

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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ALINORM 01/13

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX ALIMENTARIUS COMMISSION

*Twenty-fourth Session  
Geneva, 2-7 July 2001*

### REPORT OF THE THIRTY SECOND SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

*Washington DC, 29 November- 4 December 1999*

**NOTE:** *This report includes Codex Circular Letter CL 1999/34-FH*



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CX 4/20.2

CL 1999/34 - 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 Thirty second Session of the Codex Committee on Food Hygiene (ALINORM 01/13)

The report of the Thirty second Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Forty-seventh Session of the Executive Committee, Geneva 2000, and by the Twenty-fourth Session of the Codex Alimentarius Commission, Geneva, 2001.

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

- 1. Draft Standard for Bottled /Packaged Drinking Waters Other Than Natural Mineral Waters at Step 8, ALINORM 01/13, paras 21-50 and Appendix II.**
- 2. Draft Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food at Step 8, ALINORM 01/13, paras 51-62 and Appendix III.**

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*, Tenth Edition, pages 24-25). 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 (06)570.54593 or E-mail: codex@fao.org) **before 1 October 2000.**

## **REQUEST FOR COMMENTS AND INFORMATION ON**

- 1. Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 3; ALINORM 01/13, paras 89-100 and Appendix IV.**

Governments and interested international organizations are invited to comment on the text cited above. Comments should be forwarded to the French Codex Contact Point SGCI (Comité interministériel pour le Questions de Coopération Economique Européenne) Carré Austerlitz 2, Boulevard Diderot F-75572 Paris CEDEX 12, Fax: +33 1 44 87 16 04, or Email: sgci-codex-fr@sgci.finances.gouv.fr 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 (06) 570.54593 or E-mail: Codex@fao.org **before 1 April 2000.**

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## SUMMARY AND CONCLUSIONS

The Thirty-second Session of the Codex Committee on Food Hygiene reached the following conclusions:

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

The Committee agreed to advance to Step 8:

- Draft Standard for Bottled /Packaged Drinking Waters (Other Than Natural Mineral Waters) (ALINORM 00/13, paras 21-50 and Appendix II).
- Draft Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food ALINORM 01/13, paras 51-62 and Appendix III.

### MATTERS FOR CONSIDERATION BY THE EXECUTIVE COMMITTEE:

**The Executive Committee advice is sought for:**

- Recognizing the importance of the issue of antimicrobial resistant bacteria in food the Committee agreed to ask advice of the Executive Committee and the Commission on how to proceed with this issue in order to ensure coordination of work between concerned Committees (paras 127-132).

### OTHER MATTERS OF INTEREST TO THE COMMISSION:

THE COMMITTEE:

- Identified and agreed on the pathogen-commodity combinations to be considered by an *ad hoc* Joint FAO/WHO Expert Consultation on Microbiological Risk Assessment in Foods and suggested that the Consultation review and summarize national and regional risk assessment and other relevant data (see paras 12-20);
- Provided advice with respect to referral to the Codex Alimentarius Commission from the WTO SPS Committee on 1) *Bacillus cereus* as a potential pathogen in canned/bottled products, including jams, and 2) the necessity of certification regarding the absence of pathogens in raw meat products (see paras 8-11);
- Agreed to return to Step 3 and redraft the Proposed Draft Code of Hygienic Practice for Milk and Milk Products on the basis of comments received and discussions held during the session and circulate it for further comments and consideration (see paras 64-70);
- Agreed to return to Step 3 and redraft the Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce (see paras 71-86) and the Proposed Draft Code of Hygienic Practice for Pre-Cut Fruits and Vegetables (see paras 87-90);
- Agreed to circulate the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 3 for comments with the understanding that comments would be forwarded to the Delegation of France for redrafting, circulation and further consideration by the Committee (see paras 91-102);
- Agreed to identify the issues involved in elaborating appropriate guidance on the application of HACCP principles in redrafting the Discussion Paper on the Application of HACCP in Small and/or Less Developed Businesses (see paras 112-117);
- Agreed to proceed with the issue on *Listeria* in two ways: refer it to the Expert Consultation on Microbiological Risk Assessment in Food and develop the Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods at Step 3 for consideration at the next session (see paras 118-121);

- Agreed to discontinue work on viruses with the understanding that this issue would be revisited after 2-3 years, taking into account the progress in WHO and other international fora (see paras 122-126);
- Agreed to proceed with the elaboration and further consideration of the Proposed Draft Guidelines for Hygienic Recycling of Processing Water in Food Plants (see paras 133-134);
- Agreed to prepare a document on priorities that would identify which codes are superseded by the Code on General Principles of Food Hygiene and which codes can be combined for consideration by the next session of the Committee (see paras 135-136); and
- Agreed to prepare Discussion papers for consideration by the next session of the Committee on : Guidelines for the Validation of Food Hygienic Control Measures (see paras 139-140) and on Guidelines for Evaluating the Presence of Objectionable Matter in Food (see paras 141-142)
- Agreed to discontinue the work on Proposed Draft Annex on Cleaning and Disinfection to the Recommended International Code of Practice-General Principles of Food Hygiene (see paras 137-138).

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**LIST OF ABBREVIATIONS USED IN THIS REPORT**

|       |   |
|-------|---|
| CAC   | Codex Alimentarius Commission   |
| CCFH  | Codex Committee on Food Hygiene                                       |
| CSPI  | Center for Science in the Public Interest                             |
| CRD   | Conference Room Document  |
| EC    | European Community  |
| EXEC  | Executive Committee of the Codex Alimentarius Commission              |
| 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  |
| 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   |
| WHO   | World Health Organization   |
| WTO   | World Trade Organization  |





## **REPORT OF THE 32ND SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE**

### **INTRODUCTION**

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-second Session in Washington DC, USA, from 29 November to 4 December 1999, 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, United States Department of Agriculture. A complete list of participants is included as Appendix I to this report.

### **OPENING OF THE SESSION**

2. The Session was opened by Dr Wachsmuth who welcomed the delegates as Chairperson of the Committee on Food Hygiene. Mr Thomas J. Billy, Administrator of the Food Safety and Inspection Service, USDA and Chairperson of the Codex Alimentarius Commission, addressed the delegates and indicated that as the new millennium approached efforts should be intensified to respond to increasingly complex issues, such as emerging technologies, emerging pathogens, harmonization of food safety standards, and globalization of food trade. He emphasized that as Chairman of the Codex Alimentarius Commission (CAC) together with Vice-Chairs of the Commission he would promote four major initiatives. First, the Commission should continue to stress the importance of science in developing standards and related texts. Second, the World Health Organization (WHO) would be encouraged to match their support to the Joint FAO/WHO Food Standards Programme to the level provided by FAO. Third, sponsoring organizations, FAO and WHO, would be encouraged to establish a fund to increase participation of developing countries in Codex Committee meetings. Lastly, Codex committees should utilize the Internet and establish interactive home pages to increase participation of developing countries and transparency. Finally, Mr Billy noted the outstanding work of the CCFH in preparing fundamental documents for the Commission to ensure consumer health protection.

3. Prof. J.L. Jouve, European Commission, Directorate for Health and Consumer Protection, made a presentation entitled "Risk Assessment of Microbiological Hazards: Scientific Advice and Foodborne Microbiological Risk Management". In his presentation Prof Jouve stressed that an expert body, correctly established and managed, provides an effective mechanism to ensure the scientific adequacy of analyses and assessment for foods in international trade. He pointed out that the Joint FAO/WHO Expert Consultation held in Geneva opened new grounds in determining the scope and outputs of the expert group meetings and in identifying necessary support mechanisms and noted that additional issues still needed to be considered for an appropriate functioning of this vehicle including the need to ensure transparency, independence, credibility and plurality of sources of information/expertise.

### **ADOPTION OF THE AGENDA (AGENDA ITEM 1)<sup>1</sup>**

4. The Committee adopted the Provisional Agenda as the Agenda for the Session, and agreed to discuss proposals for new work on "Guidelines for the Validation of Food Hygienic Control Measures" (CRD 1) and on "Guidelines for Evaluating the Presence of Extraneous Material and Filth in Food" (CRD 2) under Agenda Item 15 "Other Business and Future Work".

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<sup>1</sup> CX/FH 99/1, CX/FH 99/1- Add.1 (Trilingual doc.)

## **REPORT BY THE SECRETARIAT ON MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE FOOD HYGIENE COMMITTEE (AGENDA ITEM 2)<sup>2</sup>**

### **Codex Committee on General Principles: Role of Science and Other Factors in Relation to Risk Analysis (ALINORM 99/33A, paras 64-76)**

5. The Committee recalled that the Committee on General Principles, while considering the role of other legitimate factors in relation to risk analysis, had sought information from other committees on the relevant factors taken into account in their work. It was also noted that the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety had recommended that the Commission should clarify how to apply the Statement of Principle concerning other legitimate factors, and that clarification should include explicit description of the factors which may be considered, the extent to which these factors should be taken into account, and the procedures to be used in this regard.

6. The Delegation of India pointed out that the conditions prevailing in different regions of the world represented an important factor to consider in the development of standards, in order to ensure that they were really international in their scope and application. Some delegations pointed out that the rationale for decisions taken by the Committee in the past in the elaboration of food hygiene texts needed to be clarified and explained in relation to other legitimate factors. The Committee had an exchange of views on whether to consider the application of such factors in current work on risk analysis or to provide a historical background for earlier decisions on adopted texts.

7. The Committee agreed to consider this question further under Agenda Item 8 in conjunction with the discussion on risk management in order to decide how to proceed in this area (see paras 103-111).

### **WTO Committee on Sanitary and Phytosanitary Measures**

8. With respect to the referral to the Codex Alimentarius Commission from the WTO Committee on Sanitary and Phytosanitary Measures (WTO SPS) of: 1) *Bacillus cereus* as a potential pathogen in canned/bottled products, including jams; and 2) the necessity of certification regarding the absence of pathogens in raw meat products, the Committee provided the following advice.

9. The Committee noted that both issues involved the rationale and basis for the establishment of microbiological criteria and drew attention to the *Codex Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997). This document provides guidance to countries on the development and implementation of microbiological criteria for food. The Committee recommended that countries review the guidance given in this document to establish the need and suitability of criteria for *B. cereus* in foods, for pathogens in raw meat products, or for any other microbiological criteria issue.

10. The Committee further noted that the food hygiene provisions for Codex commodity standards, as revised and adopted by the Codex Alimentarius Commission<sup>3</sup> provided general guidance to Codex Committees in establishing food hygiene requirements. Additionally, the Committee noted that the Codex standards for processed fruits and vegetables were currently under revision and encouraged the expeditious revision of pertinent standards, as appropriate, to facilitate the incorporation of updated food hygiene provisions.

11. The Committee noted that meat industry and consumer health protection problems could not be solved by certification for complete absence of pathogens in raw meat. The Committee recognized

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<sup>2</sup> CX/FH 99/2, CX/FH 99/2 Supplement, CL 1999/17 FH, August 1999, CX/FH 99/2-Add.1 (Comments of Denmark, New Zealand and US), CRD 5 (Comments of Brazil, Finland and Czech Republic), CRD 14 (Comments of European Community)

<sup>3</sup> Relations Between Commodity Committees and General Committees, *Codex Procedural Manual*. 10<sup>th</sup> ed., amended by the 23<sup>rd</sup> Session of the CAC (ALINORM 99/37 para.68 and Appendix IV).

that it was scientifically impossible to provide such certification as it concerned only one step of the HACCP system. Adherence to *good manufacturing practices, Recommended International Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3 (1997))* and application of HACCP system as well as the *Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)* provided the basis to assure that food met the requirements of safety and international food trade, and therefore there was no need to develop new documents in this area. The Delegation of Norway stated that certification of certain low levels, or statistical probability of absence of pathogens, could be useful.

## COMMENTS IN RESPONSE TO THE CODEX CIRCULAR LETTER CL 1999/17 –FH<sup>4</sup>

### Priority Issues

12. The Committee recalled that a Joint FAO/WHO Expert Consultation on Microbiological Hazards in Foods was held in Geneva in March 1999 to provide advice on the development of an international strategy and a supporting mechanism for risk assessment of microbiological hazards in foods<sup>5</sup>. The Representative of WHO stated that the Consultation had recommended that FAO and WHO establish an expert advisory body on microbiological risk assessment and that the two organizations had decided to convene a series of *ad hoc* Expert Consultations on microbiological risk assessment in order to provide advice in response to requests from CCFH.

13. The Committee had an exchange of views on the priority issues for microbiological risk assessment, which would be addressed by the Expert Consultations. The Committee agreed that there was an urgent need to establish a vehicle for providing advice on this issue and that a series of *ad hoc* Expert Consultation would be appropriate until a more formal body could be established. The Committee noted the importance of transparency, independence and pluralism of sources of information/expertise, and recommended that these matters be considered by FAO and WHO in organizing the expert consultations and the formal body. The Committee also recognized the need for technical assistance to developing countries in this area.

14. Several delegations noted that it would be necessary to clarify the terms of reference of the *ad hoc* Expert Consultation and the working procedures between the Consultation and the CCFH. It was suggested that these areas be fully developed on a priority basis while not hindering the initiation of the work by the *ad hoc* Expert Consultation. The Secretariat noted that establishing an expert body and its terms of reference fell outside the Terms of Reference of the Committee and that it should be determined by FAO and WHO themselves.

15. Concerning the priority issues that would require risk assessment by the Expert Consultation, many delegations supported the idea of a pathogen-commodity combination approach and the following combinations (some without identification of commodity) were indicated as significant public health problems in Member countries. The Committee further noted that the list below was tentative and that it would be revisited at each Session of the Committee;

- *Salmonella enteritidis* in eggs
- *Salmonella spp.* in poultry
- *Salmonella spp.* in red meat
- *Salmonella spp.* in sprout

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<sup>4</sup> CL-1999/17 FH, CRD 5 (Comments of Brazil, Finland, Czech Republic), CRD 14 (Comments of European Community) CRD 18 (Summary of discussion, prepared by the Secretariat), CRD 20 (Suggested risk management questions to the Expert Consultation, prepared by FAO/WHO)

<sup>5</sup> Report of a Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods (WHO/SDE/PHE/FOS/99.5)

- *Salmonella spp.* in fish
- *Campylobacter jejuni* in poultry
- Enterohemorrhagic *E. coli* in beef
- Enterohemorrhagic *E. coli* in sprouts
- *Listeria monocytogenes* in soft cheese
- *Listeria monocytogenes* in ready to eat products
- *Listeria monocytogenes* in smoked fish
- *Listeria monocytogenes* in minimally processed vegetables (i.e. salad and precooked frozen vegetables)
- *Vibrio parahaemolyticus* in shellfish
- *Cyclospora* in fresh produce
- *Cryptosporidium* in fresh produce
- *Shigella* in vegetables
- *Staphylococcus aureus*
- *Bacillus cereus*
- *Viruses*
- *Clostridium perfringens*
- Antimicrobial resistance

16. The Delegation of the United Arab Emirates expressed the view that *Bacillus cereus* in infant formula was a significant health problem and that *E. coli* and total count were a problem in international trade. The Delegation of Cuba stressed the importance of Salmonella in meat products and of *Staphylococcus aureus* in relation to foodborne diseases in Latin America, as reported by PAHO. The Delegation of the Netherlands proposed that risk assessment should focus on Salmonella in eggs and on *Listeria* in ready-to-eat foods which supported its growth by prolonged refrigerated storage. The Delegation of Switzerland proposed that risk assessment should focus on emerging pathogens such as *Cryptosporidium* and small round structured viruses rather than Salmonella or other pathogens for which extensive data was already available.

17. The Committee identified the following as the criteria for prioritization of the combinations:

- The issue is a significant public health problem in terms of the number and/or severity of human illnesses;
- The issue is a problem in both developing and developed countries;
- The issue is a problem in international trade;
- Data is available to conduct risk assessment;
- The issue is promising for reliable results; and,
- A risk assessment has been completed at the national level in accordance with the criteria set by CCFH in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*.

18. In the light of the background information provided in CRD 20 on the public health significance of specific pathogens, the Committee agreed on the following pathogen-commodity combinations as the priority issues for consideration by the *ad hoc* Expert Consultation:

- *Salmonella* in eggs, poultry, and pork meat
- *Listeria monocytogenes* in ready to eat food
- *Campylobacter jejuni* in poultry
- Enterohemorrhagic *E. coli* in sprout and ground beef
- *Vibrio parahaemolyticus* in shellfish

19. In relation with the combinations mentioned above, the Committee tentatively suggested on the following statement as the risk management questions on each combination, which would be addressed by the *ad hoc* Expert Consultation.

"CCFH suggested that the *ad hoc* Expert Consultation on the microbiological risk assessment review and summarize national and regional risk assessment data and other relevant data on this issue. In doing so the *ad hoc* Expert Consultation should take into consideration the general description of output provided in the Report of the Joint FAO/WHO Expert Consultation on Risk Assessment on Microbiological Hazards in Foods in 1999. Especially, the *ad hoc* Expert Consultation should consider the risk estimations and evaluate the relative influence of relevant risk factors. Additionally, the *ad hoc* Expert Consultation should evaluate the risk reduction potential of relevant risk management options from farm-to-table continuum". The Delegation of France stated that risk management options should be those suggested by risk managers.

20. The Committee recognized the importance to initiate work on microbiological risk assessment and agreed that working principles/procedures between the *ad hoc* Expert Consultation and CCFH should be further discussed in the following Sessions of the Committee, taking into account the progress made by the *ad hoc* Expert Consultation.

### **DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED/PACKAGED DRINKING WATERS (OTHER THAN NATURAL MINERAL WATERS) (AGENDA ITEM 3)<sup>6</sup>**

21. The Delegation of the United States presented the revised version of the Draft Code, which had been redrafted in the light of the discussions of the last session and the comments received. The Committee considered the Draft Code section by section and made the following amendments.

22. The Committee recalled that the Committee on Natural Mineral Waters while considering the Proposed Draft Standard for Packaged (Bottled) Waters other than natural Mineral Waters could not come to a conclusion on the need for a definition of commercial sterility and had forwarded it to the CCFH for consideration in the framework of the Code. The Committee discussed the opportunity of including a definition of commercial sterility in the Code. The Delegation of Uruguay expressed the opinion that the definition of commercial sterility should not be included in the Code since bottled waters when they meet stringent microbiological criteria were suitable for all consumers. Several delegations pointed out that the definition referred to a term which was not used in the text of the code and therefore no definition was needed.

23. The Observer from CSPI expressed the view that the definition should be included to address the specific use of bottled waters for infant formula. The Delegation of Brazil supported this view and stressed the importance of other high risk groups such as the immunocompromised. The Committee agreed not to include the definition in the Code.

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<sup>6</sup> CL 1999/9-FH, CX/FH 99/3 (Comments of Belgium, Brazil, Costa Rica, Denmark, Finland, Indonesia, Mexico, Japan, Paraguay, Peru, Poland, South Africa, United Kingdom, United States, ISDC, Consumers International, UNSEMI-GISEMES), CRD 4 (Comments of Italy, Spain) CRD 9 (Comments of European Community)

## **Section 1. Introduction**

24. The Committee recalled that the labelling section had been deleted and that some provisions related to consumer information had been included in the Introduction. After an exchange of views on the need to transfer some parts of the text to Section 5. Control of Operations, the Committee agreed to retain the current structure of the section and to clarify some of its provisions. A reference to contamination by viruses was added in the sentence on parasitic protozoa. The Observer from Consumers International stressed the importance of providing information on the public health significance of protozoa and the Committee agreed to specify that “these pathogens are difficult to detect and bacterial indicators of their potential presence are not always reliable” and therefore information on control measures the water has received can be useful to consumers.

25. The Committee recognized the need to provide information, when necessary, on the use of bottled waters to reconstitute infant formula and reworded the last sentence accordingly for clarification purposes.

### **Section 2.1 Scope**

26. Some delegations considered it inappropriate to include a specific reference to “mineral waters” (other than natural mineral waters) since these had not yet been defined by the CCNMW. After an exchange of views, the Committee agreed to refer to “all bottled/package drinking waters other than natural mineral waters” as this clearly reflected the scope of the Code.

### **Section 2.3 Definitions**

27. The Committee agreed to delete the definition of “food hygiene” as it was already defined in the General Principles of Food Hygiene. The Committee also noted that the definition of bottled waters was different from the Proposed Draft Standard.

## **Section 3. Primary Production**

28. The Committee agreed that reference should be made to microbiological safety, as it was more appropriate than “quality”. In section 3.1.1 the first sentence was slightly reworded for clarification purposes.

### **Section 3.1 Environmental Hygiene**

29. The Committee agreed that testing for radiological characteristics should be carried out where necessary, and that the frequency of testing was also determined by the amount of water collected.

### **Section 3.2 Hygienic Production of Water Supplies**

#### **Section 3.2.1.1 Consideration for Ground Water Supplies**

30. The Committee agreed that when contamination was detected, production should cease until the characteristics of the water returned to established parameters. The Delegation of India proposed to delete the reference to approval of the underground supply by an official authority or a third party as this should be left to member countries and the Code should focus on the measures intended to ensure the safety of bottled waters. The Committee agreed to retain the current wording.

### **Section 3.3 Handling, Storage and Transport of Water**

31. The Committee agreed to the following amendments: 1) in Section 3.3.1.3, to specify that wells should be properly disinfected; and 2) in Section 3.3.2 to delete the reference to piping as a “preferred” means of avoiding contamination from bulk transport

32. In section 3.3.2.2 Use and Maintenance, the Delegation of Uruguay proposed that dedicated transport should be required, and that the use of other food containers should not be allowed for other transport. The Committee had an exchange of views on this question and agreed to retain the provisions of the current text. Some editorial amendments were made to the section for clarification purposes.

## **Section 4.4 Facilities**

### **Section 4.4.1 Water supply not intended for bottling**

33. The Committee agreed that water not intended for bottling should be potable if it was expected to come into direct or indirect contact with water intended for bottling, especially if used for cleaning and disinfection of surfaces which came in contact with bottled water; and otherwise it might be non-potable. The section was rearranged accordingly for clarification purposes.

## **Section 5. Establishment: Control of Operation**

34. The reference to Section 5.1 Control of Food Hazards was deleted as this was already covered in the General Principles of Food Hygiene. The Committee recognized the need to address specific issues related to contaminants and agreed to include an introductory paragraph concerning the need for control measures to ensure the safety and suitability of waters, to be included in a new Section 5.2 (replacing Section 5.1.1 Control measures for waters intended for bottling).

### **Section 5.2 Key Aspects of Hygiene Control**

35. The Committee agreed to delete the reference to “quality” where applicable and to indicate that water should be “safe and suitable for consumption” after treatment. After an extensive exchange of views the Committee agreed to retain the sentence on the relationship between water quality and the treatment required to obtain safe bottled water.

36. The Committee agreed to reword the paragraph on hazard analysis as proposed by the Observer from the EC and to retain the sentence concerning the need for treatment of waters from different supplies.

37. The Committee discussed a proposal from the Delegation of Denmark concerning the use of water treatment agents at levels which would have the technological function of a preservative rather than a disinfectant. The Committee recalled that the levels of food additives such as preservatives were defined in commodity standards or in the General Standard for Food Additives. The Committee agreed to add a reference to “residues of chemical treatment” in the last sentence of the section, which stressed the need to avoid any type of contamination in relation to water treatment. The Delegation of Thailand expressed the view that no reference should be made to preservatives as this might encourage their use in bottled waters.

## **Section 5.4 Packaging**

38. The Committee agreed that for general packaging requirements, reference should be made to the General Principles of Food Hygiene, and that the sections should be renumbered to reflect that the issues addressed were distinct.

### **Section 5.4.1 Washing and Disinfecting of Containers**

39. The reference to “sanitizing” was replaced with “disinfection” for consistency with the corresponding sections of the General Principles. It was agreed that “reused and when necessary other containers” were covered in the section, and that washing should take place in an “appropriate system” as it was not necessary to require a closed system.

### **Section 5.4.2 Filling and Sealing of Containers**

40. The Committee agreed that the requirement for “positive air pressure” in an enclosed area was not necessary and replaced the reference to “excessive moisture” with condensation for clarification purposes, as proposed by the Delegation of Thailand.

### **Section 5.4.3 Product Containers and Closures**

41. The Committee agreed to take out the first sentence on non-toxic containers as this general requirement was covered by the General Principles of Food Hygiene. It was also agreed that new containers should be cleaned and disinfected if necessary after inspection.

#### **Section 5.4.4 Use of Closures**

42. The Committee agreed that closures should be tamper-resistant, as proposed by the Delegation of Uruguay.

#### **Section 9. Product Information and Consumer Awareness**

43. The Committee added a reference to the text in the Introduction on consumer information.

#### **Appendix 1 HACCP System and Guidelines for its Application**

44. The Committee agreed to delete this Appendix as reference should be made to the Annex to the General Principles of Food Hygiene.

#### **Appendix 2 Microbiological, Chemical and Physical Criteria**

45. The Delegation of India expressed the view that end-product specifications should not be included in codes of practice but in standards. The Committee however recalled that the General Principles included a reference to microbiological and other specifications (Section 5.2.3) and that some of the current codes included such specifications.

46. The Observer from the EC, referring to its written comments, proposed to include microbiological criteria for Enterococci, *P.aeruginosa* and colony count at 22° and 37° and to refer to *E.coli* in 250 ml (instead of 100ml) as bottled water and tap water were different. The Delegation of Austria strongly supported the proposal of the EC and pointed out the importance of reference to indicator bacteria. The Delegation of Uruguay, supported by other delegations, proposed to include the criteria which were specified in the Code of Hygienic Practice for Natural Mineral Waters. The Delegation of the United States stressed the need to review the additional criteria on the basis of Codex Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods, and expressed the view that while *E.coli* was a safety indicator, the other criteria proposed were more related to quality than to safety.

47. The Committee could not come to a conclusion on the inclusion of other criteria and agreed to retain only the reference to *Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) and to the WHO Guidelines (which included the reference to *E.coli* in 100 ml), with the understanding that the inclusion of additional criteria would be considered further in the future.

48. The Observer from Consumers International pointed out that the current limit for lead in the WHO Guidelines was too high and did not adequately protect children. The Committee agreed that the criteria for chemical and physical safety included in the WHO Guidelines should be followed and included the relevant reference in the Appendix.

49. The reference to the Proposed Draft Standard for Bottled /Packaged Waters other than Natural Mineral Waters was deleted as quality criteria were not within the scope of the Code.

#### **Status of the Draft Code of Hygienic Practice for Bottled/Packaged Drinking Waters (other than Natural Mineral Waters)**

50. The Committee agreed to advance the Draft Code to Step 8 for adoption by the 24<sup>th</sup> Session of the Commission (see Appendix II of this report).

#### **DRAFT CODE OF HYGIENIC PRACTICE FOR THE TRANSPORT OF FOODSTUFFS IN BULK AND SEMI-PACKED FOODSTUFFS (AGENDA ITEM 4)<sup>7</sup>**

51. The Committee recalled that the 23<sup>rd</sup> Session of the Codex Alimentarius Commission adopted the Proposed Draft Code at Step 5 and advanced it to Step 6. The Delegation of the Netherlands

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<sup>7</sup> CX/FH 99/4, CX/FH 99/4 Add-1 (Comments of India, Nigeria, United States), CRD 7 (Comments of Italy, Finland), CRD 11 (Comments of European Community), CRD 12 (Comments of Mexico).



introduced the draft document and highlighted the following issues to be solved: whether or not to include primary production in the scope and dedicated transport. The Committee agreed that it would first discuss these key issues.

52. The Delegation of India stated that consideration of the Draft Code should be based on risk analysis. By referring to the Commission's recommendation on the principles for risk analysis (ALINORM 99/37 para. 56), the Delegation expressed the view that the provisions of the Draft Code were not based on appropriate risk assessment and therefore discussion of this Agenda Item should be deferred. Several delegations pointed out that there was sufficient scientific evidence to discuss this issue, that the Code had already been considered in detail, and that the Agenda for the Session was already adopted. The Committee agreed that the situation of primary production in developing countries should be taken into consideration.

53. The Committee had an exchange of views on the scope of the Draft Code in relation to primary production. It was noted that the primary focus of the Draft Code was foods in international trade and that the transportation within primary production was more appropriately covered by commodity codes such as that to be discussed under Agenda item 6. The Committee agreed that the Draft Code should cover the food transportation unit and product from the point of shipment to the point of receipt but should not introduce additional guidelines covering operations such as growing, gathering or fishing beyond those in the General Principles of Food Hygiene. The Sections on Scope and Primary Production were amended accordingly.

54. The Delegation of India, supported by the Delegation of China, noted that it was impossible to apply the Draft Code to foods transported by traditional means such as carts, head-loads and animals and proposed to delete the example on food transported directly from the field to the market.

55. While considering the issue of dedicated transport, several delegations pointed out that Section 8.3 of the General Principles of Food Hygiene already covered this issue and that no specific provisions needed to be added to the Draft Code. Several other delegations and the Observer from the European Community indicated that bulk transportation in liquid, granulated or powder form required, in principle, dedicated transport in order to protect consumers' health and that it should be clearly stated in the Draft Code.

56. After an extensive exchange of views, the Committee agreed to include the wording of the General Principles (Section 8.3) and to refer to dedicated transport of bulk food in liquid, granulated or powder form unless the application of principles such as HACCP demonstrated that it was not necessary.

57. The Committee reviewed the Draft Code section by section and agreed to make the following amendments as well as editorial changes.

58. In the Introduction, the last paragraph was amended to clarify the relationship with other commodity codes with examples provided for further clarity, such as reference to the existing Revised Recommended Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk.

59. In the Section on Definitions, the definition of foodstuff was deleted, as there was no additional meaning for "foodstuff" compared with food, which was already defined in the Procedural Manual. The title of the Draft Code was also amended accordingly.

60. It was also agreed that the Draft Code be formatted according to the structure of the General Principles of Food Hygiene, as it should be used in combination with the General Principles. The provisions in the Section on Establishment were moved to Section 8 Transportation, and the Section on Training was referred to as Section 10.

61. In the Section on Transportation (Food Transportation Units), the description of the thermal heating fluids was harmonized with the text of the Revised Recommended Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk.

## **Status of the Draft Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food**

62. The Committee advanced the Draft Code to Step 8 for adoption at the 24<sup>th</sup> Session of the Codex Alimentarius Commission (See Appendix III of this report).

63. The Delegation of Germany expressed its concerns about the procedure of advancing the Code to Step 8, because of the number and extent of changes made in the text, it was not possible to see the whole document before decision.

## **PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (AGENDA ITEM 5)<sup>8</sup>**

64. The Delegation of the United States introduced the document which had been revised, as agreed by the last session of the Committee, and which focused on six major issues as follows:

- The use of annexes to describe control measures details;
- Provisions for raw milk products;
- The prescriptive nature of the primary production section;
- Provisions for the validation of control measures;
- Expansion of the Scope to include suitability; and
- Shelf life issues

65. The Delegation pointed out that the document provided a general framework but required substantial further work, in particular to develop the annexes concerning specific products, and asked the advice of the Committee on the general orientation of the document and how to proceed further in its elaboration. The Delegation also noted that the Drafting Group had recommended that because the horizontal issues of validation and suitability were not adequately defined, they should be addressed in plenary by the Committee.

66. Several delegations and the Observer from IDF expressed their appreciation to the Delegation of the United States and the Drafting Group for their constructive work and proposed that they should continue developing the document. The Delegation of Finland, expressing the views of the member states of the European Union, and some delegations pointed out that the current document did not fully reflect the conclusions of the Drafting Group, especially as it had been agreed that the code would address food suitability as well as safety, and that aspect was not included in the current text. It should therefore be taken into account in its further development. They also stated that the definition of food suitability should be reviewed. The Delegation of New Zealand stated that the Code should be developed in the context of a risk-based approach, should refer the acceptable level of protection, and should focus first on principles specific to dairy products. The Delegation of Switzerland mentioned that the HACCP principles should be applied from the feeding of milking animals to the end product and the terms used in this standard should be consistent with those used in the General Standard for the Use of Dairy Terms.

67. The Delegation of India expressed the view that the reference to the annexes should be reviewed and they should not be regarded as “additional” since they would refer to specific production conditions; in particular the reference to milking equipment and temperature control should not be generalized. The Delegation of Italy pointed out that the focus should not be on commercial sterility but on the control of the process, that physical and chemical contamination should also be addressed, and that requirements for hygienic production should not be targeted only to raw milk production.

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<sup>8</sup> CX/FH 99/5; CX/FH 99/5-Add.1 (Comments of France, New Zealand, Spain, United States of America, International Dairy Federation (IDF); CRD 3 (Comments of Finland, India, Italy, Mexico); CRD 11 (Comments of EC).

68. The Delegation of France noted that only three annexes were currently mentioned whereas the Code covered all types of dairy production and that the relationship between the main body of the code and annexes would need to be clarified after they had been developed and proposed to submit a list of annexes to be included in the Code. The Delegation of the United States indicated that the intention was to develop a comprehensive set of annexes to cover all milk and milk products, that the document needed further consideration as to its organization and that the input of all interested countries would be useful in the process, in order to present a revised text for consideration by the next session.

69. The Committee agreed that the general approach in the framework document was appropriate for the further development of the Code. The United Kingdom delegation urged delegations which had not yet submitted comments on the document (CX/FH 99/5) to do so as soon as possible.

### **Status of the Proposed Draft Code of Hygienic Practice for Milk and Milk Products**

70. The Committee agreed to return the Proposed Draft Code to Step 3 for redrafting, including development of specific annexes, by the United States with the assistance of a Drafting Group in the light of the comments received and the discussions at the current session, and to circulate it for comments prior to the next session.

### **PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE PRIMARY PRODUCTION, HARVESTING AND PACKAGING OF FRESH FRUITS AND VEGETABLES (AGENDA ITEM 6)<sup>9</sup>**

71. The Delegation of Canada introduced the Proposed Draft Code and noted the following changes that were made taking into account the discussion at the previous Session: 1) The Code addressed not only microbiological contamination but also contamination by chemicals including pesticides as they relate to GAP and GMP; 2) The Code applied to products from organic agriculture; 3) The Code was intended to be outcome based without an unnecessary level of prescriptive recommendations; 4) Recognizing the practical limitations to the use of HACCP, emphasis was made on GAP and GMP; 5) the Annex on sprouts should be examined after the Code was completed, as the Code could address hygienic requirements for the production of seeds intended for sprouting.

72. The Committee expressed its appreciation to the Delegation of Canada and the drafting group for their work in elaborating the Proposed Draft Code. The Committee, following the explanation by the Delegation of France regarding the Proposed Draft Code of Hygienic Practice for Pre-Cut Raw Vegetable Products Ready for Human Consumption that would be discussed under Agenda Item 7, discussed the appropriateness of merging the two Codes. Several delegations opposed merging the two Codes as the risks to be addressed within primary production and in the processing industry for pre-cut vegetables were different. The Delegation of France, supported by several other delegations proposed to merge the Codes as they overlapped in many sections, such as in Section 3, which would result in unnecessary discussions. The Committee agreed that the two codes should be discussed separately at this stage and that the drafting groups for the Codes should work in close cooperation.

73. The Delegation of India stressed the importance of risk assessment within the elaboration process of this Code. The Delegation also mentioned that the Commission recommended that risk assessment should take into account global data, including that from developing countries and that the Code should not be elaborated in a hasty manner. The Delegation further mentioned that the Draft Code put great emphasis on pre-harvest operations, whereas the probability of risk is greater in post harvest operations which would be borne out through risk assessment.

74. The Committee generally agreed on the changes presented by the Delegation of Canada. It recognized that the focus of the Code was not restricted to microbiological contamination and agreed to

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<sup>9</sup> CX/FH 99/6, CX/FH 99/6 Add-1 (Comments of Brazil, Costa Rica, Denmark, Finland, India, Peru, Spain, UK, USA), CRD 8 (Comments of Italy, Mexico, France), CRD 11 (Comments of European Community)

delete the words “which are not processed to eliminate pathogens” from the last sentence in the section on Introduction.

75. The Delegation of France questioned whether, for example, mushrooms, seaweeds and berries were covered by the Code. The Committee agreed that “cultivated” fruits and vegetables should be under the scope of the Code and that the word “cultivated” should be inserted after the word “vegetables” in the first sentence of section 2.1 Scope.

76. The Delegation of Malaysia sought clarification on whether genetically modified vegetables were covered by the Code. It was noted that the Code applied to all fresh fruits and vegetables so defined in the Code, regardless of the use of plant breeding or production method.

77. The Delegation of India expressed the view that application of stringent hygienic practices for small holding was impractical in developing countries because those countries have neither the appropriate infrastructure nor trained manpower. The Delegation of Thailand suggested that the Code should not be too prescriptive for developing countries as primary production in these countries heavily relies on small farms.

78. The Delegation of India proposed to add a new annex to addresses the above concern. Several other delegations proposed to take up this concern in Section 2.2 Use. The Committee agreed to add the following wording before the last sentence of Section 2.2. "However, it is recognized that the provision would be difficult to implement in areas where primary production is conducted in small holdings, in developing countries and also in areas where traditional farming is practiced. Therefore, the concerned government should cause awareness in the primary production of produce."

79. In the Section on Definition, the Delegation of the United Kingdom pointed out that the definition of “Primary Production” should be consistent with that of the General Principles of Food Hygiene and the Committee agreed to amend the definition accordingly.

80. Regarding the definition of “Fresh Fruits and Vegetables”, the Delegation of Spain mentioned that mushrooms, even cultivated, were not generally eaten raw, and that the current definition needed to be clarified to specify which produce was covered by the Code. The Delegation proposed to delete the words “and are intended to be consumed raw”, as the Code should cover all fruits and vegetables sold in the raw form whether or not they were consumed raw. After some discussion, the Committee agreed on the need for further deliberation on this matter.

81. In Section 3.1 Environmental Hygiene, it was agreed to add the words “where possible” at the beginning of the first and second paragraphs concerning the identification of sources of contamination and to delete reference to adjoining sites. In Section 3.2.1.2 it was also agreed to insert "where possible" at the beginning of para. 3 concerning the need for documentation on manure, sewage sludge and other fertilizers.

82. The Delegation of France proposed to separate clearly the issues related to manure and to sewage sludge, in view of the specific problems associated with the latter.

83. The Delegation of Sweden proposed to include a sentence on biological control of pests by applying microorganisms, which were especially used in organic production, and the associated hazards and also expressed its concern regarding the use of antibiotics for the production of fresh fruits and vegetables. The Delegation of the United States pointed out that issues related to pest control were not within the scope of the Code. The Committee did not come to a conclusion on this question.

84. The Delegation of Japan and many other delegations emphasized the importance of the annex for sprouts. The Committee reconfirmed the decision of the previous Session to include an annex on sprouts and asked the Delegations of Japan, Denmark, the Netherlands and USA to prepare a working document for consideration at next meeting.

85. Although several delegations supported the advancement of the text to Step 5, the Committee recognized that there were many other issues that could not be fully addressed during the Session,

including those comments submitted in CX/FH Add-1 and CRDs. The Committee agreed that the drafting group should further consider those issues.

### **Status of the Proposed Draft Code of Hygienic Practice for the Primary Production, Harvesting and Packing of Fresh Fruits and Vegetables**

86. The Committee returned the Proposed Draft Code to Step 3 and agreed that the drafting group led by Canada would redraft the Code on the basis of the comments received and discussions held during the session, for circulation at Step 3 and consideration by the next session.

### **PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-CUT VEGETABLE PRODUCTS READY FOR HUMAN CONSUMPTION (AGENDA ITEM 7)<sup>10</sup>**

87. The Delegation of France introduced the document and pointed out the difficulties related to overlapping with the Code on primary production discussed under Agenda Item 6, since there was no difference between the products covered as regards the risk of contamination. Moreover, some provisions in the other code related to vegetables which have been subjected to some treatments and included sections on control of temperature. The Delegation emphasized the importance of merging the two codes as it would clarify discussions and facilitate the completion of both drafts. The Committee should address the inclusion of fungi, aromatic herbs and possibly seaweed. Also the sections on the identification and control of hazards required further development.

88. The Delegation of the United States expressed the view that herbs should be included but not fruits juices and stressed the importance of coordinating the development of the Code for pre-cut vegetables with the Code on Primary production.

89. The Chairperson recalled that the Committee had agreed that juices would be outside the scope of the Code and that sprouts would be considered in the framework of the Code on primary production (see para. 84).

### **Status of the Proposed Draft Code of Hygienic Practice for Pre-cut Vegetable Products Ready for Human Consumption**

90. The Committee agreed to return the Proposed Draft Code to Step 3 for redrafting by the Delegation of France with the assistance of a Drafting Group, for circulation and consideration by the next session.

### **PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (AGENDA ITEM 8)<sup>11</sup>**

91. The Delegation of France introduced the document and pointed out that it had been restructured to take into account the recommendations of the last session and the comments received; a section on the participation of interested parties had been added; the structure of the document reflected the actual chronology followed by risk managers; the issues related to regional differences in prevalence of pathogens in the food chain had been incorporated into Section 5.2.3; the section on food safety objectives was left unchanged as this question would be considered by the Committee on General Principles as part of the general discussion on risk analysis.

92. The Committee expressed its appreciation to the Delegation of France and the countries which had participated in the redrafting for their work on this important document. The Delegation of India proposed to refer to growers in the list of stakeholders and to include as a principle the recommendation

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<sup>10</sup> CX/FH 99/7, CX/FH 99/7-Add.1 (Comments of Brazil, Denmark, Finland, India, Italy, Mexico, Peru, Republic of Korea, United States, Spain), CRD 10 (comments of Argentina), CRD 11 (Comments of the European Community), CRD 17 (Comments of Consumers International).

<sup>11</sup> CX/FH 99/8, CRD 6 (comments of Finland), CRD 14 (Comments of the European Community), CRD 15 (ALA-Asociacion Latinoamericana de Avicultura)

of the Commission to consider the feasibility of risk management options in developing countries and the need for flexibility. The Committee noted that this was not a principle but should rather be included in Section 6 (Guidelines for Implementation of Risk Management Decisions).

93. The Delegation of New Zealand pointed out that the structure of the document did not correspond to the recommendations of the FAO/WHO Expert Consultation on Risk Management and Food Safety<sup>12</sup>, and made the following remarks. Risk management was not necessarily carried out when a specific problem was identified, but might be used to establish public policy goals or the definition of equivalence; risk managers might not commission a risk assessment but in any case a structured risk approach should be followed; some aspects which were included in Section 5.2 would be more relevant in relation to risk assessment policy. Although food safety objectives would be defined from a general perspective in CCGP, they could be defined in the framework of the document as related to microbiological risk management.

94. The Representative of WHO stated that changes in the general framework described in the FAO/WHO Expert Consultation on Risk Management and Food Safety would cause confusion, and if such major changes were agreed upon, a clear description of the rationale should be provided.

95. The Observer from Consumers International proposed to refer in Principle 5 to the interaction between risk management and risk assessment (for consistency with the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*), and to add that the goals for microbiological risk assessment should be aimed at preventing or reducing risk in order to protect public health in Section 5.1.4.

96. The Committee had an extensive discussion on Principle 7 referring to a precautionary approach. The Delegation of France indicated that care had been taken not to refer to the precautionary principle since it was under discussion in the CCGP; however it was recognized that risk managers generally followed a precautionary approach to address food safety issues.

97. Some delegations pointed out that this question should not be discussed in detail as the proposal to include a reference to the precautionary principle in the Working Principles for Risk Analysis was under consideration in the Committee on General Principles and there was no consensus at this stage on this question.

98. The Observer from CSPI proposed to refer to decisions adopted “as needed to protect public health” as part of a precautionary approach. Some delegations supported the reference to public health but proposed to retain the “precautionary approach” in square brackets as there was no consensus at this stage. The Delegation of the United States proposed to replace the current text with a requirement that the stringency of control measures should be proportionate to the scientific uncertainty and the extent of the risk; alternatively the reference to public health could be included but the “precautionary approach” should be deleted or kept in square brackets.

99. The Delegation of the United Kingdom, recalling that the precautionary principle was under consideration in CCGP, proposed to put Principle 7 in square brackets as the discussion affected the concept as a whole and no conclusion could be reached at this stage. The Committee agreed with this proposal and noted that this question would be discussed further at the next session.

100. The Representative of OIE referred to the need for cooperation between Codex and OIE in many subjects of common interest in relation to animal health, including risk analysis, especially as they could provide useful regional data in this area.

101. As a general point the Committee agreed that risk management activities and risk assessment activities could be considered simultaneously.

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<sup>12</sup> Risk Management and Food Safety, Report of a Joint FAO/WHO Consultation, FAO Food and Nutrition paper No.65, Rome, 1997

## **Status of the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management**

102. As the Proposed Draft had not yet been circulated for comments in view of time constraints, the Committee agreed to circulate it at Step 3 for government comments (see Appendix IV), with the understanding that the comments would be forwarded to the Delegation of France for redrafting with the assistance of a Drafting Group, circulation and consideration by the next session.

## **OTHER LEGITIMATE FACTORS IN THE FRAMEWORK OF RISK ANALYSIS**

103. The Committee considered the request from the Committee on General Principles concerning the role of other legitimate factors in the framework of risk analysis and had an exchange of views on the factors which were taken into account in its work (see Agenda Item 2). The Committee recalled that the request concerned “other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade”.<sup>13</sup>

104. The Delegation of New Zealand referred to the role of economic feasibility, an example of which could be found in the provisions on dedicated transport in the Draft Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food; technical feasibility as discussed in relation to primary production (faecal contamination in pre-harvest areas); the practical aspects of control measures in view of the specific situation of small growers, as recognized in the discussion on primary production.

105. The Delegation of Ireland referred to the importance of sampling considerations in relation to testing for compliance with microbiological criteria, as appeared from the discussion on bottled waters. The Delegation of France also noted that consideration of water reuse was related to environmental concerns and water conservation and proposed to include such environmental aspects. The Delegation of China pointed out that the availability of expertise in developing countries was a limiting factor in the application of hygiene control measures. The Committee agreed that the above proposals reflected the factors taken into account in its decision process.

106. The Delegation of India proposed to include a reference to susceptibility to risk and eating habits; other delegations however pointed out that consideration of regional diets and susceptible population groups was part of the normal process of risk assessment.

107. The Delegation of Sweden referred to Good Agricultural Practice and Good Manufacturing Practice, and emphasized the need to minimize the use of chemical substances as a general requirement. The Observer from Consumers International supported the inclusion of consumer information, consumer concerns, environmental issues and cultural aspects in the list of other factors taken into account by CCFH in its work and proposed to include also the weight given to uncertainty in the decision process.

108. The Committee had an exchange of views on the reference to consumer information and consumer concerns. The Committee agreed that consumer information was a legitimate factor which had been taken into account in its work. as reflected in the Introduction of the Draft Code of Practice for Bottled/Packaged Drinking Waters where provisions on consumer information were included. The Committee however could not reach a conclusion on the consideration of consumer concerns at this stage. Several delegations considered that consumer concerns had been taken into account by CCFH, for example in the development of the Draft Code for Bottled/Packaged Waters. The Delegation of the United States, supported by the Observer from COMISA, pointed out that these concerns were not clearly defined.

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<sup>13</sup> *Statements of Principle Concerning the Role of Science in the Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Procedural Manual, 10<sup>th</sup> Edition, Appendix: General Decisions of the Commission)

109. The Committee could not come to a conclusion on the opportunity to consider cultural factors, as proposed by some delegations, and on the examples which could illustrate this aspect. There was no consensus on the relevance of the provisions for milk and milk products as an example; some delegations pointed out that cultural considerations had significantly delayed progress in this area and that hazard analysis was the correct approach. The Observer from ICMSF noted that the reference to food suitability in the General Principles of Food Hygiene reflected the fact that certain foods, albeit safe, were not acceptable to consumers for cultural or religious reasons.

110. The Delegation of the United States noted that there was a difference between factors that may be taken into consideration when deciding upon initiating work on a Codex standard or related text and the appropriate other legitimate factors that should be considered when actually developing the document.

111. The Committee agreed that economic and technical feasibility, practical aspects of measures (especially for small businesses), the availability of expertise, sampling, consumer information, environmental impact and Good Agricultural Practice (GAP), Good Manufacture Practice (GMP) were legitimate factors, which had been or were being taken into account in the decision process. The Committee could not come to a conclusion at this time on the reference to cultural aspects and consumer concerns.

#### **DISCUSSION PAPER ON THE IMPLEMENTATION OF HACCP IN SMALL AND/OR LESS DEVELOPED BUSINESSES (AGENDA ITEM 9)<sup>14</sup>**

112. The Delegation of the Netherlands introduced the document and pointed out that the discussion of the paper during the 31st Session of the Committee indicated substantial interest in its content, but some fundamental issues were not solved. Therefore WHO in cooperation with the Government of the Netherlands had convened a Consultation on Strategies for Implementing HACCP in Small and/or Less Developed Businesses in June 1999 to:

- review the difficulties experienced when applying the HACCP system in Small and/or Less Developed Businesses (SLDBs);
- consider the initiatives and approaches taken by different governments or sectors in assisting SLDBs in implementing the HACCP;
- define the role of governments and professional trade bodies in assisting SLDBs in implementing HACCP; and
- Develop a strategy for implementing HACCP in SLDBs, considering different options.

113. The Delegation indicated that SLDBs were defined as “businesses that because of their size, lack of technical expertise, economic resources, or the nature of their work, encountered difficulties in implementing HACCP in their food businesses” and that the term “less developed business” referred to the status of the food safety management system and not to the number of staff or volume of the production. The Consultation addressed the implementation of HACCP in SLDBs in developed and developing countries. The Delegation also noted that the revised document was mainly based on the recommendations of that Consultation, however the guidance of the Committee was sought regarding the type of document being developed, the need for sector specific guides, the application of sector specific templates, and generic HACCP plans.

114. Many delegations complimented the Delegation of the Netherlands for the revision of the discussion paper and indicated that it contained valuable and practical information on the

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<sup>14</sup> CX/FH 99/9; Strategies for the Implementing HACCP in Small and/or Less Developed Businesses: Report of a WHO Consultation in collaboration with the Ministry of Health, Welfare and Sports, The Netherlands, the Hague, 16-19 June 1999, WHO/SDE/PHE/99/7; CRD 13 (Comments of Finland), CRD 15 (Comments of Latin American Aviculture Association (ALA)); CRD 16 (Comments of EC)



implementation of HACCP, which would certainly assist governments and businesses in their work with HACCP. Some delegations stressed the need to continue working on the document but noted that before putting it into the Step Procedure it should be more clearly focused on providing practical guidance. Some delegations were of the opinion that it was preferable to elaborate additional guidance for SLDBs as an Annex to the existing Codex Guidelines on HACCP while others pointed out that the original intention was to develop a separate document. The Delegation of Germany drew the attention of the Committee to the title of the document which should refer to “application” as the content was mainly oriented to that aspect, rather than to “implementation”.

115. The Observer from IDF indicated that some small dairies could not fully apply the HACCP system and opposed generic HACCP plans that could lead to misuse of the guidelines.

116. Some delegations supported the view that prerequisite programmes were necessary for the successful application of HACCP and this should be stated in the Guidelines. The Delegation of the United States opposed this proposal and the revision of the HACCP Guidelines since it would alter the Concept of HACCP. The Delegation expressed concern about the use of generic HACCP plans and the use of third parties for international recognition and further noted that there should be no fundamental difference in HACCP, whether applied to small, medium, or large businesses.

117. The Committee agreed that the Delegation of the Netherlands with the assistance of their drafting partners should prepare a discussion paper to identify issues involved in elaborating appropriate guidance on the application of HACCP principles by SLDBs for consideration by the next Session of the Committee. The document therefore should be maintained at the stage of Discussion Paper.

#### **DISCUSSION PAPER ON THE PROPOSED DRAFT RECOMMENDATIONS FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS IN INTERNATIONAL TRADE (AGENDA ITEM 10)<sup>15</sup>**

118. The Delegation of Germany introduced the discussion paper and recalled that the issue on various aspects of control of *Listeria monocytogenes* had been on the Agenda of this Committee since its 23<sup>rd</sup> Session. The Delegation drew the attention of the Committee to the structure of the document which included elements of risk assessment and control measures and pointed out that the levels of tolerance allowed in member countries for *Listeria* in foods ranged from zero in ready to eat foods to low levels in foods that did not support its growth. Analyses accompanying epidemiological investigations indicated that listeriosis was associated with consumption of foods with elevated levels of *Listeria monocytogenes*. The Delegation indicated that it was intended to give guidelines for the management of *Listeria* in foods in trade, based on considerations of risk assessment and risk management options.

119. The Committee expressed its appreciation to the Delegation of Germany for the development of the document and generally recognized that the Committee should continue working on this public health issue. The Delegation of the United States suggested that the *ad hoc* FAO/WHO Expert Consultation address this issue as there was a need for complete risk assessment data before considering control measures in the Committee.

120. The Delegation of Denmark, supported by some other delegations and the Observer of ICMSF was of the opinion that the document should be further developed in the Step procedure. It was stated that even low levels of *Listeria monocytogenes* could be problematic for susceptible populations like elderly and infants, especially when malnutrition among them reached 60% as pointed out by the Delegation of Panama. The Delegations of Italy and Austria supported “zero-tolerance” for ready to eat foods. The Observer from ALA (Latin America Aviculture Association) indicated that requirements should not introduce any discrimination between imported and national products and that equivalence should be sought in ensuring food safety.

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<sup>15</sup> CX/FH 99/10; CRD 13 (Comments of Finland); CRD 15 (Comments of ALA)

121. The Committee agreed to proceed with the elaboration of the document in two directions, as suggested by the Representatives of FAO and WHO, and supported by several countries: the matter would be referred to the FAO/WHO Expert Consultation on risk assessment and the Delegation of Germany would prepare the Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods in accordance with the Principles and Guidelines for the conduct of Microbiological Risk assessment for circulation at Step 3 and for consideration by the next session of the Committee. Member countries and interested international organizations were invited to submit their comments and proposals on this subject to the Head of the German Delegation by 15 February 2000.

#### **DISCUSSION PAPER ON VIRUSES IN FOOD (AGENDA ITEM 11)<sup>16</sup>**

122. The Committee recalled that at the last Session the Delegation of the Netherlands proposed consideration of food safety hazards associated with viruses with a view to developing recommendations for their control. It had been agreed that the Delegation would prepare a discussion paper for the 32<sup>nd</sup> Session.

123. The Delegation of the Netherlands introduced the discussion paper prepared with the assistance of other countries and drew the attention of the Committee to the Recommendation in Section 6.2, which emphasized the importance of making current scientific knowledge widely accessible. The Delegation indicated that develop a paper it was not possible on “Control Measures for Foodborne Viruses”, comparable to the paper currently prepared for *Listeria monocytogenes* and asked the advice of the Committee on how to progress with this issue.

124. The Delegation of the United States expressed its appreciation of the excellent work done by the Delegation of the Netherlands and other drafting countries. The Delegation, while recognizing that viruses were a significant public health issue, suggested that this question, including the need for research, epidemiological data, and training could be better addressed by WHO and that the paper prepared might be published as a WHO document.

125. The Representative of WHO stated that WHO recognized the issue of viruses in food as a challenge to public health and that WHO was planning to convene an expert consultation on this issue in the year 2000 or 2001. This work would be done in addition to the work of the ad hoc Expert Consultation discussed under Agenda Item 2. The Delegation of Japan expressed the view that this matter should be addressed by the *ad hoc* Expert Consultation.

126. The Committee agreed to discontinue work on viruses for the time being and to revisit this question after 2 to 3 years, taking into account the progress in WHO and other international fora.

#### **DISCUSSION PAPER ON ANTIMICROBIAL RESISTANT BACTERIA IN FOOD (AGENDA ITEM 12)<sup>17</sup>**

127. The Delegation of Denmark presented the discussion paper which had been prepared (with the assistance of other countries) as agreed by the last session of the Committee. The document considered all sources of antimicrobial resistance and referred to the work currently underway in WHO, OIE and FAO in their respective areas of competence. The Delegation highlighted the public health concerns related to the higher pathogenicity of resistant strains of Salmonella and Campylobacter in food, and proposed that a risk profile and risk assessment policy should be defined.

128. The Secretariat noted that consideration of this issue required a multidisciplinary approach and recalled that the 23<sup>rd</sup> Session of the Commission had established an intergovernmental Task Force on Animal Feeding, the Terms of Reference of which included addressing “*aspects which are important*

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<sup>16</sup> CX/FH 99/11.

<sup>17</sup> CX/FH 99/12, CRD 6 (Comments of Italy), CRD 13 (Comments of Finland), CRD 15 (Comments of ALA)

*for food safety, such as problems related to toxic substances, pathogens, microbial resistance, new technologies, storage, control, traceability, etc..”.*

129. The Representative of WHO informed the Committee of the work of WHO on antimicrobial resistance in livestock, including the organization of an expert Consultation on Global Principles for Containment of Antimicrobial Resistance in Foodborne Bacteria (in collaboration with OIE and FAO) scheduled for March 2000, and stressed the importance of establishing a risk profile within the Codex framework, including consideration of the factors which contribute to an increase in antimicrobial resistance.

130. The Delegation of the United States expressed the view that antimicrobial resistance was one of the factors taken into account in risk assessment and there was no need for additional work in this Committee in terms of hygienic control measures. The Delegation therefore proposed to discontinue work on this issue, as it was adequately addressed in the framework of WHO, OIE and FAO, while matters related to residues of pesticides and veterinary drugs in food were addressed in the relevant Codex Committees.

131. The Delegation of Denmark pointed out that the Task Force would consider only some limited aspects of antimicrobial resistance and that a multidisciplinary approach was essential. Some delegations pointed out that antimicrobial resistance was a matter for consideration by the Committee on Residues of Veterinary Drugs in Foods. Other delegations and the Observer from IDF stressed that the expertise on microbiological hazards rested with the CCFH and that it would be appropriate to consider this issue further insofar as it related to the microbiological safety of foods.

132. The Committee agreed that this issue should be considered further at the next session, on the basis of a revised discussion paper in the form of a risk profile, to be prepared by the Delegation of Denmark, with the assistance of interested countries. Recognizing the importance of the issue, the Committee also agreed to ask the advice of the Executive Committee and the Commission on how to proceed in order to ensure coordination of work between concerned Committees.

#### **DISCUSSION PAPER ON PROPOSED DRAFT GUIDELINES FOR THE HYGIENIC REUSE OF PROCESSING WATER IN FOOD PLANTS (AGENDA ITEM 13)<sup>18</sup>**

133. The Delegation of the United States introduced the document and recalled that the last session had discussed the need to develop general guidelines or sections on water reuse in individual commodity codes. The Committee had agreed that these two approaches should be followed simultaneously and that the discussion paper considered should be redrafted for further consideration. The Delegation clarified that Annex B was included only for information purposes.

134. The Committee agreed to proceed with the elaboration of Proposed Draft Guidelines for the Hygienic Reuse of Processing Water in Food Plants at Step 3, to be drafted by the Delegation of the United States for circulation and consideration by the next session.

#### **PRIORITIES FOR THE REVISION OF CODES OF HYGIENIC PRACTICE (AGENDA ITEM 14)<sup>19</sup>**

135. The Committee recalled that priorities had been considered at the 30th Session and that it had been agreed to evaluate the need for existing codes and the opportunity to merge those which had certain common provisions. Due to its heavy programme of work, the Committee had not considered this matter at the 31st Session.

136. The Delegation of the United States pointed out that the Code of Hygienic Practice for Dried Milk should be ultimately incorporated into the Code of Hygienic Practice for Milk and Milk Products

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<sup>18</sup> CX/FH 99/13, CRD 6 (Comments of Finland and Italy)

<sup>19</sup> CX/FH 99/14, CRD 6 (Comments of Finland and Italy), CRD 15 (ALA)

(under development). The Delegation of the United Kingdom indicated that it had reviewed several codes and compared them with the General Principles of Food Hygiene and proposed that this could be used as a model for a systematic review. The Committee agreed that this would be a very useful basis to initiate work in this area and welcomed the offer of the Delegation of Australia to prepare a document on the priorities which would identify 1) which codes were superseded and 2) which codes could be combined, for consideration by the next session

## **OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 15)**

### **Proposed Draft Annex on Cleaning and Disinfection to the Recommended International Code of Practice – General Principles of Food Hygiene<sup>20</sup>**

137. The Delegation of the United States recalled that the last session was scheduled to consider a review of the earlier Annex to the General Principles of Food Hygiene and had deferred consideration of this question due to time constraints. The Delegation proposed to develop an updated Annex to provide practical advice on cleaning and disinfection of food contact and environmental material and to consider the sanitizing of raw material that is to become food.

138. The Delegation of the United Kingdom pointed out that this information was of a technical nature, would become rapidly outdated and should not be included in a code of hygienic practice. The Committee recognized that there was no support to establish the proposed Annex and agreed to discontinue work on this subject.

### **Guidelines for the Validation of Food Hygienic Control Measures<sup>21</sup>**

139. The Delegation of the United States indicated that the need for validation had been raised in the discussion on milk and milk products but that it should be addressed from a general perspective, in order to ensure the effectiveness of measures in relation to a specified level of public health protection. Some delegations supported the development of such work. The Delegation of Germany recalled that work on issues related to equivalence was underway in the framework of the Committee on Food Import and Export Inspection and Certification Systems and that duplication should be avoided.

140. The Committee agreed that the Delegation of the United States, with the assistance of Australia, Canada, France, IDF and interested countries, would prepare a discussion paper for consideration by the next session, including the rationale for validation of hygienic control measures and the type of measures that would be covered.

### **Guidelines for Evaluating the Presence of Extraneous Material and Filth in Food<sup>22</sup>**

141. The Delegation of the United States recalled that the revised hygiene provisions in commodity standards did not any longer include a reference to objectionable matter, since relevant provisions were included in the General Principles of Food Hygiene. However there was a need to develop guidance to address the presence of extraneous material in food, in view of the hazards involved, especially on the basis of recent scientific information. The Delegation proposed that this should be done through an Annex to the General Principles.

142. The Delegation of the United Kingdom pointed out that reference to wholesomeness was generally avoided in codes of practice and should be replaced with "suitability", and proposed to change the title by replacing "extraneous material and filth" with "objectionable matter". The Committee agreed that the Delegation of the United States in cooperation with Mexico should prepare a discussion paper on Guidelines for the Evaluation of Objectionable Matter for consideration by the next session.

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<sup>20</sup> CX/FH 99/15

<sup>21</sup> CRD 1

<sup>22</sup> CRD 2

**DATE AND PLACE OF THE NEXT SESSION (AGENDA ITEM 16)**

143. The Committee noted that its 33rd session was tentatively scheduled to be held in Washington, D.C. in October 2000, and the exact arrangements to be confirmed by the Host Government and Codex Secretariat.

## SUMMARY STATUS OF WORK

| <b>Subject Matter</b>  | <b>Step</b> | <b>Action by:</b>  | <b>Document reference in ALINORM 01/13</b> |
|--|-------------|--|--|
| Draft Code of Hygienic Practice for Packaged/Bottled Drinking Waters (Other Than Natural Mineral Waters)                 | 8           | <b>Governments</b> , 24 <sup>th</sup> Session of the CAC | paras 21-50 and Appendix II.               |
| Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs                       | 8           | <b>Governments</b> , 24 <sup>th</sup> Session of the CAC | paras 51-62 and Appendix III.              |
| Proposed Draft Code of Hygienic Practice for Milk and Milk Products  | 3           | <b>US</b> , 33 <sup>rd</sup> CCFH                        | paras 64-70.                               |
| Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Fruits and Vegetables | 3           | <b>Canada</b> , 33 <sup>rd</sup> CCFH                    | paras 71-86.                               |
| Proposed Draft Code of Hygienic Practice for Pre-Cut Vegetable Products Ready for Human Consumption                      | 3           | <b>France</b> , 33 <sup>rd</sup> CCFH                    | paras 87-90.                               |
| Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management                              | 3           | <b>France</b> , 33 <sup>rd</sup> CCFH                    | paras 91-102 and Appendix IV               |
| Proposed Draft Guidelines for Hygienic Reuse of Processing Water in Food Plants  | 2/3         | <b>US</b> , Governments, 33 <sup>rd</sup> CCFH           | paras 133-134                              |
| Proposed Draft Guidelines for the Control of <i>Listeria monocytogenes</i> in Foods                                      | 2/3         | <b>Germany</b> , Governments, 33 <sup>rd</sup> CCFH      | paras 119-121.                             |
| Discussion Paper on the Application of HACCP in Small and/or Less Developed Businesses                                   |             | <b>The Netherlands</b> , 33 <sup>rd</sup> CCFH           | paras 112-117.                             |
| Priorities for the Revision of Codes of Hygienic Practice  |             | <b>Australia</b> , 33 <sup>rd</sup> CCFH                 | paras 135-136.                             |
| Discussion Paper on Antimicrobial Resistant Bacteria in Food   |             | <b>Denmark</b> , 33 <sup>rd</sup> CCFH                   | paras 127-132.                             |
| Discussion Paper on the Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures                    |             | <b>US</b> , 33 <sup>rd</sup> CCFH                        | paras 139-140.                             |
| Discussion Paper on Proposed Draft Guidelines for Evaluating Objectionable Matter in Food                                |             | <b>US</b> , 33 <sup>rd</sup> CCFH                        | paras 141-142.                             |

**Appendix I**

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**Appendix II**

**DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED/PACKAGED DRINKING  
WATERS (OTHER THAN NATURAL MINERAL WATERS)**

(At Step 8 of the Procedure)

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## INTRODUCTION

International trade in bottled water has increased in recent years, both in quantity and diversity. Because of greater transport capacity, it is now possible to distribute bottled water not just as ship, rail, and road cargo but also as airfreight, the latter being used mainly in crisis situations due to the higher cost. By all these means of transport, a remedy for water shortages 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, both natural mineral water and diverse other sorts, has been brought in to meet such emergencies.

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 always be able to guarantee the microbiological, chemical and physical safety of their product to the extent previously thought possible.

The contamination of water with viruses and parasitic protozoa is a serious concern to all consumers, particularly the immunocompromised. These pathogens are difficult to detect and bacterial indicators of their potential presence are not always reliable. Therefore it may be helpful to consumers to supply information regarding control measures the water has received. Protection of natural resources and such treatments as boiling, pasteurization, distillation, reverse osmosis filtration, absolute one micron or submicron filtration are some of the control measures used to guard against, inactivate or remove possible water contaminants such as oocysts of *Cryptosporidium parvum*, *Cyclospora cayentanensis*, and *Toxoplasma gondii* and cysts of other waterborne parasitic protozoa such as *Giardia (lamblia) intestinalis*, and *Entamoeba histolytica*.

It may be necessary that bottled drinking water products of particular chemical composition provide information concerning their proper consumption and/or have directions regarding whether or not they are suitable for infants and for the rehydration of infant formula.

## SECTION II SCOPE, USE AND DEFINITIONS

### 2.1 SCOPE

This Code recommends general techniques for collecting, processing, 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). All bottled/packaged drinking waters other than natural mineral water are covered by this Code.

### 2.2 USE OF THE DOCUMENT

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)), including the HACCP Annex, whose paragraph numbers and section headings it maintains, supplementing or specifically applying them to bottled drinking waters (other than natural mineral waters). This Code should also be used in combination with the Principles for the Establishment of and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

## 2.3 DEFINITIONS

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

**Bottled/package drinking water** - Water filled into hermetically sealed containers of various compositions, forms, and capacities that is safe and suitable for direct consumption without necessary further treatment. Bottled drinking water is considered a food. The terms “drinking” and “potable” are used interchangeably in relation to water.

**Drinking water systems** - Public or private systems providing the consumer with tap water safe and suitable for direct consumption.

**Establishment** - Any suitable 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/package drinking water.

**Food handling** - Any operation pertaining to collecting, processing, bottling, packing of bottles, storing, transporting, distributing and marketing of bottled drinking water.

**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.

**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 safe and suitable for human consumption without further treatment).

**Surface water** - Waters open to the atmosphere such as streams, rivers, lakes, ponds and reservoirs.

## SECTION III PRIMARY PRODUCTION

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

Prior to using a water resource for bottling purposes, its chemical composition and microbiological safety should be established over an appropriate period to allow for variations.

### 3.1 ENVIRONMENTAL HYGIENE

#### 3.1.1 Precautions in selecting a resource site

Hydrogeological data should determine the watershed and the perimeter (area surrounding the body of water from which supplies are drawn or the water’s point of origin in the ground) that can be sources of contamination. These critical areas should be protected as much as possible.

All possible precautions should be taken within the protected perimeter (zone of protection) to avoid any pollution of, or external influence on, the quality of the ground or surface water. Disposal of liquid, solid or gaseous waste that could pollute the ground or surface water should be controlled. Disposal of pollutants such as microorganisms, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic and inorganic substances in the watershed should be avoided. Nor should drinking water resources 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 Considerations 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, where necessary, radiological characteristics. The frequency of testing is determined by the hydrogeological evaluation, the amount of water collected, and the historical constancy pattern of a particular water supply. If contamination is detected, production of bottled water should cease until the water characteristics have returned to established parameters. Any underground supply from which 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**

Surface waters intended for bottling should be protected from contamination to the fullest extent possible even when treatments follow. Surface waters may be highly variable, so supplies should be tested frequently.

#### ***3.2.2.1 Considerations for surface water supplies***

Stringency in determining which surface waters are suitable for bottling should be the rule, even when treatment(s) is foreseen.

## **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. Where sampling points are necessary, they should be designed and operated to prevent any contamination of the water.

#### ***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 only authorized persons. Wellheads and spring outflows should be protected by a suitable structure to prevent entry by unauthorized individuals, pests, dust and other sources of contamination such as extraneous matter, drainage, floodwaters, and infiltration water.

### **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 properly disinfected following construction and development of new wells nearby, after pump repair or replacement, or any well maintenance activity such as testing for and finding indicator organisms, pathogens, or abnormal plate counts in the water, and whenever biological growth inhibits proper operation. Water collection chambers should be disinfected within a reasonable time before use. Extraction devices such as those used for bore holes should be constructed and maintained in a manner that avoids contamination of the water 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.

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 *Draft Code of Hygienic Practice for Bulk Transport of Food and Semi-Packaged Foodstuffs*. Directing the supply of water through piping from the point of origin wherever possible is one of the means of avoiding risks of 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**

Means of transport of 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. When this cannot be achieved, conveyances and bulk containers should be used exclusively for food transportation and must be cleaned and disinfected as necessary to prevent contamination. See also *Code of Hygienic Practice for the Transport of Bulk and Semi-Packed Food*.

## **SECTION IV ESTABLISHMENT: DESIGN AND FACILITIES**

These guidelines are supplemental to those set forth in Section IV 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, specific preventive measures should be incorporated into the facility's design to avoid contamination of the containers used for bottled water.

## 4.4 FACILITIES

### 4.4.1 Water supply not intended for bottling

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

Water intended for bottling should be carried in completely separate lines from water not intended for bottling. These lines should be identified, preferably by different colours. There must be no cross-connections. Water used for cleaning and disinfection, should be potable (the standards of potability should not be less than those contained in the latest edition of the WHO Guidelines for Drinking Water Quality) if there is a chance that it comes into direct or indirect contact with water that is intended for bottling; otherwise it may be non-potable (if used where there is no direct or indirect contact with water for bottling). For storage, the provision in the Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3 (1997)) apply.

## SECTION V ESTABLISHMENT: CONTROL OF OPERATION

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

Water is an excellent vehicle for carrying substances in soluble, dispersed or emulsified form. Control measures must be taken at all steps of processing to ensure that food safety and suitability are not compromised by hazards or other contaminants during operations.

### 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

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 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 should be accepted by an establishment if it is known to contain pathogens or excessive residues of pesticides or other toxic substances.

Water intended for bottling should be such (i.e., microbiologically, chemically, physically, and radiologically), that treatment if necessary (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 suitable for consumption. Generally, the higher the quality of the water intended for bottling, the less treatment is required to produce safe bottled drinking water products. Surface waters should be tested for safety frequently and treated as necessary.

A hazard analysis which takes into consideration pathogens and toxic substances should be undertaken in the overall context of the application of principles such as HACCP to the production of bottled water. This should provide the basis for determining the appropriate combination of control measures to reduce, eliminate or prevent, as necessary, hazards (microbiological, chemical and radiological) for the production of safe bottled water. Waters originating from protected underground supplies are less likely to require treatment than waters originating from surface supplies or unprotected underground supplies.

When necessary, treatment of waters intended for bottling, to reduce, remove or prevent growth of pathogens, 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 pathogens of public health concern.

When necessary, treatments to remove or reduce chemical substances may include chemical and particulate (mechanical) filtration such as achieved with surface filters (e.g., pleated membrane filters) or depth filters (e.g., sand or compressed fibre (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 particulate matters.

All treatments of water intended for bottling should be carried out under controlled conditions to avoid any type of contamination, including the formation of toxic by-products (particularly bromates) and the presence of residues of water treatment chemicals in amounts that raise health concerns in accordance with relevant WHO guidelines.

#### **5.4 PACKAGING**

The requirements in the Recommended International Code of Practice – General Principles of Food Hygiene, (CAC/RCP 1-1969, Rev. 3 (1997)) cover these topics.

##### **5.4.1 Washing and Disinfecting of Containers**

Reused containers and where necessary other containers should be washed and disinfected in an appropriate system and positioned within the processing plant so as to minimize post-sanitizing contamination prior to filling and sealing. Disposable containers may be ready for use without prior washing and disinfecting. Determine if this is the case; if not, treat as carefully as reusable containers.

##### **5.4.2 Filling and sealing of containers**

Bottling operations (i.e., filling and sealing of containers) should be conducted in a manner that protects against contamination. Control measures include the use of an enclosed area and a containment enclosed system separate from other operations of the processing plant to protect against contamination. Dust, dirt, microorganisms in the air, and condensation should be controlled and monitored.

##### **5.4.3 Product containers and closures**

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 containers should be inspected and, if necessary, cleaned and disinfected.

##### **5.4.4 Use of Closures**

Closures are generally supplied in a ready to use state and should be tamper resistant; they are not reusable.

### **SECTION VI ESTABLISHMENT: MAINTENANCE AND SANITATION**

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997)) cover these topics.

### **SECTION VII ESTABLISHMENT: PERSONAL HYGIENE**

The requirements in the *Recommended International Code of Practice - General Principles of Food Hygiene*, (CAC/RCP 1-1969, Rev. 3 (1997)) cover this topic.

### **SECTION VIII TRANSPORTATION AND STORAGE OF BOTTLED WATER**

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

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## **SECTION IX PRODUCT INFORMATION AND CONSUMER AWARENESS**

These requirements are covered in the *Recommended International Code of Practice - General Principles of Food Hygiene*, (CAC/RCP 1-1969, Rev. 3 (1997)). See also the text in the Introduction of this document.

## **SECTION X TRAINING**

The requirements made in the *International Recommended Code of Practice - General Principles of Food Hygiene*, (CAC/RCP 1-1969, Rev. 3 (1997)) cover this topic.



## **APPENDIX 1- MICROBIOLOGICAL AND OTHER SPECIFICATIONS**

Section 5.2.3 Microbiological and Other Specifications of the *International Recommended Code of Practice - General Principles of Food Hygiene*, (CAC/RCP 1-1969, Rev. 3 (1997) applies.

The provisions of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) apply.

Microbiological and additional specifications for bottled drinking waters (other than natural mineral waters) are those of the World Health Organization *Guidelines for Drinking Water Quality*.

**Appendix III****DRAFT CODE OF HYGIENIC PRACTICE FOR THE TRANSPORT OF FOOD IN BULK AND SEMI-PACKED FOOD***(At Step 8 of the Procedure)*

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**INTRODUCTION**

Food may become contaminated or reach their destination in an unsuitable condition for consumption unless control measures are taken during transport. Such condition may occur even where adequate hygiene measures have been taken earlier in the food chain. Adequate transportation systems should be in place which will ensure that foods remain safe and suitable for consumption upon delivery and assist countries to assure continued trade.

Good communication between shipper/manufacturer, transporter and receiver of foods is essential. They share responsibility for food safety on this part of the food chain. Food manufacturers or receivers are responsible for communicating to transporters specific food safety control procedures required during transportation.

This document is formatted in accordance with the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3 (1997)), which must be consulted in the use of this Code. Those sections of this Code that require specific food safety requirements beyond those contained in the Recommended International Code of Practice - General Principles of Food

Hygiene (CAC/RCP 1-1969, Rev.3 (1997)), due to specific transportation characteristics, are noted and the specific requirements are detailed.

This code applies without prejudice to more specific provisions relating to bulk transport in sectors covered by specific commodity codes.

## SECTION I - OBJECTIVES

The code of hygienic practice for the transport of bulk and semi-packed foods:

- identifies additional requirements of food hygiene applicable to the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3 (1997)) applicable to the condition of the food transportation unit and the loading, transport, in-transit storage and unloading of bulk and semi-packed foods to ensure that food remains safe and suitable for human consumption.
- indicates how to implement these controls, and
- provides ways to verify that these controls have been applied.

## SECTION II - SCOPE, USE AND DEFINITIONS

### 2.1 SCOPE AND USE

This code of practice covers the condition of the food transportation unit, loading, transport, in-transit storage and unloading of bulk, semi-packed foods and fresh produce. This code covers food transportation unit and product from the points of shipment to the points of receipt. Examples of foods included in this code include:

- Food transported from the packaging or processing facility to a retail/distribution establishment,
- Food that is transported directly from the field to a market or distribution centre,
- Food transported from one process/distribution facility to another or from a process/distribution facility to another or from a process/distribution facility to a retail establishment,
- Food transported from collection points, elevators, storage facilities, etc., to processing plants/distribution sites, or retail markets.

This code does not cover growing and gathering or fishing operations that occur prior to loading product into the food transportation unit for shipment, nor does it cover in-plant conveyance of product that occurs after unloading or after off-loading and emptying. Examples of foods excluded from this code are the following:

- On farm movement of a product,
- Movement from the field to collection facility, packaging facility, or storage facility.

The code's provisions are to be applied in addition to all applicable provisions of the Recommended International Code of Practice - General Principles (CAC/RCP 1-1969, Rev. 3 (1997)) including Section 8 that specifically addresses transportation.

### 2.2 DEFINITIONS

**Food transportation unit:** Includes food transport vehicles or contact receptacles (such as containers, boxes, bins, bulk tanks) in vehicles, aircraft, railcars, trailers and ships and any other transport receptacles in which food is transported.

**Bulk:** Means unpacked food in direct contact with the contact surface of the food transportation unit and the atmosphere (for example, powdered, granulated or liquid form).

**Semi-packed food:** Semi-packed food is a food which might come in direct contact with the food transportation unit or the atmosphere (e.g. vegetables and food in crates and bags).

### SECTION III PRIMARY PRODUCTION

All sub-sections of the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

### SECTION –IV ESTABLISHMENT: DESIGN AND FACILITIES

All sub-sections of the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

### SECTION V - CONTROL OF OPERATION

#### 5.1 CONTROL OF FOOD HAZARDS

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

##### 5.1.1 Identification of potential hazards

It may be useful to refer to the listed questions (see Table 1) to identify and manage hazards during transport of bulk and semi-packed foods. Reference is made also to the HACCP approach.

**Table 1**

|   |
|---|
| Is the food "ready for direct consumption"?   |
| Are the conditions of the food transportation unit likely to introduce or support the increase of a hazard? |
| Is it likely, that a hazard is introduced or increased during loading?                                      |
| Is it likely, that a hazard may increase during transport or storage in the food transportation unit?       |
| Is it likely, that a hazard is introduced or increased during unloading?                                    |

##### 5.1.2 Records of prior cargoes and prior cleaning

The transporter should maintain records, readily available at the food transportation unit or as prescribed by the official agency having jurisdiction, of the three most recent prior cargoes and cleaning and disinfection, where necessary, method employed of the food transportation unit including volumes transported and make this information, on request, available to the food shipper, official control authorities and/or receiver/food manufacturers, for evaluation of potential hazards.

A complete record of previous cargoes should be kept over a period of six months by the transporter.

##### 5.1.3 Sources of hazards

The possibility of a hazard should be considered from the following sources, cited as examples:

### **5.1.3.1 Hazards related to the food transportation unit**

Unsuitability of the construction material and coating, lack of sealing/locking device, residues of previous cargoes, residues from cleaning and sanitizing materials.

Where appropriate consideration should be given to food transportation unit's dedicated to single commodity use.

### **5.1.3.2 Hazards related to loading and unloading**

Increase/decrease of temperature of the food. Undesirable introduction of microbes, dust, moisture, or other physical contamination.

### **5.1.3.3 Hazards related to transport**

Leakage of heating/cooling fluid. Break down of temperature control.

## **5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS**

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **5.3 INCOMING MATERIAL REQUIREMENTS**

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **5.4 PACKAGING**

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **5.5 WATER**

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **5.6 MANAGEMENT AND SUPERVISION**

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **5.7 DOCUMENTATION AND RECORDS**

Suitable controls can be formulated by shippers or receivers to ensure food safety during transport in particular cases (see questions in Table 1). Such controls should be communicated in writing. Documentation is an important tool for validation and for verification that the principles have been adhered to. This documentation may include food transportation unit number, registration of previous loads, temperature/time recordings and cleaning certificates. Such documentation should be available to the official agencies having jurisdiction. It should be noted that some food transportation unit's are intended for single use only.

## **5.8 RECALL PROCEDURES**

The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **5.9 DEDICATED TRANSPORT**

Where appropriate, particularly bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

Bulk food in liquid, granulated or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of food unless the application of principles such as HACCP demonstrates that dedicated transport for these products is not necessary to achieve the same level of food safety.

## **SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION**

All sub-sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

Food transportation unit's, accessories, and connections should be cleaned, disinfected (where appropriate) and maintained to avoid or at least reduce the risk of contamination. It should be noted that depending on the commodity relevant, different cleaning procedures are applicable, which should be recorded. Where necessary, there should be disinfection with subsequent rinsing unless manufacturers instruction indicates on a scientific basis that rinsing is not required.

## **SECTION VII ESTABLISHMENT: PERSONAL HYGIENE**

All sub-sections of the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

The General Principles of Food Hygiene should apply to all personnel in contact with the food.

## **SECTION VIII TRANSPORTATION**

All sub-sections of the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

### **8.4 FOOD TRANSPORTATION UNITS**

The design of the food transportation unit should be such as to avoid cross contamination due to simultaneous or consecutive transport. Important aspect are cleanability and appropriate coatings.

Construction and design of the food transportation unit should facilitate inspection, cleaning, disinfection and when appropriate enable temperature control.

Use of means for cooling or heating should by design and construction be such as to avoid contamination. Although hot water and steam are preferred means of heating, other substances may be used on the basis of safety and risk evaluation and inspection procedures. Upon request by the competent authority, evidence may be required to demonstrate that the heating media employed have been properly evaluated and safely used.

Inner surface materials suitable for direct food contact should be used. These should be non-toxic, inert, or at least compatible with the transported food, and which do not transfer substances to the food or adversely affect the food. Stainless steel or surface coated with food-grade epoxy resins are most suitable. The interior design should eliminate areas that are difficult to access and clean.

The appropriate design of the food transportation unit should assist in preventing access of insects, vermin, etc, contamination from the environment, and when necessary, providing insulation against loss or gain of heat, adequate cooling or heating capacity, and facilitation of locking or sealing.

There should be appropriate facilities conveniently available for cleaning and, where appropriate disinfecting of the food transportation unit.

Auxiliary equipment should be (where appropriate) subjected to the above stated requirements.

To maintain sanitary conditions, facilities should be provided for the storage of pipes, hoses and other equipment used in the transfer of foods.

## **SECTION IX PRODUCTION INFORMATION AND CONSUMER AWARENESS**

All sub-sections of the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

## **SECTION X TRAINING**

All sub-sections of the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3 (1997)) and, as appropriate, other Codex Codes of Hygienic Practice, shall be applied.

It is important that personnel responsible for the transport are well aware of the nature of the foods that are being handled/transported and the possible extra precautionary measures that may be required. Personnel should be trained on food transportation unit inspection procedures for food safety.

**Appendix IV**

**PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF  
MICROBIOLOGICAL RISK MANAGEMENT AT STEP 3**

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## INTRODUCTION

Risks from microbiological hazards are of immediate and serious concern to human health. Microbiological Risk Analysis is a process consisting of three components: Risk Assessment, Risk Management and Risk Communication, which has the overall objective to ensure public health protection. This document deals with Risk Management, which is a key element in assuring the control of microbiological hazards in food.

The following principles and guidelines present the different elements of microbiological risk management, indicating what should be considered at each step of the process. These guidelines and principles are intended to be used by public authorities. However, they are useful for risk managers in industry, in order to apply a common framework for microbiological risk management.

### 1. SCOPE

These principles and guidelines provide a framework for the management of risks arising from the occurrence of microbiological hazards in foods.

### 2. DEFINITIONS

The definitions cited here are to facilitate the understanding of certain words or phrases used in this document.

**[Food Safety Objective** - A statement expressing the level of hazard in a food that is tolerable in relation to an appropriate level of protection.]

**Hazard** - A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect<sup>1</sup>.

**Risk** - A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food<sup>1</sup>.

**Risk Analysis** - A process consisting of three components: risk assessment, risk management and risk communication<sup>1</sup>.

**Risk Assessment** - A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization<sup>1</sup>.

**Risk Assessment Policy** -- Guidelines for value judgement and policy choices which may need to be applied at specific decision points in the risk assessment process<sup>2</sup>.

**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<sup>1</sup>.

**Risk Communication**<sup>3</sup> - The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

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<sup>1</sup> Codex Alimentarius Commission Procedural Manual, 10<sup>th</sup> edition, pages 44-45

<sup>2</sup> To be developed by the Codex Committee on General Principles

<sup>3</sup> ALINORM 99/37, para. 70 and Appendix IV.

**Risk Management**<sup>3</sup> - The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

### 3. GENERAL PRINCIPLES

The following principles apply to the conduct of microbiological risk management:

- PRINCIPLE 1: Protection of human health should be the primary consideration in risk management decisions.
- PRINCIPLE 2: Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- PRINCIPLE 3: Risk management processes should be structured.
- PRINCIPLE 4: Processes and decisions should be transparent and fully documented;
- PRINCIPLE 5: Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment. In this respect there should be a clear determination of risk assessment policy before risk assessment commences.
- PRINCIPLE 6: Risk managers should take into account the uncertainty of the risk estimate when making risk management decisions.
- PRINCIPLE 7: In case where scientific knowledge on the risks is insufficient, risk management decisions may be adopted on an interim basis as part of a precautionary approach.
- PRINCIPLE 8: Arriving at a risk management decision should follow a structured process and must include identification of available risk management options and their likely impact on mitigating risk to human health.
- PRINCIPLE 9: Risk management decisions should address the whole farm to table continuum, including imported foods.
- PRINCIPLE 10: Risk managers should ensure that any control measures that are to be implemented are optimal regarding their feasibility, efficiency and are proportionate.
- PRINCIPLE 11: Risk management should be a continuing process that takes into account all newly generated data. Such data include new information on the virulence of the organism, the incidence and level of the organism in foods, the extent of sensitive populations, changes in dietary intake pattern, changes in food processing patterns, as well as epidemiological data and foodborne disease surveillance programs.
- PRINCIPLE 12: The efficiency of risk management measures has to be periodically assessed with regards to the risk management goals. As appropriate these measures have to be reviewed.

### 4. INVOLVEMENT OF STAKEHOLDERS

The involvement of stakeholders<sup>4</sup> in the risk management process is essential in order to ensure a transparent and effective process. Stakeholders involvement provides opportunities for interactive exchange of information and opinion about risk. It may also help to bridge gaps in understanding, to

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<sup>4</sup> Stakeholders means interested parties.

contribute to the sharing of values and perceptions, and to facilitate the exchange of information and ideas that enable all parties to make informed decisions;

Stakeholders may include, but not be limited to, governmental bodies, consumer organizations, representatives of the food industry and trade organizations, and representatives of education and research institutions.

Involvement of stakeholders can be implemented in many ways, ranging from public meetings to opportunities to comment on public documents.

The nature, extent, and complexity of stakeholders involvement should be appropriate to the urgency with which the problem must be addressed, the complexity and the uncertainties of the problem, the scope and impact of the decisions to be taken and the potential for the decision to generate misunderstanding or controversy.

The risk management decisions should be fully and systematically documented and available to all interested parties on request, in order to ensure transparency.

## **5. GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT**

Microbiological risk management should include the following steps:

### **5.1. INITIAL RISK MANAGEMENT ACTIVITIES**

#### **5.1.1. Identification of risk managers**

Public authorities play a pivotal role in microbiological risk management. However in many situations, risk management responsibilities should or may evolve among other stakeholders.

#### **5.1.2. Identification a problem**

A microbiological public health problem may already be well recognized or may be a latent or a new problem.

Methods and indicators to identify problems may include data on the presence, prevalence and concentration of hazards in the food chain and in the environment, disease surveillance information, epidemiological studies, clinical studies, laboratory studies, production practices including process innovation, lack of compliance with standards, expert and public opinion.

Problem identification may be performed by a single stakeholder (e.g. the public authority) or be a result of collaboration between different stakeholders.

A formal risk assessment management process as outlined in this document should normally not be undertaken for food hygiene situations that can be routinely handled or expeditiously managed by applying the "Recommended International Code of Practice: General Principles of Food Hygiene" or a specific commodity codes of hygienic practice".

#### **5.1.3. Risk profile**

Elaboration of a risk profile, that is describing a microbiological food safety problem and its context, is essential for effective risk management. Elaboration of a risk profile is a situation analysis used to determine the size and nature of the problem and what action(s) may be necessary, including whether a risk assessment should be carried out. A typical microbiological risk profile might include a brief description of the situation, the products or commodities involved, what is expected to be at risk (e.g. human health, economic concerns), the potential consequences of actions taken, the consumer perception of the risks, and the distribution of risks and benefits.

Describing a microbiological problem can involve the following:

- delineating which microbiological hazard(s) are causing the problem and the difficulty in controlling them;

- determining the source of the microbiological hazard(s), e.g.; from the entire food chain (including imported food), the environment, travel, animal contact and person to person transmission);
- considering available prevalence and concentration data from the whole food chain;
- considering disease incidence data and identifying the types and severity of the adverse effects;
- determining which populations may be affected (for example, at risk groups such as the elderly, infants and children, the immune-compromised, or those whose exposure to the microbial hazard may be increased due to dietary intake; socioeconomic status, or other characteristics);
- identifying how stakeholders perceive the problem.

#### **5.1.4. Defining goals**

The goals for a microbiological risk management activity should be identified as early as possible to guide the rest of the decision making process. However, it has to be kept in mind that the results of the risk assessment phase and subsequent steps of risk management may lead managers to modify or redefine goals.

Goals of a microbiological risk management should be risk related; they may also involve public values; they may be directed by statute, policy or regulatory considerations, or economic constraints. One management goal can be to establish Food Safety Objectives (FSOs) and gain their benefit in implementing risk management decisions.

Resolving the issue of who should be the microbiological risk managers should preferably be done at this early stage, though this may not be evident until the risk management options have been identified.

#### **5.1.5. Scope, range and risk assessment policy**

Microbiological risk assessment policy setting is a management responsibility. It serves to protect the essential scientific independence and integrity of the microbiological risk assessment. It should be carried out in full collaboration between risk managers and risk assessors.

Typically, a microbiological risk assessment policy should address the issues of transparency -and "unbiasedness" in the risk assessment process as well as the issues of clarity, consistency and reasonableness in the risk assessment products. In particular, risk assessment policy should determine the essential elements that the risk characterization will incorporate and provide guidelines for dealing with uncertainties (e.g. application of safety factors), for value judgements or policy choices, and make provisions for apportionment of adequate resources and for peer review.

#### **5.1.6. Commissioning of microbiological risk assessment**

To achieve alignment between the risk assessment process and the needs of the risk managers it is necessary to clearly define the issues that the assessors should address. To this end; the results of effective communication between assessors, the decision makers and the stakeholders prior to initiating a microbiological risk assessment should include a clear statement of the purpose and scope of the assessment. This statement must reflect the previously articulated risk management goals to ensure that the risk assessment provides the information needed by the risk manager. For example, the scope of the assessment may be limited to a specific product-pathogen pair, and the purpose of the assessment may be to reach a decision on a regulatory proposal regarding the level of a pathogen in a ready-to-eat product at the point of consumption to attain a pre-specified level of protection with a high degree of confidence.

Once the purpose and scope of the risk assessment have been defined, the assessment should follow the framework identified in the Codex *Principles and Guidelines for the Conduct of a Microbiological Risk Assessment* (CAC/GL-30 (1999)).

## **5.2 RISK MANAGEMENT OPTIONS ASSESMENT**

### **5.2.1 Consideration of the process and the results of the microbiological risk assessment**

For the best use of a microbiological risk assessment product, managers should be fully informed of the strengths and limitations of the risk assessment. To that aim, communication of the following points with regard to the microbiological risk assessment is important:

- all assumptions should be fully acknowledged and their impact thoroughly considered or recognized;
- all risk characterizations should explicitly address sources of variability and sources of uncertainties;
- estimates should be a range of risk estimates based on different data and assumptions as judged by scientists rather than the presentation of a single risk estimate. Narratives should accompany risk characterizations and be fully communicated and/or explained to users;
- risk characterization should address both the present situation and the range of reasonable options (risk reduction) or possible alternatives (substitution risks). Additionally, it may be helpful for risk characterization to include a discussion on how the specific microbiological risk under consideration compares with other health risks.

### **5.2.2 Identifying the level of tolerable risk**

Microbiological risk management options assessment should involve identifying the level of tolerable risk.

The level of tolerable risk will define the appropriate control measures.

Determining the tolerable level of risk should be an on going exercise, and may involve considerations of the following:

- the risk assessment including the magnitude, severity and reversibility of the health effects and its attendant uncertainties, and the possibility of susceptible subpopulations;
- the magnitude of nutritional benefits of a product;
- substitution risks, including chemical, physical and biological risks that may arise from microbiological risk management interventions;
- technical feasibility of prevention and control options;
- cost of prevention and control versus effectiveness of risk reduction;
- public risk reduction preferences, [public values].

### **5.2.3. Regional considerations**

For the sake of human health protection and to minimize the incidence of food-borne diseases, the existence of regional differences in the prevalence of various food-borne pathogens in the food chain could be recognized and could be taken into account in the risk management process.

Principles which apply in this regard include the following:

- risk management should be based on microbiological prevalence data from the whole food chain and, if appropriate, disease incidence data;
- risk management should take into account the existence of regional differences in the prevalence of food-borne pathogens in the food chain;
- ranking of hazards can be carried out at the national, regional or international level.

#### **5.2.4. Identification of available options**

Microbiological risk management options assessment should be aimed at setting protective goals in terms of risk reduction in a range between unacceptable and negligible magnitudes of risk.

The primary objective of microbiological risk management options assessment is an optimization of the interventions necessary to prevent and to control microbiological risks. It is aimed at selecting the option or options that achieve the chosen level of public health protection for the microbiological hazard in the commodity of concern in as cost effective manner as possible within the technical feasibility of the industry.

There might be many different approaches to measures reducing microbiological risks such as:

- avoiding foods with a substantiated history of contamination or toxicity;
- preventing contamination and/or introduction of pathogens at any stage in the food chain including reducing the level of specific pathogens in primary production;
- preventing growth of pathogens by the combined action of extrinsic factors (e.g. chilling or freezing) and/or intrinsic factors (e.g. adjusting pH, Aw; adding preservatives; employing microbiological competition);
- destroying pathogens (e.g. cooking, irradiation);
- establishing regulatory requirements and/or creating incentives for changes in attitudes that will contribute to risk reduction;
- educating / informing the population at large or affected sub-groups about the steps they can take to reduce risks.
- Usually, a combination of options will be more effective in reducing risks.
- Different tools might be available to conduct these approaches, such as:
  - establishing microbiological standards or other criteria and enforcing compliance;
  - establishing food safety objectives;
  - the precautionary principal.

##### **5.2.4.1. Food Safety Objectives**

[A Food Safety Objective (FSO) can be a useful tool in the microbiological risk management.

The function of a FSO is to express the level of a hazard in a food that is tolerable in relation to an appropriate level of consumer protection. This is reflected in the following working definition:

A FSO is a statement based on a risk analysis process, which expresses the level of a hazard in a food that is tolerable in relation to an appropriate level of protection.

When justified by the risk assessment, the FSO should express the level of the hazard as its maximum tolerable frequency and/or concentration.

The FSO must be technically achievable and practicable.

Decisions on acceptable levels of risk should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. Consideration of other factors (e.g. economic costs, benefits, technical feasibility, and societal preferences) may be appropriate in some risk management contexts, particularly in the determination of measures to be taken. These considerations should not be arbitrary and should be made explicit.

FSOs should contain three components: type of food, hazard of concern and the appropriate level of consumer protection<sup>5</sup>. The appropriate level of consumer protection is a reflection of a particular country's public health goals relative to the application of sanitary measures.

For foods in international commerce the appropriate level of protection represents a consensus of what participating countries or governments are willing to tolerate in relation to their food supplies. Once a consensus has been reached on what is considered appropriate, it should be incorporated into an FSO for communication to all affected parties. Industry and regulatory authorities should then adjust their control and inspection systems to meet the FSO.

FSOs are food safety management tools, which can provide a number of functions. A few examples are:

- FSOs provide a reference for the overall design of good hygienic practices and HACCP based food control systems;
- FSOs provide a target for the validation of sanitary measures for segments of food production systems, or for food production systems in their entirety;
- FSOs may form the basis for derivation of performance and hazard criteria for steps in a food production system.

Because significant differences in the occurrence of food borne pathogens can be found between different countries regions, FSOs in general and more specifically sampling plans, criteria etc, should not be considered universally common but should take into account national and regional situations.]

#### **5.2.4.2. Precautionary principle<sup>6</sup>**

**[Precautionary Principle** - A decision making approach which may be applicable when there is a suspicion of adverse effects but where there is no evidence as to the existence or extent of risks to human health, leading to protective measures without having to wait until the reality and seriousness of risks to human health become apparent.]

#### **5.2.5. Selection of preferred microbiological risk management option**

Once identified, potential options should be assessed by risk managers and by stakeholders.

In this assessment process, the protection of human health, based on scientific knowledge of the microbiological hazards and the scientific understanding of the primary production and processing technology, should be the primary consideration.

However, other important elements should be considered, as appropriate. These elements could include technical and economical feasibility, cost-effectiveness of alternative approaches to limiting risk, and the acceptable level of risk, taking into account all stakeholders preferences.

The assessment should also consider whether an option may cause adverse consequences such as:

- the potential for an option to increase one type of risk (e.g. chemical risk) while reducing the microbiological risk of concern; or
- the potential for an option to impact the nutritional status of the population;
- the potential for an option to disregard a population group's preferences.

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<sup>5</sup> *The appropriate level of protection is a reflection of a particular country's public health goals relative to application of sanitary measures. Decisions on appropriate levels of risk should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. The statement of appropriate level of sanitary protection in the WTO SPS Agreement is "The level of protection deemed appropriate by the Member establishing a sanitary measure to protect human health. NOTE - Many Members otherwise refer to this concept as the acceptable level of risk."*

<sup>6</sup> To be developed

### **5.2.6. Final management decision**

Which option or combination of options is optimal depends on each particular situation.

From a general point of view and in order to be meaningful and practicable, the final management decision should:

- address the whole farm to table continuum;
- be based on the best available scientific, technical and economic information;
- be feasible, with benefits reasonably related to costs;
- give priority to preventing risks, not just controlling them;
- be enforceable within the country's legal and regulatory structure.
- account for the level of risk, deemed appropriate by risk managers, considering all stakeholders preferences.

## **6. GUIDELINES FOR IMPLEMENTATION OF MICROBIOLOGICAL RISK MANAGEMENT DECISIONS**

The implementation of microbiological risk management decisions will take different forms depending upon the options that have been decided.

In some situations, it may be preferable to utilize historical regulatory approaches. These approaches may be most successful in ensuring that fundamental good manufacturing practices are maintained. The most traditional tools for implementing microbiological risk management decision have been regulatory command and control or periodic inspection/end product testing that is enforced through penalties for non-compliance. While this system has resulted in significant reduction to the contamination levels in foods, it presents certain limitations. These systems place the burden of compliance with the regulatory authority rather than with the food manufacturer and the consumer. Where a consistent amount of pathogen level reduction has already been achieved, the rigidity of existing systems cannot provide the flexibility for tailoring remedies to individual situations in a cost effective manner.

In most cases, however, an integrated systems approach to ensuring the safety of foods is preferable. Risk management decisions should address the entire farm to table continuum. ACCP, in combination with necessary prerequisites is one such system. Such an approach places the responsibility for ensuring safe foods with the manufacturer, effectively using regulatory resources to provide the necessary oversight.

[FSOs may function as important management tools in the implementation of risk management decisions. FSOs communicate to food producers the level of safety that should be achieved and facilitate the optimal use of limited regulatory resources.]

In the field of food microbiology, microbiological testing against microbiological criteria (whether included in regulations as standards or only advisory) has been widely used as a management tool to determine the acceptability of products in trade. Microbiological criteria retain their value as a possible implementation tool of microbiological risk management decisions. However, end product testing is limited in its ability to assess the safety of food and can not adequately assure the absence of pathogens. The inherent low prevalence of most food borne pathogens makes it statistically impossible for end product testing to ensure the safety of foods. Microbiological testing is most properly utilized to verify the proper implementation of HACCP or to assess problems either where HACCP has not been employed or where access to HACCP verification information is limited or unavailable. When consideration is being given to the utilization of microbiological criteria, reference should be made to the Codex document, *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).



## **7. MONITORING AND REVIEW**

Risk managers should periodically determine that risk management measures have been implemented. Moreover, they should periodically evaluate the effectiveness of measures taken.

Tools used to evaluate the risk management process may include reviewing the effectiveness of the regulatory control programs, and reviewing information relating to the food borne pathogen(s) targeted for control such as disease surveillance or research, re-analysis of costs and benefits and discussion with stakeholders.

For appropriate implementation of this stage of the microbiological risk management process, a plan should specify when evaluation should be conducted, who will conduct it and what will be evaluated.

Evaluation might first focus more on effectiveness and progress implementing the microbiological risk reduction. Later, evaluations may focus on the success of the microbiological risk management actions in reducing risk.

Results of monitoring and/or new information may warrant repeating part of the risk management and/or the risk assessment activities to ensure that the on-going risk management program remains effective.