difficulties faced by the developing countries in the application of the HACCP system, especially in view of the requirements of importing countries, and proposed that such issues should be specifically addressed to in the document. It was emphasized by the Delegation of India, supported by other delegations, that guidance in this area was needed for international reference.

88. The Delegation of the United States pointed out that the General Principles of Food Hygiene referred to HACCP or similar systems and that a risk-based approach should always be followed to ensure an appropriate level of public health protection; in some cases, those systems other than HACCP might also prove to be more prescriptive and less flexible. The Delegations of the United Kingdom and the United States commented that terms such as “HACCP-like” should not be used when describing alternative risk-based systems that did not encompass the seven principles of HACCP.

89. The Delegations of Peru and Argentina expressed the view that the HACCP system should not be applied only to foods intended for export, but to food industry in general in order to protect the consumer, and they stressed their efforts to implement these principles at the national level. The Delegation of Uruguay supported these views and noted that if other risk-based systems were recommended, the Committee should determine how to recognize them within Codex. The Delegation of Argentina indicated that in order to have a common understanding among the countries it was necessary to specify the criteria to be used to classify industry as small businesses.

90. The Delegation of the United Kingdom, supported by the Delegation of Belgium, stressed the need for additional guidelines to implement the HACCP principles in a flexible manner, as appropriate for small businesses as well as for developing countries.

91. The Representative of WHO informed the Committee that WHO had published in 1992 a Guide to Identifying Hazards and Assessing Risks Associated with Food Preparation and Storage, directed to small businesses and that another document had been revised in 1996 to explain how the HACCP approach could be applied to street-food operations. The Representative, therefore, questioned the need for additional guidance from Codex in this area.

92. The Committee agreed that the paper should be revised by the Delegation of the Netherlands in the light of the discussions of the present session, and the following countries offered to provide their assistance: Argentina, Australia, Belgium, France, Hungary, India, Indonesia, Italy, Japan, Kenya, Nigeria, Spain, Thailand, the United Kingdom and the United States. It was agreed that the revised document would be circulated for comments and considered by the next session of the Committee.

#### **CONSIDERATION OF PROPOSED DRAFT GUIDELINES FOR HYGIENIC RECYCLING OF PROCESSING WATER IN FOOD PLANTS<sup>23</sup> (Agenda Item 15)**

93. At its 29th Session, the Committee had noted that there were significant hygiene implications in the recycling of food processing water and had requested the United States to prepare a discussion paper<sup>24</sup>.

94. The Delegation of the United States introduced the document and suggested to officially invite government comments by circulating the current working paper.

95. The Committee agreed to circulate the working document for government comments, especially on the countries' practices and experiences in this area. It was agreed that the United States would revise the document in the light of these government comments and provide a revised discussion paper at the next session of the Committee

#### **CONSIDERATION OF DRAFT CODE OF PRACTICE OF GOOD ANIMAL FEEDING<sup>25</sup> (Agenda Item 17)**

96. The 22nd Session of the CAC had noted the outcome of the FAO Consultation on Animal Feeding and Food Safety (March, 1997) and had agreed to initiate elaboration of the Proposed Draft Code of Practice on Good Animal Feeding. The Commission assigned this new work to the Committees on Food Hygiene, Food Additives and Contaminants, Pesticide Residues, and Residues for Veterinary Drugs in Foods, with the co-ordinating role to be assumed by the Executive Committee<sup>26</sup>.

97. The Codex Secretariat had introduced the document that contained a number of editorial and substantive government comments received.

98. Some delegations stressed the need for close collaboration with other Codex Committees to expedite work in this area. Other delegations recognized the importance of globally applying control measures to the total food chain with collaboration with OIE. The Committee agreed to remain involved in the elaboration of the Code in close co-operation with other relevant Committees.

#### **STATUS OF THE DRAFT CODE OF PRACTICE ON GOOD ANIMAL FEEDING**

99. The Committee agreed that a Circular Letter be prepared to invite additional government comments to the Proposed Draft Code. It was also agreed that all comments, including those already received, be referred to the forth-coming session of the Codex Committee on Residues of Veterinary Drugs in Foods for consideration. The Committee also agreed to consider this issue again at its next session.

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<sup>23</sup> CX/FH 97/14 (discussion paper prepared by USA)

<sup>24</sup> ALINORM 97/13A, paragraph 66

<sup>25</sup> CL 1997/30-FH; CX/FH 97/16 (comments from Brazil, Canada, Slovak, Sweden, UK, USA, WHO and Consumers International), CRD 8 (comments from France).

<sup>26</sup> ALINORM 97/37, paragraph 129

**OTHER BUSINESS AND FUTURE WORK<sup>27</sup> (Agenda Item 19)**

100. The Committee recalled that it had noted at its 29th Session the pictorial manual on can defects included in the Procedures for the Visual Inspection of Lots of Canned Foods (CAC/GL 17-1993) had not yet been published. The Committee was informed that the Codex Secretariat was seeking ways to make the manual available on Internet or by other means.

101. The Observer from IAEA informed the Committee that the Joint FAO/IAEA Division in Vienna had established a new training and reference center on food and pesticide control, whose activities would include those related to microbiological contamination. It was indicated that the center would become shortly fully operational in the area of laboratory technique as well as HACCP training.

102. The Observer from PAHO indicated that two information centers were offering technical assistance to Member States in various areas of food control. He stressed the importance of epidemiological database in combating foodborne disease.

103. The Observer from ISO informed the Committee that a document on the ISO Validation Methods had been made available<sup>28</sup>.

104. The Representative of WHO brought to the attention of the Committee two expert meetings which had met recently: a WHO Consultation on the prevention and control of enterohaemorrhagic *Escherichia coli* infection (April 1997) and a Joint FAO/IAEA/WHO Study Group on high-dose irradiation of food.

105. The Delegation of Argentina noted that the delay in distribution of Codex working documents in Spanish and its negative impact on the development of government comments as well as on the efficiency of the interpretation during the Committee session.

106. The Delegation of Australia presented the report of the *ad hoc* working group on the priorities for the revision of the hygienic provisions of Codex Codes of Practice.<sup>29</sup> The Working Group recommended that the Codes be grouped on the basis of the likelihood of common hygiene requirements, and prioritized for revision on the basis of impacts on food safety and trade. A table of suggested groupings was attached to the report of the working group. The Working group also recommended that CCFH formally assume responsibility for work done under the Committee on Meat Hygiene and other Codes of Hygienic Practice which were currently under the responsibility of commodity committees. The Committee decided to circulate the conclusions of the working group report to governments comment and discussion at the next session of the Committee. It was noted that the text of the Code of Practice for Dried Milk could be useful in the revision work of certain codes.

107. The Delegation of Germany informed the Committee that the revised text of the Proposed Draft Recommendations for the Control of *Listeria monocytogenes*, which could not be provided at this session, would be circulated prior to the next session of the Committee. Many delegations indicated that this work should advance without delay since this document would serve as a model to the future work addressing other pathogens.

108. The Committee agreed to initiate the following new work pending approval by the Executive Committee:

- Discussion paper on the Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce, to be prepared by the drafting group lead by Canada, with assistance from Argentina, Chile, Denmark, Guatemala, Honduras, India, Japan, Mexico (as the host government of the Committee on Fresh Fruits and Vegetables), the United Kingdom and the United States. The Proposed Draft Code should also address the issue of the use of manure in the production of sprout seeds.

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<sup>27</sup> CRD 3 (proposal from Denmark); CRD 22 (Report of *Ad Hoc* working group on prioritization of the revision of Codes of Practice held on 20 October 1997).

<sup>28</sup> CRD 13

<sup>29</sup> CRD 22

- Discussion paper on the Proposed Draft Code of Hygienic Practice for Pre-cut Fruits and Vegetables, to be prepared by the drafting group lead by France, with assistance from Canada, Guatemala, Japan, Mexico (as the host government of the Committee on Fresh Fruits and Vegetables), the Netherlands, the United Kingdom, the United States and Uruguay. This and the above documents would be drafted in close cooperation with CCFV.
- Discussion paper on the Proposed Draft Annex on "Cleaning and Disinfection" to the Recommended International Code of Practice - General Principles of Food Hygiene, to be prepared by the United States, with assistance from the United Kingdom.

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

- Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment *at Step 6/7*
- Proposed Draft Code of Hygienic Practice for Packaged (Bottled) Drinking Waters (other than Natural Mineral Water) *at Step 6/7*
- Proposed Draft Code of Hygienic Practice for Milk and Milk Products *at Step 2/3/4*
- Proposed Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs *at Step 2/3/4*
- Proposed Draft Recommendations for the control of *Listeria monocytogenes* in Foods in International Trade *at Step 2/3/4*
- Proposed Draft Code of Practice on Good Animal Feeding *at Step 2/3/4*
- Proposed Guidelines for Hygienic Recycling of Processing Water in Food Plants *at Step 2/3/4*
- Prioritization of the revision of Codes of Hygienic Practice
- Recommendations for the Management of Microbiological Hazards for Foods in International Trade
- Broader Issues on the Application of Microbiological Risk Evaluation in International Food and Feed Trade
- Regular Survey of Member Countries on the Development and Implementation of HACCP and related Systems
- Development of Risk-Based Guidance for the Use of HACCP-like Systems in Small Businesses

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 20)**

110. The Committee was informed that its 31st Session was tentatively scheduled to be held in Washington, D.C., October 26-30, 1998, pending confirmation by the United States and the Codex Secretariats.

## SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document
Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life	8	23rd CAC	ALINORM 99/13, paras. 11-20; Appendix III
Hygiene Provisions of Certain Milk and Milk Products Standards	8	23rd CAC	ALINORM 99/13, paras. 54-61; Appendix VII
Revision of the Standard Wording for Food Hygiene Provisions, Section K of the Procedural Manual	8	23rd CAC	ALINORM 99/13, paras. 49-53; Appendix VI
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment	5	45th EXEC, 31st CCFH	ALINORM 99/13, paras. 21-27; Appendix IV
Proposed Draft Code of Hygienic Practice for Packaged (Bottled) Drinking Waters (Other Than Natural Mineral Waters)	5	45th EXEC, 31st CCFH	ALINORM 99/13, paras. 32-48; Appendix V
Proposed Draft Amendment to the General Principles of Food Hygiene	3/4 Accel proc.	45th EXEC, 31st CCFH	ALINORM 99/13, paras. 8-10; Appendix II
Proposed Draft Code of Hygienic Practice for Milk and Milk Products	2/3/4	US, Argentina, Australia, France, India, the Netherlands, New Zealand, UK, Uruguay, IDF, Governments, 31st CCFH	ALINORM 99/13, paras. 62-65
Proposed Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs	2/3/4	The Netherlands, Brazil, Canada, Germany, France, Indonesia, Malaysia, Philippines, US, Governments, 31st CCFH	ALINORM 99/13, paras. 28-31
Proposed Guidelines for Hygienic Recycling of Processing Water in Food Plants	2/3/4	US, Governments, 31st CCFH	ALINORM 99/13, paras. 93-95
Proposed Draft Code of Practice on Good Animal Feeding	2/3/4	Codex Secretariat, CCRVDF, CCFAC, Governments, 31st CCFH	ALINORM 99/13, paras. 96-99
Implications for the Broader Application of the HACCP System	2/3	Australia, Finland, India, Indonesia, Peru, UK, US, Governments, 31st CCFH	ALINORM 99/13, paras. 80-83
Development of Risk Based Guidance for the Use of HACCP-Like Systems in Small Business, With Special Reference to Developing Countries	1/2/3	The Netherlands, Argentina, Australia, Belgium, France, Hungary, India, Indonesia, Italy, Japan, Kenya, Nigeria, Spain, Thailand, UK, US, Governments, 31st CCFH	ALINORM 99/13, paras. 84-92

Subject Matter	Step	Action by:	Document
Recommendations for the Management of Microbiological Hazards for Foods in International Trade	1/2/3	<b>Codex Secretariat</b> , Governments, <b>France</b> , Italy, Argentina, Australia, Canada, Denmark, Germany, India, Japan, New Zealand, the Netherlands, Norway, UK, US, ICMSF, Governments, 31st CCFH	ALINORM 99/13, paras. 68-73
Broader Issues on the Application of Microbiological Risk Evaluation in International Food and Feed Trade	1/2/3	<b>Norway</b> , Denmark, France, India, Sweden, US, Governments, 31st CCFH	ALINORM 99/13, paras. 80-83
Proposed Draft Guidelines for Hygienic Recycling of Processing Water in Food Plants	1/2/3	<b>US</b> , 31st CCFH	ALINORM 99/13, paras. 93-95
Proposed Draft Recommendations for the control of <i>Listeria monocytogenes</i> in Foods in International Trade	1/2/3	<b>Germany</b> , Denmark, US, 31st CCFH	ALINORM 97/13A, paras. 50-52; ALINORM 99/13, para. 107
Discussion paper on the Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce		45th EXEC, <b>Canada</b> , Argentina, Chile, Denmark, Guatemala, Honduras, India, Japan, Mexico, UK, US, CCFFV, 31st CCFH	ALINORM 99/13, para. 108
Discussion paper on the Proposed Draft Code of Hygienic Practice for Pre-cut Fruits and Vegetables		45th EXEC, <b>France</b> , Mexico, Canada the Netherlands, Japan, Guatemala, UK, Uruguay, US, CCFFV, 31st CCFH	ALINORM 99/13, para. 108
Discussion paper on the Proposed Draft Annex on "Cleaning and Disinfection" to the Recommended International Code of Practice - General Principles of Food Hygiene		45th EXEC, <b>US</b> , UK, 31st CCFH	ALINORM 99/13, para. 108
Prioritization of the Revision of Codes of Hygienic Practice		<b>Codex Secretariat</b> , Governments, 31st CCFH	ALINORM 99/13, para. 106



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**Appendix II**

**PROPOSED DRAFT AMENDMENT TO  
THE GENERAL PRINCIPLES OF FOOD HYGIENE**  
*(at Step 3 of the Accelerated Procedure)*<sup>30</sup>

§ 6.1.2 Cleaning Procedures and Methods

Revise the fifth (5) bullet point to read:

- where necessary, disinfection, with subsequent rinsing unless the manufacturers' instructions indicate that rinsing is not required.

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<sup>30</sup> Subject to confirmation by the 45<sup>th</sup> Session of the Executive Committee.



**Appendix III**

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

*(At step 8 of the Procedure)*

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## INTRODUCTION

Refrigerated packaged foods with extended shelf life are foodstuffs that are kept refrigerated to preserve them for more than five days as described in item 2.1 Scope. In general, the heat or other preservation treatments that these products receive is not sufficient to ensure their commercial sterility. Refrigeration is an important hurdle that retards food spoilage and growth of most pathogens. It is the responsibility of the manufacturer to ensure that the product produced is safe throughout its shelf-life, taking into consideration the potential for temperature abuse. This may warrant the use of hurdles to microbial growth in addition to refrigeration.

There are possibilities for temperature abuse during manufacture, storage, distribution, sale, and handling by the consumer. These temperature abuses may allow the growth of pathogenic microorganisms unless additional hurdles are built into the product to prevent potential microbial growth. Moreover, refrigeration alone is not always sufficient to minimize microbiological risk, since some microorganisms are psychrotrophic (grow at refrigeration temperatures), for example, certain strains of *Listeria monocytogenes* or certain strains *Clostridium botulinum*, which can grow at temperatures of 4°C or lower. Therefore, in the absence of additional hurdles, there is likelihood that some of these undesirable microorganisms will proliferate at refrigeration temperatures.

There are other potential hazards associated with certain refrigerated foods. For example, with modified atmosphere packaged (MAP) foods, the anaerobic environment limits growth of aerobic microorganisms which compete with pathogenic microorganisms. Since these aerobic microorganisms are limited or do not grow in MAP foods, certain pathogenic microorganisms may proliferate. Aerobic microorganisms are also often the microorganisms that cause product spoilage. Because significant growth of aerobic microorganisms is prevented, MAP products may become unsafe without any visible signs of spoilage if not appropriately refrigerated or in the absence of additional hurdles.

Microbiological hazards can be controlled by a combination of inhibiting factors, called hurdles. These hurdles can assist in retarding or preventing growth of some microorganisms, including pathogenic microorganisms. Some of the hurdles in addition to refrigeration include: decreased pH and  $a_w$ , and addition of preservatives.

### 1 OBJECTIVES

The purpose of this code is to set out recommendations for processing, packaging, storage and distribution of refrigerated packaged foods with extended shelf-life. Its aim is preventing the outgrowth of pathogenic microorganisms and it is based on the principles of Hazard Analysis and Critical Control Point (HACCP). Section 5.1 of this code discusses the application of HACCP principles to refrigerated packaged foods with extended shelf life. The HACCP approach is described in Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev 3-1997). It should be noted that HACCP is product, process and facility specific.

For refrigerated foods, an important safety hurdle to control microbial growth is refrigeration (for example, +4°C). Any recommendation for specific temperatures should be considered guidelines only. The actual temperatures used will depend upon the requirements for the product, and processes used in terms of safety. However, a wide variety of refrigerated foods also make use of additional hurdles to achieve a synergistic effect for the control of microbial growth. When using the hurdle concept for product development, even where refrigeration is the sole hurdle, the effect of the hurdle(s) on product safety and shelf life should be considered thoroughly. Predictive microbiological models may be used to estimate both the effectiveness of preservation conditions and the effects of modifying product composition and varying handling/storage conditions on safety. Unless scientific evidence previously exists, challenge studies should be conducted to confirm the effectiveness of the chosen hurdle(s) against the pathogen(s) of concern. Such studies, in which specific organisms are inoculated into products, should use the worst case

conditions of expected storage and distribution. The results of these studies should be used to determine the appropriate shelf life for the product under consideration.

## **2 SCOPE AND USE OF THE DOCUMENT**

### **2.1 Scope**

This code covers low-acid refrigerated foods that are heat treated<sup>31</sup> and are susceptible to outgrowth of pathogenic microorganisms during their extended shelf-life.

The foods which the provisions of this code addresses are products that:

- are intended to be refrigerated during their shelf life to retard or prevent the proliferation of undesirable microorganisms;
- have an extended shelf life of more than 5 days<sup>32</sup>;
- are heat treated or processed using other treatments to reduce their original microbiological population;
- are low acid, that is, with  $\text{pH} > 4.6$  and have high water activity  $a_w > 0.92$ ;
- may use hurdles in addition to heat or other treatments and refrigeration, to retard or prevent the proliferation of undesirable microorganisms;
- are packaged, not necessarily hermetically, before or after processing (heat or other preservation treatments);
- may or may not require heating prior to consumption.

Examples of such products are:

- cooked refrigerated ready to eat meals,
- cooked refrigerated ready to eat meats, poultry, seafood and their products, sauces, dips, vegetables, soups, egg products, pasta, ...

This Code excludes: raw foods, frozen foods, low acid canned foods, acid and acidified foods stored at ambient temperature, smoked fish, milk and milk products, yellow fats and fat spreads.

It should be noted that this code is not intended to cover products such as: fermented meats and meat products, cured meats and meat products (including poultry), fermented vegetables, dried and/or salted fish and meats.

In addition, it excludes those food products for which there is a specific Codex Alimentarius Code of Practice. Foods that contain one or more ingredients that are excluded and one or more ingredients that are included are covered by this Code.

### **2.2 Use**

This document follows the structure of the Codex International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997) The General Principles of Food Hygiene must be used with this Code. Each section provides recommendations specific to safety of refrigerated packaged foods with extended shelf life.

### **2.3 Definitions**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

For purposes of this code, the terms and expressions below are defined as follows:

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<sup>1</sup> New technology such as microwave heating, ohmic heating, oscillating magnetic field, high hydrostatic pressure, irradiation, etc., may provide equivalent treatment.

<sup>32</sup> The Codex Code of Hygienic Practice for Precooked and Cooked Foods in the Mass Catering (CAC/RCP 39-1993) should be consulted for foods having a shelf life of 5 days or less.

*Container (i.e. primary package):* any box, tin, plastic or other receptacle, or wrapper in direct contact with the food product.

*Cooling equipment:* equipment to reduce a product's temperature.

*Filling and sealing:* operation consisting of placing a food product in a container and closing it.

*Hermetically sealed container:* Containers which are designed and intended to protect the contents against the entry of viable microorganisms after closing.

*High Risk (HR) Area:* An area that requires a high level of hygiene, where the practices concerning personnel, materials, equipment and the environment are managed so as to prevent contamination by pathogenic microorganisms and should be designated and segregated. The HACCP approach will allow the identification of when the use of a High Risk area is necessary.

*Hurdle:* microbial growth limiting, retarding or preventative factor.

*Hurdle technology:* the use of a combination of factors to effect control of microbial growth.

*Modified atmosphere:* atmosphere in a packaged product (vacuum or gas) that differs from the ambient atmosphere.

*Packaging:* any operation consisting of placing the food in containers (i.e. primary packaging) or placing the food containers in further packaging material.

*Packaging material:* materials such as cardboard, paper, glass, plastic film, metal, etc., used to manufacture containers or packaging for refrigerated packaged food.

*Pasteurization value:* the length of time at a given temperature required to obtain a specified level of destruction of a microorganism whose heat resistance characteristics are known.

The heat resistance of a microorganism is characterized by D and z values defined as follows:

D = time (in minutes) to achieve a 90% or one log reduction of a microbiological population at a given temperature;

z = the number of degrees required for the thermal destruction curve to traverse one log cycle (expressed in degrees Celsius or Fahrenheit).

*Rapid cooling:* lowering the temperature of the food in a way such that the critical zone for microbiological proliferation (60°C -10°C) is passed through as rapidly as possible and the specified temperature is attained.

*Refrigerated food:* Food which is kept at cold storage temperatures to maintain its safety, quality and suitability, for the intended shelf life.

*Refrigerated storage facility:* facility designed to keep refrigerated foods at the intended temperature.

*Shelf life:* The period during which the product maintains its microbiological safety and sensory qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used.

*Use-by-date:* The date after which the product should not be consumed. It is determined from the date of production, utilizing the product shelf life, building in a margin of safety as determined by the manufacturer.

### **3 PRIMARY PRODUCTION**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

For recommendations relative to incoming materials see Section 5.3.

### **4 ESTABLISHMENT : DESIGN AND FACILITIES**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

This section deals with the areas where foods are prepared, cooked, chilled, and stored.

Prevention of contamination calls for every reasonable measure to be taken to avoid direct or indirect contact of food with sources of potential contamination. There should be a strict separation in the plant of the High Risk area(s) from other production area(s).

#### **4.1 Location**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### **4.2 Premises and rooms**

##### **4.2.1 Design and layout**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

##### **In HR areas:**

- High risk areas should be designed to minimize the potential for build-up of contamination and to maximize the ease of cleaning and disinfection.
- To keep raw materials, in-process products and final products in optimal condition and protected from cross-contamination, storage and processing facilities should also follow the principles of "one-way-flow" and "first in, first out" and be equipped to maintain temperature, humidity and ventilation

##### **4.2.2 Internal structures and fittings**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

##### **In HR areas:**

- entrances should be provided with cleaning and/or changing facilities for shoes and protective clothing, and hand washing and sanitizing stations.
- windows should not be capable of being opened. Doors should be close-fitting and their condition, sitting and use should not compromise food safety.
- where appropriate the premises should be equipped with temperature monitoring and recording devices and a reliable system, to signal loss of control, for example, an audible alarm or blinking light.
- air should be filtered and under positive pressure in locations where foods are handled in order to limit contamination.
- systems for steam removal and humidity control should be effective, hygienically designed and well maintained to minimize condensation or other cross contamination between raw materials and processed products.

##### **4.2.3 Temporary/mobile premises and vending machines**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### **4.3 Equipment**

##### **4.3.1 General**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**In HR areas:**

- Equipment used for processing, handling or transport within the HR area should be used solely in this area. No equipment should enter the area without being cleaned and disinfected.
- Equipment used for handling heat-treated products should be solely for this purpose and should be kept separate from equipment used to handle material before heat or other preservation treatments. If reusable trays are used, once they are cleaned and sanitized they should not pass through an area where they may be contaminated unless they are appropriately protected.

**4.3.2 Food control and monitoring equipment**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**In HR areas:**

- All apparatus used should be regularly checked and calibrated according to an established procedure.
- Equipment for processing, thermal or otherwise, should be located so as to prevent cross-contamination between raw materials and processed products.
- All processing apparatus, thermal or otherwise, should be designed to be hygienic and should be provided with suitable instrumentation.

**4.3.3 Containers for waste and inedible substances**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**4.4 Facilities**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**4.4.1 Water supply**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**4.4.2 Drainage and waste disposal**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**In HR areas:**

- Drainage from HR areas should flow directly to a main drain via suitable traps to prevent back flow. Drainage from other areas should not flow via HR area drains.
- Waste water from refrigeration equipment, installations for hand washing and machinery should be piped to the drainage system so as to minimize contamination of products. Particular attention should be paid to splashing and/or aerosol from these sources.

**4.4.3 Cleaning**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**4.4.4 Personnel hygiene facilities and toilets**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**4.4.4.1 Cloakrooms and toilets**

Cloakroom and toilets should not open directly into any food handling areas.

**4.4.4.2 Processing areas**

For hand disinfection stations, it is preferable to have taps that do not require hand operation.

#### 4.4.5 Temperature control

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

The plant should be designed and equipped in such a way that the interior temperature is compatible with keeping products at a temperature that controls proliferation of microorganisms during the various operations, regardless of the outside temperature.

##### 4.4.5.1 Refrigeration facilities

All refrigerated rooms should have devices to monitor and record the temperature and a reliable system, such as an audible or visual alarm, to signal loss of control. These monitoring devices should be clearly visible and placed so that the maximum temperature in the refrigerated area is recorded as accurately as possible.

##### 4.4.5.2 Cooling facilities

Establishments should also have rooms or equipment which permit rapid cooling methods to be used, as well as refrigerated storage for a quantity of prepared food equal at least to the maximum daily production of the establishment.

Choice of cooling equipment depends on the products being processed. Their characteristics, (cooling capacity, etc.) should be selected based on the quantities of products produced in order to allow for:

- refrigeration without delay after the heat treatment, as soon as the internal temperature reaches 60°C and
- an even temperature distribution in the batch when it is cooled.

**In HR areas:**

- Rapid chilling of cooked products (not filled and sealed) should be in a room and/or equipment that is designed and operated to prevent contamination.

#### 4.4.6 Air quality and ventilation

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

**In HR areas:**

- The air supplying the premises should be treated to remove dust.
- The ventilation system should be designed and used so as to prevent condensation and circulation of dust.
- Air in HR areas should be filtered and kept under positive pressure.

#### 4.4.7 Lighting

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### 4.4.8 Storage

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 5 CONTROL OF OPERATION

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Refrigerated packaged foods are manufactured using a wide variety of raw materials, process technologies and types of packaging. Biological, chemical and physical hazards may vary significantly from one product to another. Each product type has its specific shelf life that the manufacturer determines based on scientific data.

In each production establishment, it is necessary to define the particular procedures that allow product safety to be ensured, with consideration given to conditions specific to the plant (raw materials, environment, processing techniques, organization of labour, etc.) and product characteristics. The application of HACCP principles is the system recommended for development of these procedures for a specified product in a specific plant.

The overall responsibility for all measures planned to ensure the safety of the product should be designated to qualified personnel.

## **5.1 Control of food hazards**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **5.1.1 Application of the HACCP Principles**

The processor should apply HACCP principles as described in Codex the Hazard Analysis Critical Control Point System and Guidelines for its Application (annex to CAC/RCP 1-1969, Rev. 3-1997) for all existing product types, and for new product design and development.

Specific hazards associated with food production/storage, and the control measures should be identified. Further, it is necessary to determine the operational steps that can be controlled to eliminate hazards or to minimize the probability that they will arise, to establish critical limits and a monitoring system to ensure their control, and to establish corrective action to be taken when deviations occur and procedures for verification to demonstrate that the control method is appropriate. Effective record keeping procedures need to be specified and maintained.

The manufacturer will find in the following sections additional information that would be useful to facilitate HACCP plan development. Moreover, it is very important to establish the shelf life of the product, using scientific data, taking into account the scheduled heat or other preservation treatments, the use of hurdles and anticipated distribution and storage temperatures.

### **5.1.2 Consideration of Design Elements**

Product shelf life, scheduled heat or other preservation treatments, hurdles, and cooling methods should be established according to scientific and technological methods. This requires qualified, knowledgeable and experienced personnel having access to adequate information, facilities and equipment.

The HACCP approach will allow the identification of when the use of High Risk area is necessary.

#### 5.1.2.1 Determination of product shelf life

Product shelf life depends on a number of factors, such as:

- product formulation (might include decreased pH, decreased  $a_w$ , other hurdles - see Appendix );
- scheduled heat or other preservation treatments;
- cooling methods applied to product;
- type of packaging (e.g., hermetically sealed or not, MAP);
- storage temperature;
- other hurdles.

#### 5.1.2.2 Development of scheduled heat or other treatments

The scheduled heat or other treatment should at least produce the desired log reduction of target microorganism(s) to achieve the desired level of safety. It is calculated for the coldest point of the product during treatment. It should take into account the worst-case scenario with regard to type of contamination, microbial load and transfer of heat in products, such as frozen raw materials or large pieces of food.

During the establishment of the scheduled heat or other treatments, the following factors should be taken into account:



- type and maximum number of microorganisms in raw materials;
- any potential for growth before heat treatment;
- desired number of log reduction of target microorganism(s);
- temperature of product before heat treatment begins;
- amount of heat required to bring the product to the desired level of safety;
- temperature distribution in heat treatment vessel;
- composition (solid to liquid ratio) and consistency (viscosity) affecting rate of heat penetration;
- type of product or container that can lead to stratification of product during heating or to a change in dimensions of container during heating;
- size of container, type of material, weight of individual portion and maximum weight for filling;
- recommended cooking by end-user before consumption (as long as the cooking temperature results in a reduction of microorganisms of public health significance).

When changes in the composition, processing and use of the product are proposed, the necessary changes to the scheduled heat treatment should be established and validated by a qualified person.

Other treatments (e.g. microwave heating, ohmic heating, oscillating magnetic field, high hydrostatic pressure, irradiation, etc.) to achieve the required reduction of the target microorganism(s) may be used, if approved for use by the regulatory agency having jurisdiction, where required.

#### 5.1.2.3 Development of Cooling Method

For these products, the intention of cooling is to achieve the specified storage temperature throughout the product as soon as possible to minimize the growth of foodborne pathogens. The cooling should be carried out so that the product reaches the specified temperature as quickly as possible. Products should be cooled so that their temperature remains for a minimum of time between 60°C and 10°C, the temperature range most favourable for microbiological proliferation. When feasible, it is recommended to bring the temperature at the centre of the product to under 10°C in two hours or less.

Alternative cooling procedures may be used provided that they are consistent with maintaining food safety and based on scientific evidence.

Factors to be taken into account in the establishment of the cooling method can include:

- temperature of product before cooling begins;
- temperature of cooling medium, circulation and temperature distribution in cooling system;
- time of cooling especially for products conveyed through cooling equipment;
- composition (solid to liquid ratio) and consistency (viscosity) affecting rate of cooling;
- size of container, type of material, weight of individual portion and maximum weight for filling;
- other packaging material affecting the rate of cooling,
- capacity/effectiveness of cooling equipment.

#### 5.1.2.4 Other Hurdles

The intention of using other hurdles is to prevent or restrict the growth of target pathogen(s) in the food.

Studies should be conducted to validate the effectiveness of the use of hurdles in product formulation that inhibit or minimize multiplication of pathogens and the synergy of these factors. See Appendix I for more information. Use of predictive microbiological modelling may assist in the design of the challenge studies.

When one or more hurdles are used in combination with heat or other preservation treatments, the critical limits need to be specified and met. Critical limits should be measured, checked and recorded as necessary.

## 5.2 *Key aspects of hygiene control systems*

### 5.2.1 **Time and temperature control**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

In all steps of processing, critical temperatures for multiplication of microorganisms (10°C to 60°C) should be avoided or in any case passed through rapidly.

If there are delays in manufacture, perishable raw materials and in-process products must be maintained at a temperature which minimizes bacterial growth. This can be achieved by placing the product quickly into refrigerated storage areas and kept at the specified temperature or else kept at  $\geq 60^{\circ}\text{C}$  until normal production is resumed.

#### **In HR areas:**

- If the air temperature has been determined to be critical and is exceeded, the manufacturer should evaluate the product's safety and take appropriate action.

#### 5.2.1.1 Thawing

When total or partial thawing is necessary, the thawing procedures should be defined in terms of time and temperature and strictly controlled by the manufacturer. The time and temperature parameters should be selected so as to avoid conditions favourable for multiplication of microorganisms.

After thawing, raw materials should immediately be processed or held at the specified refrigerated temperature until they are used. When a microwave oven is used, manufacturer's instructions should be followed to prevent overheated areas and uneven thawing.

#### 5.2.1.2 Heat and other treatments

Heat and other treatments result in a reduction of microbiological population. The lethality of heat or other treatment should be quantified. Pasteurization values or lethal rate values can be used to calculate lethality of a heat or other treatment.

The application of the scheduled heat and other treatments should be carried out by competent, specially trained personnel.

Delivery of the heat or other treatments can be monitored by measuring the time-temperature relationship of:

- the product itself during treatment;
- or the heating medium in which the food is placed (hot water, sauce, air in oven, etc.) so as to reach the prescribed time-temperature relationship at the product's coldest point.

Equipment for heating or other treatment used to control a hazard should have devices for monitoring and recording temperature and time. The temperature monitoring and recording equipment should be checked at regular intervals against a known accurate standard and adjusted, repaired or replaced.

Heat-sensitive indicators, or other effective means, to indicate whether the products have been heat-treated should be used.

It is critical to ensure that the scheduled process is applied.

The factors which were taken into consideration for the development of the scheduled process (cf. 5.1.2.2) should be controlled and recorded, as necessary.

#### 5.2.1.3 Cooling

Delivery of the cooling can be monitored by measuring the time-temperature relationship of:

- the product itself during treatment; or

- the cooling medium in which the food is placed (e.g. cold water, cold air) so as to reach the prescribed time-temperature relationship at the product's warmest point.

Cooling equipment used to control a hazard should have devices for monitoring and records should be maintained for temperature and time as necessary. The temperature monitoring and recording equipment should be checked at regular intervals against a known accurate standard and adjusted, repaired or replaced. It is critical to ensure that the cooling applied conforms to the method specified.

#### 5.2.1.4 Maintaining the cold chain

In order to ensure that safety and quality of the product are maintained during its stated shelf life, it is essential that it be kept continuously cold from the time it is packaged until it is consumed or prepared for consumption. The storage temperature should be that which will maintain product safety for the intended shelf-life of the product. If the temperature of the product is the principal means of preservation, that product should be kept at a temperature as low as possible. In any case, validation of the selected temperature must be carried out.

In addition, storage temperature may be required to meet criteria established or recognized by the agency having jurisdiction where the food is destined for consumption:

- if the temperature set out in the regulations is less than the temperature used to establish the shelf life, the temperature as per the regulations needs to be met and the shelf-life eventually re-evaluated accordingly;
- if the temperature set out in the regulations is greater than the temperature used to establish the shelf life, and the manufacturer wants to keep the same shelf life, then the manufacturer must ensure the temperature used during the shelf life determination is met. If the temperature used for shelf life determination is not met, the shelf life needs to be re-evaluated.

In the course of these successive stages, there should be adequate stock rotation, based on the principle of "first in, first out".

Regular and effective monitoring of temperatures of storage areas, transport vehicles and store display cases should be carried out:

- where the product is stored, and
- within the product load, which could be done by using temperature indicating and recording systems.

This monitoring should take place, in particular, when the transport vehicle is loaded or unloaded.

Particular attention should be paid throughout storage and distribution :

- to periods of defrosting of refrigeration units;
- to temperature abuse;
- to overloading the cold storage facility; and
- to anything that could damage the containers and/or packaging material.

Storage areas should conform to applicable requirements in paragraph 4.4.5.1.

Products should not be stacked higher than the maximum level indicated in display cases or in front of air ducts or too close to heat generating lamps; there should be good circulation of cold air. Products that have reached the prescribed use-by-date or are spoiled or have damaged container should be removed from the display case, and not offered for sale.

In case of breakdown of the refrigeration unit of the display case, the products should be moved to another case or to a cold room. If the breakdown of the refrigeration unit of the display case takes place when the establishment is closed, temperature of the products should be checked. If acceptable, the products should be moved to a suitable area; if not, they should be removed from the case, not offered for sale, and destroyed if necessary.

### 5.2.2 Specific process steps

*Refer to the International Code of Practice - General principles of Food Hygiene.*

### 5.2.3 Microbiological and other specifications

*Refer to the International Code of Practice - General principles of Food Hygiene.*

### 5.2.4 Microbiological cross contamination

*Refer to the International Code of Practice - General principles of Food Hygiene.*

#### **In HR areas:**

- This area should be maintained at a high level of hygiene, and the practices concerning personnel, materials, equipment and environment managed so as to prevent contamination from pathogenic microorganisms.

### 5.2.5 Physical and chemical contamination

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

## 5.3 Incoming material requirements

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 5.3.1 Specifications for raw materials and packaging materials

Raw material specifications, including specifications for the materials used in the hurdles (see Appendix) and for the packaging materials should be determined through application of HACCP principles and validated during the design phase. Supplier specifications may cover labelling, packaging materials, conditions for transport and storage, as well as the sensory, physical, chemical, parasitological and microbiological characteristics of delivered goods. Measures to ensure compliance with specifications should be identified in the specifications manual.

Packaging materials should be suitable for the type of product, the conditions provided for storage and the equipment for filling, sealing and packaging, as well as transportation conditions.

### 5.3.2 Receipt of raw materials and packaging materials

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

If the raw materials, ingredients and packaging materials do not conform to the specifications when goods are delivered, trained personnel should decide whether the raw materials should be immediately used for manufacture, stored for a limited period, returned to supplier, used in another way or discarded. Unacceptable raw materials and ingredients should be stored separately from raw materials and ingredients used for manufacture of refrigerated foods. Discarded raw materials should be clearly marked so as to identify them as unusable for manufacture of products.

### 5.3.3 Storage of raw materials and packaging materials

Raw materials should be stored in a suitable area as quickly as possible after delivery. Raw materials should be stored so that contamination of in-process or final products or packaging materials is prevented. Raw materials and ingredients stored within the establishment should be kept at conditions designed to prevent their spoilage, protect them from contamination by microorganisms, insects, rodents, foreign bodies and chemical products and minimize possible damage. They should be used in manufacture as soon as possible after delivery.

Raw materials that are subject to spoilage should be placed without delay in cold storage at the appropriate temperature.

There should be documented procedures specifying necessary action to be taken in case of deviation at a Critical Control Point (CCP).

All packaging materials should be stored in satisfactorily clean and hygienic conditions.

Non-edible materials, such as cleaning compounds, should be received and stored in separate locations, away from packaging materials and ingredients. Non-edible materials should not pass through or remain in processing areas during processing. All non-edible materials should be labelled clearly and distinctly so improper use is prevented.

There should be suitable rotation of stock of raw materials "first in, first out". To achieve this, all lots of raw materials should be coded and an appropriate procedure for stock management should be used. Appropriate documentation of stock rotation should be kept.

#### **5.4 Packaging**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

There may be a need to provide a method for cleaning and disinfecting containers before use, especially if there is no heat or other preservation treatments after filling and sealing.

Filling and sealing should be done so as to limit the potential for contamination (with consideration for technical constraints such as slicing, assembly, etc.). For cooled product, the ambient temperature should be controlled so as to maintain the product at the appropriate temperature. Any increase in temperature of the product during these operations should be avoided.

It is necessary to periodically check the integrity of the seal.

When necessary, some characteristics of packaging materials should be checked. It may be necessary to carry out visual examination and physical testing in order to measure their properties (maintaining a vacuum or the modified atmosphere in the container), and their resistance to mechanical, chemical and thermal stress encountered in the course of the product's shelf life.

#### **5.5 Water**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### **5.6 Management and supervision**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### **5.7 Documentation and records**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Sufficient information should be available to demonstrate control at the critical control points. Such information may include:

- Procedures, data and calculations utilized in the establishment of the scheduled heat or other preservation treatments and cooling methods;
- If applicable, procedures, data and records establishing the efficacy of hurdles to maintain the microbiological safety of the product for the intended shelf life;
- Procedures, data and records relevant to the establishment of the shelf life of the product;
- Any modifications of the product, processing or in other factors (refer to Section 5.1.2.2) used in establishing the scheduled heat or other treatments;
- Records documenting the HACCP plan (including the hazard analysis and critical control points);
- Records of process monitoring at Critical Control Points as determined in the HACCP plan.

#### **5.8 Recall procedures**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

## 6 ESTABLISHMENT: MAINTENANCE AND SANITATION

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 6.1 Maintenance and cleaning

Maintenance procedures and schedules should be established and followed especially for equipment used for thermal processing, refrigeration, cooling equipment and ventilation systems, and their controls.

#### 6.1.1 General

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### 6.1.2 Cleaning procedures and methods

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 6.2 Cleaning programmes

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Equipment, materials, utensils etc. which come in contact with foods must be cleaned and where necessary disinfected. They may have to be taken apart at frequent intervals during the day, if necessary, at least after each break and when there is a change from one food to another. The cleaning and disinfecting should be carried out at the end of the working day and equipment dismantled when necessary to prevent microbiological proliferation.

All staff assigned to cleaning the establishment should be experienced in sanitation maintenance methods and should verify that proper methods have been used and recorded.

#### **In HR areas:**

- Cleaning equipment which may cause cross-contamination such as high-pressure spray cleaning equipment should not be used to clean drains or other surfaces without subsequent disinfection of the whole area and its use should be avoided during production periods.

### 6.3 Pest control systems

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 6.4 Waste management

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Waste matter should be placed in receptacles specially designed and marked for this use. Receptacles should be kept in good condition and be easy to clean and sanitize. Reusable receptacles should be cleaned and disinfected before they are brought back into the processing areas.

### 6.5 Monitoring effectiveness

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

#### **For HR areas:**

- Environmental sampling for relevant microorganisms is recommended and appropriate corrective action taken when necessary.

## 7 ESTABLISHMENT: PERSONAL HYGIENE

*Refer to the International Code of Practice - General principles of Food Hygiene.*

### 7.1 Health status

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

## 7.2 *Illness and injuries*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

## 7.3 *Personal cleanliness*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Protective clothing should be changed frequently.

### **In HR areas:**

- Personnel (including sanitation and service staff) working in HR areas should change into work uniforms in a specific room.
- They should wear protective clothing and footwear specific to the area.
- These clothes and footwear should not be removed from this area (except for laundering) and should be taken off in the cloakroom when personnel leave the production line for any reason.
- Clean clothing should be worn at the beginning of the work day and should be changed at the end of the work day, shift or more frequently if needed.
- Footwear should be suitably cleaned and sanitized.
- When gloves are used for handling foods, they should be sturdy, clean and hygienic. Gloves should be manufactured from non porous non absorbent material. Wearing gloves does not eliminate the need to carefully wash hands. Gloves should be disposable and changed as often as necessary or should be reusable and disinfected as often as necessary.

## 7.4 *Personal behaviour*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Management should put in place a plan for movement of personnel, and also for visitors, to reduce the potential for cross-contamination. A system of colour coding may be used to identify personnel assigned to different areas of the plant.

## 7.5 *Visitors*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **In HR areas:**

- Visitors should be subjected to the same requirements for hygiene as employees.

## 8 **TRANSPORTATION**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 8.1 *General*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 8.2 *Requirements*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### 8.3 *Use and maintenance*

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

The vehicle should be cooled prior to loading. Doors should be kept open for as short a time as possible. If there is an extended delay in the loading of the vehicle, the vehicle doors should be shut to maintain the cool temperature.

Transfer to cold storage or store display cases should be made as quickly as possible after unloading.

## **9 PRODUCT INFORMATION AND CONSUMER AWARENESS**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **9.1 Lot identification**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **9.2 Product information**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **9.3 Labelling**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

Labels should conform to the requirements of the official agency having jurisdiction. They should provide the following information:

- use-by-date;
- a statement regarding the need for refrigeration, e.g. "keep refrigerated at (required temperature) or less".

### **9.4 Consumer education**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

## **10 TRAINING**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **10.1 Awareness and responsibilities**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **10.2 Training programmes**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **10.3 Instruction and supervision**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*

### **10.4 Refresher training**

*Refer to the International Code of Practice - General Principles of Food Hygiene.*



## APPENDIX – HURDLES

Microbial growth is dependent upon many environmental conditions such as: ingredients, nutrients, water activity, pH, presence of preservatives (e.g., curing salts), competitive microorganisms, gas atmosphere, redox potential, storage temperature and time. Control of these conditions can therefore be used to limit microbial growth.

The intention of using hurdles is to prevent or restrict the growth of target pathogen(s) in the food. For refrigerated foods, an important safety hurdle to control microbial growth is refrigeration. A wide variety of refrigerated foods also make use of additional hurdles to control microbial growth.

To ensure the safety of refrigerated packaged foods having an extended shelf life, often more than one hurdle is used to control microbial growth, to inhibit spoilage and to prevent foodborne disease. Suitable combinations of hurdles can be devised so that the organisms of concern can no longer grow/survive in the product. The presence of a number of hurdles inhibiting or eliminating microorganisms may be synergistic. Therefore it may require less of each hurdle to control growth than would be expected by considering the effect of each individual hurdle.

When using the hurdle concept for product development, the effect of the hurdle(s) on product safety and shelf life should be considered thoroughly. For example, a certain type of modified atmosphere might inhibit the growth of spoilage organisms in refrigerated food. The growth of these microorganisms, which could inhibit toxin production or act as an indicator of poor storage conditions, is limited. Therefore the extension of the product's shelf life may lead to the growth of pathogenic microorganisms without any signs of spoilage.

Examples of hurdles, other than refrigeration, are:

### **a) Water activity**

Microorganisms vary in their ability to grow at reduced levels of  $a_w$  and will be inhibited as the available water is reduced. A reduction of water activity can suppress the growth of pathogenic bacteria, particularly at low temperatures. Note that vegetative cells may show increased heat resistance at lower water activities.

### **b) pH**

Microorganisms vary in their ability to grow at reduced pH. A reduction in pH can suppress the growth of pathogenic bacteria. Note that microorganisms show decreased heat resistance at lower pH.

To illustrate these concepts, if a refrigerated food is to be packed in a reduced oxygen atmosphere and has a shelf life longer than 10 days, it is necessary to assess the potential risk from psychrotrophic strains of *Clostridium botulinum* and, if necessary, to control these strains through the appropriate use of hurdles in combination with a heat process, if the heat process is not equivalent to 90°C for 10 minutes. Examples of hurdles are:

- adjust water activity ( $a_w$ ) to below 0.97;
- increase acidity by lowering pH below 5.0;
- add sodium chloride to 5% in brine;
- use combinations of water activity, pH, modified atmosphere, storage temperature etc. that demonstrably will inhibit the growth of psychrotrophic strains of *Clostridium botulinum* within the shelf life and expected storage conditions.

Predictive models may be used to estimate both the effectiveness of preservation conditions and the effects of modifying product composition and varying handling/storage conditions on safety. Unless scientific evidence previously exists, challenge studies should be conducted to confirm the effectiveness of the chosen hurdles against the pathogen(s) of concern. Such studies, in which specific organisms are inoculated into products prior to storage, should use the worst case conditions of expected storage and distribution. It is advisable that scientific advice be sought.

**Appendix IV****PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF  
MICROBIOLOGICAL RISK ASSESSMENT**

*(At Step 5 of the Procedure)*

**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.

**DEFINITIONS**

*The italicized references are for informational purposes only and will not appear in the final Codex document. The definitions include those adopted on an interim basis at the 22<sup>nd</sup> Session of the Codex Alimentarius Commission. [The CAC adopted these definitions on an interim basis because they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines.]*

**Dose-Response Assessment** - The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

**Exposure Assessment** - The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

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

**Hazard Characterization** - The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of Microbiological Risk Assessment the concerns relate to microorganisms and/or their toxins.

**Hazard Identification** - The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

**Quantitative Risk Assessment** - A Risk Assessment that provides numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis).

**Qualitative Risk Assessment** - A Risk Assessment based on 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** - A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Risk Analysis** - A process consisting of three components: risk assessment, risk management and risk communication.

**Risk Assessment** - A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Characterization** - The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

**Risk Communication** - The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

**Risk Estimate** - Output of Risk Characterization.

**Risk Management** - The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

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

**Transparent** - 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.

## **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 Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
5. A Microbiological Risk Assessment should be transparent. This requires: full and systematic documentation, statement of assumptions and value judgments 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. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized.

8. The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.
9. 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 the work 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***

For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food. Hazard identification will predominately 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 microorganisms and situations.

### ***Exposure Assessment***

Exposure Assessment includes 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 or its toxins, 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 socio-economic and cultural backgrounds, ethnicity, seasonality, age differences (population demographics), regional differences, and consumer preferences and behaviour.

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 and other conditions of the food history, food handling and consumption patterns, and regulatory controls and surveillance systems.

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 description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food. A dose-response assessment should be performed if the data are obtainable.

There are several important factors that need to be considered in Hazard Characterization. These are related to both the microorganism, and the human host. In relation to the microorganism the following are important: microorganisms are capable of replicating; the virulence and infectivity of microorganisms can change depending on their interaction with the host and the environment; genetic material can be transferred between microorganisms leading to the transfer of characteristics such as antibiotic resistance and virulence factors; microorganisms can be spread through secondary and tertiary transmission; the onset of clinical symptoms can be substantially delayed following exposure; microorganisms can persist in certain individuals leading to continued excretion of the microorganism and continued risk of spread of infection; low doses of some microorganisms 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 may be 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, health and medication status, concurrent infections, immune status and previous exposure history; population characteristics such as population immunity and population behaviour; and persistence of the organism in the population.

A desirable feature of Hazard Characterization is ideally establishing a dose-response relationship. When establishing a dose-response relationship the different end points, such as infection or illness, should be taken into consideration. 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. 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 represents 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 associated with these estimates. 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 a transparent Risk Assessment a formal record, 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 was originally anticipated that these end notes would not appear in the final Codex document and were included for informational purposes only. However, after deliberations during the 30th Session of the Codex Committee on Food Hygiene it was considered that the end note information is useful, particularly for developing countries. Therefore it was decided that governments should comment on the future fate of these informational end notes with the following two possibilities:*

- a. The end notes should be deleted after the document advances beyond Step 5 of the Codex Procedure, or*
- b. Some or all of the end notes should be incorporated into the body of the document, preferably in the “Guidelines for Application Section”.*

*Therefore square brackets are placed around the entire end note section of the document so that governments could express their preference relative to the options above.*

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 judgments will need to be made.

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.

2. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.
3. A Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
4. A Risk Assessment should be transparent. This requires: full and systematic documentation, statement of assumptions and value judgments 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.
5. [Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.]
6. 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. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized.
  - 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.
8. 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.

9. 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 re-evaluation of the Risk Assessment.
11. A Microbiological Risk Assessment may need reevaluation as new relevant information becomes available.
12. Default - A type of assumption used in the absence of specific data, selected for conservative protection of public health.
13. In the absence of adequate data, risk managers in collaboration with risk assessors should make the Risk Assessment Policy decision to use an appropriate default.]



**Appendix V**

**PROPOSED DRAFT INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR  
PACKAGED (BOTTLED) DRINKING WATERS**

*(At Step 5 of the Procedure)*

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## 1. INTRODUCTION

International trade in bottled water has increased in recent years, both in quantity and diversity. Because of increased transport capacity, it is now possible to distribute bottled water not just as ship, rail, and road cargo but also as air freight, the latter being used mainly in crisis situations due to the higher cost. By all these means of transport, a water shortage remedy has become available when local water supply systems fail due to natural causes (such as droughts and earthquakes) or societal disasters (such as sieges or sabotage) and bottled water other than natural mineral water has been used to meet some of these needs.

Aside from water shortages, real and perceived needs to improve health also have contributed to an escalating trade in bottled water. Increasingly it has been recognized that traditional suppliers of drinking water such as public and private waterworks may not be able in many instances or under all circumstances to guarantee the microbiological, chemical and physical safety of their product to the extent previously thought possible.

## 2. SCOPE AND USE OF THE DOCUMENT

### 2.1 SCOPE

This Code recommends general techniques for collecting, processing, [labelling], packaging, storing, transporting, distributing, and offering for sale a variety of drinking waters (other than natural mineral water) for direct consumption. Recommendations concerning natural mineral water are provided in a separate Code (Recommended International Code of Hygienic Practice for the Collecting, Processing and Marketing of Natural Mineral Waters, CAC/RCP 33-1985). Included in this Code are the Application of the Hazard Analysis Critical Control Point (HACCP) System and Guidelines principles to ensure the production of safe and suitable bottled water.

### 2.2 USE OF THE DOCUMENT

The Codex HACCP System and Guidelines for its Application is annexed to the General Principles of Food Hygiene (CAC/RCP I-1969, Rev. 3-1997). Appended to this Code are Hazard Analysis and Critical Control Point Considerations for Bottled Water (Other than Natural Mineral Water). Also appended to this Code are Microbiological, Chemical, and Physical Criteria Considerations for Bottled Waters (Other than Natural Mineral Water). The Revised Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/CL 21-1997) are detailed in Supplement to the Codex Alimentarius Volume 1B.

It is emphasized that this document must be used in combination with the Recommended International Code of Practice - General Principles of Food Hygiene, (CAC/RCP 1-1969, Rev. 3-1997) whose paragraph numbers and section headings it maintains, supplementing or specifically applying them to packaged (bottled) drinking waters (other than natural mineral water).

### 2.3 DEFINITIONS

These definitions are supplemental to the definitions in section 2.3 of the Draft Revised Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997).

- *Disinfection* - The reduction, by means of chemical agents and/or physical methods, of the number of microorganisms to a level that does not compromise food safety or suitability.
- *Drinking water systems* - Public or private systems providing the consumer with tap water suitable for direct consumption.
- *Establishment* - Any building(s), area(s) or surroundings in which water intended for bottling is collected, processed and bottled.
- *Food* - For the purposes of this Code, the term includes bottled drinking water.

- *Food handling* - Any operation pertaining to collecting, processing, bottling, packing of bottles, storing, transporting, distributing and marketing of bottled drinking water.
- *Food hygiene* - All conditions and measures necessary to ensure the safety and suitability of bottled drinking water at all stages of its production.
- *Ground water* - Waters such as spring water, artesian water, and well water originating from subsurface aquifers. Ground waters may be classified broadly as protected or unprotected water. Protected ground waters are not directly influenced by surface water or the surface environment and thus, they are suitable from a microbiological point of view.
- *Ingredient* - Any substance, including food additives used to manufacture or prepare foods, intentionally added to a finished product, sometimes in a modified form (it may or may not be suitable for human consumption without further treatment).
- *Packaged (bottled) drinking water* - Water filled into hermetically sealed containers of various compositions, forms, and capacities that is suitable for direct consumption without necessary further treatment. Bottled drinking water is considered a food.
- *Pests* - Any animals capable of directly or indirectly contaminating bottled drinking waters.
- *Surface water* - Waters open to the atmosphere such as streams, rivers, lakes, ponds and reservoirs.

### **3. PRIMARY PRODUCTION**

These guidelines are supplemental to those set forth in Section 3 of the Recommended International Code of Practice - General Principles of Food Hygiene, (CAC/RCP 1-1969, Rev. 3-1997).

Prior to utilizing a water for bottling purposes, the chemical composition and microbiological quality of the water should be established.

#### **3.1 ENVIRONMENTAL HYGIENE**

##### **3.1.1 Protection of watershed and perimeter**

A hydrogeologist should determine the watershed and the perimeter (area surrounding the water's point of origin) that can be sources of contamination. These critical areas should be protected as much as possible.

##### 3.1.2 Protective measures

All possible precautions should be taken within the protected perimeter to avoid any pollution of, or external influence on, the quality of the ground or surface water. Preventive measures should be taken for disposal of liquid, solid or gaseous waste that could pollute the ground or surface water. Disposal of pollutants such as microorganisms, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic and inorganic substances should be controlled. Drinking water resources should not be in the path of potential sources of underground contamination, such as sewers, septic tanks, industrial waste ponds, gas or chemical tanks, pipelines and solid waste disposal sites.

#### **3.2 HYGIENIC PRODUCTION OF WATER SUPPLIES**

##### **3.2.1 Protection of ground water supplies**

###### **3.2.1.1 Criteria for ground water supplies**

It is not easy to distinguish between protected and unprotected ground water. Ground water supplies should be tested regularly for constancy of biological (including microbial), chemical, physical and radiological characteristics. The frequency of testing is determined by the hydrogeological evaluation and historical constancy pattern of a particular water supply. If abnormal contamination is detected, and the chosen corrective action is ineffective, production should cease temporarily until the water quality

has returned to normal. The underground supply, from which the water is collected, should be approved by an official authority having jurisdiction or by a third party with expertise for approving such underground supplies.

### **3.2.2 Protection of surface water supplies**

[To be developed.]

#### **3.2.2.1 Criteria for surface water supplies**

[To be developed.]

## **3.3 HANDLING, STORAGE AND TRANSPORT OF WATER INTENDED FOR BOTTLING**

### **3.3.1 Hygienic extraction or collection of water**

#### **3.3.1.1 At point of origin**

The extraction or collection of water intended for bottling should be conducted in such a manner as to prevent other than the intended water from entering the extraction or collection device. The extraction or collection of water intended for bottling should also be conducted in a hygienic manner to prevent any contamination. If necessary there should be appropriate sampling mechanisms.

#### **3.3.1.2 Protection of the area of origin**

The immediate surroundings of the extraction or collection area should be protected by limiting access to authorized persons only. Wellheads and spring outflows should be protected by a suitable structure to prevent entry by unauthorized individuals, pests and other sources of extraneous matter.

#### **3.3.1.3 Maintenance of extraction or collection facilities**

Methods and procedures for maintaining the extraction facilities should be hygienic. They should not be a potential hazard to humans or a source of contamination for the water. Wells should be disinfected following construction and development of new wells nearby, pump repair or replacement, any well maintenance, detection of indicator organisms, pathogens, or abnormal plate counts in the water, and whenever biological growth inhibits proper operation. Water collection chambers should be disinfected before use. Extraction devices such as those used for bore holes should be constructed and maintained in a manner that avoids contamination and minimizes hazards to human health.

### **3.3.2 Storage and transport of water intended for bottling**

When storage and transport of the water intended for bottling from the point of origin to the processing plant is necessary, these operations must be conducted in a hygienic manner to prevent any contamination. Relevant provisions of the Codex Alimentarius Code of Hygienic Practice for Bulk Transport of Food and Food Ingredients, which is being developed parallel to this Code, apply. In addition, see 3.3.2.1 and 3.3.2.2 below.

Guidelines that are supplemental to those set forth in Section 3 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997) are found in the Codex Code of Hygienic Practice for Bulk Transport of Food and Food Ingredients, which is being developed parallel to this Code. Supply of water through the piping directly connected to the point of origin, wherever possible, is one of the means of avoiding contamination from bulk transport.

#### **3.3.2.1 Requirements**

Where or when they are necessary, bulk containers and conveyances such as tanks, pipings and tanker trucks should be designed and constructed so that they:

do not contaminate the water intended for bottling;

can be effectively cleaned and disinfected;

provide effective protection from contamination, including dust and fumes; and  
allow any situation that arises to be checked easily.

### **3.3.2.2 Use and maintenance**

Conveyances and bulk containers for transporting water intended for bottling should be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances, particularly in bulk transport, should preferably be used only for transporting water intended for bottling and, in any case, should be used exclusively for food transportation.

## **4. ESTABLISHMENT: DESIGN AND FACILITIES**

These guidelines are supplemental to those set forth in Section 4 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997).

### **4.2 PREMISES AND ROOMS**

In those areas of the processing establishment where containers are exposed to the external environment (i.e., on the loading dock), especially prior to filling and sealing, some specific preventive measures should be incorporated into the facility's design to avoid contamination of the containers used for production of bottled water.

### **4.3 FACILITIES**

#### **4.3.1 Water supply**

This section pertains to water used for cleaning and disinfection purposes; not for bottled water.

For cleaning and disinfection purposes an ample supply of potable water not intended for bottling in compliance with Section 4.4.1 of the Codex Alimentarius International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997) under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination. The standards of potability should not be less than those contained in the latest edition of Guidelines for Drinking Water Quality (WHO).

Water not intended for bottling should be carried in completely separate lines from water intended for bottling. These lines should be identified, preferably by different colours. There must be no cross connections. Water not intended for bottling may be potable or not potable (used for steam production or refrigeration).

## **5. ESTABLISHMENT: CONTROL OF OPERATION**

These guidelines are supplemental to those set forth in Section 5 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997).

### **5.1 CONTROL OF FOOD HAZARDS**

Water is an excellent vehicle for carrying substances in soluble, dispersed, or emulsified form. Steps must be taken at all stages of processing to ensure that contamination of water intended for bottling does not occur, including the formation of treatment by-products (particularly bromides) in accordance with relevant WHO guidelines.

#### **5.1.1 Preventative measures for waters intended for bottling**

Waters, from drinking water systems, intended for bottling should meet all public drinking water standards (i.e., chemical, microbiological, physical, radiological) established by the official authority having jurisdiction. For documentation of an approved source, firms using waters from drinking water systems may use public drinking water system testing results showing full compliance with drinking water standards established by the official authority having jurisdiction in accordance with the Guidelines for Drinking Water Quality (WHO).

No waters intended for bottling or other ingredients should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, or toxic substances that are decomposed or extraneous which would not be eliminated or reduced to an acceptable level by normal treatment and/or processing. Where appropriate, specifications for ingredients should be identified and applied. Ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory testing should be done to establish fitness for use. Only ingredients which meet the above parameters should be used.

Where necessary, surface waters should be tested and treated. Water intended for bottling should be of a quality (i.e., microbiological, chemical, physical, radiological), such that treatment (including multiple barrier treatments such as combination of filtration, chemical disinfection, etc.) of that water during processing results in finished bottled drinking water products that are safe and of suitable quality for consumption. Generally, the higher the quality of the water intended for bottling, the less treatment is required to produce safe and wholesome bottled drinking water products.

A hazard analysis of the water supply for pathogenic microorganisms or harmful substances should be the basis for treating waters intended for bottling during processing to reduce, remove or prevent growth of microorganisms or to reduce or remove chemical or radiological hazards. A hazard analysis which will be based on a HACCP methodology or alternative methodology will be used to determine whether treatment is necessary and, if it is necessary, the type and degree of treatment. Waters originating from protected underground supplies are less likely to require treatment than waters originating from surface supplies or unprotected underground supplies.

Treatment of waters intended for bottling, if necessary, to reduce, remove or prevent growth of microorganisms may include the application of chemical processes (such as chlorination, ozonation, carbonation) and physical agents or processes (such as high heat, ultraviolet radiation, filtration). These treatments can be used singly or in combination as multiple barriers. Treatments vary in their effectiveness against specific organisms. Bottled waters produced with the use of an adequate multiple barrier treatment technique will be less likely to contain microorganisms of public health concern. See also Section 9.3.

Treatments to remove or reduce chemical substances, if necessary, may include particulate (mechanical) filtration such as achieved with surface filters (e.g., pleated membrane filters) or depth filters (e.g., sand or compressed fiber (cartridge) filters), activated carbon filtration, demineralization (deionization, water softening, reverse osmosis, nano-filtration), and aeration. These treatments for chemicals may not adequately reduce or remove microorganisms and, likewise, treatments for microorganisms may not adequately reduce or remove chemicals and must be conducted or carried out in a way to avoid any type of contamination.

## **[5.4 PACKAGING**

### **5.4.1 Washing and sanitizing containers**

#### ***5.4.1.1 Washing and sanitizing of reusable containers***

The washing and sanitizing of reusable and disposable containers for bottled drinking water should be conducted when necessary in an enclosed system and positioned within the processing plant so as to minimize post-sanitizing contamination of containers before the filling and sealing of containers.

#### ***5.4.1.2 Filling and sealing of containers***

Bottling operations (i.e., filling and sealing of containers) should be conducted in an enclosed area under positive air pressure. Another method of conducting bottling operations is to contain them in an enclosed system separate from other operations of the processing plant to protect against contamination. Dust, dirt, microorganisms and excessive moisture in the air should be controlled and monitored.

#### ***5.4.1.3 Product containers and closures***

The containers intended for bottling drinking waters should be non-toxic and used exclusively for that purpose. Reusable containers should not have been used for any purpose that may lead to contamination of the product and should be individually inspected for suitability. New product containers should be inspected if and as appropriate.]

## **6. ESTABLISHMENT: MAINTENANCE AND SANITATION**

No specific requirements beyond those made in the Recommended International Code of Practice - General Principles of Food Hygiene( CAC/RCP 1-1969, Rev. 3-1997) are needed.

## **7. ESTABLISHMENT: PERSONAL HYGIENE**

No specific requirements beyond those made in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997) are needed.

## **8. TRANSPORTATION**

Guidelines that are supplemental to those set forth in Section 8 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997) are found in the Codex Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs, which is being developed parallel to this Code.

## **9. PRODUCT INFORMATION AND CONSUMER AWARENESS**

These guidelines are supplemental to those set forth in Section 9 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997).

### **[ 9.3 LABELING**

*NOTE: The Labelling Section of this Code will be deleted in future drafts. However, the issues contained in it will be taken care of, as appropriate, in other sections of this Code or in the Product Standard that is to be developed.*

#### **9.3.1 BOTTLED DRINKING WATERS INTENDED FOR INFANTS**

Producers of bottled drinking water products and individual governments having jurisdiction may wish to provide information to consumers concerning bottled drinking water products intended for infants. Such information can address the concern with ingestion of water by infants, particularly 0 to 4-6 months of age, that may cause hyponatremia. The information can also address the potential confusion by parents regarding bottled drinking waters intended for infants and electrolyte solutions intended for the maintenance of an electrolyte level depleted by diarrhoea or vomiting; parents of infants mistakenly use bottled drinking water products with unsubstantiated label statements or claims of nutritional benefit in lieu of infant formula. Further, because bottled drinking water products intended for infants may not be sterile, they should have information concerning their use as directed by a physician or have labelling directions for preparation of infant formula.

#### **9.3.2 BOTTLED DRINKING WATERS INTENDED FOR IMMUNOCOMPROMISED INDIVIDUALS**

Immunocompromised consumers include persons with HIV/AIDS, patients receiving treatment for cancer, recipients of organ or tissue transplants, and persons who have congenital immunodeficiencies.

Since tests for parasitic protozoa are unreliable, it may be helpful to immunocompromised consumers to supply information regarding treatments the water has received. Boiling, pasteurization, distillation, reverse osmosis filtration, absolute one micron or submicron filtration are treatments used to inactivate or remove surface water contaminants such as the oocysts of *Cryptosporidium parvum*, *Cyclospora cayetanensis*, *Toxoplasma gondii* and the cysts of other waterborne parasitic protozoa such as *Giardia lamblia* and *Entamoeba histolytica*. All treatments which can change the composition,

whether chemical, physical, or microbiological, of the water after extraction should be mentioned on the label.]

## **10. TRAINING**

No specific requirements beyond those made in the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997) are needed.

### **APPENDIX 1: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application - Considerations for Bottled Waters (Other than Natural Mineral Water)**

[NOTE: Details for this Section to be filled in at a later date. The Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application, (annex to CAC/RCP 1-1969, Rev. 3-1997) will also apply.]

### **APPENDIX 2: Microbiological, Chemical, and Physical Criteria**

[NOTE: Details for this Section to be filled in at a later date. The Codex Alimentarius Draft Revised Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 - 1997) will also apply.]

#### **Source Water and Critical Control Points**

#### **End-Product Specifications**



**Appendix VI**

**DRAFT AMENDMENT TO THE FOOD HYGIENE PROVISIONS IN  
“RELATIONS BETWEEN COMMODITY COMMITTEES AND  
GENERAL COMMITTEES”**

*(Section K of the Procedural Manual)*

Replace the current provisions on Food Hygiene with the following text:

Food Hygiene

Commodity Committees should use in the commodity standards the following text:

- It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3-1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.
  
- The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

**Appendix VII**

**HYGIENE PROVISIONS OF THE DRAFT REVISED STANDARDS  
FOR BUTTER, MILKFAT PRODUCTS, EVAPORATED MILKS,  
SWEETENED CONDENSED MILKS, MILK AND  
CREAM POWDERS , CHEESE, AND WHEY CHEESE  
AND DRAFT STANDARD FOR CHEESES IN BRINE**

*(At Step 8 of the Procedures)*

Food Hygiene

- It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.
  
- From raw material production to the point of consumption, the products covered by this standard should be subject to a combination of control measures, which may include, for example, pasteurization, and these should be shown to achieve the appropriate level of public health protection.
  
- The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).