

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 99/13A

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION**

Twenty-Third Session
Rome, 28 June – 3 July 1999

**REPORT OF THE THIRTY-FIRST SESSION OF THE
CODEX COMMITTEE ON FOOD HYGIENE**

Orlando, United States, 26 – 30 October 1998

NOTE: This report includes Codex Circular Letter CL 1998/40-FH

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CX 4/20.2

**CL 1998/40-FH
November 1998**

TO: - Codex Contact Points
- Interested International Organizations
- Participants at the 31st Session of the Codex Committee on Food Hygiene

FROM: - Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the 31st Session of the Codex Committee on Food Hygiene (ALINORM 99/13A)**

The report of the Thirty-first Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-third Session of the Codex Alimentarius Commission (Rome, 28 June – 3 July 1999).

MATTERS FOR ADOPTION BY THE 23rd SESSION OF THE CODEX ALIMENTARIUS COMMISSION

DRAFT GUIDELINES AT STEP 8 OF THE PROCEDURE

1. *Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment (para. 34, Appendix II)*

Governments and international organizations wishing to propose amendments or to comment on the above document 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 (see Procedural Manual of the Codex Alimentarius Commission, Tenth Edition, pages 24-25) to the Secretary, Codex Alimentarius Commission, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: 39 06 570 54593, email: Codex@fao.org) **before 31 March 1999.**

DRAFT CODE OF PRACTICE AT STEP 5 OF THE ACCELERATED PROCEDURE

2. *Draft Amendment to the International Recommended Code of Practice - General Principles of Food Hygiene (Section 6.1.2) (para. 14, Appendix III)*

Governments and international organizations wishing to submit comments on all aspects of the Draft Amendment, including possible implications for their economic interests should do so in writing in conformity with the Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (see Procedural Manual of the Codex Alimentarius Commission, Tenth Edition, pages 22-23) to the Secretary, Codex Alimentarius Commission, FAO, via delle Terme di Caracalla, 00100 Rome, Italy (fax: 39 06 570 54593, email: Codex@fao.org) **before 31 March 1999.**

PROPOSED DRAFT CODE AT STEP 5 OF THE PROCEDURE

3. *Proposed Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs (para. 52, Appendix IV)*

Governments and international organizations wishing to submit comments on the implications which the Proposed Draft Code may have for their economic interests should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (at Step 5) (see Procedural Manual of the Codex Alimentarius Commission, Tenth Edition, pages 20-21) to the Secretary, Codex Alimentarius Commission, FAO, via delle Terme di Caracalla, 00100 Rome, Italy (fax: 39 06 570 54593, email: Codex@fao.org) **before 31 March 1999.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 31st Session of the Codex Committee on Food Hygiene are as follows:

Matters for consideration by the Commission:

The Committee:

- agreed to advance to Step 8 the Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment (para. 34, Appendix II);
- agreed to advance to Step 5 of the Accelerated Procedure the Draft Amendment to the General Principles of Food Hygiene (para. 15, Appendix III);
- agreed to advance to Step 5 the Proposed Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs (para. 52, Appendix IV).

Other Matters of Interest to the Commission

The Committee:

- agreed to return to Step 6 the Draft Code of Hygienic Practice for Packaged (Bottled) Waters (other than Natural Mineral Waters) (para. 41);
- agreed to return to Step 3 the Proposed Draft Code of Hygienic Practice for Milk and Milk Products (para. 45);
- agreed to redraft and circulate at Step 3 the following texts:
 - Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (para. 87)
 - Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce/Fruits and Vegetables (para. 62)
 - Proposed Draft Code of Hygienic Practice for Pre-Cut Raw Fruits and Vegetables (para. 71)
- agreed to redraft the following discussion papers for consideration by the next session:
 - Proposed Draft Guidelines for Hygienic Reuse of Processing Water in Food Plants (para. 76)
 - HACCP in Small and Less Developed Businesses (para. 108)
- agreed to discontinue work on the following items:
 - Broader Issues on the Application of Microbiological Risk Evaluation in International Food and Feed Trade (para. 95)
 - Broader Application of the HACCP System (para. 97)

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INTRODUCTION

1. The Codex Committee on Food Hygiene held its Thirty-first Session in Orlando, USA, from 26 to 30 October 1998, by courtesy of the Government of 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. The Session was attended by 205 delegates from 47 member countries and 14 international organizations. The 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 participants on behalf of the Government of United States. Dr Robert V. Tauxe, Chief Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases, National Centers for Infectious Diseases, the Center for Disease Control and Prevention, made a presentation entitled *Public health surveillance of foodborne infections: New challenge and new solutions*. He presented the concept, methodology and critical issues of surveillance of foodborne diseases. Also he introduced newly developed surveillance strategies of the United States. Considering the rapid expansion of international food trade, he stressed the need for the development of an international foodborne disease surveillance system.

ADOPTION OF THE AGENDA (AGENDA ITEM 1)

3. The Committee adopted the Provisional Agenda (CX/FH 98/1) as the Agenda for the session, and agreed to discuss the Supplementary Agenda Item, "Consideration of Discussion Paper on Broader issues on the Application of Microbiological Risk Evaluation in International Food and Feed Trade" (CX/FH 98/1-Add 1) and the relevant working paper "*The Implications of the Regional Differences in the Prevalence of Foodborne Pathogens in the Management of Microbiological Hazards for Foods in International Trade*", under Agenda Item 10. It was agreed to rearrange the order of some Agenda Items and discuss Agenda Item 10 and the Supplementary Agenda Item in conjunction with Agenda Item 3.

4. The Committee agreed to discuss the documents on Control of *Listeria monocytogenes* in Foods (CRD 3) and Antibiotic Resistance of Bacteria in Food (CRD 4) under Agenda Item 13 - Other Business.

5. The delegation of Spain and several other delegations expressed their concern that the working documents in Spanish were not received in time and the quality of the translation was totally inadequate. This created serious problems for Spanish speaking countries. In the course of the deliberations, certain delegations expressed their support for the concerns expressed. The Delegation of India expressed its concern about the late receipt of papers, especially some of the documents for Agenda Item 13. The Observer from the European Community expressed concern that the EC position paper on several agenda items had not been made available as a conference room document.

6. In order to facilitate the work of the Committee, the Chairperson proposed to apply the following working procedures: a full debate would take place on Agenda Items at Step 7 while, for the other items, the discussion would be generally limited to one intervention of 5 minutes for each delegation on each specific topic or section, unless it was necessary to extend the debate further, and editorial comments should be provided in writing.

REPORT BY THE SECRETARIAT ON MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE FOOD HYGIENE COMMITTEE INCLUDING THE PROPOSED DRAFT AMENDMENT TO SECTION 6.1.2 OF THE GENERAL PRINCIPLES OF FOOD HYGIENE AT STEP 4 OF THE ACCELERATED PROCEDURE (AGENDA ITEM 2)

7. In addition to the matters referred to in the document CX/FH 98/2, the Representative of WHO informed the Committee of activities of interest for the work of the Committee. It was noted that the publication

*Surface Decontamination of Fruits and Vegetables Eaten Raw: a Review*¹, prepared by WHO in collaboration with NSF International, described the pathogens associated with fresh fruits and vegetables and the efficacy of different methods of decontamination, with particular emphasis on chemical disinfection. This information would be useful for the discussion of the codes related to fresh fruits and vegetables under Agenda Items 7 and 8.

8. The Committee noted that the FAO/WHO/IAEA Study Group on High Dose Food Irradiation (Geneva, 1997) had reviewed the safety and nutritional adequacy of foods irradiated at doses above 10 Kgy; it had concluded that these foods were safe and wholesome and there was no need to impose an upper dose limit for safety and nutritional purposes.

9. The Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP (Geneva, June 1998)² had been organized in order to address the role and responsibilities of government agencies in the assessment of HACCP. Among other things, the Consultation recommended that a number of terms such as *food safety objectives*, *significant hazards* and *officially recognized bodies* should be clarified; the relationship between risk assessment, HACCP and food safety objectives should be addressed; and the need to provide guidance on the pre-requisites to HACCP should be considered. The Consultation recognized the complexity of the subject and the difficulty of reaching consensus in one meeting. Therefore, it recommended that government agencies and other interested parties should communicate their comments to FAO and WHO, which would review their guidance on the basis of their experience.

10. The Representative of FAO indicated that a *Training Manual on Food Hygiene and HACCP*³ had been recently published by FAO, and that several training of trainers courses had been implemented in developing countries.

11. With reference to the Expert Consultation on Validation of Analytical Methods for Food Control, some delegations pointed out that in the area of microbiology, a distinction should be made between validation and the use of equivalent methods, and that strict application of some recommendations might prevent the use of certain methods which were currently applied. The Committee however recalled that the Consultation had focused mainly on methods for chemical substances.

12. The Committee recalled the request of the Commission for the establishment of an expert advisory body to provide the scientific basis for its decisions and was informed of the preparatory work undertaken by FAO and WHO in this respect. The Representative of FAO indicated that FAO was currently working with WHO on the organization and mandate of the Consultation, planned for March 1999, and recalled that the establishment of an expert body was subject to the final decision of the FAO Council. The Representative informed the Committee that contacts would be made with member countries and international organizations with a view to the selection of experts in this field. The Representative of WHO also informed the Committee that there was great progress in WHO in the preparations for the establishment of the advisory body. The Committee agreed that the advisory body should follow the model of JECFA and should receive direction from the CCFH on priorities for its programme of work.

13. The Committee expressed its appreciation to FAO and WHO for their efforts to address these important issues and the Chairperson pointed out that this Committee would need the advice of the parent organizations in order to develop a mechanism to establish priorities and advise the expert body of its specific needs.

¹ WHO/FSF/FOS/98.2, Geneva, 1998

² WHO/FSF/FOS/98.5, Geneva, 1998

³ FAO, Rome, 1998

DRAFT AMENDMENT TO SECTION 6.1.2 OF THE GENERAL PRINCIPLES OF FOOD HYGIENE

14. The Committee agreed with the proposal of the Delegation of India to specify that if rinsing was not required according to the manufacturers' instructions, this should be "on a scientific basis", and no other changes were made to the proposed text.

Status of the Draft Amendment to Section 6.1.2 of the General Principles of Food Hygiene

15. The Committee **agreed** to forward the Draft Amendment to Step 5 of the Accelerated Procedure for adoption by the 23rd Session of the Commission (see Appendix III).

ENDORSEMENT OF FOOD HYGIENE PROVISIONS IN THE DRAFT REVISED STANDARD FOR HONEY⁴

16. The Committee noted that the text of the draft had been revised by the United Kingdom, host country of the Committee on Sugars (adjourned) and circulated for comments at Step 6. Specific provisions for food hygiene had been included, which slightly differed from those which had been previously endorsed.

17. The Committee recognized that the Hygiene section did not correspond to the standard provisions included in the Procedural Manual as these covered "substances originating from microorganisms", whereas a reference to "plants" had been added in the draft standard. Some delegations also pointed out that this could be interpreted as including pollen, which might be present in honey and was likely to create confusion. The Committee questioned the purpose of the reference to the product sold "to the final consumer", as it was not clear how this might affect food safety control in the earlier stages.

18. The Committee **requested** the Committee on Sugars or the host country responsible for the revision of the standard to provide some clarification about the inconsistencies of the section with the hygiene provisions for commodity standards presented in the Procedural Manual. The Committee, noting that the text had been presented as a CRD due to its late availability, agreed that it should be circulated for comments, according to the usual procedure for endorsement by general subject committees, and consideration at its next session.

DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT (AGENDA ITEM 3)⁵

19. The Delegation of United States introduced the draft, which incorporated the amendments agreed to by the ad hoc Working Group that had met prior to the Plenary Session. The Committee was informed that several amendments had been made and that the explanatory notes in the Section, Additional Considerations, in CX/FH 98/3, were transposed into the related sections.

20. The Committee reviewed the proposed text section by section and agreed to make the following amendments as well as many editorial changes.

21. The title of the section *Background* was replaced by *Introduction*, in order to be consistent with other Codex texts. Additional text describing the process of Risk Analysis and the primary objective of this draft was added in the section for clarification. The delegation of India, supported by other delegations, stressed the need of developing countries for training on microbiological risk assessment and for a realistic time frame to implement these Principles and Guidelines. The Delegation also drew the attention of the Committee to the issues raised by India in the Committee on General Principles in this respect. The Committee agreed to add sentences at the end of this section to address this concern.

22. The section on *Definitions* was updated to make it clear that some of the definitions were derived from the definitions adopted at the 22nd Session of Codex Alimentarius Commission, which did not only

⁴ CRD 11

⁵ CX/FH 98/3, CRD 6 (comments from Canada, Poland, and Spain), CRD 19 (report of the *ad hoc* Working Group), CRD 24 (draft which shows the changes made by the plenary session)

cover microbiological agents but also chemical and physical agents. A footnote on control options was added to clarify the definition of Risk Management.

23. In the section on *General Principles of Microbiological Risk Assessment*, the second sentence on Principle 5 was deleted since it covered the implementation of the Principle and not the Principle itself, and transparency was already defined in the Section on *Definitions*. Principle 1 and the first sentence of Principle 5 were edited.

24. The section on *Guidelines for Application* was modified. The second sentence regarding the NRC Committee and the Joint FAO/WHO Consultation was deleted since it had been included to facilitate drafting in the earlier steps.

25. A new section on *General Considerations* based on the text of paragraphs on Limitation of Data, Purpose of the Conducting of a Risk Assessment and Resource Constraints, taken from the section on Additional Considerations in CX/FH 98/3, was inserted. Further amendments were made to those paragraphs. In addition, new sentences were added to address the importance of the involvement of interested parties in the process of Risk Assessment.

26. The text of the paragraph on *Purpose of the Conducting of a Risk Assessment* in the section of Additional Consideration in CX/FH 98/3 was transposed into the section on *Statement of Purpose of Risk Assessment*. Several sentences that were not related to the purpose of Risk Assessment were deleted.

27. In the section on *Hazard Identifications*, some amendments were made for clarification purposes.

28. In the section on *Exposure Assessment*, several factors, such as regional differences, seasonality of products, role of food handlers, and environmental time/temperature relationship were incorporated as factors to be considered for Exposure Assessment.

29. In the section on *Hazard Characterization*, several factors such as pregnancy, nutrition and access to medical care were added as these may affect the severity of illness. The term “population behaviour” was deleted as this was covered in Exposure Assessment.

30. In the section on *Risk Characterization*, the first paragraph was amended to make it clear that the goal of Risk Characterization is to obtain a Risk Estimate.

31. The text of the paragraph on *Understanding Limitations of a Risk Assessment with Respect to Transparency* in the section on *Additional Considerations* was transposed into the section on *Documentation*. The Committee noted that risk managers' understanding of any limitations that influence Risk Assessment such as expert judgement was essential in decision making and that those limitations should be clearly documented and the text was amended accordingly.

32. The Committee, recognizing the importance of reassessment, included a new Section for Reassessment based on the text of the paragraph on *Reassessment of Risk Assessments* in the section on *Additional Considerations*.

33. The section on *Additional Consideration* proposed in CX/FH 98/3 was deleted. The first seven additional considerations in the document were moved to other sections with some modification, as indicated above, and the additional consideration regarding *Default Assumption* was deleted from the document.

Status of the Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment

34. The Committee **advanced** the Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment to Step 8 for adoption by the 23rd Session of the Commission (see Appendix II).

DRAFT CODE OF HYGIENIC PRACTICE FOR PACKAGED (BOTTLED) DRINKING WATERS (OTHER THAN NATURAL MINERAL WATERS) (AGENDA ITEM 4)⁶

35. The Committee recalled that it was agreed at the 30th Session to advance the Proposed Draft Code to Step 5. The 45th Session of the Executive Committee (June 1998) adopted the Proposed Draft Code at Step 5 and advanced it to Step 6. Comments received in response to the CL 1997/41-FH were incorporated in document CX/FH 98/4.

36. The Delegation of the United States, on behalf of the *ad hoc* Working Group which had met prior to the Session, presented the Draft Code as amended by the *ad hoc* Working Group. The Committee expressed its appreciation of the efforts of Working Group and reviewed the Draft Code. The Committee decided to defer the discussion on Appendix 2 since it had just been made available to the plenary session.

37. Regarding the Introduction Section, the Committee recalled that its 30th Session had agreed to delete the section on Labelling and had considered addressing the issues contained in the section in some way. The Committee was informed that those concerns were addressed in the Introduction, where it was suggested that the optimal place for such information would be on the label.

38. Many delegations expressed their concerns that the new paragraphs in the Introduction concerning both information on water treatment methods and on the consumption of this water by infants were not appropriate for a code of hygienic practice. They stressed that such issues were already covered by the Codex General Standard for the Labelling of Prepackaged Foods. The delegation of the United States and the Observer from Consumers International supported the inclusion of these new paragraphs because such information addressed safety matters and were directly related to the protection of human health. The Delegation of Argentina proposed that information regarding the use of water in infant formula should be considered as part of the labelling of infant formula.

39. The Committee noted that a number of editorial and other comments received still needed to be considered and incorporated into the document.

40. Some delegations expressed their regret that the Code could not be advanced to Step 8 in view of the extensive work which had been done so far. However, in view of the remaining issues to be addressed and of time constraints, the Committee agreed that the text should be redrafted for further consideration and that additional comments should be requested.

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

41. The Committee **agreed** that the document and its Annexes should be redrafted by the Delegation of the United States in light of the comments made and circulated for further comments at Step 6 prior to the next session of the Committee.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (AGENDA ITEM 5)⁷

42. The Committee recalled that the 30th Session had reached consensus to discontinue the development of the work on Soft Cheeses as an independent Code, with the understanding that the work would continue with the elaboration of a general Code for Milk and Milk Products. The Delegation of the United States introduced the document on behalf of the drafting group and stressed the importance of the consensus reached at the last session on the Hygiene sections of the standards for milk products, whereby a variety of

⁶ CX/FH 98/4, CRD 7 (comments from Canada, Denmark, United States, Consumers International), CRD 20 (Report of the Working Group)

⁷ CX/FH 98/5, CX/FH 98/5-Add.1, CRD 9 (comments of France); CRD 10 (IDF), CRD 12 (European Community, CRD 13 (Italy), CRD 15 (Hungary), CRD 18 (Argentina), CRD 25 (main issues presented by the Delegation of the United States)

control measures can be used, in combination, and these measures should be shown to achieve the appropriate level of public health protection (ALINORM 99/13, Appendix VII). The Delegation pointed out that the formatting approach was built upon that consensus, utilizing annexes which allowed the document to maintain a dynamic state, as no amendment of the main text was required when new control measures were introduced or the technology evolved. Some delegations expressed concern with the drafting approach taken.

43. The Delegation of the United States noted that the Proposed Draft Code was constructed to focus on the need to achieve acceptable food safety outcomes through the use of one or more control measures, rather than defining specific processes for individual products. As a number of comments had been received, some of them submitted late as CRDs, the Committee directed the Delegation of the USA, as leader of the Drafting Group, to review the comments and to present its findings to the Committee. The Delegation highlighted the essential issues to be addressed in order to provide a basis for further development of the Code, as follows:

- The expansion of the Scope beyond food safety
- The use of the annexes for control measure details
- The lack of control measure evaluation methods
- The lack of definitions for Appropriate Level of Protection (ALOP)/Food Safety Objectives (FSO)/Food Safety Outcomes
- Primary production exceptions
- Increased HACCP emphasis
- The Code should be more outcome oriented and less prescriptive
- Excessive detail in the document

44. The Delegation of Austria, speaking on behalf of the Members of the EU, indicated that this list was not exhaustive and might be expanded by addressing concerns on the Annexes, technological considerations in addition to food safety requirements, control operations in Section 5.2.2; and the application of adequate controls associated with primary production

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

45. The Committee **agreed** that the Delegation of the United States, in cooperation with its drafting partners⁸, would redraft a Proposed Draft Code on the basis of the comments received and the discussions held during the session, for circulation at Step 3 and consideration by the next session.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE TRANSPORT OF FOODSTUFFS IN BULK AND SEMI-PACKED FOODSTUFFS AT STEP 4 (AGENDA ITEM 6)⁹

46. The Delegation of the Netherlands introduced the proposed draft on behalf of the drafting group and highlighted the main issues raised in government comments, while noting that editorial comments were being incorporated into the document:

- the inclusion of primary production in the scope of the document;
- the simplification of requirements for monitoring and recording previous cargoes in order to avoid administrative burden and excessive costs;

⁸ Argentina, Australia, France, India, Netherlands, New Zealand, United Kingdom, Uruguay, IDF

⁹ CX/FH 98/6, CX/FH 98/6 Add-1 (comments of Denmark, Japan, South Africa, UK, USA; and International Council of Grocery Manufacturers Association (ICGMA), CRD 5 (France), CRD 14 (Paraguay), CRD 15 (Mexico), CRD 18 (Argentina).

- the need to clarify the definitions of “bulk” and “semi packed foodstuffs”; and;
- the issue of dedicated transport versus dual use of containers.

47. The Committee agreed to include primary production in the document and to amend the text of the paragraph 3.2 by inserting after ...”the food transportation unit” an additional sentence “Special caution should be exercised for fresh produce requiring no or little processing before consumption, which should not be transported in Transport Units used to transport manure, fertilizers, pesticides or produces which have been in contact with these”.

48. In relation to previous cargoes the Committee felt that two factors should be taken into consideration: shelf life of products and duration of voyage. It was agreed to remove square brackets at this stage from “three” prior cargoes in paragraph 5.1.1. As regards records keeping for a period of six months it was pointed out that it may not be useful in all cases and seems to be excessive. The Delegation of India suggested to develop a suitable standard format of the document describing previous cargoes.

49. The Committee agreed to update the definition of “bulk” (Section 2.2.) by inserting “for example, powder, granulated or liquid form” in addition to the current text.

50. As regards heat exchange fluids, it was agreed to amend paragraph 4.3 by inserting an additional sentence after the word “contamination”. It would read, “Those can be used which are agreed upon between sellers and buyers and are acceptable to the authorities of the receiving country, based on risk assessment”.

51. The Committee discussed the advantages and disadvantages of dedicated transport. Some delegations and the Observer from the EC supported the general application of dedicated transport while other delegations indicated that Dedicated transport itself did not entirely guarantee the safety of transported foodstuffs. No consensus was reached at this stage on the proposal of the Delegation of Germany to add the following sentence as a separate paragraph in Section 5.4: “Bulk foodstuffs in liquid, granulated or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs”. The Committee agreed to keep both options open and ask for further comments on these proposals, for consideration by the next session.

Status of the Proposed Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs

52. The Committee **agreed** to forward the proposed draft Code to the 23rd Session of the Commission for adoption at Step 5 (see Appendix IV)

DISCUSSION PAPER ON THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRIMARY PRODUCTION, HARVESTING AND PACKAGING OF FRESH PRODUCE (AGENDA ITEM 7)¹⁰

53. The Committee recalled that the last session had decided to consider the possibility of developing a code of hygienic practice for primary production, harvesting and packaging of fresh produce. The Delegation of Canada introduced the document, which had been prepared in cooperation with several countries, and focused on the microbiological hazards associated with primary production, highlighting the most common pathogens found in fresh fruits and vegetables. The main factors in the pre-harvest and post-harvest contamination of fresh fruits and vegetables were also considered and an outline of the recommendations which might be considered in a code of hygienic practice was presented.

54. The Committee expressed its appreciation to the Delegation of Canada and to the countries involved in the drafting for their work in clarifying the issues to be addressed and preparing the basis for the

¹⁰ CX/FH 98/7

development of a Code. The Committee strongly supported the continuation of this work in view of the significant food safety issues involved, and agreed to inform the Executive Committee accordingly.

55. The Delegation of Austria, expressing the views within the European Union, proposed that the Code should address not only microbiological contamination but also contamination by chemicals, including pesticides, or the Scope should be clarified by its title. Other delegations recalled that matters related to pesticide residues were addressed by the Committee on Pesticide Residues and that the Committee on Food Additives and Contaminants was working on the definition of source-directed measures for the prevention of environmental contamination. It was also proposed to consider the preservation of nutritional quality of foods in the production chain.

56. The Observer from Consumers International supported the development of prevention measures for microbiological and chemical hazards in primary production and indicated that the provisions of the Code should also apply to products from organic agriculture.

57. The Delegation of India, supported by other delegations, proposed to include a section recognizing the specific difficulties of developing countries, the need for flexibility and a realistic time frame in the application of control measures, as well as the requirements for training of personnel and technical assistance from FAO and WHO.

58. The Representative of WHO drew the attention of the Committee to the relevance of the following WHO publications to the control of hazards in primary production: Guidelines for the Safe Use of Wastewater and Excreta in Agriculture and Aquaculture, Prevention and control of Enterohemorrhagic E.coli Infection¹¹, Control of Foodborne Trematodes Infections¹². The Representative stated that there was a lack of documented outbreaks of foodborne diseases associated with fruits and vegetables from developing countries and invited member countries to report such outbreaks to WHO. The importance of this data for developing a code which would adequately address food safety problems in the developing world was stressed. The Representative noted that the title of the code referred only to fresh produce and recommended that it should be clarified to specify that fruits were included as well as vegetables. This proposal was supported by the Delegation of Argentina and the Committee agreed to amend the title accordingly.

59. The Committee discussed the opportunity of incorporating the HACCP approach in the proposed code. Several delegations stressed the difficulties related to the application of the HACCP system at the level of primary production, where the emphasis should rather be put on Good Agricultural Practice as a prerequisite to ensure the safety of the product. Some delegations indicated that although the application of HACCP to primary production of fresh fruits and vegetables might not be feasible at this stage, it should be a long-term objective. The Delegation of Japan expressed the view that the HACCP system should be applied in the production of sprouts.

60. The Representative of FAO informed the Committee about the Quality Assurance and Food Safety Programme for raw fruits and vegetables that FAO was currently implementing with the University of Arkansas and the collaboration of some countries in Latin America. The programme included a workshop on the assessment of training and research needs, to be held in Guatemala from 1-3 December 1998. The Representative indicated that "Training of Trainers (TOT)" courses would be implemented in early 1999 in Costa Rica and Mexico and that research would be conducted on the measures to prevent contamination of fresh fruits and vegetables. The development of the code would be very useful in the framework of such programmes.

61. The Representative of PAHO reported that a programme was being proposed in cooperation with IICA for the application of HACCP in primary production and considered that it was necessary to promote

¹¹ WHO/FSF/FOS/97.6

¹² WHO Technical Report Series No. 849, 1995

the use of Good Agricultural Practice if the HACCP system was to be applied successfully in primary production.

62. The Committee **agreed** that the Delegation of Canada, in cooperation with a drafting group¹³ and in the light of the above discussion, would develop a Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce/Fruits and Vegetables (including an Annex for sprouts), for circulation at Step 3 and consideration by the next session (see also para. 71 below).

DISCUSSION PAPER ON THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-CUT FRUITS AND VEGETABLES (AGENDA ITEM 8)¹⁴

63. The Committee recalled that the last session had decided to consider the possibility of developing a code of hygienic practice for pre-cut fruits and vegetables. The Delegation of France introduced the document, which had been prepared in cooperation with several countries, and focused on the specific hazards associated with pre-cut produce as issues related to raw material were covered in the document on primary production (see para.53). The Delegation noted that sprouts should not be included in the Code as the hazards related to their production were very specific and stressed some the major questions to be addressed: the extension of the Scope to fruit juices, the relationship with the primary production code, and contamination problems associated with refrigerated or non-refrigerated produce.

64. The Committee expressed its appreciation to the Delegation of France and to the other countries involved in the drafting for their work in clarifying the issues to be addressed and preparing the basis for the development of a Code. The Committee strongly supported the continuation of this work in view of the significant food safety issues involved and the growing trade in the products covered, and agreed to inform the Executive Committee accordingly.

65. The Committee had an exchange of views on the title of the document and agreed that it should refer to pre-cut raw fruits and vegetables in order to make it clear that the products covered were in the raw state; it was further agreed that composite products such as seasoned mixed salads were not included. It was noted that the title in Spanish should correspond exactly to the English and that it would be useful to mention the specific term used in French in the French version (4ème gamme).

66. The Committee discussed the opportunity of including fruits juices and sprouts in the code, possibly as Annexes, and generally agreed that document should focus on the specific hazards related to pre-cut raw fruits and vegetables. It was also agreed that the production of herbs and fruits juices should not be covered by the code as the hazards involved were different. However, the inclusion of other related products might be reconsidered at a later stage in the elaboration of the document.

67. The Committee discussed the relationship between the code under discussion and the proposed code on primary production, as discussed earlier (see Agenda Item 7). Some delegations expressed the view that the codes should be merged into a single document as they covered similar products and the current approach was to follow the entire production and processing chain in codes of hygienic practice, in accordance with the General Principles of Food Hygiene.

68. Other delegations pointed out that the problems addressed by the two codes were significantly different, as one was intended to address contamination in primary production while the other covered industrially processed fruits and vegetables. The application of the HACCP system was entirely relevant in the case of processed pre-cut and packed products, whereas its application to agriculture production raised many difficulties (see para. 59 above). These delegations proposed to discuss the codes separately at this stage, in order to avoid confusion and focus on the issues specific to each type of product. It was also noted that the production of pre-cut fruits and vegetables was an important industry in several countries, where

¹³ Argentina, Chile, Denmark, Guatemala, Honduras, India, Japan, Mexico, Netherlands, Spain, Sweden
United Kingdom, United States

¹⁴ CX/FH 98/8

specific legislation was applied. The Committee agreed that the two codes should be developed in parallel and that consideration could be given to combining them at a later stage.

69. The Delegation of Denmark, supported by some other delegations, expressed the view that systematic use of chemical substances, including chlorine, for disinfection purposes should be avoided as it might cause toxicological problems and might not significantly reduce contamination, and regrowth could appear in the residual bacterial population. The Delegation proposed that the text should therefore specify that disinfection could be used only if it appeared necessary on the basis of a thorough risk analysis, including risk/benefit analysis.

70. The Committee agreed that, when developing the code, the hazards associated with each step of the preparation and processing should be identified clearly, especially to determine how microbiological contamination was affected and could be minimized at each stage. The Delegation of Belgium pointed out that a number of issues raised in the elaboration of similar codes should also be taken into account, especially in order to avoid excessive detail and emphasize the HACCP approach.

71. The Committee agreed that the Delegation of France, in cooperation with a drafting group¹⁵, would develop a Proposed Draft Code of Hygienic Practice for Pre-Cut Raw Fruits and Vegetables in the light of the above discussion, for circulation at Step 3 and consideration by the next session. The Committee noted that an electronic mail box would be established in order to facilitate work on the Codes discussed under Agenda Items 7 and 8, the instructions to be communicated to Codex Contact Points through the Codex-L List.

DISCUSSION PAPER ON PROPOSED DRAFT GUIDELINES FOR HYGIENIC RECYCLING OF PROCESSING WATER IN FOOD PLANTS (AGENDA ITEM 9)¹⁶

72. The Committee recalled that its 30th session had agreed to circulate officially a working paper to invite government comments. The delegation of the United States, stressing the importance of water conservation, introduced a revised discussion paper and expressed the views that the reuse of processed water in food plants was becoming a more common practice in the world and that inadequate treatment of water was being recognized as a potential food safety problem.

73. The Committee expressed its appreciation to the Delegation of the United States for its work and recognized the need to discuss this issue. The Delegation of the United States proposed to incorporate these Guidelines into the General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3) as an Annex and also indicated that the title should be more general and refer to "Reuse" rather than "Recycling".

74. Several delegations and the Observer from IDF pointed out that the practices of water reuse varied widely depending on the type of industry. Therefore, careful consideration should be given to the extent to which this generic Code would be applied. The Observer from IDF proposed that Section 5.5 of the General Principles of Food Hygiene should be reconsidered as its text was not in accordance with current practice.

75. The Committee had an exchange of views on whether to develop general guidelines or to develop sections on water reuse in specific commodity codes. It was also proposed to follow these two approaches simultaneously. It was agreed that the opinions of the Commodity Committees would be requested on this issue in view of their specific expertise.

76. The Committee agreed that the discussion paper should be further developed by the delegation of the United States with the assistance of the participants in the initial drafting¹⁷ and that the paper should examine the concerns expressed in the discussion.

¹⁵ Argentina, Canada, Guatemala, Japan, Mexico, Netherlands, Spain, United Kingdom, United States, Uruguay.

¹⁶ CX/FH 98/9

¹⁷ Australia, Netherlands, India, Germany, France and IDF

DISCUSSION PAPER ON RECOMMENDATIONS FOR THE MANAGEMENT OF MICROBIOLOGICAL HAZARDS FOR FOODS IN INTERNATIONAL TRADE (AGENDA ITEM 10)¹⁸

77. The Delegation of France introduced the discussion paper which had been prepared by the drafting group in the light of the comments received. The document addressed new concepts, such as “Food Safety Objectives (FSO)” and “Risk Profile”, for managing hazards associated with food in international trade, and also emphasized the involvement of all stakeholders in each step of risk management as appropriate. The Delegation pointed out that without clear definition of those concepts, it was not easy to address the management of microbiological hazards. The Committee was informed that the discussion paper incorporated some of the concepts included in the document to be considered under the Supplementary Agenda Item.

78. The Committee expressed its appreciation to the Delegation of France for its outstanding efforts in preparing this document. Many delegations supported the structure proposed by the Drafting Group. It was pointed out that this document would be very valuable to governments in providing a coherent approach in the conduct of Risk Analysis.

79. The Delegation of India expressed its concern about the deletion of Annex 2 of CL 97/44-FH entitled *World-wide Initiatives to Develop Models and Information Systems for Improving Risk Assessment*. The Delegation of France recalled that many aspects from Annex 2 were already incorporated into the new discussion paper and this Annex focused more on Risk Assessment than on Risk Management. However, its relevance in the paper on Risk Management was noted and it was agreed that the ideas reflected in Annex 2 would be taken into account when developing the document in the future.

80. The Delegation of India supported by some other delegations stressed that the implementation of the recommendations in the document would require financial resources in developing countries and this should be recognized by the relevant international organizations.

81. The Committee had an extensive discussion as to the meaning of “Food Safety Objectives” and how they should be incorporated in the document. It was proposed to include FSO into the section on Risk Management Principles. The Observer from the European Community supported by other delegations emphasized that this concept was not clearly defined and no internationally accepted definition existed at this stage. It was pointed out that the work of other Codex Committees (CCFICS and CCGP) on this issue should be taken into account. Confusion should be avoided between principles and tools, as Food Safety Objectives represented one of the important risk management tools. Some delegations stressed the need to separate principles and tools. The Delegation of the United States, while generally supporting the development of the document, pointed out that risk management was the responsibility of individual countries and the inclusion of FSO was premature until this concept had been clearly defined.

82. Many delegations pointed out that it would be useful to merge the paper on the Implications of Regional Differences in the Prevalence in the Management of Microbiological Hazards for Foods in International Trade prepared by the Delegation of Norway with the paper under discussion since they dealt with related subjects.

83. The Committee accepted the proposal of the Delegation of the United Kingdom to change the title of the document to *Principles and Guidelines for the Conduct of Microbiological Risk Management* in order to be consistent with the document on Risk Assessment forwarded to the Commission at Step 8 (see para. 34).

84. The Observer from the European Community supported the inclusion of FSOs in the document but felt that this issue should be referred to the Committee on General Principles, although work on FSO should continue in parallel in the CCFH. The Observer stated that the document omitted the concept of a precautionary approach, in the consideration of which the principle of proportionality needed to be respected

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and the relationship between risk and benefit examined. The Observer noted that these concepts should not be misused to create unnecessary barriers to trade, and proposed to send a contribution on the precautionary approach to the Delegation of France to be considered for inclusion in the document.

85. This position was supported by the Observer from Consumers International who emphasized the need to balance the concept of "tolerable" risk or level of protection with the concept of preventing/minimizing risks when possible. The Observer also supported the notion of public involvement in Risk Assessment policy, and the inclusion of a discussion of the appropriate role of Codex in risk management, in addition to the role of national governments.

86. Several delegations, while supporting the development of this document, stressed the importance of focusing on the international aspects of risk management.

87. The Committee **agreed** that the Delegation of France, with the assistance of a drafting group¹⁹, would redraft the recommendations as Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management for circulation at Step 3 and consideration at the next session.

CONSIDERATION OF DISCUSSION PAPER ON BROADER ISSUES ON THE APPLICATION OF MICROBIOLOGICAL RISK EVALUATION IN INTERNATIONAL FOOD AND FEED TRADE (SUPPLEMENTARY AGENDA ITEM 10-ADDENDUM)²⁰

88. While adopting the agenda, the Committee had decided that document CX/FH 98/13 *The Implications of Regional Differences in the Prevalence of Foodborne Pathogens in the Management of Microbiological Hazards for Foods in International Trade*, prepared by Norway, with the assistance of Denmark, France and Sweden, should be discussed in sequence with Agenda Items 3 (Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment) and 10 (Guidelines for the Management of Microbiological Hazards for Foods in International Trade).

89. In introducing the document, the Delegation of Norway emphasized that the main objective was to recognize the existence of regional differences in the prevalence of various foodborne pathogens in the food chain and to take it into account in the risk management process in international food trade. Furthermore, this principle should be acknowledged by the Codex Alimentarius Commission and reflected in the relevant Codex documents such as risk management guidelines in general, as well as other pertinent documents. The rationale for this proposal as well as proposed recommended principles were summarized in an appendix to document CX/FH 98/13.

90. The Committee expressed its appreciation to the Delegation of Norway for its contribution to the discussion of important issues related to risk management. Many delegations and the Observer from Consumers International supported the general objectives and principles of the paper, and in particular the following concepts:

- the existence of regional differences in the prevalence of foodborne pathogens should be recognized
- risk management should be based upon microbiological prevalence data from the whole food chain, and, if appropriate, disease incidence data;
- ranking of hazards can be carried out at the national, regional or international level;
- risk management decisions should, where possible, address the whole farm-to-table continuum, and measures should be introduced as close to the source of contamination as possible.

¹⁹ Argentina, Australia, Canada, Denmark, Germany, India, Italy, Japan, New Zealand, Netherlands, Norway, United Kingdom, United States, ICMSF)

²⁰ CX/FH 98/13

91. As a result of the intervention of several delegations, the phrase "where possible" was inserted in the fourth indent above to avoid any implication that, for example, HACCP would have to be implemented at the farm level, and to reflect that the feasibility of risk management measures should be considered. It was also stressed that regional differences in disease prevalence should be based on reliable data. The Delegation of Indonesia and some other delegations pointed out that the concept of regionalization should not be used to establish trade barriers which would be especially detrimental to developing countries.

92. Many delegations supported the incorporation of the above principles into the general principles on risk management (see paras. 77-86). Some delegations agreed that they should be included in the document only with a view to their further discussion, which did not imply that they entirely accepted the rationale provided in the document. In particular, they stressed that while risk management options might differ in accordance with regional conditions, there should be a single standard for food safety at the international level; this would be consistent with the recommendations of the Committee on General Principles for a uniform and scientific approach to the elaboration of food safety standards (ALINORM 99/33, para. 41).

93. Some delegations noted that under the SPS Agreement, countries intending to establish disease-free areas should provide necessary evidence thereof, and the concept of disease prevalence currently applied to animal health could not be extended to foodborne diseases without careful consideration.

94. The Delegation of Chile expressed its concern that the question of regionalization should not be diluted as work in this area was discontinued; on the contrary, in view of its importance, it should be included not only in risk management but in each step of risk analysis. The Delegation pointed out that in this perspective, the development of guidelines on regionalization in an evolutive framework could facilitate international trade.

95. The Committee generally **agreed** that the concepts presented as recommended principles in the Appendix to document CX/FH 98/13 should be considered for incorporation in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management, for further discussion in the general framework of that document. As a result, the Committee agreed to discontinue work on the discussion paper prepared by Norway as a separate item. However, Norway and the countries involved in the drafting (Denmark, Sweden, France) were encouraged to participate actively in the elaboration of the above mentioned Guidelines. The Committee noted a proposal from the Delegation of Norway to incorporate the principles mentioned in its document into other relevant documents of Codex.

IMPLICATIONS FOR BROADER APPLICATION OF THE HACCP SYSTEM (AGENDA ITEM 11)²¹

96. The Delegation of Australia introduced this item and suggested that the Committee review its interest in this matter, considering the degree of effort already put in this task and its relevance to the mandate of the Codex Alimentarius Commission.

97. The Committee recalled that the 45th Session of the Executive Committee noted the heavy workload of this Committee and questioned the utility of conducting annual surveys on the development and implementation of the HACCP system²². The Committee, while appreciating the efforts made by Australia and recognizing the importance of exchange of information, **agreed** to defer the discussion on this Item for two to three years until the HACCP system had been more widely implemented in member countries.

²¹ CX/FH 98/11, CRD 8 (comments from Costa Rica, Czech Republic, Hungary, Jamaica, Madagascar, Slovak Republic and Spain)

²² ALINORM 99/3 paragraph 34

DISCUSSION PAPER ON THE DEVELOPMENT OF RISK-BASED GUIDANCE FOR THE USE OF HACCP-LIKE SYSTEMS IN SMALL BUSINESSES, WITH SPECIAL REFERENCE TO DEVELOPING COUNTRIES (AGENDA ITEM 12)²³

98. The Delegation of the Netherlands introduced the document *Discussion paper on HACCP in Small and Less Developed Businesses*, which had been developed following a meeting of the drafting group in April 1998, and pointed out that the revised title did not any longer refer to developing countries but to "small and less developed businesses" because difficulties existed both in developed and developing countries in the application of the HACCP system.

99. Several delegations stressed the difficulties related to a definition of small businesses, as this term might be understood to include retailers or restaurants, whereas the focus of the paper should rather be on small and medium industry; it was proposed to refer to processing units and to put more emphasis on the level of technological development and food safety education. The Delegation of Argentina proposed to delete the reference to "small businesses" in view of these difficulties and the Committee agreed that this issue should be addressed in the redrafting of the document.

100. The Committee generally recognized that there might be some flexibility in the application of the seven principles of HACCP but that the principles themselves should be retained. It was proposed to develop generic plans to facilitate HACCP application but these should be used only as examples.

101. The Committee discussed whether or not the scope should cover both export industry and production for the domestic market. In this context and with a view to suggesting a practical orientation for the document, the Delegation of Mexico highlighted the importance of HACCP application in exporting industries, which although being small, would serve as a model and motivate other businesses of all sizes for its application within the country, thereby facilitating a generalized application of HACCP. Some delegations noted that manufacturers involved in international trade had to apply the HACCP System in order to export their products, irrespective of their size. The Delegation of Argentina pointed out that there should be no distinction on the basis on the destination of the product (export or domestic market) as the essential objective was to ensure consumer protection. In this sense, the concept of equivalence should be taken into account, as currently under discussion in the CCFICS in order to ensure food safety. This view was supported by several delegations, the Observer from Consumers International and the Representative of WHO. The Representative pointed out that according to the WTO/SPS Agreement countries that require application of the HACCP system for imported food should apply similar requirements to their local food productions.

102. Some delegations pointed out that exchange of information between governments on the implementation of HACCP programmes and training would be useful to official authorities, as they would benefit from the experience of other countries in this relatively new discipline.

103. The Representative of FAO informed the Committee about the experience of FAO in technical assistance to small and medium industry in developing countries and drew the attention of the Committee to the Training Manual on Food Hygiene and the HACCP System. Although the usefulness of the HACCP system was recognized, the application of Good Hygienic/ Manufacturing Practices seemed to be the priority for this type of industries. The difficulties in the identification of the hazards and the Critical Control Points appeared to be the major problems in the implementation of HACCP. The measures which could be taken to solve these difficulties included direct technical assistance from governments and research institutes.

104. The Representative of PAHO stressed the limitations of small and medium businesses and the need to apply GMP before the introduction of the HACCP system could be envisaged. The Representative underlined the necessity to stimulate the involvement of industry at the management level in the application of HACCP, and that the Committee should define clearly how HACCP could be applied with flexibility in those cases.

²³ CX/FH 98/12

105. The Representative of WHO supported work on this Agenda Item and offered its collaboration in the further development of the document. The Representative referred to the long standing experience of WHO in the application of HACCP and stressed the importance of the document in order to address food safety problems associated with small businesses as they are the source of a significant proportion of foodborne diseases. The Representative recommended that the outcome of the work on this question could be in the form of guidance to governments in the implementation of HACCP in small businesses.

106. The Committee had an extensive exchange of views on the purpose of the document; there was general support for the application of HACCP and the need to address the difficulties of food businesses which were unable to apply the present HACCP system, irrespective of their size and of their involvement in international trade. The Delegation of Germany, supported by other delegations, pointed out that in situations where the GPFH and HACCP could not be applied, alternative systems to ensure food safety were likely to be more complex and onerous for the industry, as was the case in certain current codes of practice.

107. The Delegation of France expressed the view that the current Annex on HACCP in the General Principles of Food Hygiene already provided valuable guidance and that it was the responsibility of governments to implement HACCP and Good Hygienic Practice at the national level in view of specific conditions in their industry; it did not therefore appear necessary to develop other texts as international recommendations in the framework of Codex. Several delegations supported further development of this document in order to provide useful guidance on the application of HACCP, while some delegations questioned the purpose of this exercise as related to the elaboration of Codex Guidelines on this specific subject. The Delegation of the United Kingdom expressed the view that guidelines for the application of HACCP were needed for all businesses unable to apply the present application Guidelines.

108. The Committee **agreed** that the discussion paper would be revised by the Delegation of the Netherlands, assisted by the countries involved in the initial draft (see ALINORM 99/13, para. 92), taking into account the above discussion, for circulation and further consideration at the next session.

OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 13)

PROPOSED DRAFT ANNEX ON CLEANING AND DISINFECTION TO THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE – GENERAL PRINCIPLES OF FOOD HYGIENE (CRD 1)

109. The Delegation of the United States recalled that the Annex, which provided guidance on cleaning and disinfection procedures, was initially included in the Draft General Principles of Food Hygiene and it appeared useful to reintroduce it. The Delegation however proposed to defer consideration of this question in view of the current programme of work and the Committee **concurred** with this proposal.

PROPOSED DRAFT CODE OF PRACTICE ON GOOD ANIMAL FEEDING

110. The Committee **noted** that the comments received in reply to CL 1997/43-FH on the Code could not be discussed in view of time constraints, and noted that the Committee on Residues of Veterinary Drugs in Foods had recently considered this issue (September 1998). As all relevant Committees had had the opportunity to review the Code, the next session of the Executive Committee and the Commission would consider their recommendations in order to decide how to proceed in this area.

PRIORITIES FOR THE REVISION OF THE CODES OF PRACTICE (CRD 2)

111. The Committee noted that the proposals received in reply to CL 1998/43-FH (CRD 2) could not be discussed in detail in view of time constraints, and agreed to circulate them for comments and consideration at the next session. Antibiotic Resistance in Bacteria in Food (CRD 4).

ANTIBIOTIC RESISTANCE IN BACTERIA IN FOOD (CRD 4)

112. The Delegation of Denmark introduced CRD 4, which outlined the need to evaluate and address the risks associated with the development of drug resistance in bacteria following the use of antibiotics. Some delegations and the Observer from Consumers International supported this proposal as antibiotic resistance was a significant emerging public health problem. The Delegation of Switzerland expressed the view that

antibiotic resistance was essentially related to medical use of antibiotics, and it did not appear relevant to address it as a food hygiene issue. Some delegations pointed out that matters concerning antibiotic resistance as related to their use in veterinary medicine was under the responsibility of the CCRVDF and should be addressed accordingly.

113. Some delegations indicated that scientific research was being conducted in their countries on antibiotic resistance and antibiotic use for different purposes, and it would be useful to consider this question in the perspective of food hygiene concerns. It was also proposed that the development of such work could be undertaken in conjunction with the CCRVDF and other interested committees. The Committee noted that the Executive Committee was responsible for the assignment of specific work to Codex Committees and that careful consideration should be given to the entire issue of antibiotic resistance in bacteria before deciding whether further action was required. The Committee agreed that the Delegation of Denmark (with the participation of Brazil, Canada, Finland, France, Hungary, Iceland, Netherlands, Norway, Sweden, United Kingdom, United States) should prepare a discussion paper to clarify the issues involved and their relevance to the work of the Committee, for further consideration at the next session.

CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS (CRD 3)

114. The Delegation of Germany informed the Committee that, as indicated at the last session, it was prepared to continue to develop a discussion paper including some elements of risk assessment and recommendations for the control of *Listeria monocytogenes*. The Committee noted that the Delegation of Denmark had presented a paper on this issue under CRD 3 and was prepared to assist in this work. The Delegation of Germany welcomed the offer of several countries (Austria, Denmark, France, Italy, Japan, Norway, United Kingdom, United States) and ICMSF to contribute to the document, and indicated that consideration was being given to the organization of a meeting in early 1999 to facilitate this work.

115. The Representative of FAO informed the Committee that FAO and the University of Massachusetts were organizing an expert consultation on the Trade Impact of *Listeria* in Fish and Fishery Products, which would be held in January 1999.

CONSIDERATION OF VIRUSES (CRD 23)

116. The Delegation of the Netherlands referred to a scientific paper on caliciviruses (CRD 23), and proposed that the Committee should consider food safety hazards associated with viruses with a view to developing recommendations for their control, as was envisaged in the case of *Listeria*.

117. The Delegation of Germany drew the attention of the Committee to the work of the WHO Collaborating Centre for Virology in Munich and offered to participate in this work. Some delegations felt that caution should be exercised before initiating additional activities on viruses in view of the heavy workload of the Committee, and as risk assessment may be carried out by the expert advisory body to be established; it would therefore be more appropriate for the Committee to address risk management issues. The Committee however recognized that the expert body was not yet operational, and that in the meantime it might be useful to review matters related to risk assessment in the framework of a discussion paper intended to clarify issues. The Committee agreed that the Delegation of the Netherlands would prepare the discussion paper in cooperation with some other countries (Italy, Finland, France, Germany, United Kingdom, United States) for consideration by the next session.

118. The Committee was informed that hazards related to molluscan shellfish, including viruses, were currently being considered in the revision of current codes of practice for fish and fishery products by the CCFFP, to be integrated into a single code incorporating the HACCP approach.

OTHER MATTERS (WORKING LANGUAGES)

119. The Delegation of Argentina, following the conclusion of Agenda Item 3 made a representation with respect to the translation of documents and the establishment of working groups without interpretation in the framework of the Committee. The Delegation especially stressed that such inconvenience should not be

repeated in future Committee sessions, pointing out the non-compliance with Rule XII.1 Languages and Section 7 b) iv (Guidelines)

120. The Delegation of Costa Rica expressed the formal protest of the Spanish-speaking delegations for the non-compliance with the provisions of Rule XII.1 (Languages) and Section 7 b)iv) of the Guidelines for Codex Committees regarding the interpretation and translation into the three languages of the Commission, including Spanish, all of which should be suitable and of good quality. Simultaneous interpretation should be provided in the Working Groups, as these are an integral part of the session. Notwithstanding, the Spanish-speaking Delegations recognized the efforts of the Chair and the Secretariat to endeavour to improve the situation during the current session.

121. This point was made with the objective of improving the mechanisms for the analysis of the documents to be discussed and to ensure the transparency of the process.

DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 14)

122. The Committee noted that the 32nd Session was tentatively scheduled to be held in the United States in October 1999, the exact arrangements to be determined by the host country and Codex Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Reference in ALINORM 99/13A
Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment	8	23rd CAC	ALINORM 99/13A, para. 34, Appendix II
Draft Code of Hygienic Practice for Packaged (Bottled) Drinking Waters (Other Than Natural Mineral Waters)	6	USA, Governments, 32nd CCFH	ALINORM 99/13A, para. 41.
Draft Amendment to Section 6.1.2 of the General Principles of Food Hygiene	5 Acc. proc.	23rd CAC 32nd CCFH	ALINORM 9/13A, para. 15, Appendix III
Proposed Draft Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs	5	23rd CAC, 32nd CCFH	ALINORM 99/13A, para. 52, Appendix IV.
Proposed Draft Code of Hygienic Practice for Milk and Milk Products	3	USA, Governments, 32nd CCFH	ALINORM 99/13A, para. 45.
Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce/Fruits and Vegetables	3	Canada, Governments, 32nd CCFH	ALINORM 99/13A, para. 62.
Proposed Draft Code on the of Hygienic Practice for Pre-Cut Raw Fruits and Vegetables	3	France, Governments, 32nd CCFH	ALINORM 99/13A, para. 71
HACCP in Less Developed Business	3	Netherlands, Governments, 32nd CCFH	ALINORM 99/13A, para. 108
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	3	France, Governments, 31st CCFH	ALINORM 99/13A, para. 87
Discussion Paper on on the Proposed Draft Recommendations for the control of <i>Listeria monocytogenes</i> in Foods in International Trade		Germany, Denmark 32nd CCFH	ALINORM 99/13A, para. 14
Proposed Guidelines for Hygienic Reuse of Processing Water in Food Plants		USA 32nd CCFH	ALINORM 99/13A, para. 76
Prioritization of the Revision of the Codes of Hygienic Practice		Governments, 32nd CCFH	ALINORM 99/13A, para. 111
Discussion Paper on on Antibiotic Resistance in Bacteria in Food		Denmark, 32nd CCFH	ALINORM 99/13A, para. 113
Discussion Paper on Consideration of Viruses in Food		Netherlands 32nd CCFH	ALINORM 99/13A, para. 117
Implications for the Broader Application of the HACCP System	Discontinue	23rd CAC	ALINORM 99/13A, para. 97
Broader Issues on the Application of Microbiological Risk Evaluation in International Food and Feed Trade	Discontinue	23rd CAC	ALINORM 99/13A, para. 95

APPENDIX I

LIST OF PARTICIPANTS

(See separate file)

APPENDIX II**DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT**

(At Step 8 of the Procedure)

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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 Assessment which is a key element in assuring that sound science is used to establish standards, guidelines and other recommendations for food safety to enhance consumer protection and facilitate international trade. The Microbiological Risk Assessment process should include quantitative information to the greatest extent possible in the estimation of risk. A Microbiological Risk Assessment should be conducted using a structured approach such as that described in this document. This document will be of primary interest to governments although other organizations, companies, and other interested parties who need to prepare a Microbiological Risk Assessment will find it valuable. Since Microbiological Risk Assessment is a developing science, implementation of these guidelines may require a period of time and may also require specialized training in the countries that consider it necessary. This may be particularly the case for developing countries. Although Microbiological Risk Assessment is the primary focus of this document, the method can also be applied to certain other classes of biological hazards.

1. SCOPE

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

2. DEFINITIONS

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

Where available the definitions are those adopted for microbiological, chemical, or physical agents and Risk Management and Risk Communication on an interim basis at the 22nd Session of the Codex Alimentarius Commission. The CAC adopted these definitions on an interim basis because they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines.

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

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

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

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

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

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

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

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

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

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

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

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

Risk Estimate - Output of Risk Characterization.

Risk Management - The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control²⁴ options, including regulatory measures.

Sensitivity analysis - A method used to examine the behavior of a model by measuring the variation in its outputs resulting from changes to its inputs.

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

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

3. GENERAL PRINCIPLES OF MICROBIOLOGICAL RISK ASSESSMENT

1. Microbiological Risk Assessment should be soundly based upon science.
2. There should be a functional separation between Risk Assessment and Risk Management.

²⁴

Control means prevention, elimination, or reduction of hazards and/or minimization of risks.

3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.
4. A Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.
5. The conduct of a Microbiological Risk Assessment should be transparent.
6. Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.
7. The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.
8. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Estimate is minimized.
9. A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human illness data.
11. A Microbiological Risk Assessment may need reevaluation, as new relevant information becomes available.

4. GUIDELINES FOR APPLICATION

These Guidelines provide an outline of the elements of a Microbiological Risk Assessment indicating the types of decisions that need to be considered at each step.

4.1 GENERAL CONSIDERATIONS

The elements of Risk Analysis are: Risk Assessment, Risk Management, and Risk Communication. The functional separation of Risk Assessment from Risk Management helps assure that the Risk Assessment process is unbiased. However, certain interactions are needed for a comprehensive and systematic Risk Assessment process. These may include ranking of hazards and risk assessment policy decisions. Where Risk Management issues are taken into account in Risk Assessment, the decision-making process should be transparent. It is the transparent unbiased nature of the process that is important, not who is the assessor or who is the manager.

Whenever practical, efforts should be made to provide a Risk Assessment process that allows contributions by interested parties. Contributions by interested parties in the Risk Assessment process can improve the transparency of the Risk Assessment, increase the quality of Risk Assessments through additional expertise and information, and facilitate risk communication by increasing the credibility and acceptance of the results of the Risk Assessment.

Scientific evidence may be limited, incomplete or conflicting. In such cases, transparent informed decisions will have to be made on how to complete the Risk Assessment process. The importance of using high quality information when conducting a Risk Assessment is to reduce uncertainty and to increase the reliability of the Risk Estimate. The use of quantitative information is encouraged to the extent possible, but the value and utility of qualitative information should not be discounted.

It should be recognized that sufficient resources will not always be available and constraints are likely to be imposed on the Risk Assessment that will influence the quality of the Risk Estimate. Where such resource constraints apply, it is important for transparency purposes that these constraints be described in the formal record. Where appropriate, the record should include an evaluation of the impact of the resource constraints on the Risk Assessment.

4.2 STATEMENT OF PURPOSE OF RISK ASSESSMENT

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

The microbiological risk assessment may require a preliminary investigation phase. In this phase, evidence to support farm-to-table modeling of risk might be structured or mapped into the framework of risk assessment.

4.3 HAZARD IDENTIFICATION

For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food. Hazard identification will predominately be a qualitative process. Hazards can be identified from relevant data sources. Information on hazards can be obtained from scientific literature, from databases such as those in the food industry, government agencies, and relevant international organizations and through solicitation of opinions of experts. Relevant information includes data in areas such as: clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous microorganisms and situations.

4.4 EXPOSURE ASSESSMENT

Exposure Assessment includes an assessment of the extent of actual or anticipated human exposure. For microbiological agents, Exposure Assessments might be based on the potential extent of food contamination by a particular agent or its toxins, and on dietary information. Exposure assessment should specify the unit of food that is of interest, i.e., the portion size in most/all cases of acute illness.

Factors that must be considered for Exposure Assessment include the frequency of contamination of foods by the pathogenic agent and its level in those foods over time. For example, these factors are influenced by the characteristics of the pathogenic agent, the microbiological ecology of the food, the initial contamination of the raw material including considerations of regional differences and seasonality of production, the level of sanitation and process controls, the methods of processing, packaging, distribution and storage of the foods, as well as any preparation steps such as cooking and holding. Another factor that must be considered in the assessment is patterns of consumption. This relates to socio-economic and cultural backgrounds, ethnicity, seasonality, age differences (population demographics), regional differences, and consumer preferences and behavior. Other factors to be considered include: the role of the food handler as a source of contamination, the amount of hand contact with the product, and the potential impact of abusive environmental time/temperature relationships.

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

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

antimicrobial substances, and competing microflora. Predictive microbiology can be a useful tool in an Exposure Assessment.

4.5 HAZARD CHARACTERIZATION

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

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

In relation to the host the following may be important: genetic factors such as Human Leucocyte Antigen (HLA) type; increased susceptibility due to breakdowns of physiological barriers; individual host susceptibility characteristics such as age, pregnancy, nutrition, health and medication status, concurrent infections, immune status and previous exposure history; population characteristics such as population immunity, access to and use of medical care, and persistence of the organism in the population.

A desirable feature of Hazard Characterization is ideally establishing a dose-response relationship. When establishing a dose-response relationship, the different end points, such as infection or illness, should be taken into consideration. In the absence of a known dose-response relationship, risk assessment tools such as expert elicitations could be used to consider various factors, such as infectivity, necessary to describe Hazard Characterizations. Additionally, experts may be able to devise ranking systems so that they can be used to characterize severity and/or duration of disease.

4.6 RISK CHARACTERIZATION

Risk Characterization represents the integration of the Hazard Identification, Hazard Characterization, and Exposure Assessment determinations to obtain a Risk Estimate; providing a qualitative or quantitative estimate of the likelihood and severity of the adverse effects which could occur in a given population, including a description of the uncertainties associated with these estimates. These estimates can be assessed by comparison with independent epidemiological data that relate hazards to disease prevalence.

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

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

It is important to demonstrate the influence of the estimates and assumptions used in Risk Assessment; for quantitative Risk Assessment this can be done using sensitivity and uncertainty analyses.

4.7 DOCUMENTATION

The Risk Assessment should be fully and systematically documented and communicated to the risk manager. Understanding any limitations that influenced a Risk Assessment is essential for transparency of the process that is important in decision making. For example, expert judgements should be identified and their rationale explained. To ensure a transparent Risk Assessment a formal record, including a summary, should be prepared and made available to interested independent parties so that other risk assessors can repeat and critique the work. The formal record and summary should indicate any constraints, uncertainties, and assumptions and their impact on the Risk Assessment.

4.8 Reassessment

Surveillance programs can provide an ongoing opportunity to reassess the public health risks associated with pathogens in foods as new relevant information and data become available. Microbiological Risk Assessors may have the opportunity to compare the predicted Risk Estimate from Microbiological Risk Assessment models with reported human illness data for the purpose of gauging the reliability of the predicted estimate. This comparison emphasizes the iterative nature of modeling. When new data become available, a Microbiological Risk Assessment may need to be revisited.

APPENDIX III

**DRAFT AMENDMENT TO THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE -
GENERAL PRINCIPLES OF FOOD HYGIENE**

(at Step 5 of the Accelerated Procedure)

§ 6.1.2 Cleaning Procedures and Methods

Revise the fifth (5) bullet point to read:

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

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

(At Step 5 of the Procedure)

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INTRODUCTION

Foodstuffs 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 foodstuffs remain safe and suitable for consumption upon delivery and assist countries to assure continued trade.

Good communication between shipper/manufacturer, transporter and receiver of foodstuffs 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 does not supersede the existing proposal for the Codex Draft Revised Code of Practice for the Transport of Edible Fats and Oils in Bulk.

1. OBJECTIVES

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

- 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 foodstuffs 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.

2. SCOPE AND DEFINITIONS

2.1. SCOPE

This code of practice covers the condition of the food transportation unit, loading, transport, in-transit storage and unloading of bulk, semi-packed foodstuffs and fresh produce. 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 which specifically addresses transportation.

2.2. DEFINITIONS

Foodstuff: Means primary- intermediary- as well as finished products (including food additives) intended [or suitable] for human consumption.

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 foodstuff in direct contact with the contact surface of the food transportation unit and the atmosphere (for example, powdered, granulated or liquid form e.g. oil, potato flakes).

Semi-packed foodstuff: Semi-packed foodstuff 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).

3. PRIMARY PRODUCTION

3.1. The provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1- 1969, Rev.3, 1997) shall be applied.

3.2. However in the case of fresh produced and seasonal crops it should be noted that these could contaminate the food transportation unit more than other foodstuff, due to treatment of the land prior to planting, use of raw sewage, animal manure, harvesting practice, processing conditions and unit operations such as peeling, cutting and slicing. Measures to overcome this problem should be directed to the foodstuff and/or the food transportation unit. Special caution should be exercised for fresh produce requiring no or little processing before consumption, which should not be transported in food transportation units used to transport manure, fertilizers, pesticides or produces which have been in contact with these.

4. ESTABLISHMENT: DESIGN AND FACILITIES

4.1 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.

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

4.3 Use of means for cooling or heating should by design and construction be such as to avoid contamination. Those Thermal Heating Fluids can be used which are agreed upon between sellers and buyers and are acceptable to the authorities of the receiving country, based on risk assessment.

4.4 Inner surface materials suitable for direct food contact should be used. These should be non-toxic, inert, or at least compatible with the transported foodstuff, and which do not transfer substances to the foodstuff or adversely affect the foodstuff. 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.

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

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

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

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

5. CONTROL OF OPERATIONS

5.1 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 foodstuffs. Reference is made also to the HACCP approach.

Table 1

Are you dealing with a foodstuff "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?

5.1.1. 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 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] month.

5.2. Sources of hazards

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

5.2.1. 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.

5.2.2 Hazards related to loading and unloading

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

5.2.3 Hazards related to transport

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

5.3. Communication and documentation of controls during transport

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.

5.4. Dedicated Transport

[Bulk foodstuffs in liquid, granulated or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs.]

In some cases it may be justified, after a proper assessment of the risks, to require transport dedicated to the foodstuff, however this does not exempt from taking the appropriate precautionary measures.

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

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. Rinsing and drying, where appropriate, should follow disinfection.

7. ESTABLISHMENT: PERSONNEL HYGIENE

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

8. TRAINING

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.