codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-Second Session
Geneva, 23-28 June 1997

REPORT OF THE TWENTY-EIGHTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE
Washington D. C., 27 November - 1 December 1995

SUMMARY AND CONCLUSIONS

The Twenty-eighth Session of the Codex Committee on Food Hygiene reached the following conclusions:

MATTERS FOR CONSIDERATION BY THE COMMISSION AND THE EXECUTIVE COMMITTEE

The Committee recommended the adoption of the following texts:

(a) Draft Revised Recommended International Code of Practice - General Principles of Food Hygiene at Step 8 (para. 13 & Appendix II);

(b) Revised Guidelines for the Application of the Hazard Analysis Critical Control Point System at Step 5 (para. 18 & Annex to Appendix II);

(c) Revised Principles for the establishment and application of microbiological criteria for foods at Step 5 (para.32 & Appendix III); and

(d) Proposed draft Code of Practice for refrigerated foods with extended shelf-life at Step 5 (para. 39). The draft code will be distributed separately.

OTHER MATTERS OF INTEREST TO THE COMMISSION

- agreed to recommend to the Commodity Committees to consider utilising Method A in the elaboration/revision of their Product Codes (para. 25);

- agreed to discuss comments on the "Application of the HACCP Approach for the Specific Production of Normandy Camembert" at its 29th Session (para. 45);

- requested a re-draft of "Recommendations for the control of *Listeria monocytogenes*", and agreed that background documents on the revised text should include criteria for *Listeria monocytogenes, Salmonella* with special reference to *S. Enteriditis, Campylobacter* and entero haemorrhagic *Escherichia coli* (para. 50);

- requested the preparation of a discussion paper on "Guidelines on the application of the principles of risk assessment and risk management to food hygiene including strategies for their application (para.58);

- requested the further development of a paper on "Implications for the broader application of the HACCP system (para. 60);

- requested the preparation of a first draft Code of Practice for all Foodstuffs Transported in Bulk (para 64); and

- requested the preparation of a first draft Code of Hygienic Practice for Bottled Water (other than natural mineral water).(para. 68)

TABLE OF CONTENTS

	Paragraphs
INTRODUCTION	1
OPENING OF THE SESSION	2
ADOPTION OF THE AGENDA	4
REPORT BY THE SECRETARIAT ON MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES	5 - 7
CONSIDERATION OF THE DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE	8 - 13
REVISION OF THE GUIDELINES FOR THE APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM	14 - 18
REVISION OF THE CODEX CODE OF HYGIENIC PRACTICE FOLLOWING ADOPTION OF THE REVISED GENERAL PRINCIPLES OF FOOD HYGIENE	19 - 25
REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS	26 - 32
PROPOSED DRAFT CODE OF PRACTICE FOR REFRIGERATED FOODS WITH EXTENDED SHELF-LIFE	33 - 39
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNRIPENED/ UNCURED CHEESE AND RIPENED SOFT CHEESE	40 - 45
RECOMMENDATIONS FOR THE CONTROL OF *LISTERIA MONOCYTOGENES*	46 - 50
GUIDELINES ON THE APPLICATION OF PRINCIPLES OF RISK ASSESSMENT AND RISK MANAGEMENT TO FOOD HYGIENE INCLUDING STRATEGIES FOR THEIR APPLICATION	51 - 58
IMPLICATIONS FOR THE BROADER APPLICATION OF THE HACCP SYSTEM	59 - 60
PROPOSED CODE OF PRACTICE FOR ALL FOODSTUFFS TRANSPORTED IN BULK	61 - 64
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED WATER (OTHER THAN NATURAL MINERAL WATER)	65 - 68
OTHER BUSINESS AND FUTURE WORK	69 - 72
DATE AND PLACE OF NEXT SESSION	73

Page

SUMMARY STATUS OF WORK 15

APPENDICES

APPENDIX I — LIST OF PARTICIPANTS 16

APPENDIX II — DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE 35

ANNEX - REVISED GUIDELINES FOR THE APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM 66

APPENDIX III — PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS 76

ALINORM 97/13

REPORT
OF THE TWENTY-EIGHTH SESSION
CODEX COMMITTEE ON FOOD HYGIENE
Washington D. C., 27 November - 1 December 1995

INTRODUCTION

1. The Codex Committee on Food Hygiene held its Twenty-eighth Session from 27 November to 1 December 1995, by courtesy of the Government of the United States of America. The session was chaired by Dr. I. Kaye Wachsmuth, Deputy Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration. The session was attended by 170 delegates and observers from 39 countries and 14 international organizations. A complete list of participants, including the Secretariat, is provided in Appendix I to this report.

OPENING OF THE SESSION (Agenda Item 1)

2. The Committee was addressed by Dr. Sanford A. Miller, Professor and Dean, Graduate School of Biomedical Sciences, University of Texas, Health Sciences Center.

3. The subject of his talk was "The Globalization of Food Safety: A Proposal". Dr. Miller proposed the need for the separation of science based risk assessment from the application of risk management by governments, as well as the need for applying a harmonized food safety approach internationally.

ADOPTION OF THE AGENDA[1] (Agenda Item 2)

4. The Committee adopted the Provisional Agenda as proposed, and agreed to discuss matters regarding other business and future work under Agenda item 13.

REPORT BY THE SECRETARIAT ON MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES[2] (Agenda Item 3)

5. The Committee was informed that the Commission at its 21st Session approved the Medium-Term plan recommended to it by its Executive Committee. The Codex Committee on Food Hygiene noted the high priority rating accorded to work on *Listeria* and on the Principles for the establishment of microbiological criteria. The Committee further proposed that priority should be given to entero-haemorrhagic *Escherichia coli, Campylobacter* and *Salmonella,* (see Agenda Item 13).

---

1 CX/FH 95/1

2 CX/FH 95/2, CX/FH 95/2 Addendum 1

6. The Committee noted action being taken by the Codex Committee on Milk and Milk Products in reviewing the technical aspects of the Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese.

7. The Committee was informed that the Codex Committee on Methods of Analysis and Sampling at its 20th Session requested the Codex Committee on Food Hygiene to examine the Draft Codex General Guidelines on Sampling and advise on the applicability of the Guidelines for microbiological investigations, (see Agenda Item 13).

CONSIDERATION OF THE DRAFT REVISED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE[3] (Agenda Item 4(i))

8. The Code of Practice revised at the 27th Session of the Codex Committee on Food Hygiene (ALINORM 95/13, Appendix III), had been adopted by the 21st Session of the Codex Alimentarius Commission at Step 5 (ALINORM 95/37, para. 51). Subsequent to the Commission meeting, comments were requested on the draft code (including definitions) at Step 6 under Circular Letter CL 1995/24-FH.

9. The Committee decided to form an *ad hoc* Working Group under the direction of the Delegation of the United Kingdom to review the Code, to consider the comments submitted and the definitions proposed.

10. The Committee reviewed the revised Code elaborated by the *ad hoc* Working Group and agreed to the proposed text with minor changes.

11. Notwithstanding the opinion of the delegations of Indonesia and the Philippines that Section 8.3 concerning Use and Maintenance was overly restrictive and should be deleted since it might constitute a trade barrier, the Committee agreed to leave this section as drafted.

12. The Committee also noted the opinion of the Delegation of Brazil in Section 5.8 concerning Recall Procedures, that adequate measures should be taken in plant design and operation to prevent cross-contamination, especially for recalled products that could not be reused or reprocessed.

STATUS OF THE DRAFT REVISED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE

13. The Committee thanked the working group for its outstanding efforts and **agreed** to forward the draft revised International Code of Practice - General Principles of Food Hygiene to the 22nd Session of the Codex Alimentarius Commission for adoption at Step 8. The Code is attached to this report as Appendix II.

---

[3] ALINORM 95/13,Appendix III; CL 1995/24-FH; CX/FH 95/3 comments by Canada, Czech Republic, Denmark, Hungary, New Zealand, South Africa, Spain, Switzerland, United Kingdom, United States, and the International Dairy Federation; CRD 1 comments by France and the Netherlands; CRD 3 comment by WHO; and CRD 12 comment by the European Community.

REVISION OF THE GUIDELINES FOR THE APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM[4] (Agenda Item 4(ii))

14. The 20th Session of the Codex Alimentarius Commission had adopted the Guidelines and decided that improvements to the Guidelines could be carried out by the Codex Committee on Food Hygiene in the course of the revision of the Code of Practice - General Principles of Food Hygiene. Comments were requested under CL 1995/24-FH.

15. The Committee decided to convene an *ad hoc* Working Group under the direction of the United States to review the Guidelines, to consider the comments submitted and to present a revised draft to the Committee.

16. The Delegation of the United States presented the revised draft to the Committee for discussion section by section. The Committee noted that several amendments to the text were based on the result of a WHO Consultation (with the participation of FAO) on the Hazard Analysis Critical Control Point System: Concept and Application, which was held in Geneva from 29-31 May 1995 (unpublished document WHO/FNU/FOS 95.6).

17. The Committee agreed to the revised text as presented by the Working Group with minor modifications. The Committee also agreed that additional comments should be requested, including an appropriate definition for the term "flow diagram", as well as requirements concerning record keeping and documentation (Principle 7), especially as related to flexibility for small businesses.

STATUS OF THE REVISED GUIDELINES FOR THE APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM

18. The Committee thanked the *ad hoc* Working Group for its outstanding efforts, and **agreed** to forward the proposed draft Guidelines to the 43rd Session of the Executive Committee for adoption at Step 5, with the understanding that additional comments would be requested immediately. The Guidelines, which will eventually be annexed to the Code of Practice - General Principles of Food Hygiene, are annexed to Appendix II of this report.

REVISION OF CODEX CODES OF HYGIENIC PRACTICE FOLLOWING ADOPTION OF THE REVISED GENERAL PRINCIPLES OF FOOD HYGIENE[5] (Agenda Item 4 (iii))

19. At its 27th Session, the Committee recommended that appropriate sections of all product codes which contained materials based on sections of the current Recommended International Code of Practice - General Principles of Food Hygiene be highlighted and amended following the final adoption of the Revised General Principles of Food Hygiene by the Commission (ALINORM 95/13, para. 27). In view of the progress being made

---

4 CL 1995/24-FH; CX/FH 95/3 Addendum 1 comments by Canada, New Zealand, United Kingdom and the United States; CRD 2 comment by the Netherlands, CRD 3 comment by WHO; CRD 12 comment by the European Community

5 CX/FH 95/3, Addendum 1 and CX/FH 95/3 Annexes to Addendum 1

with regard to the elaboration of the Code of Practice - General Principles of Food Hygiene and in order not to delay the elaboration of new codes or the revision of current ones, the Delegation of the United Kingdom had been requested by the Codex Secretariat to consider how the product Codes could be revised.

20. The Delegation of the United Kingdom stated that the relevant document outlined administrative process presenting three ways by which the product Codes could be revised for consideration by the Committee. Five product Codes had been selected for this purpose. The Committee was informed of the rationale behind the three approaches, i.e. Method A, Method B and Method C, and also of their advantages and disadvantages.

21. In Method A, the revised Product Code contained references made to relevant sections of the General Principles of Food Hygiene. Although this method would result in a less voluminous text and cost less to produce, it would have to be read in conjunction with the General Principles. The user could refer to product specific differences to the General Principles of Food Hygiene and it would be less time-consuming to carry out the changes to the Product Codes. It was suggested that Method A might be preferred by Government Agencies.

22. On the other hand, in Method B, the Product Code was made by inserting product specific sections at relevant points in the General Principles of Food Hygiene and by amending various sections in the General Principles. By this approach, there would be no need for cross-referencing because all the information would be in one document, in logical order. However, the size and cost of production of the Code would be more than for Method A. It was also suggested that some industry users might prefer this option.

23. Method C was a variation of Method A, in which the objectives and rationale for each section were included to add reinforcement to the importance of the General Principles of Food Hygiene.

24. The majority of the delegations indicated their preference for Method A, while some others preferred Method B. It was suggested to seek the opinions of the Commodity Committees. It was noted that within the European Union, an approach which was closely related to Method A was being considered in the review of all the EU Directives.

STATUS OF THE REVISION OF CODEX CODES OF HYGIENIC PRACTICE FOLLOWING ADOPTION OF THE REVISED GENERAL PRINCIPLES OF FOOD HYGIENE

25. The Committee **agreed** to recommend to the Commodity Committees to consider utilising Method A in the elaboration or revision of their Product Codes, with the understanding that the opinions of the Commodity Committees should also be taken into account.

REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS[6]
(Agenda Item 5)

26. The paper was prepared and introduced by the Representative of the International Commission on Microbiological Specifications for Foods (ICMSF). The Committee was informed that at its 27th Session, the ICMSF was requested to revise the draft document in view of the substantial comments made.

27. The Committee was informed that the draft document which was circulated under CL 1995/31-FH took account of most of the improvements and suggestions made during the Committee's 27th Session. The draft also contained square bracketed elements which required further discussion by the Committee.

28. In view of the written comments received in response to the circular letter and in order to facilitate work on this subject matter, the Committee agreed that an *ad hoc* Working Group chaired by the Delegation of France should revise the document during the session.

29. The Committee was informed by the Delegation of France that the document was revised by the working group and that consensus was reached on the amendments proposed. Some of the changes made included replacement of the word "specifications", which appeared throughout the document, with "criteria" and where appropriate with "criterion".

30. The Committee considered the amended draft prepared by the *ad hoc* Working Group section by section and made several editorial changes, in addition to those submitted for its consideration.

31. Although some delegates supported forwarding the text for adoption by the Commission at Step 8 by omitting Steps 6 and 7, other delegations felt that in view of the significant changes made during the session, the text should be re-circulated for additional comment. The draft text is attached as Appendix III to this report

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

32. The Committee thanked the Working Group for its efforts, and **agreed** to forward the proposed draft Principles for the Establishment and Application of Microbiological Criteria for Foods to the 43rd Session of the Executive Committee for adoption at Step 5. Governments were requested to direct their comments to the Delegation of France.
(see para. 50).

---

6 CL 1995/31-FH; CX/FH 95/4, comments by Canada, Czech Republic, Hungary, Republic of South Africa, Spain, Switzerland, United Kingdom United States, Asean Executing Agency, and the IDF
CRD 4, comments by France, the Netherlands and New Zealand;
CRD 12, comment by European Community

PROPOSED DRAFT CODE OF PRACTICE FOR REFRIGERATED FOODS WITH EXTENDED SHELF LIFE[7] (Agenda Item 6)

33. The proposed draft Code had been revised by the Delegations of Canada and France based on comments made at the 27th Session of the Committee.[8] Revisions and/or additions were made to those sections concerning the Scope, HACCP principles and guidelines, general hygienic principles and barrier methods to prevent contamination.

34. Several delegations felt that the text of the draft should be strengthened to allow for greater flexibility with respect to refrigeration requirement, storage temperature other than 4°C and methods to ensure the safety of extended shelf life products might be suitable if supported by scientific evidence.

35. Most delegations agreed that the mention of specific pasteurization values was unadvisable, especially in view of the broad spectrum of products covered by the Scope of the Code (Section 1). It was also noted that HACCP principles should be incorporated throughout the text, instead of their somewhat limited reference in Section VIII.

36. The Committee decided to form an *ad hoc* Working Group under the direction of the Delegation of Canada to review the Code, to consider the comments submitted and to present a revised draft to the Committee.

37. In presenting the revised text elaborated by the *ad hoc* Working Group, the Delegation of Canada indicated that the group focussed attention on those sections related to Scope, Refrigeration Requirements (Section 7.7.1) and Important Elements (Section 8.3). The Delegation also noted that in future drafts, sections already covered in the General Principles of Food Hygiene would be highlighted to identify possibilities for eliminating redundant text.

38. The Committee agreed to the revised draft Code as presented with minor modifications. The draft Code will be distributed separately.

STATUS OF THE PROPOSED DRAFT CODE OF PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF LIFE

39. The Committee thanked the Working Group for its outstanding efforts, and **agreed** to forward the proposed draft Code to the 43rd Session of the Executive Committee for adoption at Step 5, with the understanding that government comments would be requested immediately.

---

7 CL 1995/34-FH; CX/FH 95/5, comments by Denmark, Hungary, Spain, United Kingdom, United States; CRD 13, comment by the Netherlands; CRD 12, comment by the European Community

8 ALINORM 95/13, paras. 47-52

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED/ UNRIPENED CHEESE AND RIPENED SOFT CHEESE[9] (Agenda Item 7)

40 The Chairperson informed the Committee that the body of the text was not available for discussion, primarily because the Codex Committee on Food Hygiene was awaiting action to be taken by the Codex Committee on Milk and Milk Products in May 1996. It was proposed that in revising the body of the text, the Code should also address the health condition of the milk cows, the hygienic conditions for the treatment and conservation of the milk on the farm, criteria for somatic cell counts and microbiological criteria for the raw milk prior to processing and the criteria for milk destined for the manufacture of soft cheeses where the milk is not to be pasteurised.

41. The Delegation of France presented the Annex to the Draft Code. The delegation recalled the background to the development of the Annex, from the 25th to the 27th Sessions[10] of the Committee. As requested by the Committee, the paper prepared by the Delegation of France addressed the microbiological criteria for products covered by the Code and for raw milk used in the production of soft cheese.

42. The Delegation also prepared a practical example for the application of the HACCP approach for the specific production of Normandy Camembert. The Scope of the document was defined and microbiological risks which were the main concern of such types of products were identified. Some specific definitions were taken from the French legislation and a model production diagramme was also provided. The document proposed risk analysis for microorganisms of concern which included: *Mycobacterium tuberculosis, Brucella abortus, Salmonella spp., Listeria monocytogenes, Staphylococcus aureus* and *Escherichia coli.* Specification Sheets were included in the annex to the document as well as applicable excerpts from the French legislation.

43. The view was expressed that the safety of cheeses made with unpasteurised milk, regardless of the use of HACCP principles, could not be consistently assured and that the use of raw milk for cheese production should not be considered by the Committee. It was also noted that the document should evaluate the risk of entero-haemorrhagic *Escherichia coli* in order to enhance protection of the consumer.

44. The opposing view was that with strict compliance to HACCP system throughout the production of such cheeses and the application of animal health standards in milk production, it was possible to achieve a sufficient guarantee of quality and safety.

45. The Committee **agreed** that comments to be requested on the document prepared by the Delegation of France (CRD 5), would be discussed at the Committee's 29th Session. These discussions would include the possibility of elaborating a document concerning Hygienic Practice for Cheeses made from Unpasteurized Milk. It was understood that if

---

9 CRD 5, Paper prepared by France; CRD 6, comments by Canada, the Netherlands and New Zealand; CRD 12 comment by European Community

10 ALINORM 95/13, para. 72

such a document was elaborated, it would eventually be included as an Annex to the Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese.

RECOMMENDATIONS FOR THE CONTROL OF *LISTERIA MONOCYTOGENES*[11] (Agenda Item 8)

46. The Representative of the International Commission on Microbiological Specifications for Foods (ICMSF), stated that the revised document included comments made during the 27th Session of the Committee, as well as a harmonized approach to the certification of HACCP based procedures for use in trade for the control of *Listeria monocytogenes*.

47. The Committee was informed that ICMSF felt it was too early to propose protocols or guidelines for certification as the HACCP text[12] was under revision and some general principles on certification ought to be provided by the Codex Committee on Food Export and Import Certification and Inspection Systems. The revised draft document therefore focussed on the control of *Listeria monocytogenes*.

48. The revised draft text was meant to give guidance for the development of criteria and also to provide governments, industries and food handlers, guidance for the inspection of lots of consignments of foods of unknown history. The ICMSF re-iterated that control over *Listeria monocytogenes* hazard could only be achieved by applying HACCP based systems. The Committee was informed that the sampling plans proposed followed closely the principles for the establishment and application of microbiological criteria for foods.

49. Some delegations provided clarifications on some of the issues raised in their written comments. The following points were discussed:

- the tolerance level for *Listeria monocytogenes* for foods with unknown history should be at the point of entry, which was more useful for regulatory purposes, than at the point of consumption;

- that the standard of 100 cells of *Listeria monocytogenes*/g of food at the point of consumption was unacceptable to some countries which already have a zero tolerance;

- that the draft text should define foods which have potential to support growth of *Listeria monocytogenes* and also to address approaches to assessing the safety of imported foods of unknown history;

---

11 CL 1995/32-FH, Paper prepared by the International Commission on Microbiological Specifications for Foods;
CX/FH 95/7, comments by Canada, Czech Republic, Hungary, New Zealand, Republic of South Africa, Spain, United Kingdom, United States and IDF; CRD 7, comment by France;
CRD 11, comment by Denmark and CRD 12, comment by the European Community

12 ALINORM 95/13, Appendix III - Guidelines for the Application of the HACCP System

- that there was need to make distinction between foods specifically intended for high risk groups and foods for the general population of consumers which also includes high risk groups;

- that the strategy for the control of *Listeria monocytogenes* should include using both HACCP throughout production and educational approaches because public health advice was considered to be important in the control of *Listeria monocytogenes;*

- in the case of vulnerable consumer groups in combination with high risk foods, safety was not ensured by taking high number of samples, nor can that approach be applied cost-effectively;

- that the sampling plan with n=5, c=0 was not a sensitive sampling plan, because it would not offer sufficient confidence that *Listeria monocytogenes* would be detected; and

- that the epidemiological link early in the Decision Tree was considered inappropriate. Also that it was difficult to use the decision tree in real-life sampling situation. A 3-class sampling plan was suggested.

50. The Committee **agreed** to request the ICMSF to re-draft the text in light of the discussions and the comments made. It was also agreed that background documents on the revised text should include criteria for *Listeria monocytogenes, Salmonella* with special reference to *S. enteriditis, Campylobacter* and entero haemorrhagic *Escherichia coli*. (see para.32).

GUIDELINES ON THE APPLICATION OF PRINCIPLES OF RISK ASSESSMENT AND RISK MANAGEMENT TO FOOD HYGIENE INCLUDING STRATEGIES FOR THEIR APPLICATION[13] (Agenda Item 9)

51. The Committee noted that the 21st Session of the Codex Alimentarius Commission considered the report of the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues, which was held in Geneva from 13-17 March 1995.

52. The Commission agreed that there was a need for further clarification of terms and definitions used for risk analysis and therefore, comments were solicited under CL 1995/37-CAC. The circular letter drew the attention of governments to amendments proposed for the terms risk communication (to include explicit reference to consumers), risk assessment (to include reference to severity of effects) and risk characterization (to include reference to probability).

53. The Commission also recommended further work to address risk management, risk communication and defining the roles and responsibilities of the different bodies involved in

---

[13] ALINORM 95/9 and WHO/FNU/FOS/95.3; CRD 8, comments by the Netherlands and the United States; CRD 12, comment by the European Community

the risk analysis process as well as on uncertainty and variability in risk analysis in relation to standard setting and food regulation.

54. The Commission agreed that the Report and recommendations of the Consultation should be examined by relevant Codex Committees, including the Codex Committee on Food Hygiene. The Commission noted the need for taking into consideration the problems of developing countries in regard to implementing the risk analysis approach in their food regulations.

55. The Committee was informed that the Consultation examined both chemical and biological risks; the latter were addressed in part by Codex codes of hygienic practice. It was noted that the need for qualitative and/or quantitative risk assessment approaches for biological hazards should be incorporated into the texts elaborated by the Codex Committee on Food Hygiene.

56. The Committee supported a science-based approach to incorporate risk analysis into its work, while recognizing the use of HACCP as a primary means to this end. It was noted, however, that a more formalized approach was required when quantitative values were incorporated into those CCFH texts under consideration.

57. Although it was noted that FAO and WHO contemplated the convening of another expert consultation related to risk management, the development of a specific framework, including principles and guidelines specific to the work of the Committee was required. The importance of examining current private and government approaches to these issues was also highlighted, especially as related to the relationship between HACCP and risk analysis.

58. The Committee **agreed** that a discussion paper, including a preliminary framework, would be developed under the direction of the United States, with assistance provided by Canada, Denmark, France, Germany, the Netherlands, New Zealand, Norway, Spain and the United Kingdom, for consideration at its 29th Session. It was noted that the paper should address the implementation of the recommendations of the FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues in the work of CCFH.

IMPLICATIONS FOR THE BROADER APPLICATION OF THE HACCP SYSTEM[14] (Agenda Item 10)

59. The Committee at its 27th Session requested the Delegation of Australia to further develop the above document based on government comments[15] to be submitted. Additional comments had not been received.

---

14 CX/FH 95/9

15 ALINORM 95/13, para. 102

60. The Committee **accepted** the offer of the Delegation of Australia to further develop the discussion paper (i.e. CX/FH 95/9) into a general guidance document for circulation and comment prior to its next session.

PROPOSED CODE OF PRACTICE FOR ALL FOODSTUFFS TRANSPORTED IN BULK[16] (Agenda Item 11)

61. The Committee was informed that this new work was approved by the 21st Session of the Commission. The Commission requested that the Codex Committee on Food Hygiene take first action on this matter in cooperation with the Codex Committee on Food Additives and Contaminants.

62. The Committee was informed by the Delegation of the United States that food-borne disease outbreaks had been associated with food conveyed in unsanitary vehicles. It was therefore necessary to address this issue in order to protect the consumer. In this regard, the delegation referred to concerns highlighted in the discussion paper which should be considered in developing the proposed code. These concerns included methods of eliminating prior cargo contamination, construction materials for food contact surfaces in bulk food conveyances so as to eliminate contamination, minimum requirements for refrigerated or frozen food transport or storage, maximum temperature during transportation or during loading and unloading, methods of live animal haulage, record keeping and the incorporation of relevant sections of the General Principles of Food Hygiene.

63. Several delegations felt that live animals should not be included in the proposed code as this issue was addressed by other international bodies. However, it was recognized that live animal transport could contaminate further processed products. The Committee recognised the work of other bodies such as the International Dairy Federation, the ATP Agreement on the international transport carriage of perishable foodstuffs and on the special equipment to be used for such carriage and the draft Code of Practice for the Storage and Transport of Fats and Oils in Bulk[17] and agreed that these would be taken into account in the elaboration of the proposed code.

64. The Committee **agreed** that a drafting group lead by the Delegation of the Netherlands, in cooperation with Canada, Indonesia, Malaysia, the Philippines, Republic of South Africa and the United States, would prepare an initial draft for circulation for comments at Step 3 of the Procedure.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR BOTTLED WATER (OTHER THAN MINERAL WATER)[18] (Agenda Item 12)

65. The Committee was informed that the 21st Session of the Codex Alimentarius Commission endorsed this proposal for new work at Step 1 (ALINORM 95/37, para. 85).

---

16 CX/FH 95/10, Paper prepared by the Delegation of the United States; CRD 9, comments by the Netherlands

17 CL 1995/42-FO (currently in circulation for comment)

18 CX/FH 95/11; CRD 10, comment by France

66. In introducing the document, the Delegation of the United States noted the increased trade in bottled water (other than natural mineral water), especially as a means to provide relief to areas affected by drought or other natural disasters. Although it was noted that some bottled water was of questionable quality, adequate treatment and good bottling practices could assure the production of safe products. The issue of contamination of bottled water by various protozoa was also noted.

67. The Committee supported the elaboration of the code in order to insure the protection of consumers' health. The Committee suggested that the following items should be considered in the elaboration of the proposed draft code:

- the scope should be adequately defined to prevent confusion with other similar products;

- limits of protozoan contamination should be established;

- heat treatment, as well as other purification methods highlighted in the discussion paper, should be considered;

- the water source, including naturally protected and subsurface sources, should be defined;

- appropriate validated methods of analysis should be defined;

- provisions concerning surface water contamination by algae should be addressed; and

- labelling provisions concerning water origin, treatment and microflora should be included.

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

68. The Committee **agreed** that a proposed draft Code would be prepared under the direction of the United States based on the discussion, with assistance provided by France, Indonesia, Japan, Spain and Switzerland, for consideraton at its next session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 13)

(a) Other Business

69. The Committee addressed two issues.

- The Committee considered the request of the Codex Committee on Methods of Analysis and Sampling (CCMAS) (see CX/FH 95/2, Addendum 1) to indicate the applicability of the Codex General Guidelines on Sampling to microbiological

investigations. The Committee **decided** that individual governments should provide comments directly to the CCMAS in this regard.

- The Committee noted the view expressed by the Delegation of Sweden that for consistency within Codex system, the terms of reference for the CCMAS may need to be reviewed to include the endorsement of microbiological methods.

(b) Future Work

70. The Committee agreed to continue work on the following items:

- Revision of the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System;

- Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods;

- Proposed Draft Code of Practice for Refrigerated Packaged Foods with Extended Shelf-Life;

- Proposed Draft Code of Hygienic Practice for Unripened/Uncured Cheese and Ripened Soft Cheese;

- Recommendations for the control of *Listeria monocytogenes*;

- Guidelines on the Application of the Principles of Risk Assessment and Risk Management to Food Hygiene including Strategies for their application;

- Implications for the Broader Application of the HACCP System;

- Code of Practice for all Foodstuffs Transported in Bulk; and

- Code of Hygienic Practice for Bottled Water.

The Committee also agreed to follow the Commission's request to embark on new work related to the microbiological contamination of food, especially in regard to entero-haemorrhagic *Escherichia coli*. The Committee also decided that work should commence on *Salmonella* and *Campylobacter*. The Committee accepted the offer of the Representative of the ICMSF to prepare a discussion paper for the aforementioned pathogens including *Listeria monocytogenes*, with assistance provided by Denmark.

71. The Committee noted that the 42nd Session of the Executive Committee had not approved its proposal to establish "Guidelines for the Education of Consumers in Food Hygiene", as FAO was preparing guidelines for consumer education in food handling and food safety and that WHO had published materials to promote health education in food safety. The Committee was of the opinion that the active role of the Codex Committee on Food Hygiene was required. The Delegation of the United States agreed to prepare a short

explanation of such a proposal for the 43rd Session of the Executive Committee in this regard.

72. In regard to the request of the United States to develop an annex to the General Principles of Food Hygiene concerning cleaning and disinfection and the recycling of water used in food processing, the Representative of WHO indicated that these subjects were already addressed.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 14)

73. The Committee was informed that its 29th Session was tentatively scheduled to be held in Washington D. C. in October 1996, the exact dates will be determined by the United States and the Codex Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 97/13
Adoption of the Draft Revised International Code of Practice - General Principles of Food Hygiene	8	22nd Session CAC	Appendix II, para. 13
Adoption of the Revised Guidelines for the Application of the HACCP System	5	43rd Session of the Executive Committee	para. 18
Adoption of the Revised Principles for the Establishment and Application of Microbiological Criteria for Foods	5	43rd Session of the Executive Committee	para. 32
Adoption of the Proposed Code of Practice for Refrigerated Packaged Foods with Extended Shelf-Life	5	43rd Session of the Executive Committee	paras 38 & 39
Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese	3	France/Netherlands/ USA 29th Session CCFH	para. 45
Proposed Code of Practice for all Foodstuffs Transported in Bulk	3	The Netherlands, Canada, Indonesia, Malaysia, The Philippines, South Africa, & USA	para. 64
Recommendations for the control of *Listeria monocytogenes*	-	29th Session CCFH & ICMSF	para. 50
Consideration of approaches to be adopted in revising the Commodity Codes	-	Commodity Committees	para. 25
Guidelines on the Application of Principles of Risk Assessment and Risk Management to Food Hygiene including Strategies for their Application	-	Canada, Denmark, France, Germany, the Netherlands, New Zealand, Norway, Spain, & the United Kingdom & 29th Session CCFH	para. 58
Implications for the Broader Application of the HACCP System	-	Australia & 29th Session CCFH	para. 60
Proposed Draft Code of Hygienic Practice for Bottled Water (other than natural mineral water)	-	USA, France, Indonesia, Japan, Spain, Switzerland & 29th Session CCFH	para. 68
Preparation of background documents on *Listeria monocytogenes, Salmonella*, with special reference to *S. enteriditis, Campylobacter* & entero haemorrhagic *Escherichia coli*	-	29th Session CCFH & ICMSF	para. 50

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

Chairperson:
Président:
Presidente:

Dr. I. Kaye Wachsmuth
Deputy Director
Center for Food Safety and Applied Nutrition (HFS-2)
Food and Drug Administration
200 "C" Street, S.W.
Washington, DC 20204, USA
Tel: 202/205-4057
Fax: 202/205-5025

Assistant to the Chairperson:
Assistant du Président:
Asesor del Presidente:

Dr. John Kvenberg
Strategic Manager for HACCP Policy
Food and Drug Administration
Room 3014, HFS-20
330 "C" Street, S.W.
Washington, DC 20204, USA
Tel: (202) 205-4010
Fax: (202) 205-4121

MEMBER COUNTRIES
PAYS MEMBRES
PAISES MIEMBROS

AUSTRALIA
AUSTRALIE

Dr. Jack Haslam
Veterinary Counsellor
Embassy of Australia
1601 Massachusetts Ave., N.W.
Washington, DC 20036, USA
Tel: 202-797-3319
Fax: 202-797-3037

Mr. Richard A. Souness
Director, Food Hygiene
National Food Authority
P.O. Box 7186
Canberra ACT 2610
Australia
Tel: (06)2712249
Fax: (06)2712209

BELGIUM
BELGIQUE
BELGICA

M. B. Horion
Inspecteur des denrées alimentaires
Service d'Inspection des denrées alimentaires
Ministère de la Santé publique
Cité Administrative de l'Etat
Bd. Pacheco, 19, Bte 5
B-1010 Brussels, Belgium

BOTSWANA

Dr. Kereng Masupu
Deputy Director of Animal Health
and Production
Private Bag 0032
Gaborone, Botswana

Ms. Seingwaeng Kgafela
Chemist, Animal Health and
Production
Private Bag 0032
Gaborone, Botswana

Mr. Anderson Dintle Chibua
Director
District Administration & Food Relief
Services
Private Bag 443
Gaborone, Botswana
Tel: 354-124/125
Fax: 373-483

BRAZIL
BRESIL
BRASIL

Dilma Scala Gelli
Food Microbiology
Inst. Adolfo Lutz
Av. Dr. Arnaldo, 355
Sao Pãulo, Brazil
01246902
Tel: 55-11-851-0011
Fax: 55-11-853-3505

Manuel C. Montenegro
Brazilian Embassy
3006 Massachusetts Ave., NW
Washington, DC 20008, USA
Tel: (202) 745-2750
Fax: (202) 745-2827

Maria Angelica Ribeiro de Oliveira
Chefe de Divisão
Ministerio da Agricultura
Esplanada dos Ministerios Bloco "B"
Anexo "A" 10 Andar, Sala 314
Brasilia, Brazil
Tel: 061-223-7073
Fax: 061-226-3446

Adauto Lima Rodrigues
Coordenador Para Assuntos do
Codex Alimentarius no MAARA
Ministerio da Agricultura
Esplanada dos Ministerios (ADD)
Anexo Maara 40 Andar 5/408
Brasilia, Brazil
Tel: 55-61-5536182/2269799
Fax: 55-61-2243995

Francisco Bezerra Da Silva
Ministerio da Agricultura (PNCRB)
Edificio Auetfo 4o andar s/411
70043.900 Brasilia DF
Brazil
Tel: (061) 226-9771/6182
Fax: (061) 224-3995/218-2316

CANADA

Dr. Joost Harwig
Director, Bureau of Microbial Hazards
Food Directorate
Health Canada
Room C309, Sir F.G. Banting Bldg.
2203G3, Tunney's Pasture
Ottawa, Ontario K1A 0L2
Canada
Tel: 613/957-0880
Fax: 613/954-1198

Dr. Murray A. Johnston
Section Head, Food Inspection Standards
Health Canada
Health Protection Branch Building
Tunney's Pasture
Ottawa, Ontario K1A 0L2
Canada
Tel: 613/957-1750
Fax: 613/957-3537

Mr. Bertrand G. Gagnon
Chief, Food Preservation Systems
Agriculture and Agri-Food Canada
59 Camelot Drive
Nepean, Ontario K1A 0Y9, Canada
Tel: 613/952-8000
Fax: 613/993-8959

Dr. Bruce Brown
B.E. Brown Associates
Representing Food Institute of Canada
328 Stone Quarry Priv.
Ottawa, Ontario
K1K 3Y2, Canada
Tel: 613/749-9230
Fax: 613/749-8793

Mr. Adrien Gervais
Chief, Scientific and Technical Programs
Inspection Branch
Fisheries and Oceans Canada
200 Kent Street, Station 906
Ottawa, Ontario
K1A 0E6, Canada
Tel: 613/990-0148
Fax: 613/990-4668

CHINA
CHINE

Chaowei Li
First Secretary, Chinese Embassy
Embassy of P.R. China
2133 Wisconsin Ave., NW
Washington, DC 20007, USA
Tel: (202) 625-3356
Fax: (202) 337-5864

CÔTE D'IVOIRE

Mr. Bakayoko Aboubakar
Secretary General
National Committee for Food Development
BP V 190 Abidjan
Côte d'Ivoire
Tel: (225) 21 4934
Fax: (225) 21 5754

CZECH REPUBLIC
REPUBLIQUE TCHEQUE
REPUBLICA CHECA

Hana Rambouskova
Embassy of the Czech Republic
Washington D.C., USA

DENMARK
DANEMARK
DINAMARCA

Mr. Sven Qvist
Chief Microbiologist
Ministry of Agriculture and Fisheries
Danish Veterinary Service
Food Control Laboratory
Howitzvej 13
DK-2000 Frederiksberg
Denmark
Tel: 45-3187-1133
Fax: 45-3834-6265

Dr. Jørgen Schlundt
Head of Section, D.V.M., Ph.D.
National Food Agency of Denmark
Mørkhøj Bygade 19
DK-2860 Søborg
Denmark
Tel: 45-396-96600
Fax: 45-396-60100

Ms. Cristina Galliano
Scientific Advisor, D.V.M., M.Sc.
National Food Agency of Denmark
Mørkhøj Bygade 19
DK-2860 Søborg
Denmark
Tel: 45-3969-6600
Fax: 45-3966-0100

Ms. Kirsten Jacobsen
Head of Department, M.Sc.
Confederation of Danish Industries
DK-1787 København V
Denmark
Tel: 45-3377-3377
Fax: 45-3377-3300

ECUADOR
EQUATEUR

Mireyz Nunoz
Government of Ecuador
2535 15th St., N.W.
Washington, DC 20009, USA
Tel: 202/234-7200
Fax: 202/667-3482

Pablo Yanez
Government of Ecuador
2535 15th St., N.W.
Washington, DC 20009, USA
Tel: 202/234-7200
Fax: 202/667-3482

EGYPT
EGYPTE
EGIPTO

Agr. Engineer Hassan Khamis Soliman
Tech. Sector Manager
Alexandria Oil and Soap Co.
Member of the Egyptian Codex Committee
76 Canal Elmahmoudia
Alexandria, Egypt

FINLAND
FINLANDE
FINLANDIA

Mr. Veli-Mikko Niemi
Senior Health Officer
Ministry of Social Affairs and Health
Box 197
00531 Helsinki
Tel: 358-0-0164121
Fax: 358-0-160-4120

Mr. Pekka Pakkala
Deputy Director
National Food Administration
Box 5
00531 Helsinki
Tel: 358-0-7726-7616
Fax: 358-0-7726-7666

Mr. Olli Sorvettula
Deputy Director General
Ministry of Agriculture and Forestry
Box 232
00171 Helsinki
Tel: 358-0-1603-380
Fax: 358-0-1603-338

FRANCE
FRANCIA

Mr. Pierre Veit
Inspecteur Principal DGCCRF
Ministry of Economy
59 boulevard Vincent Auriol
75703 Paris Cedex 13
France
Tel: 1.44973207
Fax: 1.44973033

Mr. Jacky Le Gosles
Direction Générale de l'Alimentation
Ministère de l'Agriculture, de la Pêche
et de l'Alimentation
175 rue du Chevaleret
75646 Paris Cedex 13
France
Tel: 1.49.558417
Fax: 1.49.55568

Mr. Jean Lessirard
Directeur des Services Vétérinaires
Ministère de l'Agriculture, de la Pêche
et de l'Alimentation
175 rue du Chevaleret
75646 Paris Cedex 13
France
Tel: 76633302
Fax: 76548223

Mr. Jean Pierre Doussin
Vice-Président du Comité National
du Codex Alimentarius
Ministry of Economy
59 Boulevard Vincent Auriol
75703 Paris Cedex 13
France
Tel: 1.44973470
Fax: 1.44973037

Mr. Jean-Louis Jouvé
Professeur
Ecole Nationale Vétérinaire de Nantes
Case Postale 3013
F-44087 Nantes Cedex 03
France
Tel: 40687679
Fax: 40687762

Mme. Dominique Burel
Chef de Service
Centre national industrie et economie laitière
34, rue de Saint-Petersbourg
75382 Paris Cedex 08
France
Tel: 1.49.70.71.15
Fax: 1.42.50.63.45

Mme. Nelly Delfaut
Chargée de Mission
Association de la Transformation Laitière Française (ATLA)
34, Rue de Saint-Petersbourg
75382 Paris Cedex 08
France
Tel: 1.49.70.72.72
Fax: 1.42.80.63.62

Mr. François Falconnet
Délégué Scientifique
Syndicat National des Fabricants des Plats Preparés (SYNAFAP)
44, Rue d'Alesia
75682 Paris Cedex 14
France
Tel: 33.1.43.2138.21
Fax: 33.1.43.21.8839

Mme. Catherine Vigreux
Advisor, International Scientific Regulatory Affairs
Groupe Danone
8, rue de Téhéran
78381 Paris Cedex 08
France
Tel: 1.44.35.24.60
Fax: 1.45.61.49.69

GERMANY
ALLEMAGNE
ALEMANIA

Dr. Hans Dieter Böhm
Chief, Dept. of Food Hygiene
Federal Ministry of Health
AM Propsthoe 78a
D-53121 Bonn
Germany
Tel: 0228-941-4220
Fax: 0228-941-4944

Dr. Edda Bartelt
Federal Institute for Health Protection of Consumers and Veterinary Medicine (BGVV)
Thielallee 88-92
D-141195 Berlin
Germany
Tel: 49-30-84122107
Fax: 49-30-84122951

Dr. Hans-Herbert Pott
Federal Ministry of Defence
POB 1328
D-53003 Bonn
Germany
Tel: 0228-126275
Fax: 0228-126689

Mr. Georg Wittich
Adviser
Association for Food Legislation (BLL)
Marktbreiterstr. 74
D-97195 Ochsenfurt
Germany
Tel: 01149-9331-91436
Fax: 01149-9331-91428

INDONESIA
INDONESIE

Dr. Sumpeno Putro
Director, Center for Standardization and Accreditation
Agency for Agribusiness
Ministry of Agriculture
Jalan Harsono, Rm. No. 3
Jakarta, Indonesia
Tel: 021-780-4367
Fax: 021-780-4367

Mr. MPhil Surono
Center for Standardization and Accreditation, Agency for Agriculture
Ministry of Agriculture
J.RH Harsono No. 3, Ps Mingqu
Jakarta, Indonesia 12550
Tel: 021-780-4367
Fax: 021-780-4367

Ms. Untari Takain
Head, Subdirectorate of Food Registration
Directorate of Food Control
Directorate General of D&F Control
Dept. of Health of the Republic of Indonesia
Jl. Percetakoni Negara 23
Jakarta 10560, Indonesia
Tel: (202) 775-5340
Fax: (202) 775-5365

Dr. A. Suwita
PT Smart Corporation
JITC BLD Lt. 9
Mangga Dua Raya
Jakarta 14430
Indonesia
Tel: 21-260-1088
Fax: 21-260-1059

Ms. B.R. Trisilowati
PT Indofood Sukses Makmur
Jl. ANCOL I/4-5
Ancol Barat
Jakarta 14430
Indonesia
Tel: 62-21-690-9432
Fax: 62-21-690-9433

P. Natigor Siagian
c/o Office of the Agricultural Attaché/
Indonesian Embassy
2020 Massachusetts Avenue, NW
Washington, DC 20036, USA
Tel: (202) 775-5340
Fax: (202) 775-5365

Teuku Faizasyah
Embassy of the Republic of Indonesia
2020 Massachusetts Avenue, NW
Washington, DC 20036, USA
Tel: (202) 775-5340
Fax: (202) 775-5365

Susilawati Sukmadji
Directorate For Standardization and
Quality Control
Ministry of Trade
Jl. M.I. Ridwan Rais No. 5
Jakarta 10110
Indonesia
Tel: 021.3858203
Fax: 021.3858203

IRELAND
IRLANDE
IRLANDA

Mr. James Egan
Senior Veterinary Inspector
Department of Agriculture,
Food and Forestry
Kildare Street
Dublin 2, Ireland
Tel: (01) 607 2000
Fax: (01) 661 6263

Mr. John O. Mahony
Agricultural Inspector
Floor 1 East
Department of Agriculture,
Food and Forestry
Kildare Street
Dublin 2, Ireland
Tel: (01) 607 2219
Fax: (01) 676 7100

ITALY
ITALIE
ITALIA

Dr. Dario De' Medici
Istituto Superiore di Sanità
Lab. Alimenti
Viale Regina Elena, 299
Roma 00161
Italy
Tel: (06) 49902477
Fax: (06) 4451767

Prof. ssa Maria L. Cortesi
Facoltà di Medicina Veterinaria
Università di Napoli
Via Delpino 1
Napoli 80137
Italy
Tel: (081) 858683
Fax: (081) 858683

JAPAN
JAPON

Mr. Hideyuki Takuma
Chief, JAS Affairs
Standards and Labelling Division
Foods and Marketing Bureau, MAFF
1-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan
Tel: 03-3501-4094
Fax: 03-3052-0438

Mr. Yoshiaki Hayasaka
Director
International Affairs Division
Center for Quality Control and
Consumer Service, MAFF
4-4-7 Konan Minato-ku
Tokyo, Japan
Tel: 03-3474-4501
Fax: 03-3458-1461

Mr. Koichi Hiruta
Chief
Section of Standards and Specifications
Food Sanitation Division
Environmental Health Bureau
Ministry of Health and Welfare
2-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan
Tel: 81-3-3501-4867
Fax: 81-3-3503-7965

Susumu Kumagai, Ph.D.
Director
Department of Biomedical
Food Research
National Institute of Health
2-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan
Tel: 03-5285-1111
Fax: 03-5285-1176

Mr. Masahiko Fukuda
Technical Advisor
Japan Food Hygiene Association
2-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan

Morita Takeshi
Branch Chief
Ministry of Health and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo, Japan
Tel: 81-3-3591-1786
Fax: 81-3-3503-7964

KENYA

Dr. Julius Kithinji Kajume
Deputy Director of
Veterinary Services
Ministry of Agriculture
Livestock Development and
Marketing
Department of Veterinary Services
P.O. Kabete
Nairobi, Kenya
Tel: 632 231
Fax: 631 273

LEBANON
LIBAN
LIBANO

Jad El-Hassan
Counsellor
Embassy of Lebanon
2560 28th Street, NW
Washington, DC 20008, USA

Houssan Diab
First Secretary
Embassy of Lebanon
2560 28th Street, NW
Washington, DC 20008, USA

MADAGASCAR

Biclair Henri Gabriel Andrianantoandro
Counsellor (Economic & Commercial)
Embassy of Madagascar
2374 Massachusetts Avenue, NW
Washington, DC 20008, USA
Tel: (202) 265-5525
Fax: (202) 265--3034

MALAYSIA
MALAISIE
MALASIA

Mrs. Mariam Abdul Latif
Food Quality Control Division
Ministry of Health Malaysia, Block E
Jln. Dungun, Bukit Damansara
50490 Kuala Lumpur
Malaysia
Tel: 03-254-0088 ext. 204
Fax: 03-253-7804

Mohammad Jaaffar Ahmad
Science Attaché
Embassy of Malaysia
1900 24th Street, NW
Washington, DC 20008, USA
Tel: (202) 328-2794/99
Fax: (202) 332-2902

Dr. Akma Ngah Hamid
Veterinary Public Health Laboratory
Department of Veterinary Services
Ministry of Agriculture
Persiavan Barat
46630 Pataling Jaya
Selangor Darul Ensan
Malaysia
Tel: 03-757-0960
Fax: 03-757-0973

MAURITIUS
MAURICE
MAURICIO

Mr. Israhyananda Dhalladoo
Deputy Chief of Mission
Embassy of the Republic of Mauritius
4301 Connecticut Ave., NW
Suite 441
Washington, DC 20008, USA
Tel: (202) 244-1491
Fax: (202) 966-0983

MEXICO
MEXIQUE

Ms. Elvira Espinoza Gutierrez
Q.F.B. Directora de Normalización Sanitaria
Secretaría de Salud
Control Sanitario de Bienes y Serv.
Donceles 39 Col. Centro
C.P. 06010, Mexico, D.F.
Tel: 91705/518-36-96
Fax: 915/512-96-28

NETHERLANDS
PAYS-BAS
PAISES BAJOS

J. T. Jansen
Ministry of Health, Welfare and Sports
General Inspectorate for Health Protection
P.O. Box 5406
2280 HK Rijswijk (Z.H.)
Netherlands
Tel: 31-70-340 5089
Fax: 31-70-340 5465

A. F. Onneweer
Ministry of Agriculture, Nature Management and Fisheries
Department for the Environment, Quality and Health
P.O. Box 20401
2500 EK The Hague
Netherlands
Tel: 31-70-3792361
Fax: 31-70-3477552

M. J. M. Michels
Unilever Research Laboratory
P.O. Box 114
3130 AC Vlaardingen
Netherlands
Tel: 31-10-4605182
Fax: 31-10-4605383

G. M. Koornneef
General Commodity Board for Arable Products
P.O. Box 29739
2502 LS The Hague
Netherlands
Tel: 31-70-3708323
Fax: 31-70-3708444

NEW ZEALAND
NOUVELLE ZELANDE
NUEVA ZELANDIA

Dr. Steve Hathaway
National Manager
(Research and Development)
MAF Regulatory Authority
(Meat and Seafood)
Ministry of Agriculture
P.O. Box 646
Gisborne, New Zealand
Tel: 06-867-1144
Fax: 06-868-5207

Mr. Dennis G. Butler
Environmental Resources Manager
Alliance Group Limited
P.O. Box 1472
Christchurch, New Zealand
Tel: 64-3-3793100
Fax: 64-3-3660595

Dr. Judith Lee
National Advisor (HACCP)
MAF Regulatory Authority, Meat and Seafood
95 McGregor Road
R D 2, Papakura, New Zealand
Tel: 64-9-2929131
Fax: 64-9-2929131

Dr. Barry L. Marshall
Counsellor (Veterinary Services)
New Zealand Embassy
37 Observatory Circle, N.W.
Washington, DC 20008, USA
Tel: (202) 328-4861
Fax: (202) 332-4309

NORWAY
NORVEGE
NORUEGA

Mr. John Race, DVM
International Liaison Officer
Norwegian Food Control Authority
P.O.B. 8187 Dep.
N-0034 Oslo, Norway

Mrs. Nina Aas, DVM
Senior Executive Officer
Norwegian Food Control Authority
P.O.B. 8187 Dep.
N-0034 Oslo, Norway

Dr. Hilde Kruse, DVM
Department of Pharmacology, Microbiology
and Food Hygiene
Norwegian College of Veterinary Medicine
P.O.B. 8416 Dep.
N-0033 Oslo, Norway
Tel: 47-2296-4802
Fax: 47-2296-4850

Mr. Anders Oterholm
Norwegian Dairies Association
P.O.B. 9051 Grønland
N-0133 Oslo, Norway
Tel: 47-2293-8800
Fax: 47-2217-2299

PERU
PEROU

Dr. Carlos Felipe Pastor Talledo
Head of Delegation
Ministry of Health
Department of Environmental Health
DIGESA
Las Amapolas No. 350
Lince-Lima 14
Peru
Tel: (5114) 402340/400399
Fax: (5114) 406562

Ing. José Sánchez Torres
Member of the Board of Directors
Empresa Nacional Pesquera
Pesca Peru S.A.
Tel: (5114) 333524
Fax: (5114) 333135

Ing. Javier Mapelli Ripamonti
Production Manager
Empresa Nacional Pesquera
Pesca Peru S.A.
Tel: (5114) 333165/3531
Fax: (5114) 333165

Ing. Dionicio Azañedo Diaz
Quality Assurance Manager
Empresa Nacional Pesquera
S.A. Pesca Peru S.A.
Tel: (5114) 333568
Fax)5114) 333540

PHILIPPINES
FILIPINAS

Victoriano Leviste
Agricultural Attaché
Embassy of the Philippines
1600 Massachusetts Avenue, N.W.
Washington, DC 20036, USA
Tel: (202) 467-9422
Fax: (202) 467-9421

POLAND
POLOGNE
POLONIA

Mrs. Anna Skrzyńska
Chief of Section
Quality Inspection Office
Ministry of Foreign Economic Relations
32/34 Zurawia St.
00-950 Warsaw, Poland
Tel: (48-2) 625-20-28
Fax: (48-2) 621-48-58

SOUTH AFRICA
AFRIQUE DU SUD
AFRICA DEL SUR

Mr. Jan J.A. Nel
Department of Health
Directorate - Environmental Health
Private Bag X828
Pretoria 0001
South Africa
Tel: 27-12-3120369
Fax: 27-12-3120376

SPAIN
ESPAGNE
ESPAÑA

Dr. Perez Bonilla Quintiliano
Subdirector General de Planificación
Alimentaria
Ministerio de Agricultura,
Pesca y Alimentación
Pº. Infanta Isabel 1
28071 Madrid
Spain
Tel: 3.47.5118
Fax: 3.47.5728

Dr. José Antonio Garrido
Dr. Veterinario
Ministerio de Sanidad y Consumo
Paseo Del Prado, 18-20 (Desp. 747)
28071 Madrid, Spain
Tel: 1-5962095
Fax: 1-5964409

Mr. Jesus L. Miranda
Counsellor for Agriculture, Fisheries
and Food
Embassy of Spain
2375 Pennsylvania Ave., NW
Washington, DC 20037, USA
Tel: (202) 728-2339
Fax: (202) 728-2320

Mr. Antonio Novas
Attaché, Agriculture, Fisheries
and Food
Embassy of Spain
2375 Pennsylvania Ave., NW
Washington, DC 20037, USA
Tel: (202) 728-2339
Fax: (202) 728-2320

SWEDEN
SUEDE
SUECIA

Mrs. Eva R. Lonberg
Codex Coordinator
National Food Administration
Box 622
S-751 26 Uppsala
Sweden
Tel: 46-18-175547
Fax: 46-18-105848

Dr. Sven E. Lindgren
Professor
National Food Administration
Box 622
75126 Uppsala
Sweden
Tel: 46-18-175500
Fax: 46-18-105848

SWITZERLAND
SUISSE
SUIZA

Dr. Andreas Baumgartner
Federal Office of Public Health
Postfach
CH-3000 Berne 14
Switzerland
Tel: 41-31-322 95 82
Fax: 41-31-322 95 74

Mr. O. Bindschedler
Nestec SA
CH-1800 Vevey
Switzerland
Tel: 41/21 924 4213
Fax: 41/21 924 4547

TANZANIA
TANZANIE

R. M. Kukula
Principal Health Officer
The United Republic of Tanzania
Ministry of Health
P.O. Box 9083
Dar-es-Salaam, Tanzania
Tel: 20261

THAILAND
THAILANDE
TAILANDIA

Mr. Sala Choochongkol
Director, Food Hygiene Division
Department of Health
Ministry of Public Health
Food Hygiene Division
Tivanond Road
Nonthaburi 11000, Thailand
Tel: (662) 591-8175
Fax: (662) 591-8174

Ms. Wannee Sompron
Senior Specialist
Department of Science Service
Ministry of Science, Technology and
Environment
Rama VI Rd.
Bangkok 10400, Thailand
Tel:(662) 248-0117
Fax: (662) 245-8993

Ms. Warunee Sensupa
Food and Drug Specialist
Food and Drug Administration
Ministry of Public Health
Tivanond Road
Nonthaburi 11000, Thailand
Tel: (662) 591-8460-2
Fax: (662) 591-8460-2 Ext. 123

Mrs. Jirawatana Fasawang
Standards Officer
Office of the National Codex Alimentarius Committee
Thai Industrial Standards Institute
Ministry of Industry
Rama VI Rd.
Bangkok 10400, Thailand
Tel:(662) 202-3443-4
Fax: (662) 247-8741

Mrs. Helen Arromdee
Scientist
Department of Industrial Works
Ministry of Industry
Rama VI Rd.
Bangkok 10400, Thailand
Tel: (662) 202-4087/202-4092
Fax: (662) 202-4087/202-4081

Dr. Suwimon Keeratipibul
Assistant Professor
Department of Food Technology
Faculty of Science
Chulalongkorn University
Phyathai Road
Bangkok 10330, Thailand
Tel: (662) 218-5515-6/218-5532
Fax: (662) 254-4314

Wilailuk Padungkittimal
Second Secretary
Office of Industrial Affairs
Royal Thai Embassy
1024 Wisconsin Ave., N.W. #304
Washington, D.C. 20007-3620, USA
Tel: (202) 944-3620
Fax: (202) 944-3623

Sasiwat Wongsinsawat
Second Secretary
Royal Thai Embassy
1024 Wisconsin Ave., NW
Washington, DC 20007, USA
Tel: (202) 944-3632
Fax: (202) 944-3611

UNITED KINGDOM
ROYAUME-UNI
REINO UNIDO

Dr. Roger Skinner
Principal Medical Officer
Department of Health
Skipton House, Room 539B
80 London Road
London, SE1 6LW
United Kingdom
Tel: (0) 171 972 5361
Fax: (0) 171 972 5155

Mr. John Francis Barnes
Principal Environmental Health Officer
Department of Health
Room 636B, Skipton House
80 London Road
London, SEI 6LW
United Kingdom
Tel: (0) 171 972 5067
Fax: (0) 171 972 5141

Dr. David Ross Harper
Chief Scientific Officer
Department of Health
Room 537B
Skipton House
80 London Road
London SEI 6LW
United Kingdom
Tel: (0) 171 972 5353
Fax: (0) 171 972 5332

Dr. David Ian Jervis
Food Safety Advisor
Unigate UK Food
Group Technical Centre
Station Road
Wootton Bassett
Swindon SN4 YEF
United Kingdom
Tel: 44 (0) 1793 852451
Fax: 44 (0) 1793 853915

Mr. Malcolm Charles Kerr Kane
Chief Food Technologist
J. Sansbury Plc.
Stamford House
Stamford Street
London SE1 9LL
United Kingdom
Tel: (0)71-921-6672
Fax: (0)71-921-7608

Mr. Christopher Pratt
Head of Branch
Food Hygiene Division (Legislation)
Ministry of Agriculture, Fish and Food
Room 508, Ergon House
c/o Nobel House
Smith Square
London, SWIP 3JR
United Kingdom
Tel: (0)171-238-6466
Fax: (0) 171-238-6745

UNITED STATES OF AMERICA
ETATS-UNIS D'AMERIQUE
ESTADOS UNIDOS DE AMERICA

Mr. E. Spencer Garrett
Laboratory Director
DOC/NOAA/National Marine Fisheries Service
705 Convent Street
Pascagoula, MS 39567, USA
Tel: (601) 769-8976
Fax: (601) 762-7144

Dr. Leslie Bluhm
Strategic Manager for Food Processing and Packaging (HFS-15)
Food and Drug Administration
Room 5844
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-8884
Fax: (202) 401-2893

Dr. Stanley S. Green
Branch Chief, Microbiological Monitoring & Surveillance Branch
USDA, FSIS, S&T, MD
Room 310, Annex Building
Washington, DC 20250, USA
Tel: (202) 205-0212
Fax: (202) 720-4662

Ms. Betty Harden
Assistant Director for Enforcement (HFS 627)
Food and Drug Administration
Room 1042
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-8145
Fax: (202) 205-5560

Dr. Anthony D. Hitchins
Supervisory Microbiologist (HFS-516)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 260-0874
Fax: (202) 401-7740

Dr. George Hoskin
Director, DSAT, (HFS-425)
Food and Drug Administration
1110 Vermont Ave., NW, Suite 1110
Washington, DC 20005, USA
Tel: (202) 418-3170
Fax: (202) 418-3196

Dr. George Jackson
Acting Director, Office of Special Research Skills (HFS-500)
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204, USA
Tel: (202) 205-4051
Fax: (202) 401-7740

Dr. LeeAnne Jackson
Division of HACCP Programs
Food and Drug Administration
200 C Street, SW (HFS-615)
Washington, DC 20204
Tel: (202) 205-4231
Fax: (202) 260-0136

Dr. Ann Marie McNamara
Director, Microbiology Division
USDA/FSIS, S&T
Room 310, Annex Building
Washington, DC 20250, USA
Tel: (202) 205-0212
Fax: (202) 720-4662

Dr. Joseph M. Madden
Strategic Manager, Microbiology (HFS-12)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-4197
Fax: (202) 401-2893

Mr. Jack Mowbray
Office of Plant and Dairy Foods
and Beverages (HFS-306)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-4681
Fax: (202) 205-4422

Dr. Morris Potter
Assistant Director Foodborne Diseases
Center for Disease Control and Prevention
1600 Clifton Road (A-38)
Atlanta, GA 30333, USA
Tel: (404) 639-2213
Fax: (404) 639-2212

Mr. Steve Sims
Milk Specialist
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-9180
Fax: (202) 205-5560

Mr. Stephen Spinak
Food Technologist (HFS-617)
Division of HACCP Programs
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-4842
Fax: (202) 260-0136

Ms. Martha Hudak-Roos
Vice President
Technical Food Information Spectrum
1913 Triple Mast Circle
League City, TX 77573, USA
Tel: (713) 538-4145
Fax: (713) 538-4741

Dr. John Humber
Research Principal, Microbiology & Food Safety
Kraft Foods, Inc.
801 Waukegan Road
Glenview, IL 60025, USA
Tel: (708) 646-4286
Fax: (708) 646-3864

Mr. Roy E. Martin
Vice President for Science and Technology
National Fisheries Institute, Inc.
1525 Wilson Blvd., Suite 500
Arlington, VA 22209, USA
Tel: (703) 524-8883
Fax: (703) 524-4619

Ms. Virginia N. Scott
Director, Processing Technology
and Microbiology
National Food Processors Association
1401 New York Avenue, NW
Suite 400
Washington, DC 20005, USA
Tel: (202) 639-5985
Fax: (202) 639-5991

Dr. Donn Ward
Professor, Extension Leader Dept. of Food Science
North Carolina State University
Box 7624
Raleigh, NC 27695-7624, USA
Tel: (919) 515-2951
Fax: (919) 515-4694

Dr. Michael Wehr
Director, International Foods Standards
TAS, Inc.
The Flour Mill Building
1000 Potomac St., NW
Washington, DC 20007, USA
Tel: (202) 337-2625
Fax: (202) 337-1744

Mr. Raymond Beaulieu
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-8140
Fax: (202) 205-2530

URUGUAY

Dra. Delvey Anchieri
División Salud Ambiental
Ministerio de Salud Pública
18 de Julio de 1892
Montevideo
Uruguay
Tel: 98-24-71; 91-78-91
Fax: 98-24-71

INTERNATIONAL ORGANIZATIONS
ORGANISATIONS INTERNATIONALES
ORGANIZACIONES INTERNACIONALES

INTERNATIONAL FROZEN FOOD ASSOCIATION

Mr. Robert L. Garfield
Vice President
Regulatory and Technical Affairs
American Frozen Food Institute
2000 Corporate Ridge
Suite 2000
McLean, VA 22102, USA
Tel: (703) 821-0770
Fax: (703) 821-1350

AOAC INTERNATIONAL

Dr. George Heavner
Technical Coordinator
AOAC International
Suite 400
2200 Wilson Boulevard
Arlington, VA 22201-3301, USA
Tel: 703/522-3032
Fax: 703-522-5468

ASSOCIATION VETERINAIRE D'HYGIENE ALIMENTAIRE

Dr. Jean Vignal
Assoc. Vétérinaire d'Hygiène Alimentaire
Siège social
Maison des Vétérinaires
10, Place Leon Blum
75011 Paris, France
Tel: 1-43-96-71-18
Fax: 1-43-96-71-21

CONSUMERS INTERNATIONAL

Ms. Lisa Lefferts
6719, Chillum Manor Road
Hyattsville, MD 20783, USA
Tel: (301) 559-3630
Fax: (301) 853-3272

Representing Consumers International
Head Office
24 Highbury Crescent
London N5 1RX
United Kingdom
Tel: (44) 171 226-6663

EUROPEAN COMMISSION

Ms. C. Majewski
Directorate General Industry
European Commission
Rue de la Loi 200
B-1049 Bruxelles/Welstraat 200
B-1049 Brussels, Belgium
Tel: (32-2) 299.11.11

Mr. H. Belvèze
Principal Administrator
Directorate General Agriculture
European Commission
Rue de la Loi 200
B-1049 Bruxelles/Welstraat 200
B-1049 Brussel, Belgium
Tel: (32-2) 299.11.11

COUNCIL OF EUROPEAN UNION

Mr. Paul Culley
Council of the European Union
Secretariat
175, Rue de la Loi
1048 Brussels, Belgium
Tel: (32-2) 285 6197
Fax: (32-2) 285 76 86

HUMANE SOCIETY INTERNATIONAL

Dr. Melanie Adcock
Director of Farm Animals
Humane Society International
2100 L Street, NW
Washington, DC 20037, USA
Tel: (301) 258-3010
Fax: (301) 258-3077

INTERNATIONAL DAIRY FEDERATION (IDF)

Mr. Thomas M. Balmer
Vice President
International Dairy Federation
International Dairy Foods Association
1250 H Street, NW
Washington, DC 20005, USA
Tel: (202)737-4332
Fax: (202) 331-7820

Prof. Dr. W. Heeschen
Institute for Hygiene
Federal Dairy Research Centre
Hermann-Weighmann-Str. 1
D 24103 Kiel
Germany
Tel: 49.431.609 392
Fax: 49.431.609 222

Mr. C. Heggum
Danish Dairy Board
Frederiks Alle 22
DK-8000 Aarhus C
Denmark
Tel: 45-86-132611
Fax: 45-86-132693

Mr. Johnnie G. Nichols
Consultant
International Dairy Federation
10326 Hampshire Green Ave.
Fairfax, VA 22032, USA
Tel: (703) 250-7487
Fax: (703) 250-7487

INSTITUTE OF FOOD TECHNOLOGISTS (IFT)

Dr. Merle Pierson
Dept. of Food Science and Technology
Virginia Polytechnic Institute and State University
Blacksburg, VA 24061
USA
Tel: (540) 231-8641
Fax: (540) 231-9293
E-Mail: piersonm@vt.edu

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

Dr. Stephen A. Ziller
Vice President
Scientific and Technical Affairs
Grocery Manufacturers of America, Inc.
1010 Wisconsin Avenue, NW.
Washington, DC 20007, USA
Tel: (202) 337-9400
Fax: 202) 337-4508

Mr. Sherwin Gardner
Executive Secretary, ICGMA
5504 Goldsboro Road
Bethesda, MD 20817, USA
Tel: 301/229-0832
Fax: 301/229-0489

Dr. Jorge H. Alonso
Director
Quality Assurance, Corporate
ICGMA, CPC International
P.O. Box 8000, International Plaza
Englewood Cliffs, NJ 07632, USA
Tel: (201) 894-2398
Fax: (201) 894-2355

INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF)

Dr. M. van Schothorst
Avenue Nestlé 55
CH-1800
Vevey, Switzerland
Tel: 41-21-924-42-41
Fax: 41-21-921-18-85

INTERNATIONAL FEDERATION OF MARGARINE ASSOCIATIONS (IFMA)

Dr. Alain Léon
Technical Advisor to IFMA
Rue de la Loi, 74
1040 Brussels, Belgium
Tel: (322) 230 48 10
Fax: (322) 230 22 74

PAN AMERICAN HEALTH ORGANIZATION (PAHO)/WORLD HEALTH ORGANIZATION (WHO)

Dr. Claudio R. Almeida
Regional Advisor for Food Protection
PAHO/WHO
525 Twenty-Third Street, N.W.
Washington, DC 20037-2895
USA
Tel: 202/861-3193
Fax: 202/861-8488

WORLD SOCIETY FOR PROTECTION OF ANIMALS

Mr. Leesteffy Jenkins
Legal Counsel
3445 Oakwood Terrace, NW
Washington, DC 20010, USA
Tel: (202) 265-6231
Fax: (202) 265-6237

WORLD HEALTH ORGANIZATION (WHO)

Dr. F. Käferstein
Chief
Food Safety Unit
Division of Food and Nutrition
WHO
CH-1211 Geneva 27
Switzerland
Fax: 41.22.791.0746

Dr. Kazuaki Miyagishima
Scientist, Food Safety
World Health Organization
WHO/FNU/FOS
CH-1121 Geneva 27
Switzerland
Tel: 41.22.791.4324
Fax: 41.22.791.0746

U.S. SECRETARIAT

Ms. Rhonda S. Nally
Executive Officer for Codex Alimentarius
Food Safety and Inspection Service
U.S. Department of Agriculture
West End Court-Room 311
1255 22nd Street, NW
Washington, D.C. 20037, USA
Tel: (202) 254-2517
Fax: (202) 254-2530

Ms. Natalie Zalc
Program Assistant
Food Safety and Inspection Service
U.S. Department of Agriculture
West End Court-Room 311
1255 22nd Street, NW
Washington, D.C. 20037, USA
Tel: (202) 254-2517
Fax: (202) 254-2530

Ms. Patty L. Woodall
Staff Assistant For Codex Alimentarius
Food Safety and Inspection Service
U.S. Department of Agriculture
West End Court-Room 311
1255 22nd Street, NW
Washington, D.C. 20037, USA
Tel: (202) 254-2517
Fax: (202) 254-2530

Ms. Emille A. Cole
Principal Staff Assistant, Special Projects
Office of the Director
National Marine Fisheries Service
705 Convent Street
Pascagoula, MS 39567, USA
Tel: (601) 769-8964
Fax: (601) 762-7144

Ms. Patricia Brickerd
FSIS/S&T/SISPD
U.S. Department of Agriculture
Room 202- Annex Building
12th & C Street, SW
Washington, DC 20250, USA
Tel: (202) 720-3219

Ms. Darlene Riden
FSIS/IP/ODA
U.S. Department of Agriculture
Rm. 341-E; Jamie L. Whitten Bldg.
14th & Independence Ave., SW
Washington, DC 20250, USA
Tel: (202) 720-3473
Fax: (202) 690-3856

Ms. Edith Kennard
International Liaison Specialist
U.S. Department of Agriculture
FSIS/IP
Room 314-Franklin Court
Washington, DC 20250, USA
Tel: (202) 501-6022
Fax: (202) 501-6929

Mr. Craig T. Fedchock
Advisory Committee Specialist
Food Safety and Inspection Service
U.S. Department of Agriculture
West End Court-Room 311
1255 22nd Street, NW
Washington, D.C. 20037, USA
Tel: (202) 254-2517
Fax: (202) 254-2530

Special

Dr. Sanford (Sandy) A. Miller
Dean, Graduate School of Biomedical Sciences
Health Science Center at San Antonio
University of Texas
7703 Floyd Curl Drive
San Antonio TX 78284, USA
Tel: (210) 567-3709
Fax: (201) 567-3719

Dr. Marvin A. Norcross
U.S. Coordinator for Codex Alimentarius
Food Safety and Inspection Service
U.S. Department of Agriculture
West End Court-Room 311
1255 22nd Street, NW
Washington, D.C. 20037, USA
Tel: (202) 254-2517
Fax: (202) 254-2530

Mr. Richard B. Boyd
Senior Marketing Specialist
Fruit and Vegetable Division
Agricultural Marketing Service
U.S. Department of Agriculture
Room 0717, South Building
14th & Independence Ave., SW
Washington, DC 20250, USA
Tel: (202) 720-5021
Fax: (202) 690-1527

Col. Dale Boyle
Staff Veterinarian
Defense Logistics Agency
8725 John J. Kingman Rd., Suite 4235
Fort Belvoir, VA 22060-6221, USA
Tel: (703) 767-2667
Fax: (703) 767-2628

LTC. David Goolsby
Chief, Food Safety Officer
DOD Veterinary Service Activity
Office of the Surgeon General, U.S. Army
5109 Leesburg Pike
Falls Church, VA 22041-3258, USA
Tel: (703) 681-3058
Fax: (703) 681-3035

Mr. William V. Eisenberg
Consultant
Factory and Laboratory Controls
Food Quality Assurance
6408 Tone Drive
Bethesda, MS 20817, USA
Tel: (301) 229-6441

Dr. Michael Jahncke
Program Coordinator
Office of the Director
National Seafood Inspection Laboratory
3209 Frederic St.
Pascagoula, MS 39568, USA
Tel: (601) 762-7402
Fax: (601) 769-9200

Dr. Tari Kindred
Chief, Residue Planning Branch
USDA, FSIS
Room 305, Annex Building
300 12th Street, SW
Washington, DC 20250, USA
Tel: (202) 205-0007
Fax: (202) 205-0281

Ms. Diane D. Lewis
Marketing Specialist
U.S. Department of Agriculture
Agricultural Marketing Service
Room 2750, South Building
14th & Independence Ave., SW
Washington, DC 20250, USA
Tel: (202) 720-9385
Fax: (202) 720-26437819

Mr. Duane Spomer
Chief, Dairy Standardization Branch
U.S. Department of Agriculture
Agricultural Marketing Service
Room 2750, South Building
14th & Independence Ave., SW
Washington, DC 20250, USA
Tel: (202) 720-9385
Fax: (202) 720-2643

Ms. Ellen E. McCleskey
Staff Editor
Bureau of National Affairs
1231 25th Street, NW
Washington, DC 20037, USA
Tel: (202) 452-5350
Fax: (202) 452-7549

Dr. Wallace E. Garthright
Division of Mathematics
Food and Drug Administration
HFS-708
200 C Street, SW
Washington, DC 20204, USA
Tel: (202) 205-5080

JOINT FAO/WHO SECRETARIAT

Mr. George O. Baptist
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization
Viale delle Terme di Caracalla
00100 Rome, Italy
Tel: 39-6-522-53832
Fax: 39-6-522-54593

Mr. David H. Byron
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization
Viale delle Terme di Caracalla
00100 Rome, Italy
Tel: 39-6-522-54419
Fax: 39-6-522-54593

DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF PRACTICE -

GENERAL PRINCIPLES OF FOOD HYGIENE
(At Step 8 of the Procedure)

Contents

INTRODUCTION

1. OBJECTIVES OF THE GENERAL PRINCIPLES OF FOOD HYGIENE

2. SCOPE AND USE OF THE DOCUMENT
   - 2.1 Scope
     - *2.1.1 The food chain*
     - *2.1.2 Roles of Governments, industry, and consumers*
   - 2.2 Use
   - 2.3 Definitions

3. PRIMARY PRODUCTION
   - 3.1 Environmental hygiene
   - 3.2 Hygienic production of food sources
   - 3.3 Handling, storage and transport
   - 3.4 Cleaning, maintenance and personnel hygiene at primary production

4. ESTABLISHMENT: DESIGN AND FACILITIES
   - 4.1 Location
     - *4.1.1 Establishments*
     - *4.1.2 Equipment*
   - 4.2 Premises and rooms
     - *4.2.1 Design and layout*
     - *4.2.2 Internal structures and fittings*
     - *4.2.3 Temporary/mobile premises and vending machines*

4.3 Equipment
4.3.1 General
4.3.2 Food control and monitoring equipment
4.3.3 Containers for waste and inedible substances
4.4 Facilities
4.4.1 Water supply
4.4.2 Drainage and waste disposal
4.4.3 Cleaning
4.4.4 Personnel hygiene facilities and toilets
4.4.5 Temperature control
4.4.6 Air quality and ventilation
4.4.7 Lighting
4.4.8 Storage

5. CONTROL OF OPERATION
5.1 Control of food hazards
5.2 Key aspects of hygiene control systems
5.2.1 Time and temperature control
5.2.2 Specific process steps
5.2.3 Microbiological and other specifications
5.2.4 Microbiological cross-contamination
5.2.5 Physical and chemical contamination
5.3 Incoming material requirements
5.4 Packaging
5.5 Water
5.5.1 In contact with food
5.5.2 As an ingredient
5.5.3 Ice and steam
5.6 Management and supervision
5.7 Documentation and records
5.8 Recall procedures

6. ESTABLISHMENT: MAINTENANCE AND SANITATION
6.1 Maintenance and cleaning
6.1.1 General
6.1.2 Cleaning procedures and methods
6.2 Cleaning programmes
6.3 Pest control systems
6.3.1 General
6.3.2 Preventing access
6.3.3 Harbourage and infestation
6.3.4 Monitoring and detection
6.3.5 Eradication
6.4 Waste management
6.5 Monitoring effectiveness

7. ESTABLISHMENT: PERSONAL HYGIENE
   - 7.1 Health status
   - 7.2 Illness and injuries
   - 7.3 Personal cleanliness
   - 7.4 Personal behaviour
   - 7.5 Visitors

8. TRANSPORTATION
   - 8.1 General
   - 8.2 Requirements
   - 8.3 Use and maintenance

9. PRODUCT INFORMATION AND CONSUMER AWARENESS
   - 9.1 Lot identification
   - 9.2 Product information
   - 9.3 Labelling
   - 9.4 Consumer education

10. TRAINING
   - 10.1 Awareness and responsibilities
   - 10.2 Training programmes
   - 10.3 Instruction and supervision
   - 10.4 Refresher training

INTRODUCTION

People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria. The document follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage. It recommends a HACCP - based approach wherever possible to enhance food safety as described in the Guidelines for the Application of the Hazard Analysis Critical Control (HACCP) system [Annex].

The controls described in this General Principles document are internationally recognised as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, industry (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.

1. OBJECTIVES OF THE GENERAL PRINCIPLES OF FOOD HYGIENE

The Codex General Principles of food hygiene:

- **identify the *essential* principles of food hygiene applicable *throughout the food chain* (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption;**
- **recommend a HACCP based approach as a means to enhance food safety;**
- **indicate *how* to implement those principles; and**
- **provide a *guidance* for specific codes which may be needed for - sectors of the food chain; processes; or commodities; to amplify the hygiene requirements specific to those areas.**

2. SCOPE AND USE OF THE DOCUMENT

2.1 Scope

2.1.1 The food chain

This document follows the food chain from primary production to the final consumer, setting out the necessary hygiene conditions for producing food which is safe and suitable for consumption. The document provides a base-line structure for other, more specific, codes applicable to particular sectors. Such specific codes and guidelines should be read in conjunction with this document and the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) system (Annex).

2.1.2 Roles of Governments, industry, and consumers

Governments can consider the contents of this document and decide how best they should encourage the implementation of these general principles to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food; and

- provide health education programmes which affectively communicate the principles of food hygiene to industry and consumers.

Industry should apply the hygienic practices set out in this document to:

- provide food which is safe and suitable for consumption;

- ensure that consumers have clear and easily-understood information, by way of labelling and other appropriate means, to enable them to protect their food from contamination and growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and

- maintain confidence in internationally traded food.

Consumers should recognise their role by following relevant instructions and applying appropriate food hygiene measures.

2.2 Use

Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food.

Section 3 covers primary production and associated procedures. Although hygiene practices may differ considerably for the various food commodities and specific codes should be applied where appropriate, some general guidance is given in this section. Sections 4 to 10 sets down the general hygiene principles which apply throughout the food chain to the point of sale. Section 9 also covers consumer information, recognising the important role played by consumers in maintaining the safety and suitability of food.

There will inevitably be situations where some of the *specific* requirements contained in this document are not applicable. The fundamental question in *every* case is "what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

The text indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate". In practice this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of activities and varying degrees of risk involved in producing food. Additional guidance is available in specific food codes.

2.3 Definitions

For the purpose of this Code, the following expressions have the meaning stated:

Cleaning - the removal of soil, food residue, dirt, grease or other objectionable matter

Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability

Contamination - the introduction or occurrence of a contaminant in food or food environment

Disinfection - the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

Establishment - any building or area in which food is handled and the surroundings, under the control of the same management

Food hygiene - all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Hazard - [as in the Annex to the Code]

HACCP - [as in the Annex to the Code]

Risk - To be defined

Food handler - any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements

Food safety - assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability - assurance that food is acceptable for human consumption according to its intended use.

Primary production - those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

3. PRIMARY PRODUCTION

Objectives:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

- **avoiding the use of areas where the environment poses a threat to the safety of food;**
- **controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;**
- **adopting practices and measures to ensure food is produced under appropriately hygienic conditions.**

Rationale:

To reduce the likelihood of introducing a hazard which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

3.1 Environmental hygiene

Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

3.2 Hygienic production of food sources

The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimise that probability. The HACCP-based approach may assist in the taking of such measures - see Annex.

Producers should as far as practicable implement measures to:

- control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; and

- protect food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately. On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and should be encouraged.

3.3 Handling, storage and transport

Procedures should be in place to:

- sort food and food ingredients to segregate material which is evidently unfit for human consumption; and

- dispose of any rejected material in a hygienic manner.

- Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

3.4 Cleaning, maintenance and personnel hygiene at primary production

Appropriate facilities and procedures should be in place to ensure that:

- any necessary cleaning and maintenance is carried out effectively; and

- an appropriate degree of personal hygiene is maintained.

4. ESTABLISHMENT: DESIGN AND FACILITIES

Objectives:

Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

- **contamination is minimised;**
- **design and layout permit appropriate maintenance, cleaning and, disinfections and minimise air-borne contamination;**
- **surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;**
- **where appropriate, suitable facilities are available for temperature, humidity and other controls; and**
- **there is effective protection against pest access and harbourage.**

Rationale:

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

4.1 Location

4.1.1 Establishments

Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
- areas subject to flooding unless sufficient safeguards are provided.
- areas prone to infestations of pests;

- areas where wastes, either solid or liquid, cannot be removed effectively.

4.1.2 Equipment

Equipment should be located so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates good hygiene practices, including monitoring.

4.2 Premises and rooms

4.2.1 Design and layout

Where appropriate, the internal design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.

4.2.2 Internal structures and fittings

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;
- ceilings and overhead fixtures should be constructed and finished to minimise the build up of dirt and condensation, and the shedding of particles;
- windows should be easy to clean, be constructed to minimise the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;
- doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;

- working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

4.2.3 Temporary/mobile premises and vending machines

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, temporary premises in which food is handled such as tents and marquees.

Such premises and structures should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food.

4.3 Equipment

4.3.1 General

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed to ensure that, where necessary, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

4.3.2 Food control and monitoring equipment

In addition to the general requirements in paragraph 4.3.1, equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable microorganisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;

- where appropriate, critical limits established in HACCP-based plans can be monitored; and

- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

4.3.3 Containers for waste and inedible substances

Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

4.4 Facilities

4.4.1 Water supply

An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

4.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

4.4.3 Cleaning

Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

4.4.4 Personnel hygiene facilities and toilets

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

- adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water;
- lavatories of appropriate hygienic design; and
- adequate changing facilities for personnel.

Such facilities should be suitably located and designated.

4.4.5 Temperature control

Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

4.4.6 Air quality and ventilation

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimise air-borne contamination of food for example from aerosols and condensation droplets;
- control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity, where necessary, to ensure the safety and suitability of food.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.

4.4.7 Lighting

Adequate natural or artificial lighting should be provided to enable the undertaking to operate in an hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

4.4.8 Storage

Where necessary, adequate facilities for the storage of food, ingredients and non-food chemicals eg cleaning materials, lubricants, fuels, should be provided.

Where appropriate, food storage facilities should be designed and constructed to:

- permit adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination during storage; and
- where necessary, provide an environment which minimises the deterioration of food (e.g. by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

5. CONTROL OF OPERATION

Objective:

To produce food which is safe and suitable for human consumption by:

- **formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items; and**

- **designing, implementing, monitoring and reviewing effective control systems.**

Rationale:

To reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

5.1 Control of food hazards

Food business operators should control food hazards through the use of systems such as HACCP. They should:

- **identify** any steps in their operations which are critical to the safety of food;

- **implement** effective control procedures at those steps;

- **monitor** control procedures to ensure their continuing effectiveness; and

- **review** control procedures periodically, and whenever the operations change.

These systems should be applied throughout the food chain to control food hygiene throughout the shelflife of the product through proper product and process design.

Control procedures may be simple, such as checking stock rotation calibrating equipment, or correctly loading refrigerated display units. In some cases a system based on expert advice, and involving documentation, may be appropriate. A model of such a food safety system is the guidelines for the application of the Hazard Analysis Critical Control Point (HACCP) system (Annex).

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

Inadequate food temperature control is one of the most common causes of foodborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.

Temperature control systems should take into account:

- the nature of the food eg its water activity, pH,and likely initial level and types of micro-organisms;
- the intended shelf-life of the product;
- the method of packaging and processing; and
- how the product is intended to be used eg further cooking/processing or ready-to-eat.

Such systems should also specify tolerable limits for time and temperature variations.

Temperature recording devices should be checked at regular intervals and tested for accuracy.

5.2.2 Specific process steps

Other steps which contribute to food hygiene may include, for example:

- chilling
- thermal processing
- irradiation
- drying
- chemical preservation
- vacuum or modified atmospheric packaging

5.2.3 Microbiological and other specifications

Management systems described in paragraph 5.1 offer an effective way of ensuring the safety and suitability of food. Where microbiological, chemical or physical specifications are used in any food control system, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits.

5.2.4 Microbiological cross-contamination

Pathogens can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated,

either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and where appropriate disinfection.

Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.

Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed.

5.2.5 Physical and chemical contamination

Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary.

5.3 Incoming material requirements

No raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied.

Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.

Stocks of raw materials and ingredients should be subject to effective stock rotation.

5.4 Packaging

Packaging design and materials should provide adequate protection for products to minimise contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use . Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

5.5 Water

5.5.1 In contact with food

Only potable water, should be used in food handling and processing, with the following exceptions:

- for steam production, fire control and other similar purposes not connected with food; and

- in certain food processes e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food eg. the use of clean seawater.

Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

5.5.2 As an ingredient

Potable water should be used wherever necessary to avoid food contamination.

5.5.3 Ice and steam

Ice should be made from water that complies with section 4.4.1. Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

5.6 Management and supervision

The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure effective monitoring and supervision takes place.

5.7 Documentation and records

Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

5.8 Recall procedures

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for public warnings should be considered.

Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

Objective:

To establish effective systems to:

- **ensure adequate and appropriate maintenance and cleaning;**
- **control pests;**
- **manage waste; and**
- **monitor effectiveness of maintenance and sanitation procedures.**

Rationale:

To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food.

6.1 Maintenance and cleaning

6.1.1 General

Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures;
- function as intended, particularly at critical steps (see paragraph 5.1);
- prevent contamination of food eg. from metal shards, flaking plaster, debris and chemicals.

Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning.

Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, seperated from food,in clearly identified containers to avoid the risk of contaminating food.

6.1.2 Cleaning procedures and methods

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces;
- applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;
- rinsing with water which complies with section 4, to remove loosened soil and residues of detergent;
- dry cleaning or other appropriate methods for removing and collecting residues and debris; and
- where necessary, disinfection.

6.2 Cleaning programmes

Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment.

Cleaning and cleaning programmes should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

Where written cleaning programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned;
- responsibility for particular tasks;
- method and frequency of cleaning; and
- monitoring arrangements.

Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors.

6.3 Pest control systems

6.3.1 General

Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be

employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimise the liklihood of infestation and thereby limit the need for pesticides. [Insert reference to FAO document dealing with Integrated Pest Management].

6.3.2 Preventing access

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

6.3.3 Harbourage and infestation

The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.

6.3.4 Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of infestation.

6.3.5 Eradication

Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

6.4 Waste management

Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

Waste stores must be kept appropriately clean.

6.5 Monitoring effectiveness

Sanitation systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.

7. ESTABLISHMENT: PERSONAL HYGIENE

Objectives:

To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- **maintaining an appropriate degree of personal cleanliness;**
- **behaving and operating in an appropriate manner.**

Rationale:

People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

7.1 Health status

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

Medical examination of a food handler should be carried out if clinically or epidememologically indicated.

7.2 Illness and injuries

Conditions which should be reported to management so that any need for medical examination and\or possible exclusion from food handling can be considered, include:

- jaundice
- diarrhoea
- vomiting
- fever
- sore throat with fever
- visibly infected skin lesions (boils, cuts, etc)
- discharges from the ear, eye or nose

7.3 Personal cleanliness

Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where

personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personnel should always wash their hands when personal cleanliness may effect food safety, for example:

- at the start of food handling activities;
- immediately after using the toilet; and
- after handling raw food or any contaminated material, where this could result in contamination of other food items; they should avoid handling ready to eat food, where appropriate.

7.4 Personal behaviour

People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:

- smoking;
- spitting;
- chewing or eating;
- sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

7.5 Visitors

Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

8. TRANSPORTATION

Objectives:

Measures should be taken where necessary to:

- **protect food from potential sources of contamination;**
- **protect food from damage likely to render the food unsuitable for consumption; and**
- **provide an environment which effectively controls the growth of pathogenic or spoilage microorganisms and the production of toxins in food.**

Rationale:

Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

8.1 General

Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

8.2 Requirements

Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;
- can be effectively cleaned and, where necessary, disinfected;
- permit effective separation of different foods or foods from non-food items where necessary during transport;
- provide effective protection from contamination, including dust and fumes;

- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and

- allow any necessary temperature, humidity and other conditions to be checked.

8.3 Use and maintenance

Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

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

9. PRODUCT INFORMATION AND CONSUMER AWARENESS

Objectives:

Products should bear appropriate information to ensure that:

- **adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly;**
- **the lot or batch can be easily identified and recalled if necessary.**

Consumers should have enough knowledge of food hygiene to enable them to:

- **understand the importance of product information;**
- **make informed choices appropriate to the individual; and**
- **prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly.**

Information for industry or trade users should be clearly distinguishable from consumer information, particularly on food labels.

Rationale:

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

9.1 Lot identification

Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the labelling of Prepackaged Foods (CODEX STAN 1-1985) applies.

9.2 Product information

All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

9.3 Labelling

Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) applies.

9.4 Consumer education

Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and foodborne illness.

10. TRAINING

Objective:

Those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform.

Rationale:

Training is fundamentally important to any food hygiene system. Inadequate hygiene training, and/or instruction and supervision of *all* people involved in food related activities pose a potential threat to the safety of food and its suitability for consumption.

10.1 Awareness and responsibilities

Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

10.2 Training programmes

Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage microorganisms;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected length of time before consumption.

10.3 Instruction and supervision

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

10.4 Refresher training

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

ALINORM 97/13
Annex to Appendix II

PROPOSED DRAFT ANNEX - HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION
(At Step 5 of the Procedure)

PREAMBLE

The first section of this document sets out the principles of the Hazard Analysis Critical Control Point (HACCP) system adopted by the CAC. The second section provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.[1]

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

HACCP can be applied throughout the food chain from the primary producer to final consumer. As well as enhanced food safety, benefits include better use of resources and more timely response to problems. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a team approach; this team might include appropriate experts such as agronomists, veterinarians, production personnel, microbiologists, medical experts, public health specialists, food technologists, environmental health practitioners, chemists, and engineers according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

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

---

1 **The Principles of HACCP set the basis for the minimum requirements for the application of HACCP, while the Guidelines provide general guidance.**

[DEFINITIONS

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

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

Control measures: Actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective Actions: Actions to be taken when the results of monitoring at the CCP indicate a loss of control.

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

Critical Limit: A criterion which separates acceptability from unacceptability.

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

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

Hazard: A biological, chemical or physical agent or factor with the potential to cause an adverse health effect.

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

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

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

Verification: The application of methods, procedures, and tests, in addition to those used in monitoring to determine compliance with the HACCP plan, and/or whether the HACCP plan needs modification.

Definitions to be developed and added [perhaps by adopting ISO definitions]:

- Audit
- Deviation
- Validation
- Flow diagram]

PRINCIPLES

The HACCP system consists of the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

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

PRINCIPLE 6

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

PRINCIPLE 7

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

GUIDELINES FOR THE APPLICATION OF THE OF HACCP SYSTEM

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

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

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

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

It is important when applying HACCP to be flexible given the context of the application.

Application

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

1. Assemble HACCP team

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified.

2. Describe product

A full description of the product should be drawn up, including relevant safety information on composition and method of distribution.

3. Identify intended use

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

4. Construct flow diagram

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

5. On-site verification of flow diagram

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

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

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

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

In conducting the hazard analysis the following should be included:

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

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

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

7. Determine Critical Control Points (Principle 2)[2]

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

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

---

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

8. Establish critical limits for each CCP (Principle 3)

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

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

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

10. Establish Corrective Actions (Principle 5)

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

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

Corrective action should also be taken when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process back into control before the deviation leads to a safety hazard.

11. Establish Verification Procedures (Principle 6)

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

Review of the HACCP system and its records.

Review of deviations and product dispositions.

Confirmation that CCPs are kept under control.

Validation of established critical limits.

12. Establish Record Keeping and Documentation (Principle 7)

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented [, and should be applied as appropriate to the nature and size of the food operation.]

Examples are:

CCP records associated with:

Ingredients
Product safety
Processing
Packaging
Storage and distribution

Deviation file

Modifications to the HACCP system

An example of a HACCP worksheet is attached as Diagram 3.

TRAINING

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

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

DIAGRAM 1 Logic Sequence for Application of HACCP

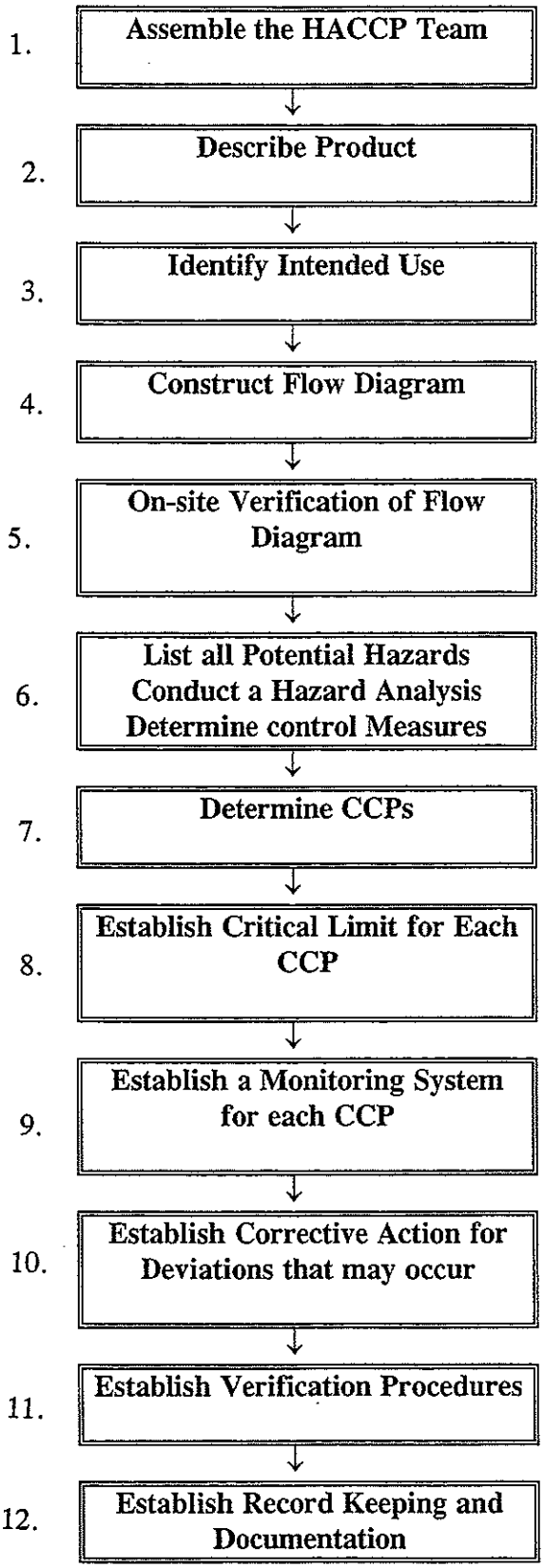
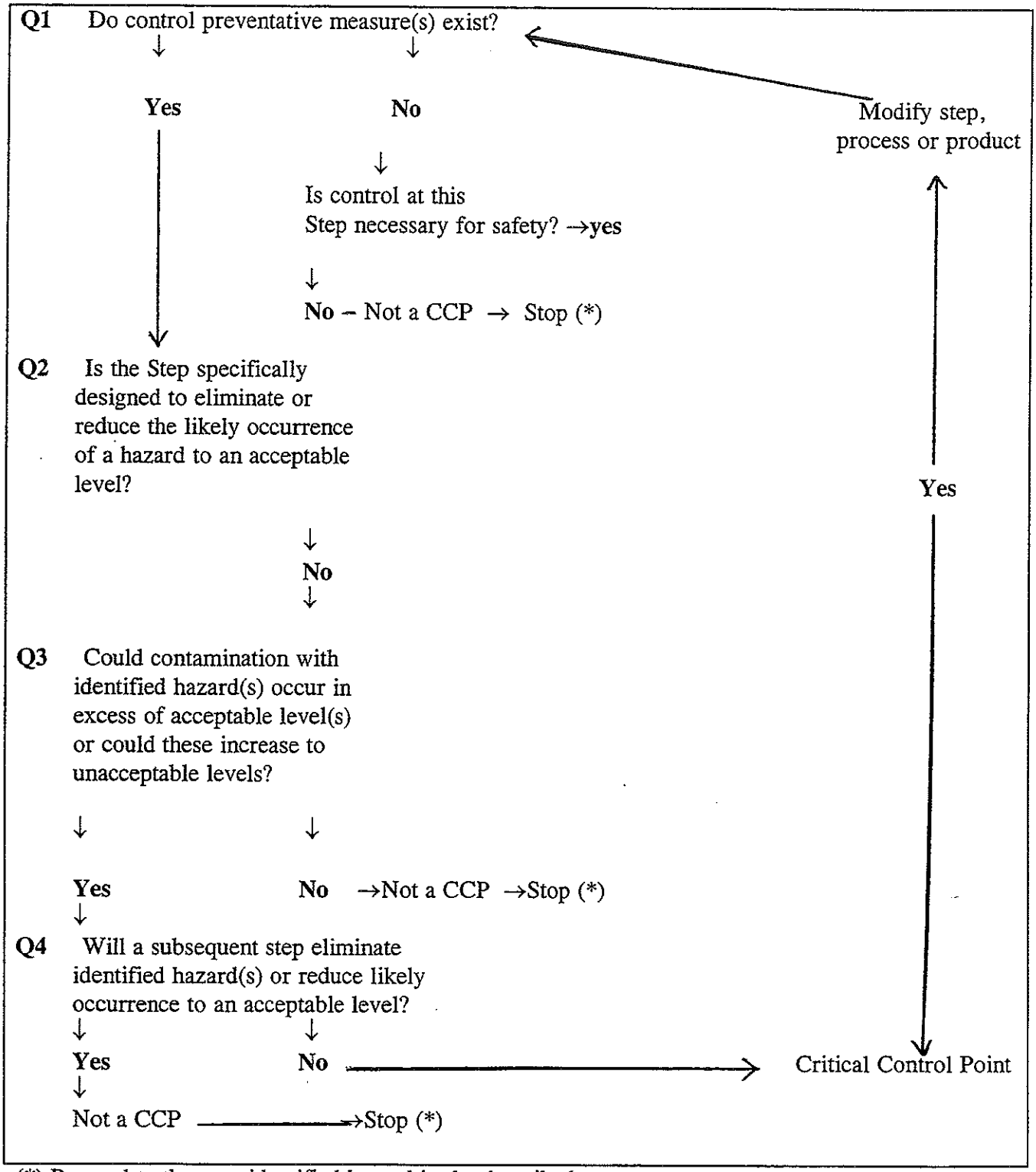


DIAGRAM 2 Example of a Decision Tree to Identify CCPs
(answer questions in sequence)



(*) Proceed to the next identified hazard in the described process

DIAGRAM 3 Example of a HACCP Worksheet

1. Describe Product

2. Diagram Process Flow

3.

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

4. Verification

PROPOSED DRAFT REVISED PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS
(At Step 5 of the Procedure)

TABLE OF CONTENTS

INTRODUCTION

1. DEFINITION OF MICROBIOLOGICAL CRITERIA

2. COMPONENTS OF MICROBIOLOGICAL CRITERIA FOR FOODS

3. PURPOSES AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS

3.1.1 Application by Regulatory Authorities

3.1.2 Application by a Food Business Operator

4. GENERAL CONSIDERATIONS CONCERNING PRINCIPLES FOR ESTABLISHMENT AND APPLYING MICROBIOLOGICAL CRITERIA

5. MICROBIOLOGICAL ASPECTS OF CRITERIA

5.1 MICRO-ORGANISMS, PARASITES AND TOXINS OF IMPORTANCE IN A PARTICULAR FOOD

5.2 MICROBIOLOGICAL METHODS

5.3 MICROBIOLOGICAL LIMITS

6. SAMPLING PLANS, METHODS AND HANDLING

7. REPORTING

PROPOSED DRAFT REVISED PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS

INTRODUCTION

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

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

1. DEFINITION OF MICROBIOLOGICAL CRITERIA

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

2. COMPONENTS OF MICROBIOLOGICAL CRITERIA FOR FOODS

2.1 A microbiological criterion consists of:

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

2.2 A microbiological criterion should also state:

- the food to which the criterion applies,
- the point(s) in the food chain where the criterion applies,
- any actions to be taken when criterion is not met.

2.3 When using microbiological criteria for assessing products it is essential, in order to make the best use of money and manpower, that only appropriate tests be applied (see § 5) to those foods and at those points in the food chain that offer maximum benefit in providing the consumer with a food that is safe and suitable for consumption.

3. PURPOSES AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS

3.1 Microbiological criteria may be used to indicate the microbiological status of raw materials, ingredients and end-products at any stage of the food chain as appropriate. They may be relevant to the examination of foods, including raw materials and ingredients, of unknown or uncertain origin or when other means of verifying the efficacy of HACCP based systems and Good Hygienic Practices are not available.

Generally, microbiological criteria may be applied to define the distinction between acceptable and unacceptable raw materials, ingredients, products, lots, or processes by regulatory authorities and/or food business operators.

3.1.1 Application by regulatory authorities.

Microbiological criteria can be used to check compliance with hygienic and microbiological safety provisions in regulations.

Mandatory microbiological criteria shall be limited to those products and/or points of the food chain where no other more effective tools are available, or where they are expected to improve the degree of protection offered to the consumer. Where these are appropriate they shall be product-type specific and only applied at the point of the food chain as specified in the regulation.

Depending on the assessment of the risk to the consumer, the point in the food chain and the product-type specified, the regulatory control actions may be sorting, reprocessing, rejection or destruction of product, and/or further investigation.

Criteria used for this application may be contained in a Codex Standard, may form part of a technical regulation as defined by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, or any other legal requirement.

3.1.2 Application by a food business operator.

In addition to checking compliance with regulatory provisions (see § 3.1.1) microbiological criteria may be applied by food business operators to examine end-products as one of the measures to verify and/or validate the efficacy of the HACCP system..

Such criteria will be specific for the product, the production-line or -site. They may be stricter than the criteria used for regulatory purposes and should, as such, not be used for legal action.

They may also be used by the processor to assess products and raw materials of unknown origin or those not known to have been produced according to Good Hygienic Practices and by applying HACCP principles.

3.2 Microbiological criteria as described here, are not normally suitable for monitoring Critical Limits as defined in the Codex Guidelines for the Application of HACCP. Monitoring procedures must be able to detect loss of control at a Critical Control Point (CCP). Monitoring should provide this information in time for corrective actions to be taken to regain control before there is a need to reject the product. Consequently, on-line measurements of physical and chemical parameters are often preferred to microbiological testing because results are often available more rapidly and at the production site.

Moreover, the establishment of Critical Limits may need other considerations than those described in this document.

4. GENERAL CONSIDERATIONS CONCERNING PRINCIPLES FOR ESTABLISHING AND APPLYING MICROBIOLOGICAL CRITERIA .

4.1 **The hygiene, including safety, of foods should be ensured through the application of Good Hygienic Practices, and the development and implementation of a HACCP plan** or an equivalent HACCP-based system.

A microbiological criterion should be established and applied only where there is a definite need and where its application is practical. Such need is demonstrated, for example, by epidemiological evidence that the food under consideration may represent a public health hazard and that a criterion is meaningful for consumer protection, or by the result of a risk analysis. The criterion should be technically attainable by applying good manufacturing practices (codes of practice).

4.2 To fulfil the purposes of a microbiological criterion, consideration should be given to:

- the evidence of actual or potential hazards to health;
- the microbiological status of the raw material(s);
- the effect of processing on the microbiological status of the food;
- the likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage and use;
- the category(s) of consumers concerned;
- the cost/benefit ratio associated with the application of the criterion;
- the intended use of the food.

4.3 The number and size of analytical units per lot tested should be as stated in the sampling plan and should not be modified. A lot should be not be subjected to repeated testing, in order to bring the lot into compliance.

5. MICROBIOLOGICAL ASPECTS OF CRITERIA.

5.1 Microorganisms, parasites and toxins of importance in a particular food.

5.1.1 For the purpose of this document these include:

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

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

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

5.1.4 Where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms. If a test for an indicator

organism is applied, there should be a clear statement whether the test is used to indicate unsatisfactory hygienic practices or a health hazard.

5.2 **Microbiological methods.**

5.2.1 Whenever possible, only methods for which the reliability (accuracy, reproducibility, inter- and intra-laboratory variation) has been statistically established in comparative or collaborative studies in several laboratories should be used. Moreover, preference should be given to methods which were validated for the commodity concerned preferably in relation to reference methods elaborated by international organizations.

While methods should be the most sensitive and reproducible for the purpose, methods to be used for in-plant testing might often sacrifice to some degree sensitivity and reproducibility in the interest of speed and simplicity. They should, however, have been proved to give a sufficiently reliable estimate of the information needed.

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

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

5.3 **Microbiological limits.**

5.3.1 Limits used in criteria should be based on microbiological data appropriate to the food and should be applicable to a variety of similar products. They should therefore be based on data gathered at various production establishments operating under Good Hygienic Practices and applying the HACCP system.

In the establishment of microbiological limits, any changes in the microflora likely during storage and distribution (e.g. decrease or increase in numbers) should be taken into account.

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

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

5.3.3 It should be borne in mind that no feasible sampling plan can ensure complete absence of a particular organism in a lot, and thus that criteria cannot assure the safety of a lot.

6. SAMPLING PLANS, METHODS AND HANDLING

6.1 A sampling plan includes the sampling procedure and the decision criteria to be applied to a lot, based on examination of a prescribed number of sample units and subsequent analytical units of a stated size by defined methods. Sampling plans should be administratively and economically feasible.

In particular, sampling plans should take into account:

- the severity of the hazard and an assessment of the likelihood of its occurrence (risk),
- the susceptibility of the target group of consumers

- the heterogeneity of distribution of microorganisms
- the acceptable quality level (AQL, percentage of defective sample units) and the desired statistical probability of accepting a defective lot.

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

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

7. REPORTING

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

Distributed by USJ 26/96

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 52251 Telex: 625825-625853 FAO I Cables: Foodagri Rome Facsimile: (6)5225.4593

ALINORM 97/13
ADDENDUM
January 1996

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-Second Session
Geneva, 23-28 June 1997

REPORT OF THE TWENTY-EIGHTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE
Washington D. C., 27 November - 1 December 1995

CX 4/20.2

To: - Codex Contact Points
- Participants at the 28th Session of the Codex Committee on Food Hygiene
- Interested International Organizations

From: Chief, Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

Subject: **Distribution of the Proposed Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-Life**

The 28th Session of the Codex Committee on Food Hygiene revised the Draft Code and recommended its adoption by the 43rd Session of the Executive Committee at Step 5 of the Procedure, (ALINORM 97/13, para. 39).

The Draft is being distributed separately, but it should be read in conjunction with the main Report i.e. ALINORM 97/13 and the circular letter CL 1995/48-FH (Part A (4))

Governments wishing to propose amendments or to submit comments on the Proposed Draft Code of Hygienic Practice for Refrigerated Packaged Foods with extended shelf-life, should do so in writing, in conformity with the Codex Alimentarius Commission Procedural Manual, to the Chief, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, **not later than 30 April 1996.**

ALINORM 97/13
APPENDIX IV

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

TABLE OF CONTENTS

Foreword

Section I - Scope

Section II - Definitions

Section III - Hygiene in production and harvest areas

Section IV - Design of establishment and installations

Section V - Establishment : hygiene recommendations

Section VI - Hygiene for personnel and sanitation specifications

Section VII - Processing hygiene recommendations

Section VIII - Hazard Analysis Critical Control Point

Section IX - Records management

Appendix 1 - Hurdles

Appendix 2 - Examples

Reference Texts

FOREWORD

Refrigerated packaged foods with extended shelf life are foodstuffs that are kept refrigerated to preserve them. In general, the heat or other preservation treatment that these products receive is not sufficient to ensure their commercial sterility. Refrigeration is an important hurdle that retards food spoilage and prevents growth of most pathogens.

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

There are other potential risks with certain refrigerated foods. For example, with Modified Atmosphere Packaged (MAP) foods, the anaerobic environment limits growth of aerobic flora. Aerobic flora compete with pathogenic microorganisms; since these aerobic flora are limited or do not grow in MAP, certain pathogenic microorganisms may proliferate. Aerobic flora are also often the flora that cause product spoilage. Because significant growth of aerobic microorganisms is prevented, MAP products may become unsafe without any visible signs of spoilage.

Moreover, heat or other preservation treatments and refrigerated storage are not necessarily the only factors to be controlled. Microbiological hazard can be controlled by a combination of inhibiting factors, called hurdles. These hurdles can assist in retarding or preventing growth of some microorganisms, including pathogenic microorganisms. Some of the hurdles which may be used in addition to heat or other preservation treatments are: refrigeration, pH, a_w, preservatives, competitive microflora, modified atmosphere, etc.

The purpose of this code is to set out recommendations for processing, packaging, storage and distribution of refrigerated packaged foods. Its aim is preventing the outgrowth of pathogenic microorganisms and it is based on the principles of Hazard Analysis Critical Control Point (HACCP). Section VIII of this code discusses the application of HACCP principles to refrigerated packaged foods with extended shelf life. The HACCP method is described in Codex document " HACCP system and guidelines for its application".

SECTION I - SCOPE

This code is concerned only with those refrigerated packaged foods which are formulated and processed to critically rely upon maintenance of the integrity of the cold chain for their safety, quality and wholesomeness.

The refrigerated packaged foods which the provisions of this code concern are products that:

- are heat treated or processed using other technologies to reduce their original microbiological population;
- may use hurdles in addition to heat or other technologies and refrigeration, to retard or prevent the proliferation of undesirable microorganisms;
- are packaged, not necessarily hermetically, before or after the process (heat or other preservation treatments);
- are low acid, that is, with pH > 4.6 and are high water activity $a_w > 0.92$;
- are intended to be refrigerated during their shelf life to retard or prevent the proliferation of undesirable microorganisms;
- have an extended shelf life of more than 5 days[1]
- may not necessarily require heating prior to consumption.

It includes, but is not limited to :

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

It excludes:

- Raw foods,
- Frozen foods,
- Low acid canned foods stored at ambient temperature,
- Fermented meats and meat products,
- Cured meats and meat products,

Fermented vegetables,

- Dried and/or salted and/or smoked fish and meats,
- Milk, creams and dairy products,
- Cheeses,
- Yellow fats and fat spreads,

---

[1] Recommended International Code of Hygienic Practice for Procooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993), should be consulted for foods having a shelf life of 5 days or less

- Acid or acidified foods.

Foods that contain one or more ingredients that are excluded and one or more ingredients that are included are covered by this code (see Appendix II - Examples - 3, Assembled salad).

SECTION II - DEFINITIONS

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

Container ("récipient"): any box, tin, plastic or other receptacle, or wrapper in direct contact with the food product.

Cooling equipment ("appareil de refroidissement"): equipment to reduce a product's temperature to a given refrigeration temperature.

Filling and sealing ("conditionnement"): operation consisting of placing a food product in a container and closing it.

Good manufacturing practices (GMP) ("BPF"): basic requirements as defined in this Code and the Code of Practice - General Principles of Food Hygiene.

Hermetically sealed container ("récipient hermétiquement fermé"): Containers which are designed and intended to protect the contents against the entry of viable microorganisms after closing.

High Risk Area (HR): In addition to the characteristics of GMP, the high-risk area is an isolated area, designed to maintain a high level of hygiene, where the practices concerning personnel, materials, equipment and the environment are managed so as to prevent contamination by pathogenic microorganisms. The HACCP approach will allow the identification of when the use of High Risk area is necessary.

Lot: all units of a product in the same container type and size, produced using the same conditions and during the same processing period, usually not exceeding 24 hours.

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

Packaging ("emballage"): any case, carton or container for the food containers. Any operation consisting in placing the containers in cases, cartons, etc.

Packaging material (matériau pour récipient ou emballage"): materials such as cardboard, paper, glass, plastic film, metal, etc., used to manufacture containers or packaging for refrigerated packaged food.

Pasteurization value ("valeur pasteurisatrice"): The pasteurization value is the length of time at a given temperature to obtain a specified level of destruction of a microorganism whose heat resistance characteristics are known.

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

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

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

Rapid cooling ("refroidissement rapide"): lowering the temperature of the food in a way such that the critical zone for microbiological proliferation (60°C -10°C) is passed through as rapidly as possible. The cooling time is established during HACCP application.

Refrigerated food ("aliment réfrigéré"): Food which is kept at cold storage temperatures to maintain its safety, quality and wholesomeness, for the intended shelf life.

Refrigerated storage facility ("enceinte réfrigérée"): facility designed to keep refrigerated foods at the intended temperature.

Shelf life ("durée de vie"): This is the period during which the product maintains its microbiological and sensory qualities. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles that may be used and storage temperature.

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

For sections III, IV, V and VI, specific provisions applicable to General Principles of Food Hygiene will be identified when this draft is circulated for Government comments.

SECTION III - HYGIENE IN PRODUCTION AND HARVEST AREAS

These are not covered by the present code; for recommendations relative to raw materials see Section VII.

SECTION IV - DESIGN OF ESTABLISHMENT AND INSTALLATIONS

This section deals with the areas where foods are prepared, cooked, chilled, and stored. Prevention of contamination calls for every reasonable measure to be taken to avoid direct or indirect contact of food with sources of potential contamination. Starting with the design and setting up of installations, several fundamental principles should be respected to prevent cross contamination:

- "one-way-flow", or rational progression of the product in the course of successive processing operations;
- separation of the prepared foods from the raw materials and waste;
- strict separation in the plant of the HR area from other production areas;
- ease of cleaning, sanitizing and maintenance of installations and equipment

When designing installations, it is also necessary to take into account:

- types of products to be processed and technologies to be used;
- amounts of product intended to be processed.

When installations are registered by the health authorities or some other Agency, the Agency having jurisdiction should be contacted at the design phase for advice and agreement in principle. While the installations are being constructed, it is important to verify on a regular basis that the work is being done properly and the specifications manual is followed.

4.1 Location

The establishment should be located in a suitable area that is in compliance with applicable building codes and requirements, that is free from unpleasant odors, smoke, dust or other contaminants and not subject to floods, unless sufficient safeguards are provided.

4.2 Access roads and areas suitable for motor vehicles

The access roads and areas serving the establishment, situated on its perimeter or immediately adjacent, should be suitable for motor vehicle traffic and have a suitable drainage system.

4.3 Buildings and installations

4.3.1 Buildings and installations should be constructed according to building regulations and maintained in good condition. Construction materials used should not be capable of transmitting undesirable substances to the foodstuffs. It is advisable to avoid use of materials that are difficult to clean and disinfect, unless it is certain that they are not a source of contamination. All dimensions of buildings and installations should be sufficient to maintain good sanitary processing conditions.

4.3.2 Sufficient work spaces should be provided to allow each operation to be properly carried out.

4.3.3 The design should allow for adequate, easy cleaning, sanitation and good control of food hygiene.

4.3.4 Buildings and installations should be designed to prevent pests from entering and becoming established, and to prevent entry of contaminants from outside, such as smoke, dust, etc.

4.3.5 Buildings and installations should be designed in such a way that operations which might give rise to cross contamination are separated either by their location, by partition walls or any other effective means. They should also be designed so that the principle of one-way-flow of product can be respected.

Storage facilities should also respect the principle of "one-way-flow" and "first in, first out" and be looked at from the point of view of temperature, humidity and ventilation to keep raw materials, in-process products and final products in optimal conditions.

It would be preferable to have separate storage facilities for raw materials, in process goods and finished product. If it is not possible to use separate facilities, the products should be separated and protected from cross contamination.

Similarly, the design of areas for unwrapping and unpacking should be based on a detailed study of this kind of work area, including aspects relative to disposal of garbage and non-edible materials. All operations that might present risks of food contamination: preparation, trimming, cutting, washing of material and utensils, etc., should be done in separate rooms or in areas specially designed for the purpose.

4.3.6 Buildings and installations should be designed to facilitate hygienic conditions of operations through their regular progression, from arrival of raw materials to final product, and should ensure appropriate temperature for the processing of the product.

The plant should be designed and equipped in such a way that the interior temperature is compatible with keeping products at a temperature that controls proliferation of microorganisms during the various operations, regardless of the outside temperature. These premises should also allow for work to be organized so that the periods of time products spend in critical areas are limited to the time strictly necessary for operations to be carried out.

Meeting these temperature requirements may call for an air conditioning system to be installed.

4.3.7 In areas for handling foodstuffs:

- floors should be made of material that is waterproof, smooth and crack resistant, non-absorbent, washable and should not have cracks. They should be easy to clean and disinfect and be kept in good sanitary condition. They should be sloped enough to allow liquids to flow through drains equipped with traps.

- walls should be constructed of materials that are waterproof, non-absorbent and washable, and should be light in color. The surface should be smooth and crack resistant and without cracks up to a suitable height for operations. They should also be easy to clean and disinfect and be kept in good sanitary condition. Angles of walls, walls and floor and walls and ceiling should be joined and rounded to facilitate cleaning so that they cannot conceal insects or microorganisms.

- ceilings should be designed, constructed and finished to prevent accumulation of filth and to minimize vapor condensation, development of molds and flaking. They should be constructed of materials that are waterproof, crack resistant, easy to maintain and kept in good sanitary condition.

- windows and other openings, in particular ventilation ducts, should be constructed in such a way as to avoid accumulation of dirt, and those opening to the outside should be sealed tight and equipped with insect screens. The screens should be easily removable to facilitate their cleaning and maintenance. The inside of window frames and sills of windows should be slanted to prevent their being used as shelves. Windows should be kept in working order. In the packaging area, windows should remain closed at all times after cleaning and disinfection of the area until such time as the packaging of the product is completed.

- doors should be smooth and water-tight and, when necessary, close automatically and be sealed to assure a tight fit within frames.

- stairways, elevator shafts, equipment and accessories such as platforms, ladders, chutes, etc., should be located and constructed in such a way as not to cause contamination of foods. Chutes should be equipped with openings for inspection and cleaning.

In HR areas:

- entrances should be provided with foot baths or shoe change facilities, and hand washing and sanitizing installations.

- windows should be closed and not capable of being opened.

- where appropriate the premises should be equipped with temperature monitoring and recording devices and a reliable system, to signal loss of control, for example, an audible alarm or blinking light.

- if the temperature in the HR areas has been determined to be critical and is exceeded, the manufacturer should demonstrate the product's safety.

- air should be filtered and under positive pressure in locations where foodstuffs are handled in order to limit risks of contamination.

- doors, apart from fire doors and emergency exits, should not open directly to the outside of the building or into areas that are potential sources of contamination, such as areas for handling raw materials or unprocessed products, toilets, etc. Doors should be closed when not in use, fit tightly and kept in good sanitary condition and in working order.

- fire doors and emergency exits opening directly to the outside should fit tightly and be used only in case of emergency.

4.3.8 In areas where foodstuffs are handled, all equipment and accessories situated in an elevated position should be installed so as to avoid direct or indirect contamination of foods and raw materials by formation of condensation that could drop onto products. Their design should not hinder cleaning operations. Equipment should be insulated when necessary. The construction should be such that dirt

accumulation, development of mold and chipping is prevented. They should be easy to clean and sanitize.

4.3.9 Living areas, toilets and outside areas where animals are kept should be kept entirely separate from areas where food is handled and should not open directly into them.

4.3.10 Establishments should be designed so that access can be controlled.

4.3.11 Water supply

A plentiful supply of water, conforming to the WHO's "Guidelines for Drinking Water Quality", maintained at an appropriate pressure and temperature, should be supplied, as well as suitable installations for its storage and distribution, with sufficient protection from contamination.

Samples for analysis should be taken regularly to monitor the continued potability of the water. The sampling frequency depends on the source and use of water, for example, sampling usually being more frequent when there is a private water supply versus a municipal water supply. According to the analytical results of these checks, if disinfection is necessary, chlorine or other disinfectants must be used. In the case of chlorination, it is best to determine the amount of free chlorine daily, using chemical tests. Water should be sampled at point of use. When a problem exists at the point of use, samples must be taken at the establishment's water intake or source as a check on the integrity of the water system.

Ice should be made from potable water; it should be made, handled and stored in conditions protecting it from any contamination.

Steam which comes in direct contact with foods, or surfaces in contact with food, should be free from any substance presenting a health risk or apt to contaminate the product.

Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), should have a separate system. Non-potable water systems should be easily identified. They should not connect with, nor should there be a risk of back flow into potable water systems.

Recycled water within the establishment should be treated so that its use does not contribute to health risk. Treatment should be monitored. Recycled water should circulate in separate, easily identifiable pipes. Approval for use of recycled water for any food processing procedure should be requested from the agency having jurisdiction.

4.3.12 Removal of effluent and waste

Establishments should have and keep in good working order an effective system for removing effluent and waste.

All pipes for evacuation of effluent, including sewer lines, should be sufficiently large to ensure they can handle drainage during peak periods and should be constructed in such a way so as to avoid any contamination of potable water supplies. All drainage pipes should be connected to a sewerage system or appropriate septic system.

Drainpipes should be designed and maintained to prevent back flow (equipped with traps, for example), to be regularly cleaned and to prevent accumulation of water during periods of normal usage and when the plant is not in operation.

For HR areas:

Drains from the HR areas should be planned so that there is no contamination from other drains, that is to say no waste water from contaminated areas of the plant should flow into drainpipes from the areas where products are handled.

Waste water from refrigeration equipment, installations for hand washing and machinery should be piped to the sewerage system so as to minimize any risk of contamination of products. Particular attention should be paid to the risk of back flow of condensed water from the drain systems for refrigeration equipment.

4.3.13 Cooling and Refrigeration Equipment

4.3.13.1 Refrigeration

Establishments should have refrigerated rooms and/or freezers that are sufficient to hold raw materials at an adequate temperature, in conformity with sections 7.1.4 and 7.1.5.

All refrigerated rooms should have devices to monitor and record the temperature and a reliable system, such as an alarm, to signal loss of control. These devices should be clearly visible and placed so that the maximum temperature in the refrigerated area is recorded as accurately as possible. Devices should be checked at regular intervals, against a known accurate standard, and adjusted, repaired or replaced.

4.3.13.2 Cooling

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

Rapid cooling of large quantities of food requires equipment capable of rapidly extracting heat from the maximum quantity of food likely to be produced. Ideally, the method used should ensure that the foodstuffs are not kept for more than two hours at temperatures between 600C and 100C where feasible. Other cooling regimens can be used provided there is evidence to assure the safety of the product.

The equipment's operation should be checked periodically to make sure that it remains within the specified margins to ensure that the appropriate product temperature is maintained.

4.3.14 Cloakrooms and toilets

All establishments should have suitable, well-located cloakrooms and toilets. Toilets should be designed to ensure sanitary operation. These areas should be well lit, ventilated and, when necessary, heated; they should not open directly into food handling areas. Washbasins with warm or hot water

and cold water, suitable products for washing and disinfecting hands and a hygienic single-use drying device should be located immediately adjacent to the toilets and placed so that employees should pass in front of them when returning to the work area. Installations dispensing hot and cold water should be equipped with mixers. When paper towels are used, a sufficient number of distributors and receptacles should be located next to each washbasin. It is preferable to have taps that cannot be operated by hand. Signs should be posted instructing personnel to wash their hands every time after using toilets.

4.3.15 Washbasins in processing areas

In all cases where the nature of the operation requires it, there should be adequate, convenient installations for staff to wash and dry their hands and, when necessary, disinfect them. These installations should be equipped with warm or hot water and cold water, as well as suitable products for washing and disinfecting hands. Installations dispensing hot and cold water should be equipped with mixers. When paper towels are used, there should be a sufficient number of distributors and receptacles next to each washbasin. It is preferable to have taps that cannot be operated by hand. Installations should be equipped with traps and waste pipes connected to sewers.

4.3.16 Disinfecting installations

When necessary, adequate installations should be provided for cleaning and disinfection of utensils and work equipment. These installations should be constructed of corrosion-resistant material that is easy to clean and supplied with a sufficient supply of hot and cold water.

4.3.17 Lighting

Sufficient natural or artificial light should be provided throughout the establishment. When needed, lighting should not alter colors and light intensity should not be less than:

- 540 lux at all inspection points
- 220 lux in workrooms
- 110 lux elsewhere.

Bulbs and fixtures installed over foodstuffs, at whatever stage of preparation, should be of the type known as safety lights and protected so as to prevent contamination of foods in case of breakage. Light fixtures should be designed and installed to minimize accumulation of dust and debris and should be kept clean and dust-free.

4.3.18 Ventilation

The ventilation system should be designed to be hygienic. Attention should be paid to the location of the establishment as well as to other environmental conditions which may lead to the contamination of the products.

Adequate ventilation should be provided to prevent dust, excessive heat, condensation on walls and ceilings, as well as to adequately circulate air. Air should never flow from a contaminated area to a clean area. Ventilation outlets should be equipped with grilles or any other protective apparatus

constructed of a corrosion-resistant material. Grilles should be easily removable for cleaning. Air should be filtered and a positive pressure maintained in food handling areas.

Precautions should be taken to ensure that the roofs and ledges beside which the intake pipes for the ventilation system are located are not a source of contamination for ventilated air.

In HR areas:

The ventilation system should be capable of maintaining a sufficiently low temperature, where appropriate, to assure that the temperature of the product is not adversely affected. It should be designed and used so as to prevent condensation and circulation of dust.

The air supplying the premises should be treated to remove particles.

Ventilation systems, including filters, should be inspected with sufficient frequency to ensure they are functioning properly. The program shall also describe corrective actions required in cases of deficiencies revealed on inspection. Air in HR areas should be kept under positive pressure around surfaces and areas where final products are assembled.

4.3.19 Installations for storage of waste and non-edible material

Installations should be provided for short term storage of waste and non-edible material before they are removed from the establishment. These installations should be designed to prevent pests from having access and to avoid contamination of foods, potable water, equipment, premises or access roads on the plant site.

4.4 Equipment and materials

4.4.1 Materials

All equipment and utensils used in food-handling areas that might come in contact with food should be made of materials that cannot transfer toxic substances or undesirable odors or flavors. They should be non-absorbent, corrosion-resistant and strong enough to withstand repeated cleaning and disinfection operations. Surfaces should be smooth and free of cavities and cracks. Some suitable materials are stainless steel and synthetic rubber. It is best to avoid use of wood and other materials that are difficult to clean and disinfect, unless it can be determined that they will not be a source of contamination. Utilize corrosion resistant metals for food contact surfaces.

Equipment and utensils are a potential source of contamination transfer and should not be used indiscriminately for raw and cooked foods. All equipment and utensils used for raw foods should be thoroughly cleaned and disinfected before being used for cooked and precooked foods. Entry into the product-assembly or preparation area of equipment used for processing, handling or transport outside of the area should not be authorized. Equipment leaving the product assembly area should be cleaned and disinfected before being readmitted.

In HR areas:

Equipment designed for handling heat-treated products should be used solely for this purpose and should be kept separate from equipment used to handle material before heat or other preservation

treatments. If reusable trays are used, once they are cleaned and sanitized they should not pass through a area where they may be contaminated unless they are appropriately covered.

4.4.2 Hygienic design of equipment

All equipment and utensils, including filling machines, transport equipment, conveyor belts and packaging equipment, should be designed and constructed to minimize any contamination risk and to allow for easy, complete cleaning and disinfecting. Equipment and utensils should be accessible for inspection. Fixed equipment should be installed in such a way that it is easily accessible and can be thoroughly cleaned and disinfected in place.

All apparatus used in the establishment should be regularly checked and calibrated according to a written procedure.

Containers intended for non-edible matter and waste should have tight fitting covers and be watertight, made of metal or any other impermeable material, and be easy to clean or disposable after use.

4.4.3 Identification of equipment

Equipment and utensils used for non-edible matter or waste should be identified and not used for edible products.

4.4.4 Particular recommendations for certain equipment

4.4.4.1 Compressed air

Compressed air coming in direct contact with food or with food contact surfaces(including fillers) should be filtered or treated in such a manner to remove contaminants.

4.4.4.2 Thermal Processing Equipment

Thermal processing equipment should be properly maintained and be cleaned and disinfected as required.

For HR areas:

Thermal processing equipment should be designed and located so as to create a barrier between the area for preparation of raw materials and the HR areas for product processing. It should be possible to easily load such equipment with raw materials from the GMP areas and unload hygienically in the HR areas preventing any risk of cross-contamination by utensils, products, equipment or personnel.

All thermal processing apparatus should be designed to be hygienic and should be provided with suitable instrumentation. Systems for steam removal and humidity should be effective, hygienically designed and well maintained to minimize risk of condensate or other cross contamination of heat-treated product.

4.4.4.3 Cooling equipment

Equipment should be designed to allow for ease of cleaning and to minimize accumulation of condensation. It should be cleaned and sanitized as required.

4.4.4.4 Transport vehicles

Vehicles should be constructed, insulated, and have adequate refrigeration equipment to maintain the product at the prescribed temperature or less throughout loading and transit. The vehicle should be equipped with a temperature-monitoring and recording system that is easy to read and should be checked regularly against a known accurate standard and adjusted, repaired or replaced. The temperature sensor should be so located to measure the temperature of the refrigerated compartment. This system should be suitably positioned with sensors located beside the air return system and the outflow from the evaporators. Vehicles should be suitably equipped to prevent water entry and allow drainage of condensate.

SECTION V - ESTABLISHMENT: HYGIENE RECOMMENDATIONS

5.1 Maintenance

Buildings, material, utensils and all equipment in the establishment — including manholes for the waste-water drainage system — should be maintained in good order. As far as possible, the premises should remain free of steam, condensation and waste water.

5.2 Cleaning and disinfecting

5.2.1 Cleaning and disinfection should meet the requirements Appendix I of General Principles of Food Hygiene (CAC/RCP 1 - 1969, Rev. 2 (1985)) and to those of this code.

Cleaning standards, including those for cleaning protective clothing, should be compatible with the hygiene standards required for the area concerned.

5.2.2 Equipment, materials, utensils etc. which come in contact with foods, especially raw materials (fish, meat, vegetables) are contaminated by microorganisms. These could contaminate other products which could be subjected to further processing. This is why it is necessary to clean them and if necessary to take them apart at frequent intervals during the day, at least after each break and when there is a change from one food to another. The dismantling, cleaning and disinfecting at the end of the work day is necessary to prevent microbiological proliferation. Implementing sanitary controls is recommended.

Drainpipes should be regularly cleaned and disinfected; tools used to clean these pipes should not be used for other purposes.

For HR areas:

- Equipment and utensils for handling products after heat or other preservation treatments should be cleaned and sanitized at regular intervals.

5.2.3 Necessary precautions should be taken to prevent contamination of foods from splashing of water, detergents or diluted or undiluted disinfectants during cleaning or disinfection of premises, equipment or utensils.

Detergents, disinfectants or sanitizers should be suitable for the job for which they are being used and there should be documentation and approval for the use described.

Any residue from these substances left on surfaces that may come in contact with food should be removed where permitted using an adequate method, for example, rinsing with potable water, before the premises or equipment are used again for food handling. Regular monitoring of the cleanliness of the surfaces that come in contact with foods should be done before production begins. This monitoring should be verified by regular microbiological validations.

For HR areas:

Environmental sampling for microorganisms is recommended.

5.2.4 Immediately after work ends for the day, or at any other time circumstances require it, floors, including drainage channels and manholes for waste-water drains, auxiliary structures and walls of food-handling areas should be thoroughly cleaned and disinfected, where appropriate.

5.2.5 Sponge mops, scrapers, cloths, equipment for condensation removal and spray hoses are particular sources of contamination. They should not be used, or if such use is necessary, they should be frequently cleaned and sanitized.

High-pressure spray cleaning equipment should not be used. If such use is necessary, they should be used only between production periods in the absence of product and by designated and trained staff. They should not be used to clean drains unless the entire area is subsequently cleaned and sanitized.

5.2.6 Cloakrooms and toilets should be kept clean at all times.

5.2.7 Access roads and the yards immediately adjacent to and serving the buildings should be kept clean.

5.3 Hygiene control program

Each establishment should be provided with a continuing program for cleaning and disinfection to ensure that all areas are suitably cleaned and that particular attention is paid to critical equipment and areas. This program should be regularly reviewed and regular examination of cleaning methods should be done to verify the program's effectiveness. This review should include evaluation of detergents and disinfectants, as well as the temperatures, pressures and concentrations at which they are used.

This program should state precisely the methods for cleaning and sanitizing to be used as well as methods for checking the cleaning schedule, the kind of detergents and disinfectants used and instructions for cleaning and the results of cleaning.

One person should have overall responsibility for cleanliness of the establishment. This person should be completely familiar with the inherent dangers of contamination. All staff assigned to cleaning the establishment should be experienced in sanitation maintenance methods and should verify that proper methods have been used and recorded.

5.4 By-products of raw materials

By-products such as trimmings, peelings, scraps and so on, that are not classed as waste and that can be put to later use, should be stored in such a way as to avoid contamination of foods and so that they do not spoil. They should be removed from work areas as often as necessary.

5.5 Storage and removal of waste

In rooms used for processing of prepared refrigerated foods, waste matter should be placed in receptacles specially designed and marked for this use. Receptacles should be kept in good condition and be easy to clean and sanitize. They should be sealed or provided with covers and removed from the work area when they are full, or after each work shift, and emptied into covered garbage bins,

which should never be brought into preparation areas. Reusable receptacles should be cleaned and disinfected every time they are brought back into the processing areas.

Garbage bins should be kept in a closed area reserved for this purpose, away from food storage rooms. This location should be kept at as low a temperature as possible and be well-ventilated and protected from insects and rodents; it should be easy to clean, wash and disinfect. It should be designed so as to avoid contamination of foods, potable water, equipment or premises. Garbage bins should be regularly emptied, cleaned and disinfected.

Cartons and packaging, when they have been emptied, should be treated in the same way as waste. Waste-compressing equipment should be placed away from food-handling areas.

If a system for waste disposal through chutes is installed, it is essential that debris and waste are placed in single-use closed bags. The chute openings should be cleaned and disinfected every day.

5.6 Excluding domestic animals

The presence of animals at large or which could possibly be a health hazard should be prohibited in the establishment.

5.7 Pest control

5.7.1 An ongoing effective pest-control program should be implemented. Establishments and surrounding areas should be checked regularly to detect any sign of infestation.

5.7.2 If pests do get into the establishment, necessary measures should be taken to eliminate them. These measures, including treatment with chemical, physical or biological agents, should not be applied without direct supervision of a staff member who is completely aware of the dangers inherent in such treatment, including possible risks from product residue. These measures should be carried out only on the recommendation of the authority concerned.

5.7.3 Pesticides should not be used unless other precautionary measures cannot be used effectively. Before using pesticides, it is advisable to protect all food, equipment and utensils from possible contamination. After their use, contaminated equipment and utensils should be thoroughly cleaned and disinfected before they are used again.

5.8 Storage of hazardous substances

Pesticides or other substances should carry appropriate labeling including how they are to be used. They should be stored in locked rooms or cupboards that are kept exclusively for this purpose. They should be distributed and handled only by authorized and duly-trained personnel. Every precaution should be taken to avoid contamination of foods.

5.9 Personal effects and clothing

Personal effects and clothing should not be left in food-handling areas. They should be placed in the cloakrooms provided for in paragraph 4.3.14.

SECTION VI - PERSONNEL HYGIENE FOR AND SANITATION SPECIFICATIONS

6.1 Hygiene training

Because the health status, clothing and behaviour of personnel is of utmost importance in hygiene, everything should be done to motivate food handlers to adopt practices and attitudes consistent with food hygiene.

The establishment's management should organize continuing training and information in methods of food handling and personal hygiene for all persons responsible for handling food, so that they understand precautions and responsibilities for the safety and quality of the food product.

This training, bearing in particular on the sections of the present code which deal with these matters, should be done at the time persons are hired and regular refresher sessions should take place. Content should be in a printed, possibly illustrated, text so that it can be easily consulted by staff. Permanent posting of hygiene rules is advised.

All employees should be given a printed copy of the establishment's rules on hygiene policy.

Personnel that specialize in certain tasks should receive detailed descriptions of the work they are to do.

For HR areas:

Personnel, including cleaning and service staff, working in these areas should be specially trained and instructed about the need for a high level of personal hygiene at all times.

6.2 Medical examination

Persons who come in contact with food in the course of their work should have had a medical examination before being employed. A medical examination should also be given every time it is necessary for clinical or epidemiological reasons, in particular, after interruption of work caused by an infection that can have after-effects that could cause contamination of handled food. A regular medical examination -- at least once a year -- is strongly advised.

6.3 Transmittable diseases

Management should take necessary measures to see that any person who is known to have or is suspected of having a disease that can be transmitted by food, or is a carrier of such a disease, or has infected wounds, infected skin irritations or diarrhea, cannot contaminate food directly or indirectly. These measures include:

- looking out for persons who are sick or have an infection.
- prohibiting affected persons from handling foodstuffs or packaging material during the period of time when they present a potential hazard.
- in exceptional cases and with medical advice, keeping healthy, asymptomatic carriers on the job, when stronger precautions can be taken.

Any person who presents a risk of this kind should immediately inform management.

6.4 Wounds

Any person with an open cut or wound should not touch foods or surfaces that come in contact with food unless the wound is entirely covered with a waterproof dressing which is firmly affixed, clearly visible and can be worn along with appropriate gloves for effective protection. A first-aid service should be provided for this purpose.

6.5 Hand washing

During work, any person working in the food-handling area should wash his or her hands as well as arms and fingernails often and thoroughly, using a product suitable for cleaning and disinfection of hands, in hot, running, potable water. A one time use means of drying hands should be provided. Personnel should always wash hands before starting work, immediately after using toilets, after touching soiled objects, after each break, when staff moves between different production areas, and whenever necessary.

After handling materials that are apt to transmit disease, such as uncooked raw materials (meat, fish, poultry, vegetables), staff members should immediately wash and disinfect hands. Signs should be posted encouraging staff to wash their hands and checks should be made to see that this instruction is complied with.

6.6 Personal cleanliness

Persons assigned to food handling should maintain a high level of personal cleanliness during working hours. This includes wearing hair nets and beard covers, and footwear should be of construction to not contribute to poor hygiene, washable or disposable after use and should be kept as clean as is required by the nature of the employee's job.

Protective clothing should be changed at least daily, more often if necessary and not reused until it has been cleaned. These clothes should not be worn outside the establishment; they should be put on and removed on the premises.

Aprons and other accessories should be washed in a suitable place. When food is handled, staff working in food handling should not have on their person jewelry or any object that could fall into the food.

For HR areas:

Personnel (including sanitation and service staff) working in HR areas should change into work uniforms in a specific room. They should wear protective clothing and footwear specific to the area. These clothes should not be removed from this area and should be taken off in the cloakroom before personnel leave the production line for any reason. Clean clothing should be worn at the beginning of the work day and should be changed at the end of the work day, shift or more frequently if needed. Footwear should be suitably cleaned and sanitized.

6.7 Behaviour of personnel

Anything that might cause contamination of food, for example, eating, smoking, or any other unhygienic practice, chewing (gum, candies, betel nuts, etc.), spitting, should be prohibited in food-handling areas. Personnel that sneeze or cough should be kept out of food handling areas.

Management should put in place a plan for movements of personnel, and also for visitors, to reduce cross-contamination. A system of color coding may be used to identify personnel assigned to different areas of the plant. Visitors should move from the cleanest areas towards the most contaminated.

6.8 Gloves

When gloves are used for handling foodstuffs, they should be sturdy, clean and hygienic. Gloves should be manufactured from non porous non absorbent material. Wearing gloves does not eliminate the need to carefully wash hands. Gloves should be disposable and changed as often as necessary or should be reusable and disinfected as often as necessary. Metal-mesh gloves are particularly difficult to clean and disinfect because of their texture. Careful cleaning is necessary and should be followed by heating or long immersion in disinfectant.

In HR areas:

Personnel should wear gloves to handle products. When disposable sterile gloves are used, they should be changed at least every two hours or when they are damaged or when the employee leaves the production line. For some tasks, heavier-duty sterilizable gloves may be used and should be kept satisfactorily sanitized.

6.9 Visitors

Precautions should be taken to prevent persons who visit or are involved in the food-handling areas from contaminating them. These precautions include wearing protective clothing or garments.

Visitors should respect the provisions of sections 5.9, 6.3, 6.4 and 6.7 of this code and should be warned in advance of the rules they will have to comply with.

6.10 Supervision

Responsibility for ensuring observation by all personnel of the requirements of sections 6.1 to 6.9 should be given specifically to a competent staff member.

Management should understand the requirements with regard to microbiological safety of products for the establishment under their responsibility and should set a good example.

SECTION VII - PROCESSING HYGIENE RECOMMENDATIONS

7.1 Recommendations for raw materials and packaging materials

7.1.1 Any raw material or ingredient known to contain parasites, microorganisms, toxic or decomposed substances or foreign matter which cannot be brought to acceptable levels by visual sorting procedures, preparation; or processing should not be accepted by the establishment. HACCP principles should be used to determine which hazards may be associated with raw materials/ingredients to be used in the product.

7.1.2 Specifications for raw materials and packaging materials

Based on the hazard analysis, appropriate specifications for raw materials and packaging materials should be established with suppliers. These specifications should cover labeling, packaging, conditions for transport and storage, as well as the sensory, physical, chemical, parasitological and microbiological characteristics of delivered goods. Control measures should be listed in detail in the specifications manual. Suppliers should be encouraged to operate under a HACCP plan. Manufacturers should ensure, by means of audits, for example, that suppliers have put in place a program to ensure the safety of their products.

Raw material specifications, including those for the hurdles (e.g. pH, water activity, salt - see Annex I), should be determined with the HACCP application and validated during the product design phase (Section VIII).

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

7.1.3 Controls on receipt

Raw materials and ingredients should be inspected, sorted and if needed subjected to laboratory examination before being introduced on the processing line. Type and frequency of examinations depend upon the hazard identified and on the ability of suppliers to meet specifications. They may be received refrigerated, frozen or at ambient temperature. They may have suitable hurdles to prevent microbiological growth, such as being dehydrated, acidified, fermented, salted, cured or processed such as shelf stable canned foods.

Raw materials and ingredients should be examined and analyzed when necessary, for the following:

- temperature measurement;
- visual examinations, in particular for foreign materials;
- sensory observations (e.g. odor, visual appearance);
- hurdles used (e.g. pH, % salt, water activity, etc.);
- microbiological analysis.

When such analyses are conducted, raw material and ingredients should meet specifications established in agreement with the supplier.

When refrigerated or frozen raw materials and ingredients are received, their temperatures as well as the temperature inside the delivery vehicle, should be measured and recorded to ensure that they are within the limits specified in the specifications manual. Cleanliness of the vehicle should also be checked.

If the required temperature limits have been exceeded when goods are delivered, trained personel should decide whether the raw materials should be immediately used for manufacture, stored for a limited period, returned to supplier, used in another way or discarded. Unacceptable raw materials and ingredients should be stored separately from raw materials and ingredients used for manufacture of refrigerated foods. Discarded raw materials should be clearly marked so as to identify them as unusable for manufacture of products.

When necessary, some characteristic of packaging materials and of materials from which containers are made should be checked. It may be necessary to carry out visual examination and physical testing in order to measure their properties (maintaining a vacuum or the modified atmosphere in the package), and their resistance to mechanical, chemical and thermal stress encountered in the course of the product's shelf life. All results of these tests should be recorded and filed.

7.1.4 Storage of raw materials and packaging materials

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

Raw materials that are subject to spoilage should be placed without delay in cold storage at the required temperature. There should be documented procedures specifying necessary action to be taken in case of deviation.

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

7.1.4.3 Non-edible materials, such as cleaning compounds, should be received and stored in separate locations, away from packaging materials and ingredients. Non-edible materials should not pass through or remain in processing areas during processing.

7.1.5 Storage temperatures

Raw materials should be stored at temperatures appropriate for the product. Temperatures should be checked and recorded at least once a day.

There should be suitable rotation of stock of raw materials -- "first in, first out". So that this can be achieved, all lots of raw materials should be coded and an appropriate procedure for stock management should be used. Documentation of stock rotation should be kept.

7.2 Preventing cross contamination

7.2.1 Effective measures should be established and taken to avoid contamination by direct or indirect contact with sources or vectors of potential contamination. Proper procedures should be defined. In particular, raw foods should be sufficiently separated from in process foods.

7.2.2 Persons who handle raw materials or in-process products that are apt to contaminate final products should not touch the latter. If they must, they should first sanitize or change their footwear, wash their hands, change into clean protective clothing and change gloves.

7.2.3 Unpacking of raw materials should be done with a maximum of precautions to limit risk of contamination by soil, filth, etc., on the outside of the packaging.

7.2.4 If there is a possibility of contamination, personnel should wash and disinfect hands between handling operations at different stages of processing.

7.2.5 All equipment that has been in contact with raw materials or contaminated material should be cleaned and disinfected before coming in contact with cooked and pre-cooked foods. It is preferable to provide separate utensils for raw materials and in-process or final products, especially for cutting, slicing and chopping.

7.3 Use of water in food processing (See 4.3.11)

7.4 Processing

7.4.1 Production of refrigerated foods involves a sequence of several separate operations for the processing and assembling of raw materials into a final product. It requires supervision by technically competent personnel. All processing operations should be performed in accordance with a HACCP plan.

7.4.2 All steps in production, including packaging, should be accomplished without delays and in conditions such that contamination, deterioration or growth of microorganisms is prevented. In all steps of processing, critical temperatures for multiplication of microorganisms (10°C to 60°C) should be avoided or in any case passed through rapidly.

If there are delays in manufacture, raw materials and in-process products should quickly be placed in refrigerated storage areas and kept at ≤4°C or else kept at ≥60°C until normal production is resumed.

7.4.3 Raw materials of differing origin (meats, vegetables, fish, etc.) should be prepared in different places. If this is not possible, these operations should be carried out at different times, with cleaning and disinfection being done between operations.

In order to prevent microbiological recontamination and growth, special care should be maintained during the debrining, rehydration, neutralization of raw materials or ingredients used for further processing.

7.4.4 Thawing (total or partial)

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

Particular attention should be paid to controlling condensation and drip from the product during thawing.

After thawing, raw materials should immediately be processed or refrigerated until they are used, usually a temperature of 4°C or less. When a microwave oven is used, manufacturer's instructions should be scrupulously followed to prevent overheated areas and uneven thawing. Thawing equipment should be kept clean.

7.4.5 Heat or other preservation treatments

Heat or other preservation treatments result in the reduction of microbiological population. Pasteurizing values can be used to quantify the lethality of a heat treatment on a reference microorganism.

7.4.5.1. Scheduled Heat Treatment

The selection of an appropriate heat treatment(s) depends upon the pasteurization values needed for product safety up to the end of its shelf life. These values should take into consideration all factors used. For example, the heat treatment used may be less severe if it is combined with one or more hurdles such as pH reduction, use of preservatives, reduced water activity, etc.

The selection of the reference microorganism, the determination of the desired pasteurization value and the establishment of the scheduled heat treatment should be made by personnel specially trained in this area.

For more information on the development of product and process refer to Section 8.3.

7.4.5.2 Application and Monitoring of Scheduled Heat Treatment

The application of the scheduled heat treatment should be carried out by competent, specially trained personnel. Heat treatment equipment should have devices for monitoring and recording temperature and time. The temperature monitoring and recording equipment should be checked at regular intervals against a known accurate standard and adjusted, repaired or replaced. For example, by measuring the time-temperature relationship of:

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

Heat-sensitive indicators, or other effective means, to indicate whether the products have been heat-treated should be used, [where warranted]. It is important to ensure that the heat treatment applied conforms to the scheduled process and that the desired pasteurization value has been reached.

The critical factors which were taken into consideration during the development of the process (cf. 8.3) should also be measured, checked and recorded at regular intervals. Records should be kept for at least six months past the shelf life of the product.

7.4.5.3 - Other Preservation Treatments {To be drafted.}

7.4.6 Cooling

The cooling should be carried out so that the centre of the product reaches 4°C in less than 6 hours. Products should be cooled quickly so that their temperature remains for a minimum of time between 60°C and 10°C, the temperature range most favorable for microbiological proliferation. This means bringing the temperature at the centre of the product to under 10°C in less than two hours when feasible.

Other safe alternative cooling methods may be used provided that these are based on scientific evidence.

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

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

The same equipment should be provided with a system for checking and recording the temperature in the cooling environment or at the centre of the product as well as a reliable system, for example an alarm, to signal any loss of control. There should be specified procedures for action to be taken in case of loss of control. Records should be kept for at least six months longer than the shelf life of the product.

Use of equipment for both heat treatment and cooling reduces the time between these two operations, permits continuous recording of temperature and thus results in better control of the microbiological quality of the food and the smooth running of the process. The factors which were taken into consideration during the development of the cooling procedure (c.f. 8.3.3) should be measured, checked and recorded at regular intervals.

7.4.7 Hurdles

When one or more hurdles (see Appendix I) are used in combination with the heat or other preservation treatments, their critical limits need to be specified and met. Critical limits should be measured, checked and recorded at regular intervals.

7.4.8 Non-compliance and corrective actions

When deviations have been noted as a result of monitoring critical control points, corrective actions need to be initiated. Corrective actions may include the following:

- proper disposition of the affected product

- identification of the source of the problem and corrections to prevent reoccurrence. This may result in modification of working procedures.

Non-compliance and corrective actions need to be recorded.

7.5 Packaging

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

Reusable containers should not have been used for other purposes. They should be inspected immediately after use to ensure that they are in satisfactory condition and, if necessary, they should be cleaned and/or disinfected. If they are washed, they should be dry before being refilled.

7.5.2 If filling and sealing is done after heat or other preservation treatments and before cooling, it should be done +- (except for technical constraints (slicing, assembly, etc.) in manner that limits contamination and growth of microorganisms.

If filling and sealing is done after cooling, it should be done so as to limit risks of contamination. The ambient temperature should be such so as to maintain the product at the required temperature. Any increase in temperature of the product during this operation should be avoided.

7.5.3 It may be necessary to check the seal of the packaging.

7.5.4 Each container, at time of filling and sealing, should be marked indelibly on one side to identify the production plant and the production batch or unit.

7.6 Labelling

Labels should conform to the requirements of local authorities. They should provide the following information:

- use-by-date
- type of food
- identification of the processing establishment
- the statement "keep refrigerated at required temperature or less"
- preparation method (microwave, oven, water or other), time and temperature required for cooking, other important information for preparation of the product
- other information required by regulations, for example, the list of ingredients.

7.7 Storage, transport, distribution and use of final product

7.7.1 General

In order to ensure that safety and quality of the product are maintained during its stated shelf life, it is essential that it be kept continuously cold from the time it is packaged until it is consumed or prepared for consumption. Storage temperatures required, indicated on the product's label, should be maintained, measured and recorded during successive stages of transport, storage, distribution and retail. Refrigerated foods are best kept at 4°C or less if refrigeration is the principal means of preservation and the product has not been processed to destroy relevant pathogens.

Storage temperatures higher than 4° C may be suitable provided that shelf life is appropriate or hurdles (for example product formulation, pH, water activity, B) are incorporated into the product and sufficient scientific evidence can be presented with respect to the safety of such products. In addition storage temperatures may be required to meet criteria established or recognized by the agency having jurisdiction where the food is destined for consumption.

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

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

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

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

Particular attention should be paid throughout storage and distribution:

- to periods of defrosting
- to temperatures
- to the risk of overloading the cold storage and
- to anything that could damage the containers and/or packaging.

Personnel (distribution, transport, sales) should be trained in the basic principles of hygiene, in particular, personal hygiene, the requirements for cleaning and disinfection, cross-contamination and the importance of appropriate storage of foods.

Storage areas should conform to applicable requirements in paragraphs 4.3.13.1 and 7.1.4.1.

7.7.2 Loading - Unloading

Loading and unloading should be carried out under conditions of good hygiene and as quickly as possible. Product temperature should be measured and recorded prior to loading. The loading and unloading areas for transport vehicles should be designed so as to protect the products and should be refrigerated.

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

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

7.7.3 Sale

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

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

7.7.4 Use of product

Refrigerated packaged foods should remain in their containers, at the recommended temperatures, until the final stage of reheating or use.

When reheating is necessary, it should be done so that the product is brought to and held at the desired temperature until the time it is served.

When products are used in a restaurant or institutional setting, refer to the mass catering code (refer to Codex alimentarius ALINORM 91/13).

SECTION VIII - HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

8.1 General

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

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

Specific hazards -- that is, any biological, chemical or physical property that has an unfavorable effect on the safety of the food -- that are associated with food production, and the preventive measures for their control should be identified. Further, it is necessary to determine the operational steps that can be controlled to eliminate hazards or to minimize the probability that they will arise, to establish critical limits to be respected and a monitoring system to ensure their control, and to establish corrective action to be taken and procedures for verification to demonstrate that the control method is appropriate. Effective record keeping procedures need to be maintained.

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

8.2 Application of the HACCP Principles

The processor should apply HACCP principles as described in Codex document " HACCP system and guidelines for its application " for all existing product types, and for new product design and development.

It is not possible in this general document to precisely define:

- hazards specific to a food plant, a process or a product
- critical control points (CCPs)
- critical limits associated to CCPs
- monitoring procedures
- corrective actions
- verification procedures
- record keeping.

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

In Appendix 2, three examples are provided which illustrate the application of HACCP principles to different product types.

8.3 Important elements

Establishment of product shelf life, scheduled heat or other preservation treatments and cooling methods require sufficient knowledge, facilities and experience. This code does not provide a comprehensive sequence to follow to produce refrigerated foods. Such recommendations may be unduly restrictive and inadequate as new information and preservation technologies become available. It is recommended that the users of this code consult experts to establish procedures which will ensure that their products are safe for consumption. A number of useful references have been supplied in the appendices.

8.3.1 Determination of product shelf life

Product shelf life depends particularly on the following:

- product formulation;
- scheduled heat or other preservation treatments and cooling methods applied to product;
- type of packaging (hermetically sealed or not, MAP);
- storage temperature;
- hurdles used, if applicable.

Product shelf life should be determined using scientific studies (challenge studies[2] or other scientific data can be used) and should incorporate a margin of safety as determined by the manufacturer.

8.3.2 Development of scheduled heat or other preservation treatments

8.3.2.1 - Development of scheduled heat treatment

During the establishment of the scheduled heat treatment, the following factors should be taken into account, if necessary:

- microbial flora and maximum number of microorganisms expected in raw materials;
- any potential for growth before heat treatment;

---

[2] Technical Manual No. 20 - Guidelines for Microbiological Challenge Testing - CFDRA - 1987

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

The scheduled heat treatment should at least destroy vegetative forms of pathogenic bacteria. It is calculated for the coldest point of the product during treatment. It should take into account the worst-case scenario with regard to transfer of heat to the product, for example, use of frozen raw materials or large pieces of meat and with regard to the microbiological contamination. When changes in the composition, processing and use of the product are carried out, the necessary changes should be established and validated by a qualified person.

8.3.2.2 - Development of other preservation treatments {To be drafted}

8.3.3. Development of Cooling Method

During the establishment of the cooling method, the following factors should be taken into account, if necessary:

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

8.3.4 Hurdles

Studies validating use of hurdles in product formulation that inhibit or minimize multiplication of pathogens, and the synergy of these factors, should be conducted. See Appendix I for more information. Use of predictive modelling may assist in the conduct of such studies.

8.3.5 Filing

The following information should be filed:

- Procedures, data and calculations leading to the establishment of the scheduled heat or other preservation treatments and cooling methods;

- If applicable, procedures, data and records establishing the efficacy of hurdles to maintain the microbiological safety of the product for the intended shelf life;

- Procedures, data and records relevant to the establishment of the shelf life of the product;

- Any modifications of the product formulation and their validation.

SECTION IX - RECORDS MANAGEMENT

For each production lot, permanent, legible, dated records with information on processing should be kept. These documents should be readily available. These records should be kept for a period of six months beyond the shelf life.

Documents that should be kept are, for example:

- for the incoming materials: records of processor's audits on suppliers' premises, suppliers' certificates of conformity of ingredients with the processor's specifications, records of temperature at delivery and during storage of ingredients with a limited shelf life.
- for processing steps including storage: records for critical control points monitored, records for non-conformity and corrective action taken
- for transportation and distribution: records indicating storage temperatures.
- for the equipment used to control critical control points: reports on maintenance.
- for deliveries: initial delivery records for each lot.

Appendix I - Hurdles

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

For refrigerated foods, an important safety hurdle to control microbial growth is refrigeration. A wide variety of refrigerated foods also make use of additional factors to control microbial growth called hurdles.

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

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

Examples of hurdles, other than refrigeration, are:

a) Water activity

Microorganisms vary in their ability to grow at reduced levels of a_w and will be inhibited as the available water is reduced. A reduction of water activity to 0.94 is, to varying degrees, usually adequate to suppress the growth of most pathogenic bacteria, particularly at low temperatures. Yeast and mold are the only organisms that can grow below a water activity below 0.85. Note that vegetative cells may show increased heat resistance at lower water activities.

b) pH

It is well known that decreasing pH is an effective way of controlling the growth of microorganisms. For example, pasteurized products with pH less than 4.5 are bacteriologically stable, because most vegetative microorganisms are inactivated by a mild heat treatment and surviving bacilli and clostridia are inhibited by the low pH. However, for meat and vegetable products, a small reduction of pH from their normal range (6.0-6.5) to about 5.0-5.2 will have a beneficial effect in the context of combined hurdles.

c) Inoculation with competitive microbiological flora

It is recognized that many foodborne pathogens are poor competitors. Therefore, inoculation with harmless/non pathogenic competitive microbiological flora such as lactic acid bacteria may reduce the pH and may inhibit growth of pathogens. The effect of such inoculation should be proven to be effective against the target organism(s).

For instance, if a refrigerated food is to be packed in a reduced oxygen atmosphere and has a shelf life longer than 10 days, one or more of the following hurdles should also be considered as a way to control psychrotrophic strains of *Clostridium botulinum* (non proteolytic) in combination with a heat process, if this heat process is not equivalent to 90°C for 10 minutes:

- adjust water activity (a_w) to below 0.97;
- increase acidity by lowering pH below 5.0;
- add sodium chloride to 3% in brine;
- use combinations of water activity, pH, modified atmosphere, storage temperature etc. that demonstrably will inhibit the growth of psychrotrophic strains of *Clostridium botulinum* within the shelf life and expected storage conditions.

Predictive models may be used to estimate both the effectiveness of preservation conditions and the effects of modifying product composition and varying handling/storage conditions on safety.

Whenever there is doubt that the conditions applied might not effectively control the microorganisms of concern (including estimation resulting from predictive modelling), challenge studies should be conducted. Such studies, in which specific organisms are inoculated into products prior to storage, should use the worst case conditions of expected storage and distribution. It is advisable that scientific advice is sought.

Useful References

"Retail Guidelines: Refrigerated Foods in Reduced Oxygen Packages'", US Association of Food & Drug Officials.

"Interaction of Factors to Control Microbial Spoilage of Refrigerated Foods"', VN Scott, J. Food Prot., 1989, 52(6), 431-5.

"Guidelines for the Development, Production, Distribution and Handling of Refrigerated Foods" 1989, US National Food Processors Association.

"Mechanism of Action of Food Preservation Procedures", 1989, GW Gould (Editor) Elsevier Applied Science London.

"Food Preservatives and the Microbiological Consequences of their Reduction or Omission". TA Roberts, PJ McClure, Proc. Nutr. Soc., 1990, 49(1), 1-12.

"Guidelines for Microbiological Challenge Testing" 1987. CFDRA. Technical Manual No.20.

APPENDIX II: Examples

This appendix includes three examples of refrigerated packaged foods. Each of these examples present different:

- process technologies;
- barrier(s) used;
- specific shelf lives;
- risks.

These examples will illustrate the use of the HACCP approach. Under no circumstances should they be used as such for the implementation of a HACCP program in a specific facility.

1) BEEF BOURGUIGNON

1.1 Product Definition

Incoming materials as received:

- frozen beef
- bacon
- sliced raw carrot
- sliced frozen mushrooms
- dried broth
- sterilized spices
- concentrated red wine
- trays and plastic film

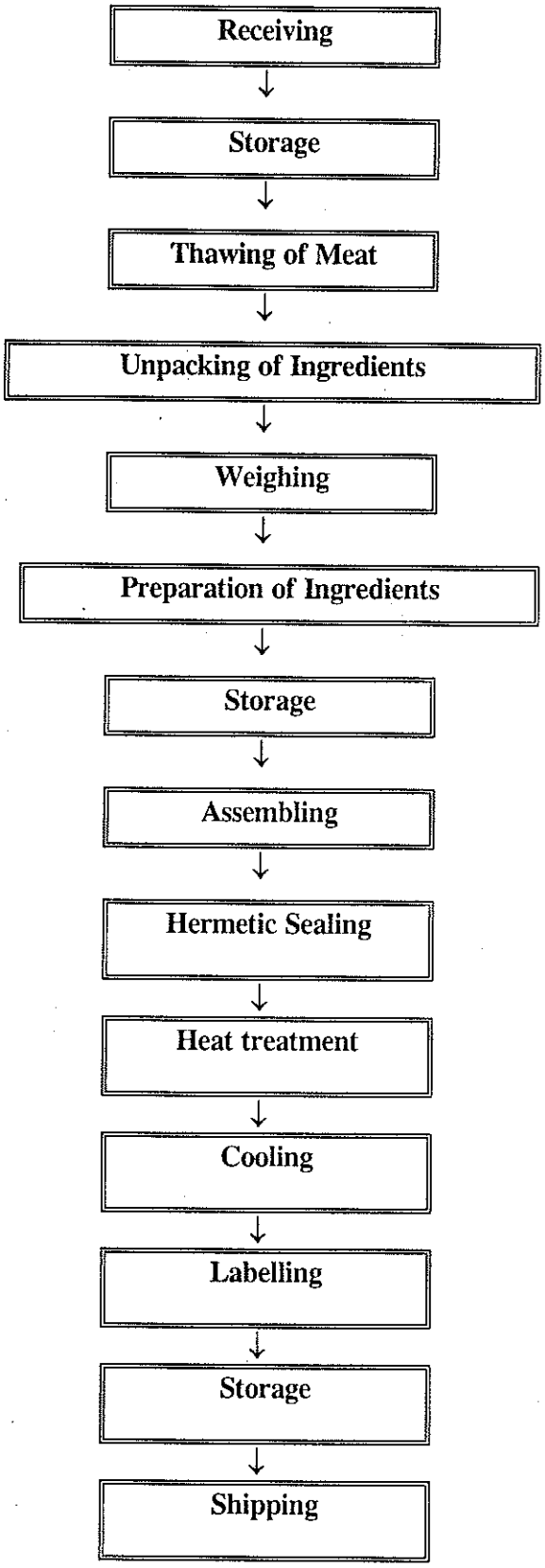
Important processing characteristics:

- preparation of ingredients before use
- packaged hermetically
- heat treatment after packaging

1.2 Intended use

- shelf life: 42 days
- ready-to-eat, reheating prior to consumption
- to be kept under refrigeration at 4°C or less

1.3 Process flow diagram



1.4 Hazard Identification

For this beef bourguignon, the foodborne pathogen of concern is *Clostridium botulinum*. Other pathogens of concern (e.g. *Listeria, Salmonella)* can be controlled by the heat treatment.

1.5 Identification of Preventative Measures

Control of *Clostridium botulinum* can be accomplished by:

- heat treatment (minimum of 90°C for 10 min, internal temperature, or equivalent).
- other pathogens of concern (e.g. Salmonella) will be controlled by the heat treatment designed for *Clostridium botulinum*. A more severe heat treatment may be required to control spoilage bacteria. This should be verified in shelf life studies.
- cooling after heat treatment.
- refrigerated storage.
- specification for a maximum shelf life.

Hermetic sealing is required to prevent recontamination by other foodborne pathogens (e.g. *Listeria*) after heat treatment.

1.6 Examples of CCPs

It is not possible to present an exhaustive list of all CCPs required to control all hazards. In reality, one would need to be in specific food premise situation. However, an illustration of a number of CCPs follows. It [should be] is remembered that HACCP is product/process and plant specific.

TABLE 1 - BEEF BOURGUIGNON - EXAMPLES OF CCPs

Step	Hazard	Preventive Measyres (CCP)	Critical Limit	Monitoring	Corrective Action	Verification	Records
Heat treatment	Inadequate reduction of *Clostridium botulinum*	Scheduled process and adherence to proper procedures	90°C for 10 mins. Or equivalent No deviation from procedures	Recording of time/temperature Cook check indicator. Foreman to check procedures	Lot retention for evaluation and proper disposition.	QC to check log book.	Time/Temperature Charts Log book.
Cooling	Growth of Spore-formers (e.g. *C. Botulinum, B. Cereus)*	Fast cooling and adherence to proper procedures	Cooling from 60°C to 10°C in less than 2 hours. From 10°C to 4°C in less than 6 hours. No deviation from procedures	Recording of Time/Temperature. Foreman to check procedures.	Lot retention for evaluation and proper disposition.	QC to check log book.	Cooling charts Log book.

2 FRESH STUFFED PASTA

2.1 Product Definition

Incoming materials as received:

- cooked meat stuffing (cooked in original package)

  pasteurized liquid eggs (refrigerated ,in bulk)

- hard wheat semolina

- bread crumbs

- trays and plastic film

Important processing characteristics:

- preparation of ingredients before assembling

- heat treatment before packaging

- cooling before packaging

- modified atmosphere packaging

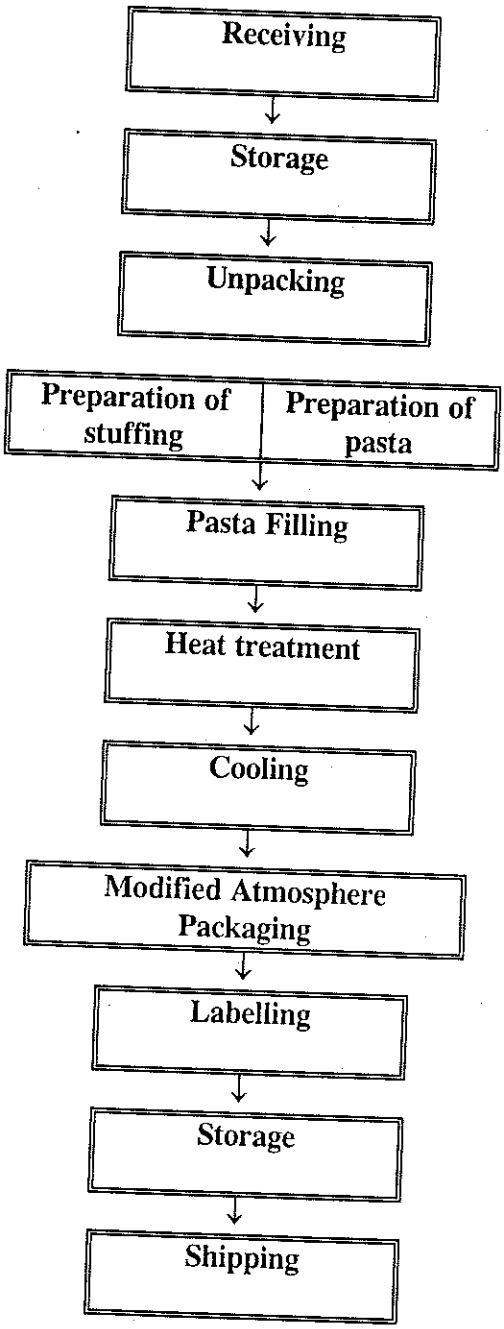
2.2 Intended use

- shelf life: 30 days

- must be cooked by end-user in boiling water as early as clearly indicated on product label. Cooking in boiling water will be equivalent or superior to 70°C for 2 min.

- to be kept under refrigeration at 4°C or less.

2.3 Process flow diagram



2.4 Hazard Identification

For stuffed pasta, many foodborne pathogens may be of concern. *Listeria monocytogenes*, as well as other pathogens (e.g., *S. aureus, B. cereus*), should be considered since they may contaminate the product. *Clostridium botulinum* should be considered since it may come from raw ingredients and will not be completely inactivated by the heat treatment. Pathogens of concern are controlled by heat treatment, adherence to strict hygiene conditions and refrigerated storage.

2.5 Identification of Preventative Measures

Control of *Listeria monocytogenes* can be accomplished by:

- incoming materials as free as possible of such contamination
- heat treatment (minimum of 70°C for 2 minutes, internal temperature, or equivalent). A more severe heat treatment may be required to control spoilage bacteria. This should be verified in shelf life studies.
- adherence to strict hygiene conditions (as defined for High Risk Area) to prevent recontamination and growth
- hermetic sealing
- refrigerated storage

Control of *Clostridium botulinum* can be accomplished by:

- water activity less than 0.97 (for non-proteolytic strains)
- refrigerated storage (for proteolytic strains)
- specification for a maximum shelf life.

2.6 Examples of CCPs

It is not possible to present an exhaustive list of all CCPs required to control all hazards. In reality, one would need to be in specific food premise situation. However, an illustration of some CCPs follows. It [should be] is remembered that HACCP is product/process and plant specific.

TABLE 2 - FRESH STUFFED PASTA - EXAMPLES OF CCPs

STEP	HAZARD	PREVENTATIVE MEASURE (CCP)	CRITICAL LIMIT	MONITORING	CORRECTIVE ACTION	VERIFICATION	RECORDS
Stuffing preparation	Growth of *Clostridium botulinum*	Product formulation/ Reduction of water activity to less than 0.97	Strict adherence to formulation and prescribed procedures	Designated employee to fill formulation log Foreman to check that procedure followed at specified frequency	Retention of lot for further evaluation and proper disposition	QC to sample for water activity measurement at regular intervals	Formulation log Report of water activity analysis
Pasta preparation	Growth of *Clostridium botulinum*	Product formulation/ Reduction of water activity to less than 0.97	Strict adherence to formulation and prescribed procedures	Designated employee to fill formulation log Foreman to check that procedure followed at specified frequency	Retention of lot for further evaluation and proper disposition	QC to sample for water activity measurement at regular intervals	Formulation log Report of water activity analysis
Packaging	Recontamination by *Listeria*	Procedures for cleaning and disinfection of [food control] surfaces	Strict adherence to procedures	Foreman to check that procedures followed at specified frequency	Repeat cleaning and disinfection	Environmental sampling of food contact surfaces	Sanitation report Report of analyses
	Growth of *Listeria*	Proper room temperature and respect lapse time	Room temperature less than 10°C Lapse time less than 2 hours	Temperature measurement Foreman to check lapse time	Set proper room temperature Measure of product temperature; if above 6°C, reject product. If between 4°C and 6°C rapid cooling and evaluation by an expert	Environmental and product sampling	Report of analysis Production reports
Storage	Proliferation of *Listeria* and *Clostridium*	Temperature less than 4°C	4°C or less	Temperature measurement of refrigerated facilities	Set room temperature to 4°C or less. If product temperature above 6°C, reject product If between 4 and 6°C, rapid cooling and evaluation by an expert	QC to verify procedures in place Temperature measurement inside product Micro analysis of product	Room and product temperature records Test reports

3. ASSEMBLED SALAD

3.1 Product Definition

Incoming materials as received:

- cooked packaged potatoes (cooked in original package)
- canned tomatoes
- cooked packaged ham (cooked in original package)
- peeled hard boiled eggs in MAP
- pickles
- mayonnaise (pH 4.0)
- trays and plastic film

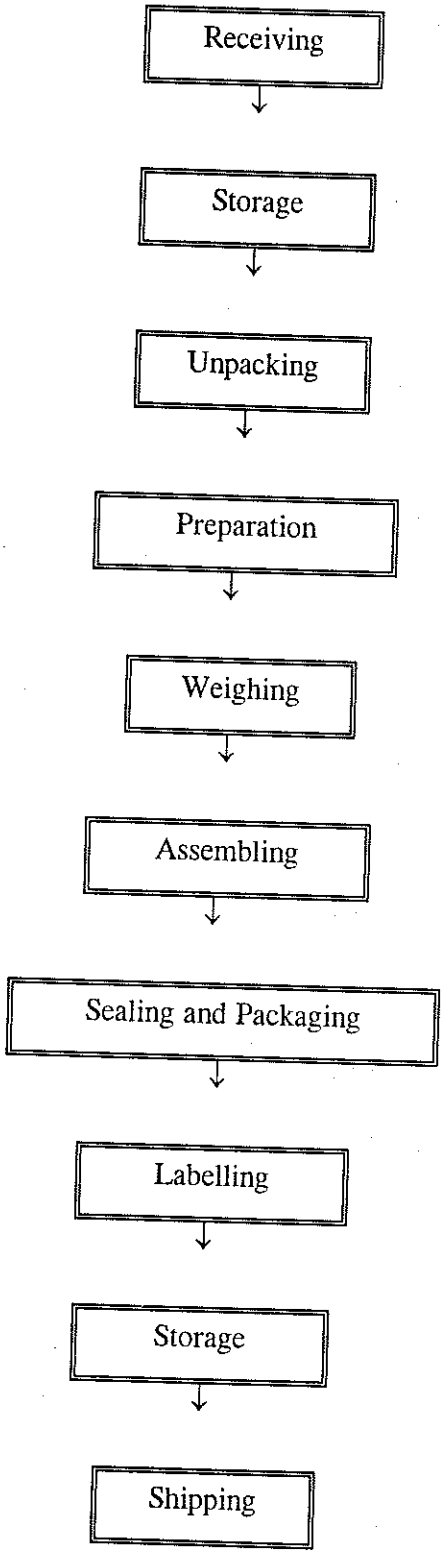
Important processing characteristics:

- ingredients used as such and assembled
- packaged hermetically
- no further heat treatment after packaging
- maximum pH of final product: 4.8

3.2 Intended use

- shelf life: 15 days
- ready-to-eat, without any heating or cooking
- to be kept under refrigeration at 4°C or less

3.3 Process flow diagram



3.4 Hazard Identification

For this assembled salad, the foodborne pathogen of concern is *Listeria monocytogenes*. Other pathogens of concern can be controlled by either the low pH (4.8) or refrigerated storage.

3.5 Identification of Preventative Measures

Control of *Listeria monocytogenes* can be accomplished by:

- incoming materials as free as possible of such contamination
- adherence to strict hygiene conditions (as defined for High Risk Area) to prevent recontamination and growth
- control of pH
- refrigerated storage
- specification for a maximum shelf life.

3.6 Examples of CCPs

It is not possible to present an exhaustive list of all CCPs required to control all hazards. In reality, one would need to be in specific food premise situation. However, an illustration of a number of CCPs follows. It is to be remembered that HACCP is product/process and plant specific.

extended refrigerated shelf life and that are ready to eat or prepared with little or no additional heat treatment - USA, 1990.

NFPA - *Guidelines for the development, production, distribution and handling of refrigerated foods* - Microbiology and Food Safety Committee, NFPA (National Food Processors Association) -USA, 1989 *

NFPA - *Safety Considerations for New Generation Refrigerated Foods* - Dairy and Food Sanitation, 8:1, 5-7, January 1988 - USA.

Palumbo, S.A. 1987. Is refrigeration enough to restrain foodborne pathogens? J. Food Prot. 49:1003-1009.

Principles and Practices for the Safe Processing of Foods - HJ Heinz Company - 1991 - Butterworth Heinemann.

Report on Vacuum Packaging and Associated Processes - Advisory Committee on the Microbiological Safety of Food - September 1992 - England.

SCOTT (V.N.) - *Interaction of Factors to Control Microbiological Spoilage of Refrigerated foods* - Journal of Food Protection, 52:5, 431-435, June 1989 - USA.

SYNAFAP - *Aide à la mise en place d'un système d'assurance de la qualité pour les produits traiteurs frais et réfrigérés* - SYNAFAP -France, 1992. *

The Canadian Code of Recommended Handling Practices for Chilled Foods - The Food Institute of Canada - Canada, 1991. *

* Texts used in the preparation of this document.