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 95/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-First Session
Rome, 3-12 July 1995

REPORT OF THE TWENTY-SEVENTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE
Washington D.C., 17-21 October 1994

Note: This document incorporates Codex Circular Letter CL 1994/33-FH.

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CX 4/20.2

CL 1994/33-FH
December 1994

TO: - Codex Contact Points
- Participants at the 27th Session of the Codex Committee on Food Hygiene
- Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Progamme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **DISTRIBUTION OF THE REPORT OF THE 27TH SESSION OF THE COMMITTEE ON FOOD HYGIENE (ALINORM 95/13)**

The Report of the 27th Session of the above Committee (ALINORM 95/13) will be considered by the Twenty-first Session of the Codex Alimentarius Commission (Rome, 3-12 July 1995).

PART A: MATTERS FOR ADOPTION BY THE COMMISSION

1. Draft Code of Hygienic Practice for Spices and Dried Aromatic Plants at Step 8 (Appendix II, para. 85).

2. Proposed Draft Code of Practice on the General Principles of Food Hygiene at Step 5 (Appendix III, para. 29).

Governments wishing to propose amendments or to submit comments on the above documents should do so in writing, in conformity with the Codex Alimentarius Commission Procedural Manual, to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, **not later than 31 March 1995.**

PART B: DOCUMENTS TO BE ELABORATED FOR GOVERNMENT COMMENTS PRIOR TO THE NEXT SESSION OF THE COMMITTEE

3. Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods (para. 46).

4. Proposed Draft Code of Practice for Refrigerated Packaged Foods with Extended Shelf-life (para. 52).

5. Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese (para. 72).

6. Recommendations for the Control of *Listeria monocytogenes* (para. 93).

7. Implementation of Risk Assessment - Development of Guidelines on the Application of the Principles of Risk Assessment and Risk Management to Food Hygiene Including Strategies for Their Application (para. 100).

PART C: REQUEST FOR COMMENTS AND INFORMATION

8. Draft Revised International Code of Practice - General Principles of Food Hygiene (Appendix III, para. 25).

9. Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods (para. 46).

10. Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese (Appendix V, para. 72).

Governments are invited to provide information on: (a) the control of *L. monocytogenes* and on the efficacy of the control systems (para. 94); and (b) microbiological criteria for fresh and soft cheese to also include *Salmonella* and especially toxigenic strains of *E. coli* (paras 62, 68-69).

Governments and international organizations wishing to submit comments and information on points 8 to 10, are invited to do so **not later than 31 March 1995** to the Chairman of the Committee at the following address:

Dr. John Kvenberg
Strategic Manager for HACCP Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Room 3014 (HFS 20)
200 "C" Street, S.W.
Washington, D.C., 20204, USA

with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy.

SUMMARY AND CONCLUSIONS

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

Matters for Consideration by the Commission

The Committee:

- recommended the adoption of the Draft Code of Hygienic Practice for Spices and Dried Aromatic Plants at Step 8 (Appendix II, para. 85);

- recommended the adoption of the Proposed Draft Code of Practice on the General Principles of Food Hygiene at Step 5 (Appendix III, para. 29);

Other Matters of Interest to the Commission

- agreed to return to Step 3 the Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods (para. 46);

- agreed to return to Step 3 the Proposed Draft Code of Practice for Refrigerated Packaged Foods with Extended Shelf-Life (Appendix IV, para. 52);

- agreed to return to Step 3 the Revised Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese (Appendix V, para. 72);

- welcomed the proposal to convene a Joint FAO/WHO Expert Consultation to provide guidance in the application of risk analysis by Codex (para. 99);

- requested the Secretariat to initiate work on the development of a first draft of guidelines on the application of the principles of risk assessment and risk management to food hygiene including strategies for their application (para. 100);

- encouraged relevant Codex Commodity Committees, including CCFFP, to elaborate appropriate guidance on such products (covered by the respective Committee), whether in specific codes or in other more general codes covering several product types (para. 13);

- endorsed the proposal of the CCTFFV to modify the Section dealing with Hygiene in all Codex Standards for tropical fresh fruits and vegetables (ALINORM 95/30, para. 68), (para. 14);

- invited the Codex Committee on Milk and Milk Products to review the technical aspects of the Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese (para. 72);

- Proposed that the following items be considered in its work (para. 102):

    - implications for the broader application of the HACCP System;

    - Guidelines for Consumer Education in Food Hygiene;

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

    - Code of Hygienic Practice for Bottled Water.

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APPENDICES

INTRODUCTION

1. The Codex Committee on Food Hygiene held its Twenty-Seventh Session in Washington D. C., from 17 to 21 October 1994, at the kind invitation of the Government of the United States of America. The Session was chaired by its new Chairman, Dr. John Kvenberg, Strategic Manager for HACCP Policy, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration. The Session was attended by 125 Delegates and observers representing 29 Member countries and 11 International Organizations.

2. A list of participants, including the officers of the Secretariat is attached to this report as Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

3. The Session was opened by the Chairman, who invited Dr. Douglas L. Archer, former Chairman of the Committee and now currently Professor and Chair, Food Science and Human Nutrition Department, University of Florida, to address the Committee. Dr. Archer's address was titled, **"An elephant is a mouse built to Government specifications".**

4. Dr. Archer emphasized that food safety was an important issue throughout the world. Microorganisms travelled easily and outbreaks of infectious disease in one region may rapidly give rise to other outbreaks around the world. The Guest Speaker gave examples of newly emerging pathogens such as *Listeria monocytogenes* and *Escherichia coli* 0157:H7. These pathogens often diverted attention from intransigent problems such as *Salmonella.*

5. Dr. Archer mentioned that, at its 26th Session, the Committee was addressed by Dr. Griffin of the US Centers for Disease Control and Prevention, who demonstrated how the *E. coli* 0157:H7 pathogen had spread worldwide and more significantly, all isolates, no matter where from, are derived from a single clone. Microorganisms travelled with travelers, water used on ships for ballast, waste disposal and they travel with foods. Several of the significant pathogenic microorganisms, if "zero tolerances" were enforced, would threaten the availability of food.

6. Dr. Archer affirmed that the title of his presentation: "An Elephant is a Mouse built to Government Specifications", appropriately applies to many governments, which have not provided the leadership necessary to deal with problems associated with foods. Too often, investments were short-term only, and long-term planning was lacking. The genetics of virulence of many of the foodborne pathogens was known, but there had not been a plan for studying the microbial ecology of foods. In the United States there had been virtually no funds for anything other than reacting to disasters. Recently, the issue of infectious diseases such as plague and cholera, was getting much more attention.

7. Dr. Archer suggested that developed countries had become complacent because antibiotics are readily available. However, due to the rapid spread of antibiotic resistant strains and the travel of microorganisms the threat had become real. All governments were reminded that infectious agents know no national boundaries and they were the oldest enemy of mankind. In conclusion, Dr. Archer advocated additional funding, coordination of resources and well developed long-term plans for the control of infectious agents.

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

8. The Committee considered the Provisional Agenda for the Session. In order to facilitate its discussions the Committee agreed to establish the following *ad hoc* Working Groups:

Agenda Item 4 - General Principles of Food Hygiene (United Kingdom, Chairman), and

Agenda Item 6 - Proposed Draft Code of Practice for Refrigerated Packaged Foods with Extended Shelf-Life (Canada, Chairman).

9. The Committee adopted Document CX/FH 94/1 as the agenda for its 27th Session.

REPORT OF MATTERS REFERRED TO THE COMMITTEE BY THE COMMISSION OR OTHER CODEX COMMITTEES [2] (Agenda Item 3a)

10. The Commission at its 20th Session, June/July 1993, had requested the Committee "to develop a general document defining a common language and philosophy of risk analysis" (ALINORM 93/40, para. 64). It was also noted that the Executive Committee at its 41st Session had requested FAO and WHO to convene an Expert Consultation to consider the elaboration of harmonized definitions for use in risk analysis and to develop guidance on the development of consistent risk analysis (risk assessment) methodology and decision-making criteria for use by the CAC and its subsidiary bodies (ALINORM 95/3, para. 48). The Committee noted that these matters would be taken up under Item 10 of the present Agenda (see paras 95 to 100).

11. The Committee noted with particular interest the proposal that consideration be given to broader application of the HACCP System, especially as it referred to the regulatory control of HACCP systems operated by food processors and producers, and how this control could be integrated into an overall food inspection and certification system (Executive Committee, 41st Session, ALINORM 95/3, Para. 32). In the first instance, it agreed to consider the matter in conjunction with its discussion on the Proposed Draft General Principles of Food Hygiene (Agenda Item 4, see Paras. 23 to 29, below. See also Para. 102).

Proposed Draft Code of Practice for Fish and Fishery Products in Controlled and Modified Atmosphere Packaging

12. The Codex Committee on Fish and Fishery Products (CCFFP), had decided not to proceed with the elaboration of the above draft Code, pending clarification as to whether or not appropriate provisions relating to fish and fishery products would be included in the Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life (ALINORM 95/18, Para. 118). This decision had been endorsed by the Executive Committee. The Committee noted, however, its previous decision that the Refrigerated Foods Code excluded raw, salted and smoked fish and other raw animal-protein foods subject to modified atmosphere packaging (ALINORM 93/13A, Para. 54).

13. The Committee expressed the view that experts familiar with these commodities would be better placed to develop guidance on the necessary process controls relative to low-temperature bacterial growth and toxin development (particularly from *Clostridium botulinum*) especially as toxin development could

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[1] CX/FH 94/1.

[2] CX/FH 94/2.

occur without overt signs of spoilage. The Committee encouraged the relevant Codex Commodity Committees, including CCFFP, to elaborate appropriate guidance on such products, whether in specific codes or in other more general codes covering several product types.

Codex Committee on Tropical Fresh Fruit and Vegetables (CCTFFV)

14. The Committee endorsed the proposal of the CCTFFV to modify the Section dealing with Hygiene in all Codex Standards for tropical fresh fruit and vegetables (ALINORM 95/30, Para. 68). The revised common text for these Standards is attached as Appendix VII to this report.

MATTERS ARISING FROM ACTIVITIES OF OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 3b)

Safety of Food in Relation to Plague Emergencies

15. The Representatives of the World Health Organization and the Commission of the European Commission stated that numerous enquiries had been received in relation to the control of food from areas affected by the recent outbreak of pneumonic plague, caused by *Yersinia pestis*. Both Organizations confirmed that food did not play any role in the transmission of plague and that therefore there was no need for any specific food control measures nor any need to restrict the import of foodstuffs from the affected areas.[1]

World Health Organization (WHO)

16. The Representative of WHO reported that a comprehensive evaluation of the safety of **Food Irradiation** had recently been published.[2] In addition, WHO had published a leaflet on Hygiene in Mass Catering, two documents on HACCP,[3] and was providing training courses in the use of the Hazard Analysis/Critical Control Point (HACCP) system in a number of countries. It was also reported that a WHO Study Group on Food-Borne Trematode Diseases, held in Manila in 1993, had found that food, especially fresh-water fish, infested by trematodes was a serious public health problem in all regions of the world due to the significant number of illnesses caused.

17. Attention was drawn to a formal Circular Letter issued by the Director-General of WHO which called upon Ministries of Health to play a more active role in the work of the Codex Alimentarius Commission in view of the new importance of the Commission's work within the framework of the Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement").

Pan-American Health Organization (PAHO)

18. The Representatives of PAHO noted that food protection activities were conducted within the framework of the Regional Programme of Technical Cooperation in Food Protection, approved by the Pan American Sanitary Conference and the Ministers of Health and Agriculture in the region of the Americas. Specific activities in 1993/94 included:

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[1] The advice of WHO has been published in the *Weekly Epidemiological Record* of 30 September 1994 (Vol. 69, No. 39, pp. 289-291).

[2] Safety and Nutritional Adequacy of Irradiated Food. World Health Organization, Geneva, 1994.

[3] WHO/FOS 93.1 and 93.3.

- The initiation of a coordinated research project to study the use of food irradiation as a public health measure to control foodborne diseases (together with the FAO/IAEA/WHO International Consultative Group on Food Irradiation);

- Regional Workshop on Microbiological Contamination of Foods and its Implication in International Trade, Brasilia, March 1993 (together with FAO); and

- Workshop on Food Legislation for the English-Speaking Caribbean, Kingston, Jamaica, October 1993 (together with FAO);

- Workshop on the Control of Biological Residues in Meats, Sao Paulo, Brazil, September 1993; and

- Publication of Guidelines for the Epidemiological Surveillance of Foodborne Diseases.

International Organization for Standardization (ISO)

19. The Representative of ISO reported that within ISO international reference methods for microbiological analysis were being developed for use in food control and international trade, in particular in response to the needs of the Committee. General methods (all foods) for the enumeration of *Salmonella* and *E. coli* and several non-pathogens had been published; methods for *Clostridium perfringens* and *Staphylococcus aureus* were being revised and methods of detection for *Campylobacter* and *Yersinia enterocolitica* were to the point of being published in the near future. A detection method and a method for the enumeration of *Listeria monocytogenes* were being developed. ISO was developing procedures for the validation of the performance of commercial test kits by comparison with standard reference methods.

International Dairy Federation (IDF)

20. The IDF Representative reported that 14 groups of experts within that organization were working on different aspects of hygiene of dairy products. Special emphasis had been paid to the recently adopted Recommendations on Hygienic Storage, Transportation and Distribution, which supplemented the existing IDF recommendations for hygienic production of milk products. Further hygienic recommendations specific to groups of products were in preparation. In addition, IDF Monographs would soon be available on pathogens in raw milk and on pathogenic spore-formers in milk and milk products. In early 1996 an IDF meeting on the application of risk analysis to dairy products was to be held. Hygiene was still considered to be a strategic issue for IDF.

AOAC International

21. The Representative of AOAC International reported that 18 analytical test methods had been adopted as Official "First Action" Methods in 1994. The AOAC® Peer-Verified Programme had recently accepted its first method for evaluation. This Programme was available for testing of methods which could not be submitted to a full collaborative study. Several test kits for aflatoxins in grains, *Listeria* on environmental surfaces, *Salmonella* in food and feeds and various antibiotic substances in milk had been granted "Performance-Tested" status.

22. It was reported that the 16th Edition of the AOAC Official Methods of Analysis would be published in 1995 as a loose leaf publication to allow the inclusion of supplements and additional and revised methods. A CD-ROM version was to be published in 1995. Other publications expected in 1995 included

topics on the *Control and Accessibility of Food-Related Data*, and *Chemical Analysis of Antibiotics used in Agriculture.*

CONSIDERATION OF THE DRAFT REVISED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE [1] (Agenda Item 4)

23. At its 25th Session (1991) the Committee had discussed the prevention and control of Salmonellosis and similar foodborne diseases.[2] As a result of this discussion, the Committee agreed that a comprehensive revision of the Code of Hygienic Principles - General Principles of Food Hygiene was needed, as the current Code was considered not to provide for the adequate control of contamination throughout the food chain. It was agreed that the Code should be revised so as to be broadly based and to explain public health reasons for the approach adopted. A draft outline of the Revised Draft Code was presented to the Committee at its 26th Session. It was agreed that this outline should form the basis of the Revised General Principles and that document should be prepared and circulated for government comments at Step 3. The Delegation of the United Kingdom subsequently provided a revision of this text (CL 1994/4-FH Revised) which took into account many of the comments received.

24. As noted above, an *ad hoc* Working Group met during the Session to consider all of the comments received and to propose appropriate amendments. The Committee was informed that among the strategies included in the revised document was the prominence given to the role played by HACCP based systems and to recognition of the responsibility of industry (including individual primary producers, manufacturers, distributors, processors, food service operators and retailers) in the application of the Code. The Committee accepted that the Code should recommend the application of HACCP based systems, and reflect this throughout the Code.

25. A new section on Definitions was developed, but the Committee could not finalize the definitions within the time allowed for consideration. The Section was placed in square brackets to allow for further comments and discussion.

26. The Delegation of Germany noted that for the first time a Codex document had established a policy as to the responsibility of consumers in relation to food hygiene, and questioned whether such advice fell within the mandate of the Joint FAO/WHO Food Standards Programme. The Committee noted that the Programme was responsible for making proposals to FAO and WHO on all matters pertaining to the implementation of the Programme including protecting the health of consumers. Other Codex advice, in labelling for example, had direct consequences for consumers and implied that consumers had responsibility in following labelling and other food safety advice.

27. The Committee noted that there were a number of Codes of Hygienic Practice, either under elaboration or in the course of revision, which contained material based on sections of the current Recommended International Code of Hygienic Practice - General Principles of Food Hygiene. It agreed that it would not be appropriate to delay the elaboration of these Codes. It recommended that the appropriate sections of these Codes be highlighted and that these sections be amended following the final adoption of the Revised General Principles by the Commission.

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[1] CL 1994/4-FH and CL 1994/4-FH Revised; CX/FH-94/3 (Comments of Canada, Denmark, New Zealand, Poland, Switzerland, United States, IDF and WHO); CX/FH-94/3-Add. 1, CRD 1, (Comments by The Netherlands); and CRD 6 (Comments by France and Malaysia).

[2] ALINORM 93/13, paras. 57-65.

28. The Committee further noted that when the 20th Session of the Commission had adopted the Guidelines for the Application of the HACCP System as a matter of urgency, it had been agreed that these would be attached to the Revised General Principles of Food Hygiene as an Annex. The Chairman of the Commission had noted that any improvements in the text of the Guidelines could be made when they were incorporated into the text of the Revised General Principles of Food Hygiene (ALINORM 93/40, para. 241).

Status of the Proposed Draft Code of Practice on the General Principles of Food Hygiene

29. The Committee agreed to advance the Code to Step 5 of the Procedure for consideration by the Commission. The Proposed Draft Code, including the Annex on the Application of the HACCP System, is contained in Appendix III to the present report.

REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS [1] (Agenda Item 5)

30. The Committee at its 26th Session (1993) had agreed that the Principles and existing Codex microbiological criteria for foods should be reviewed, considering that to a considerable extent they were out of date and had originally been established with end-product testing in mind rather than the application of systems such as HACCP (ALINORM 93/13A, Paras. 87 - 89).

31. The Committee also noted the views expressed by the Codex Committee on General Principles that the "Principles for the Establishment and Application of Microbiological Criteria for Foods", being primarily advice for governments would be more appropriately included in the Codex Alimentarius than in the Procedural Manual. (ALINORM 95/33, Para. 50). It was considered that guidelines for the establishment of microbiological criteria should form part of a set of related documents containing the General Principles of Food Hygiene, and the Codex Guidelines on the Application of the HACCP System. In this matter, the Guidelines would then be also applicable outside the Codex framework.

32. In introducing the paper, the Observer from the International Commission for Microbiological Specifications for Foods (ICMSF) stated that the revision was done prior to the decision of the CCGP referred to above, and therefore the document retained the original format as a document for Codex purposes. The observer further said that guidelines on critical limits which were necessary for the application of HACCP had been omitted from the document because these were meant to be covered elsewhere.

Introduction

33. Some Delegations felt that the text had not fully addressed the issues which had led to its review. The need to differentiate between criteria depending on the stage of processing and distribution had not been fully covered. The application of microbiological criteria, for end-product testing although useful in checking compliance with HACCP, was considered not adequate in itself to assure the safety of food. It was, however, considered useful to enable regulatory agencies to verify that hygienic conditions have been met. There was consensus to include HACCP by reference in the introduction.

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[1] CX/FH-94/4; CX/FH-94/4-Add.1, containing comments from The Netherlands, Sweden, the United States and the International Dairy Federation; Conference Room Document 7 - comments by Canada and France.

34. In view of the introduction of risk analysis [1] principles as the basis for Codex standards, guidelines and other recommendations, it was also agreed that the following statement, be reflected with regard to the principles for the establishment of microbiological criteria:

> *wherever possible, for scientific analysis and advice, together with risk analysis, to form the basis of the development of standards, guidelines and recommendations.* [2]

35. The Committee agreed that the words "wholesomeness" and "fairness" should be replaced with the more precise terminology contained in the Statutes of the Commission and in the Revised Draft General Principles of Food Hygiene.

Section 1 - Components of Microbiological Criteria for Foods

36. The Committee noted that microbiological criteria could be established for a wide variety of microorganisms, not all of which were of public health concern. In some cases, the criteria referred to organisms which indicated potential public health problems although the organisms themselves were not pathogenic. In other cases, the microbiological criteria referred to organisms which were indicative of the degree to which good manufacturing practices or effective HACCP programmes had been followed. It was therefore agreed that Section 1.1 be amended to specify the organisms concerned and the reasons for that concern. It was also agreed that in this context microorganisms should be considered to include bacteria, viruses, yeasts, moulds and parasites. The Committee also requested that recognized terms used in sampling be harmonized with internationally accepted nomenclature.

Section 2 - Purpose and Types of Microbiological Criteria for Foods

37. The Committee decided that the statement " The purpose of microbiological criteria for foods is to protect the health of the consumer by providing safe, sound and wholesome products and to meet the requirements of fair practices in trade" was redundant and the statement was deleted.

38. The Committee considered the status of "Mandatory" and "Advisory" criteria and the need to apply caution in the use of any statement which might indicate that Codex standards, guidelines or other recommendations were formally binding. It was pointed out that Codex Standards were not obligatory or binding in themselves. They were, however, intended for mandatory application once they had been accepted or adopted by a Member Government. The Committee therefore decided not to classify the types of microbiological criteria into separate groups. It amended the definition of **Microbiological Standard** to indicate that it was a criterion contained in a Codex Standard or which formed part of a technical regulation (as defined in the Uruguay Round Agreement on Technical Barriers to Trade) and therefore applied by the official agency having jurisdiction.

39. The Committee stated that point of application of **end-product specifications** needed clarification; i.e., whether at the production stage or during shipment, distribution, marketing and sale.

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[1] Terms relating to risk analysis and risk assessment have not been defined for Codex purposes at the time of writing this report.

[2] ALINORM 95/3, para. 22c - Report of the Forty-first Session of the Executive Committee of the Codex Alimentarius Commission.

Section 3 - Application of Microbiological Criteria for Foods

40. The Committee noted that the extension of Scope of the document to cover the use of microbiological criteria outside the Codex framework required some modifications. In particular, special provisions describing the use of microbiological criteria outside the Codex framework were deleted.

41. The Committee considered the use of microbiological criteria in the context of HACCP concept and agreed that in most cases microbiological criteria may be useful to verify HACCP based systems, but are generally not useful for end-product testing to ensure good manufacturing practice on a lot by lot basis.

Section 4 - General Considerations concerning Principles for Establishing and Applying Criteria

42. The Committee agreed that Section 4.1 should be carefully revised to explain how and when a "definite need" could be demonstrated. It was also indicated that the nature of the criterion should be appropriate to the demonstrated need. The Committee indicated that the document should not contain critical limits as defined and used in the context of the Codex Guidelines on the Application of the HACCP System. Some Delegations expressed the view that risk analysis should be explicitly mentioned in Section 4.2.

Section 5 - Interpretation of Results

43. The Committee held the view that rejection of products as being unfit for their intended use was only one of the regulatory actions that could be taken. Other actions could include the review of hygienic practices. The Committee was of the opinion that the presence in food of pathogenic microorganisms might not necessarily render that food unfit for use; the nature and number of the microorganisms present was considered to be important in this regard, taking into account the public health significance of any numerical values proposed.

Section 6 - Components of a Microbiological Criterion

44. The Committee agreed that it was necessary to define reference methods which should be validated for the commodity of concern, elaborated by an appropriate and recognized international body. The selection of reference methods should be based on data which are reliable and test kits must be validated for official use. The Committee noted however that methods used in quality control by industry need not be validated.

Section 7 - Sampling Methods and Handling Samples

45. The Committee requested that the sampling plans contained in this section needed further clarification.

Status of the Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods

46. The Committee agreed that in view of the in-depth review to which the draft document was subjected, the text should be retained at Step 3 of the Procedure, and requested the ICMSF to provide a revised draft based on the comments reported above. The revised draft would be circulated to governments and international organizations for comments, to be discussed at the Committee's 28th Session.

PROPOSED DRAFT CODE OF PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF-LIFE [1] (Agenda Item 6)

47. The Proposed Draft Code of Practice for Refrigerated Packaged Foods with Extended Shelf-Life had been revised by the Delegations of Canada and France based on comments made during the 26th Session of the Committee. The revision also took into account the re-evaluation of the Scope of the document and the foods to be covered by it. The Delegation of Canada, reporting on behalf of a Working Group established to consider the comments made on the Proposed Draft Code, presented the rationale for the major modifications. The amendments attempted to eliminate the overly "prescriptive" nature of the draft.

48. It was reported that the Code should take into account the seven principles of HACCP and should address the need for corrective actions to be taken when process deviations occur. The document should also be structured in line with the Codex Guidelines for the implementation of HACCP.

49. In view of the complexity of technology, the draft should provide for flexibility in order to provide alternatives to the conditions specified. For example, it should be stated that, in addition to the 4°C specified for storage, other temperatures may be suitable provided sufficient evidence on the safety of the product could be provided.

50. The Committee agreed that sections containing information on general food hygiene should, for the time being, be left in the Draft Code. These sections would be deleted as soon as reference could be made to the completed Code on General Principles of Food Hygiene (See Para. 27).

51. It was also agreed to include a description of the hurdle or barrier approach to preventing contamination of food during processing. In order to provide more specific information on the hurdle or barrier approach it was agreed that the document should contain an Appendix on this concept, and to include appropriate references to sources on product design, predictive modelling, heat processing and other relevant information. Examples of the preparation of three specific refrigerated foods would also be included in the revised draft.

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

52. In view of the amendments made to the Proposed Draft Code, the Committee agreed to return it to Step 3 of the Procedure. The revised Proposed Draft Code is attached to this report as Appendix IV. The Committee requested the Delegations of France and Canada to review the comments and prepare a revised draft for consideration at the Committee's next session.

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[1] CL 1994/15-FH; CX/FH 95/5 (Comments from The Netherlands, Norway, Switzerland, United Kingdom, United States).

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED/UNRIPENED CHEESE AND RIPENED SOFT CHEESE [1] (Agenda Item 7)

53. At its 25th Session (1991) the Committee had agreed to prepare a single Draft code for uncured/unripened cheese and soft cheese instead of having separate codes for cheese made from pasteurized milk and raw milk respectively. It had further agreed that a separate annex should be prepared containing provisions relating to soft cheese made from unpasteurized milk. The 26th Session of the Committee (1993) had agreed to maintain this approach. It requested that the Proposed Draft Code, which had been prepared by The Netherlands in cooperation with France, be circulated at Step 3 of the Procedure for comments and asked governments to provide information regarding the risk assessment procedures and monitoring they applied to ensure the safety of cheese made with raw milk and thermized milk (ALINORM 93/13A, Paras. 56-62).

Section I - Scope

54. Noting that the process for the manufacture of unripened/uncured cheeses and soft cheese was the same whether unpasteurized or pasteurized milk was used, the Committee agreed that both groups of cheeses should continue to be included in the Code at the present time, pending a final decision on whether the Code should indeed provide for the manufacture and international trade in cheeses made from unpasteurized milk.

55. The Delegation of the United States drew attention to the provisions in the Scope related to the preparation of cheese from unpasteurized milk. It stated that experience in the United States showed that soft cheese could not be made safely from raw milk on a consistent basis even when the milk had been obtained and handled in accordance with the provisions contained in the special Annex to the Code. Referring to the risk evaluation contained in its comments (CX/FH 94/6), the Delegation expressed the opinion that milk for manufacture of soft cheese needed to be pasteurized or else given an equivalent treatment.

56. Other delegations (France, Germany, Netherlands) and the Observer from the European Community were of the opinion that the special provisions contained in the Annex were sufficient to ensure safety and indicated that such provisions were necessary to allow the continued sale of certain soft cheese types. It was noted that similar hygienic requirements were used to ensure the safety of raw chopped meat and raw oysters which were consumed directly.

57. The Committee noted that the Section required significant editorial correction.

Section II - Definitions

58. The Committee noted that most of the definitions contained in this Section had been derived from the current version of the General Principles of Food Hygiene and would need to be reconsidered in light of the revision of this basic document (see Para. 27 above). It was also noted that the definition of ***Pasteurization*** had been taken from the Codex Code of Hygienic Practice for Dried Milk [2]. It was noted

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[1] ALINORM 93/13A - Appendix IV, and Documents CX/FH 94/6 containing comments by the United States and the IDF; CX/FH-94/6-Add.1 (CRD 2), comments by Sweden; and CRD 8, comments by Canada and France.

[2] CAC/RCP 31-1983.

that in some countries, the definition of pasteurization included provisions for the milk alkaline phosphatase test (negative) and the lactoperoxidase test (positive). The Committee, however, did not include these provisions in the Definition.

Section III - Hygienic Requirements in the Milk Production Area

59. Several delegations referred to the requirements spelled out in detail in the Annex to the Code on ***Hygiene Requirements in the Milk Production Area*** and ***Hygiene Requirements in the Holding Area***. In particular, these sections dealt with the health of the animal, the condition of the udder, and the presence of hazardous substances used in animal health, or their residues. It was suggested that these sections should be included in the body of the Code as they referred to basic hygiene requirements for all milk production for manufacturing purposes. The Committee noted that if this suggestion were to be taken up, such requirements would probably need to be incorporated into other Codex Codes of Hygienic Practice for milk and milk products. The Secretariat was requested to bring this matter to the attention of the Codex Committee on Milk and Milk Products.

Section IV - Establishment: Design and Facilities
Section V - Establishment: Hygiene Requirements
Section VI - Personnel: Hygiene and Health Requirements

60. The Committee noted that these Sections had been derived from the current version of the General Principles of Food Hygiene and would need to be reconsidered in light of the revision of this document (see Para. 27 above).

Section VII - Establishment: Hygienic Processing Requirements

61. The Committee agreed that some of the provisions relating to design and operation of the cheese milk pasteurizer (Section 7.5.1) related to only one type of pasteurizer and should be modified to allow other equivalent systems to be used. The Committee did not include special provisions for "thermized" milk processing at 57-68°C, as it was considered that all cheeses made from non-pasteurized milk would be considered in the special Annex to the Code.

Section VIII - Microbiological Criteria

62. The Committee was unable to agree on microbiological criteria to be applied to products covered by the Code. The various criteria recommended or proposed during the discussion are reported in Appendix VI to the present report. The Committee invited comments on the proposed criteria for discussion at its next Session.

Hazard Analysis Critical Control Point System: Principles and Example

63. The Committee was of the opinion that the outline of principles of the HACCP system contained in the Proposed Draft Code was no longer required in view of the adoption of the General Principles for the Application of HACCP by the 20th Session of the CAC. However, it agreed that a generic model for the application of the HACCP system to these products could prove useful but was of the opinion that the model attached to the Proposed Draft Code was not suitable for this purpose. Particularly as there were a number of inconsistencies between the text of the Code and the Proposed HACCP Model. The Committee requested the Codex Committee on Milk and Milk Products to consider the development of a generic model for application of the HACCP system to these products. In this context, it was noted that

there were a number of inconsistencies between the text of the Proposed Draft Code and the draft generic HACCP model.

Special Provisions for Soft Cheese Made with Raw Milk

64. The Committee debated extensively the adequacy of control measures aimed at ensuring the safety of soft cheese from raw or unpasteurized milk. The Delegation of the United States, referring to the risk evaluation presented in its written comments,[1] stated that experience within the United States and an assessment of the scientific literature indicated that the safety of raw milk could not be consistently guaranteed. In particular, the Delegation drew attention to the fact that even periodic controls of animal health or the establishment of eradication programmes for diseases such as brucellosis and tuberculosis, were not adequate to prevent infection of the milking herd from wild or feral animals. Such infections would not be detected in the period between routine inspections. Furthermore, the Delegation stated that sub-clinical or asymptomatic infections could allow contamination of raw milk with human pathogens. It stated that intra-mammary shedding of pathogens such as toxigenic strains of *E. coli*, *Salmonella*, and *Listeria monocytogenes* had been demonstrated. The views of the Delegation were supported by the Delegation of Canada for the same reasons which drew attention to the costs of applying controls and identifying contaminated lots.

65. The Delegation of France, referring to its written comments,[2] stated that experience in that country over many years indicated that soft cheese could be made safely in accordance with the provisions of the Annex. Particular attention had to be paid to control of the milking herd, care and attention of the udder, good milking practices, and regular monitoring and analysis of the raw milk. It was pointed out that if satisfactory control of animal health could not be achieved in the producing areas, or if a disease eradication programme was still in progress, the quality of the milk could not be guaranteed and therefore the manufacture of soft cheese from this raw milk was prohibited. Furthermore, the Delegation drew attention to the epidemiological and health survey data listed in the bibliography attached to its written comments. It stated that these data did not indicate that the consumption of soft cheese made from raw milk was associated with any public health problems. These views were shared by the Delegations of Germany and Spain and by the Observer from the European Commission, all drawing attention to EC Directive 94/46 covering these products. The Delegation of Spain pointed out that standards and codes for these products were essential, since without such standards and codes the illegal manufacture of related products could lead to major health hazards. It was pointed out that the maintenance of controls necessary to ensure the safety of these products was expensive and that these costs were passed on to consumers. However, certain consumers were willing to pay a premium price for these products.

66. The Committee was unable to achieve consensus on the safety of soft cheese made with raw or unpasteurized milk due to the divergence of opinion of the several delegations which spoke. It requested governments to examine the risk evaluation information provided by Delegations in their written comments in order that a decision might be taken at the Committee's next session on whether or not to maintain the provisions for the manufacture of such cheeses.

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[1] CX/FH 94/6.

[2] CX/FH 94/6-Add.1 (Conference Room Document 8 with Addendum containing a bibliography).

Labelling

67. It was agreed that soft cheese made from raw milk should be labelled with the words "made from raw milk". A new section was included in the Annex to the Proposed Draft Code accordingly. The section included all of the labelling provisions in the Code. It was further noted that the management of risks associated with soft cheese could be further strengthened by consumer education.

Microbiological Criteria

68. In addition to the earlier discussion on microbiological criteria (See Para. 62, above), the Committee noted that the proposed criteria did not contain a provision for the absence of *Salmonella*. A level of absence in 5 samples of 25 g (n=5, c=0) was proposed, in conformity with the requirements of the EC Directive covering these products. The Delegation of the United States pointed out that the statistical risk of accepting a consignment with 20 per cent defective or contaminated units under such a sampling plan was 33 per cent, which it considered to be unacceptable.

69. The Committee agreed to request government comments on the proposal to include this criterion for *Salmonella*, and on the need to include additional criteria especially for toxigenic strains of *E. coli*.

Application of the HACCP System to the Production of Soft Cheeses made with Raw Milk

70. The Committee agreed that the development and application of suitable HACCP-based plans was the responsibility of the manufacturer or processor, and in this regard several Delegations were of the opinion that the guidance contained in the present text was not suitable to be retained in its present format. It was also noted that some of the terms and procedures used were not in conformity with the Codex General Principles on the Application of HACCP. Other Delegations found that the generic model and the specific example could be useful to potential manufacturers and as advisory material for government control authorities.

71. It was agreed that the Annex on the **Application of the HACCP System to the Production of Soft Cheeses made with Raw Milk** should be revised in a manner which would indicate how an official control programme could be applied for the verification of the HACCP system. Specific examples could be included.

Status of the Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese

72. The Committee agreed that the revised text of the Proposed Draft Code should be returned to Step 3 for further government comments. It noted that microbiological criteria for raw milk and all end-products covered by the Code, a generic model for the application of a HACCP-based plan and a specific example for cheeses made from raw milk were to be developed. It further invited the Codex Committee on Milk and Milk Products to review the technical aspects of the Proposed Draft Code. The Committee invited the Delegation of France to review, in the light of comments, the microbiological criteria for all products covered by the Code and for raw milk used in production of soft cheese, and prepare a generic model for the application of a HACCP-based plan with a specific example based on one type of soft cheese made from raw milk. The Delegation of The Netherlands was invited to review the main text of the Code also in line with comments. The Delegation of the United States offered to assist both delegations in these efforts.

73. The full revised text of the Proposed Draft Code is attached as Appendix V to the present report.

DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS AT STEP 7 [1] (Agenda Item 8)

74. The Committee was informed that work on the Code was initiated by the International Organization for Standardization (ISO). In the light of working arrangements between Codex and ISO, it was agreed that further development of the Code should be undertaken within the framework of the Joint FAO/WHO Food Standards Programme.

75. At its 20th Session, the Commission noted that the Scope of the Code had been limited to dried spices and condiments and blends thereof, as these were the main subject of public health concern, and that specific government comments had been requested on the necessity of microbiological specifications for treated spices. The Commission had adopted the Draft Code at Step 5 of the Procedure, (ALINORM 95/40, Paras. 243 and 244).

76. The Committee agreed that some sections in the Code were covered by relevant sections in the General Principles on Food Hygiene, and so revision of those sections in this Code, could await the final decisions on the review of the General Principles on Food Hygiene.

Section I - Scope
Section II - Definition

77. The Committee agreed to replace the word "condiments" with a more appropriate name, because of the different meanings attributed to the word in different countries. The Committee agreed that the Code should cover herbs used for food purposes and agreed to substitute "condiments" with "dried aromatic plants", throughout the Code.

Section III - Hygienic Requirements in the Production/Harvesting Area

78. In order to emphasize that the products should be thoroughly dried to assure a measure of safety of the products, the first paragraph of Section 3.2 was amended to read, "Plants or parts of plants used for the preparation of spices and dried aromatic plants may be dried naturally or artificially, provided adequate measures are taken to prevent contamination or alteration of the raw material during the process, of a safe moisture level so as to prevent the growth of microorganisms, specially mycotoxin producing mould, etc."

79. Although the Code prescribed that excessive heating should be avoided (Section 3.2, Para. 4), this was considered not applicable to containerized shipments in which the containers are not ventilated. It was therefore proposed to amend the second sentence in Section 3.5 - Transportation as, "...In addition, as appropriate, bulk transportation such as ship ..... from day to night."

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[1] ALINORM 93/13A, Appendix V; CX/FH 94/7 - Comments from Canada, Costa Rica, Denmark, Poland, Spain, United Kingdom, United States of America and the European Spice Association; CX/FH 94/7-Add.1 (Conference Room Document 3) - Comments from The Netherlands and Switzerland; Conference Room Document 9 - Comments from Malaysia.

Section IV - Establishment: Design and Facilities
Section V - Establishment: Hygiene Requirements
Section VI - Personnel: Hygiene and Health Requirements

80. The Committee noted that these Sections had been derived from the current version of the General Principles of Food Hygiene and would need to be reconsidered in light of the revision of this document (see Para. 27).

Section VII - Establishment: Hygienic Processing Requirements

81. The Committee noted that ethylene oxide was used in fumigation of spices and some Delegations therefore proposed to include limits for residues. The Committee requested the Codex Committee on Food Additives and Contaminants to give consideration to the establishment of maximum levels for residues from treatment with ethylene oxide.

82. The Committee also agreed that consignments of treated spices should be accompanied by a certificate stating the type of treatment to which the product had been subjected. The Committee was informed that relevant provisions already existed in regard to irradiated spices in the General Standard for Irradiated Foods and for the labelling of consumer products in the Codex General Standard for the Labelling of Prepackaged Foods.

Section VIII - End-Product Specifications

83. The Section was revised to provide for limits established by the Codex Alimentarius Commission, or if these did not exist by the official agency having jurisdiction, for residues of treatment chemicals (See also Para. 81, above). The same general wording was applied to the other sub-paragraphs of this Section.

Microbiological Criteria

84. The Committee noted the sampling plans and microbiological criteria proposed by Delegations in their written comments. It was however agreed that absence of Salmonella in ready-to-eat spices was the major factor in public health protection. The Committee agreed that when examined by appropriate sampling plans ready-to-eat spices, whether treated or untreated, should be free from Salmonella. It agreed to include a provision to this effect based on a sample size of 10 units. The Delegation of South Africa reserved its position in view of national legislation prescribing maximum limits for a number of other potentially pathogenic organisms other than Salmonella.

Status of the Draft Code of Hygienic Practice for Spices and Dried Aromatic Plants

85. The Committee agreed to advance the Draft Code to Step 8 of the Procedure for consideration by the Commission at its next Session. The revised text of the Draft Code is contained in Appendix II to the present report.

RECOMMENDATIONS FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* [1] (Agenda Item 9)

86. The Committee recalled that at its 26th Session, the Committee noted a paper prepared by ICMSF on a "decision tree" approach to the control of *L. monocytogenes*. The Committee agreed to circulate the paper for comments and to request specific proposals for consensus on establishing control measures for *L. monocytogenes* in foods in international trade and information on experience in reducing the incidence of Listeriosis by the application of these measures (ALINORM 93/13A, Para. 86).

87. The Representative of the ICMSF noted that the paper had not been prepared for Codex purposes, but was the result of an ICMSF study over a period of several years. It had been published as a scientific contribution in the International Journal of Food Microbiology. The document dealt particularly with those situations where sampling of a consignment was the only available means of control and it provided a "decision-tree" approach as to how this should be undertaken. The Representative confirmed that ICMSF remained of the opinion that the application of HACCP procedures was the best means of consumer protection.

88. The Committee noted that the initial step in the decision tree was to determine whether or not the food was intended for highly susceptible consumers. Although the Committee recognized that specialized products existed on the market for use by highly vulnerable persons, it agreed that separate sampling plans leading to separate levels of protection should not be established on the basis of different groups of consumers. The major decision, when the examination of the lot is the only means of control available, should be made on the basis of the nature of the food, in particular whether or not it supported potentially the growth of the organism. Foods intended for highly susceptible persons should in general be treated or maintained in a way that growth of *L. monocytogenes* or other pathogens was not possible.

89. Several Delegations questioned the statement that foods containing less than 100 *L. monocytogenes* per gram did not pose a risk to normal individuals. The Committee noted that several countries had established maximum target levels of 100/g at the time of consumption for guidance in the establishment and operation of HACCP plans, but it was stated that this value was arbitrary and was not based on scientific risk analysis nor on knowledge of the minimum infective dose. Other countries had applied the same level at the stage of production as a level achievable by HACCP-based systems and considered that this was an acceptable limit. The use of HACCP-based systems as the procedure of choice for the control of *L. monocytogenes* was endorsed by all Delegations which spoke.

90. The reliability of test methods for enumeration of the organism was raised as a matter of concern by several delegations. Questions were also raised as to the efficacy of sampling plans based on a number of samples as low as 5 because of the elevated risk of accepting as satisfactory a high proportion of contaminated lots (See also Para. 68, above).

91. Most Delegations which spoke indicated that different levels were applied depending on whether or not the food potentially supported the growth of *L. monocytogenes*. However some countries applied a zero tolerance for foods which did not support the growth of the organism, while others applied a level of 100 cfu/g to these foods. Other countries preferred to apply a zero tolerance to ready-to-eat foods with a long shelf-life. If such a tolerance could not be maintained over the life of the food, manufacturers were

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[1] CL 1994/14-FH; CX/FH 94/8 (Comments of Canada, Denmark, Egypt, Switzerland and the United States of America); CX/FH 94/8-Add.1 CRD 4 (Comments of The Netherlands, Norway, Switzerland, ISO, IDF); CRD 5 (Comments of France).

encouraged to make changes in the microbiological environment by lowering pH or water activity, or by marketing the food as a frozen food.

92. In regard to inspection at the point of import, several Delegations stated that a risk assessment approach was followed, taking into account the origin of the food and its epidemiological significance or history of involvement in previous outbreaks. Other countries applied the same criteria as used for domestic production.

93. The Committee agreed to request ICMSF to provide a revised discussion paper in the light of the points raised above, with the objective of addressing the trade issues, national application and providing a harmonized approach to the certification of HACCP-based procedures for use in trade for the control of *L. monocytogenes*.

94. The Delegation of Germany expressed disappointment that the Committee had been unable to accept the ICMSF decision-tree approach, which it believed was a suitable means of addressing the problem of dealing with a zero tolerance. It proposed that the ICMSF decision-tree approach should be applied by countries on a trial basis to determine its usefulness for Codex purposes. This sugestion was supported by the Delegations of France and The Netherlands. The Committee, however, noted the objections raised by many Delgations in the course of the debate to the initial decision in the ICMSF paper of separating potential consumers into separate risk groups and decided that it could not make such a recommendation. The Committee, however, stated that the gathering of more information on the control of *L. monocytogenes* and on the efficacy of these systems could be useful in view of the fact that to a considerable degree the contamination of many foods was unavoidable.

IMPLEMENTATION OF RISK ASSESSMENT (Agenda Item 10)

95. The March 1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, convened in cooperation with GATT, recommended that the Codex Alimentarius Commission should make explicit the risk assessment procedures used in the development of Codex standards, guidelines and other recommendations. Following discussion of a paper [1] presented to its 20th Session the Commission agreed that all relevant Codex Committees should review and further discuss the paper.

96. Subsequently, the 41st Session of the Executive Committee had considered proposals for new work arising from discussions of this paper by the Codex Committee on Residues of Veterinary Drugs in Foods and the Codex Regional Coordinating Committee for North America and the South-West Pacific. These proposals included the elaboration of harmonized definitions for use in risk analysis and the development of risk assessment methodology and decision-making criteria. [2] The Executive Committee decided there was considerable urgency for developing guidance in this area and asked FAO and WHO to consider convening a joint expert consultation to provide advice to be considered by the 42nd Session of the Executive Committee and the 21st Session of the Commission (ALINORM 95/3, Para. 48). The Executive Committee had also stated that, wherever possible, scientific analysis and advice, together with risk analysis, should form the basis of the development of standards, guidelines and recommendations. [3]

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[1] *Risk Assessment Procedures Used by the Codex Alimentarius Commission and its Subsidiary and Advisory Bodies*, ALINORM 93/37, prepared by Dr. S.C. Hathaway (New Zealand).

[2] ALINORM 95/31, paras. 38-41 and ALINORM 95/32, paras. 58-59.

[3] ALINORM 95/3, para. 22c - Report of the Forty-first Session of the Executive Committee of the Codex Alimentarius Commission.

97. The document which had been presented to the 20th Session of the Commission was introduced to the Committee by its author. Dr. Hathaway stressed that risk analysis was essential to the management of risks from foodborne diseases; in particular it was an essential component of the HACCP process, risk assessments being undertaken at each control point in a HACCP plan. However, it was noted that such assessments for the most part were qualitative and that there was a need for them to become more scientifically quantitative. Dr. Hathaway noted that the Office Internationale des Epizoöties had made important progress in this area and had developed a Code of Practice for the application of risk assessment principles.

98. The Committee fully supported the move towards an improved science-based approach to the development of food hygiene recommendations based on risk analysis. It further recognized that risk management decisions taken by governments or by the Codex Alimentarius Commission required the consideration of all legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

99. The Committee welcomed the proposal to convene a joint FAO/WHO expert consultation to provide guidance in the application of risk analysis by Codex. Attention was drawn to the need to consider means of improving transparency in the Codex, FAO and WHO decision-making processes in regard to food safety.

100. The Committee agreed that consideration should be given to the development of guidelines on the application of the principles of risk assessment and risk management to food hygiene including strategies for their application; that such guidelines should stress the role of these principles in the application of HACCP systems; and that HACCP systems provided an effective means of delivering a scientifically-based risk management system for food hygiene. The Committee requested the Secretariat to initiate work on the development of a first draft of such guidelines on the basis of the advice provided by the joint expert consultation referred to above.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

101. The Committee agreed that work would continue on the following items:

- Draft Code of Practice on General Principles of Food Hygiene;
- 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 Uncured/Unripened Cheese and Ripened Soft Cheese;
- Recommendations for the Control of *Listeria monocytogenes*; and
- Guidelines on the Application of the Principles of Risk Assessment and Risk Management to Food Hygiene including Strategies for their Application.

102. The Committee also agreed to propose that the following items be considered in its future work:

- **Implications for the Broader Application of the HACCP System:** The Committee noted that a paper prepared for consideration by the 3rd Session of the Codex Coordinating Committee for North America and the South-West Pacific [1] was being circulated to all Member countries for comment. It was agreed that the paper would be further developed by the Delegation of Australia and would be considered by the Committee at its next Session.

- **Guidelines for Consumer Education in Food Hygiene:** The Delegation of the United States stated that the development of such guidelines would form an important part of risk communication and would complement the Guidelines on the Application of the HACCP System. This view was supported by the Observer from IOCU.

- **Code of Practice for All Foodstuffs Transported in Bulk:** The Committee noted that this work had been assigned to the Codex Committee on Food Additives and Contaminants and this Committee. It was noted that problems relating to transport of foods in bulk were not restricted to chemical hazards, and the Committee stated that appropriate provisions concerning food hygiene would need to be incorporated into the code. Attention was drawn to the current Codex Code on the Transport of Edible Fats and Oils Transported in Bulk [2] and to developments within the European Union to develop a code which would apply to foods imported into the Union.

- **Code of Hygienic Practice for Bottled Water:** The Delegation of the United States proposed that such a Code, which would not conflict with the existing Code of Hygienic Practice for Natural Mineral Waters, [3] could provide valuable advice on preventing hazards from this commodity. The Delegation agreed to provide information relative to the Criteria for the Establishment of New Work Priorities.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 12)

103. The Committee noted that its 28th Session was provisionally scheduled to be held from 4 to 8 December 1995 in Washington, D.C.. The final dates would be decided between the Host Government and the Codex Secretariat.

104. The Committee expressed its appreciation to the Delegations of Canada, France and the United Kingdom for the work undertaken in the revisions of the draft codes considered under Items 4 and 6 of the present agenda and to the Delegations participating in the *ad hoc* Working Groups which considered the comments on these items. Appreciation was also expressed to the Observer from the ICMSF for the preparation of the basic documents considered under Items 5 and 9.

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[1] CX/NASWP 94/4.

[2] CAC/RCP 36-1987.

[3] CAC/RCP 33-1985.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 95/13
Adoption of Draft Code of Hygienic Practice for Spices and Dried Aromatic Plants	8	21st Session CAC	Appendix II, para. 85
Proposed Draft Code of Practice on the General Principles of Food Hygiene	5	Governments, 21st Session CAC	Appendix III, paras 23-29
Revision of the Principles for the Establishment of Microbiological Criteria for Foods	3	Governments, ICMSF	Paras 30-46
Proposed Draft Code of Practice for Refrigerated Packaged Foods with Extended Shelf-Life	3	Governments, Canada and France	Appendix IV, paras 47-52
Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese	3	Governments, France, The Netherlands and U.S.A.	Appendix V, paras 53-73
Recommendations for the Control of *Listeria monocytogenes*	-	Governments, ICMSF	Paras 86-94
Implementation of Risk Assessment	-	Codex Secretariat	Paras 95-100
Implications for the Broader Application of the HACCP System	-	28th Session of CCFH, Australia	Para. 102, 1st bullet.
Guidelines for Consumer Education in Food Hygiene	-	28th Session of CCFH	Para. 102, 2nd bullet.
Code of Practice for All Foodstuffs Transported in Bulk	-	28th Session of CCFH	Para. 102, 3rd bullet.
Code of Hygienic Practice for Bottled Water	-	28th Session of CCFH, U.S.A.	Para. 102, 4th bullet.

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PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND DRIED AROMATIC PLANTS
(At Step 8 of the Procedure)

TABLE OF CONTENTS

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND DRIED AROMATIC PLANTS
(At Step 8 of the Procedure)

Section I - SCOPE

This Code of Hygienic Practice applies to spices and dried aromatic plants -whole, broken, ground or blended. It covers the minimum requirements of hygiene for harvesting, post harvest technology (curing, bleaching, drying, cleaning, grading, packing, transportation and storage including microbial and insect disinfestation) processing establishment, processing technology (grinding, blending, freezing and freeze drying, etc.) packaging and storage of processed products.

Section II - DEFINITIONS

2.1 Spices and Dried Aromatic Plants

The term spices, which includes dried aromatic plants, relates to natural dried components or mixtures thereof, used in foods for flavouring, seasoning and imparting aroma. The term applies equally to spices in the whole, broken or ground form.

2.2 Spice Blends and Products

2.2.1 Spice Blends

Spice blends are obtained by mixing and grinding, cleaned, dried and sound selected spices.

Section III - HYGIENIC REQUIREMENTS IN THE PRODUCTION/HARVESTING AREA

3.1 Environmental Hygiene in Areas where Raw Materials are Produced

3.1.1. Unsuitable Growing or Harvesting Areas

Spices should not be grown or harvested where the presence of potentially harmful substances would lead to an unacceptable level of such substances in the final product.

3.1.2. Protection from Contamination by Wastes

3.1.2.1 Raw spices should be protected from contamination by human, animal, domestic, industrial and agricultural wastes which may be present at levels likely to be a hazard to health. Adequate precautions should be taken to ensure that these wastes are not used and are not disposed of in a manner which may constitute a hazard to health through the food.

3.1.2.2 Arrangements for the disposal of domestic and industrial wastes in areas from which raw materials are derived should be acceptable to the official agency having jurisdiction.

3.1.3 Irrigation Control

Spices should not be grown or produced in areas where the water used for irrigation might constitute a hazard to health to the consumer through the spices.

3.1.4 Pest and Disease Control

Control measures involving treatment with chemical, physical or biological agents should only be undertaken under direct supervision of personnel who have a thorough knowledge of the potential hazards to health. Such measures should only be carried out in accordance with the recommendations of the Codex Alimentarius Commission or, where these do not exist, by the official agency having jurisdiction.

3.2 Drying (Curing)

Plants or parts of plants used for the preparation of spices may be dried naturally or artificially, provided adequate measures are taken to prevent contamination or alteration of the raw material during the process. To prevent the growth of microorganisms, especially mycotoxin producing mould, a safe moisture level should be achieved.

If dried naturally, plants or part of plants should not be in direct contact with the soil. They should be placed on raised platforms or on a floor made of a suitable material.

New concrete floors should be used for drying only when it is absolutely certain that the new concrete is well-cured and free of excess water. It is safer to use an approved plastic cover spread over the entire new concrete floor as a moisture barrier prior to use for spices.

Excessive heating/drying of material should be avoided in order to retain its aromatic principles. Suitable precautions should be taken to protect the spices from contamination by domestic animals, rodents, birds, mites and other arthropods or other objectionable substances during drying, handling and storage.

3.3 Cleaning

The spices should be cleaned properly to the desired levels prescribed in the national and international standards.

3.4 Packaging

Packaging should protect the clean, dried spices from contamination and the entry of water or excess moisture. In particular, the reabsorption of ambient moisture in humid tropical climates should be prevented. Contamination from mineral oils used for processing natural fibre bags should be prevented by the use of liners where appropriate. Reusable containers should be properly cleaned and disinfected before reuse.

3.5 Transportation

The conveyances for transporting the harvested, cleaned, dried and packed spices from the place of production to storage for processing should be cleaned and disinfected before loading. In addition, bulk transport such as ship or rail car should be cleaned and, as appropriate, well ventilated with dry air to remove moisture resulting from the respiration of spices, and to prevent moisture condensation as the vehicle moves from a warmer to a cooler region or from day to night.

Section IV - ESTABLISHMENT DESIGN AND FACILITIES

4.1 Location

Establishments should preferably be located in areas which are free from objectionable odours, smoke, dust or other contaminants and are not subject to flooding.

4.2 Roadways and Areas used by Wheeled Traffic

Such roadways and areas serving the establishment which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage and provision should be made to allow for cleaning.

4.3 Building and Facilities

4.3.1 Buildings and facilities should be of sound construction and maintained in good repair. All construction materials should be such that they do not transmit any undesirable substances to food. All construction materials should be such, that when construction is completed, they do not emit toxic vapours.

4.3.2 Adequate working space should be provided to allow for satisfactory performance of all operations.

4.3.3 The design should be such as to permit easy and adequate cleaning and to facilitate proper supervision of food hygiene.

4.3.4 The buildings and facilities should be designed to prevent the entrance and harbouring of pests and the entry of environmental contaminants such as smoke, dust, etc.

4.3.5 Buildings and facilities should be designed to provide separation, by partition, location or other effective means, between those operations which may cause cross-contamination.

4.3.6 Buildings and facilities should be designed to facilitate hygienic operations by means of a regulated flow in the process from the arrival of the raw materials at the premises to the finished product, and should provide for appropriate temperature conditions for the process and the product.

4.3.7 Spices handling areas

4.3.7.1 Floors - Where appropriate, should be of water-proof, non-absorbent, washable, non-slip and non-toxic materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should slope sufficiently for liquids to drain to trapped outlets.

4.3.7.2 Walls - Where appropriate, should be of water-proof, non-absorbent and washable materials, sealed and free of insects and should be light coloured. Up to a height appropriate for the operation these should be smooth and without crevices, and should be easy to clean and disinfect. Where appropriate angles between walls, between walls and floors, and between walls and ceilings should be sealed and coved to facilitate cleaning.

4.3.7.3 Ceilings - should be so designed, constructed and finished as to prevent the accumulation of dirt and minimize condensation, mould development and flaking, and should be easy to clean.

4.3.7.4 Windows and other openings - should be so constructed as to avoid accumulation of dirt and those which open should be fitted with insect-proof screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.

4.3.7.5 Doors - should have smooth, non-absorbent surfaces and where appropriate, be self-closing and close fitting.

4.3.7.6 Stairs - Lift cages and auxiliary structures such as platforms, ladders and chutes should be so situated and constructed as not to cause contamination to food. Chutes should be constructed with inspection and cleaning hatches.

4.3.8 Overhead structures and fittings - should be installed in such a manner as to avoid contamination of the finished product and raw materials by condensation and drip, and should not hamper cleaning operations. These should be insulated, where appropriate, and be so designed and finished as to prevent the accumulation of dirt and to minimize condensation, mould development and flaking. They should be easy to clean.

4.3.9 Living quarters, toilets and areas where animals are kept should be completely separated from and should not open directly on to spice handling areas.

4.3.10 Where appropriate, establishments should be so designed that access to various sections can be controlled.

4.3.11 The use of materials which cannot be adequately cleaned and disinfected, such as wood, should be avoided unless its use would clearly not be a source of contamination.

4.3.12 Water Supply

An ample supply of water, in compliance with section 7.3 of this Code, under adequate pressure and at suitable temperature should be available with appropriate facilities for its storage, where necessary, and distribution, and with proper protection against contamination.

Ice should be made from potable water; it should be manufactured, handled and stored so as to protect it from contamination.

Steam used in direct contact with food or surfaces in contact with food should contain no substances which may be hazardous to health or contaminate the food.

Non-potable water - used for steam production, refrigeration, fire control and other similar purposes not connected with processing should be carried in completely separate lines, identifiable preferably by colour, and with no cross-connection with or back siphonage into the system carrying potable water.

4.3.13 Effluent and Waste Disposal

Establishments should have an efficient effluent and waste disposal system which should at all times be maintained in good order and repair. All effluent lines (including sewer systems) should be large enough to carry peak loads and should be so constructed as to avoid contamination of potable water supplies.

4.3.14 Changing Facilities and Toilets

Adequate, suitable and conveniently located changing facilities and toilets should be provided in all establishments. Toilets should be so designed as to ensure hygienic removal of waste matter. These areas should be well lit, ventilated and, where appropriate, heated and should not open directly into the handling areas. Hand washing facilities with warm or hot and cold water, a suitable hand-cleaning preparation, and hygienic means of drying hands, should be provided adjacent to toilets and in such a position that the employee must pass them when returning to the processing area. Where hot and cold water are available mixing taps should be provided. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Taps of a non-hand operation type are desirable. Notices should be posted directing personnel to wash their hands after using the toilet.

4.3.15 Hand-washing Facilities in Processing Areas

Adequate and conveniently located facilities for hand washing and drying should be provided wherever the process demands. Where appropriate, facilities for hand disinfection should also be provided. Warm or hot and cold water and a suitable hand cleaning preparation should be provided. Where hot and cold water are available mixing taps should be provided. There should be suitable hygienic means of drying hands. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps of a non-hand operated type are desirable. The facilities should be furnished with properly trapped waste pipes leading to drains.

4.3.16 Disinfection Facilities

Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be constructed of corrosion-resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying hot and cold water in sufficient quantities.

4.3.17 Lighting

Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colours and the intensity should not be less than:

540 lux (50 foot candles) at all inspection points
220 lux (20 foot candles) in work rooms
110 lux (10 foot candles) in other areas.

Light bulbs and fixtures suspended over food materials in any stage of production should be of a safety type and protected to prevent contamination of the material in case of breakage.

4.3.18 Ventilation

Adequate ventilation should be provided to prevent excessive heat, steam condensation and dust and to remove contaminated air. The direction of the air-flow within the plant should never be from a dirty area to a clean area. Ventilator openings should be provided with a screen or other protective enclosure of non-corrodible material. Screens should be easily removable for cleaning.

4.3.19 Facilities for storage of waste and inedible material

Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of food, potable water, equipment and buildings or roadways on the premises.

4.4 Equipment and utensils

4.4.1 Materials

All equipment and utensils used in food handling areas and which may contact food should be made of materials which do not transmit toxic substances, odour or taste, is non-absorbent, is resistant to corrosion and is capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would clearly not be a source of contamination. The use of different metals in such a way that contact corrosion can occur should be avoided.

4.4.2 Sanitary design, construction and installation

4.4.2.1 All equipment and utensils should be so designed and constructed as to prevent hygienic hazards and permit easy and thorough cleaning and disinfection and, where practicable, be visible for inspection. Stationary equipment should be installed in such a manner as to permit easy access and thorough cleaning.

4.4.2.2 Containers for inedible materials or waste should be leak-proof, constructed of metal or other suitable impervious materials, should be easy to clean or disposable and should close securely.

4.4.2.3 All refrigerated spaces should be equipped with temperature measurement or recording devices.

4.4.3 Equipment identification

Equipment and utensils used for inedible materials or waste should be identified and should not be used for edible products.

Section V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in an orderly condition. As far as practicable, rooms should be kept free from steam, vapour and surplus water.

5.2 Cleaning and Disinfection

5.2.1 Cleaning and disinfection should meet the requirements of this code. {For further information on cleaning and disinfection procedures, see Appendix I of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 2 - 1985)}.

5.2.2 To prevent contamination of spices, all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.

Note: Equipment, utensils, etc. that are in contact with plants or parts of plants used in the preparation or processing of spices will be contaminated by microorganisms. There is an inherent risk of affecting other plants or spices that will be manipulated later. It is therefore necessary to clean the equipment and when appropriate, dismantle it at frequent intervals during the day, at least after each break and when changing from one food product to another. Dismantling, cleaning and disinfection at the end of the work day are aimed at preventing the proliferation of pathogenic flora. Control should be exercised through regular inspections.

5.2.3 Adequate precautions should be taken to prevent spices from being contaminated during cleaning or disinfection of rooms, equipment or utensils by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the official agency having jurisdiction. Any residues of these agents on a surface which may come in contact with spices should be removed by rinsing with potable water or rinsing and drying with steam before the surface or equipment is again used for handling food.

5.2.4 Either immediately after cessation of work for the day or at such other times as may be appropriate, floors including drains and orifices for the evacuation of liquid wastes, auxiliary structures and walls of handling areas should be thoroughly cleaned.

5.2.5 Changing facilities and toilets should be kept clean at all times.

5.2.6 Roadways and yards in the immediate vicinity of and serving the premises should be kept clean.

5.3 Hygiene control programme

A permanent cleaning and disinfection schedule should be drawn up for each establishment to ensure that all areas are appropriately cleaned and that critical areas, equipment and materials are designated for special attention. A single individual, who should preferably be a permanent member of the staff of the establishment and whose duties preferably should be independent of production, should be appointed to be responsible for the cleanliness of the establishment. He or she should have a thorough understanding of the significance of contamination and the hazards involved. All cleaning personnel should be well trained in cleaning techniques.

5.4 By-products

By-products such as trimmings, peelings, discards, etc. not classed as waste material and which may have some future use should be stored in a manner to avoid contamination of food. They should be removed from the work zones as often as necessary and at least daily.

5.5 Storage and disposal of waste

Waste material should be handled in such a way as to avoid contamination of food or potable water. Care should be taken to prevent access to waste by pests. Waste should be removed from the spice handling and other working areas as often as necessary and at least daily. Immediately after disposal of waste, receptacles used for storage and any equipment which has come into contact with the waste should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

5.6 Exclusion of domestic animals

Animals that are uncontrolled or that could be a hazard to health should be excluded from establishments.

5.7 Pest Control

5.7.1 There should be an effective and continuous programme for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation.

5.7.2 Should pests gain entrance to the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from residues retained in the product. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

5.7.3 Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard all spices, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned prior to being used again.

5.8 Storage of Hazardous Substances

5.8.1 Pesticides or other substances which may represent a hazard to health should be suitably labelled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets used only for that purpose and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating foods.

5.8.2 Except when necessary for hygienic or processing purposes, no substance which could contaminate food should be used or stored in spice handling areas.

5.9 Personal effects and clothing

Personal effects and clothing should not be left in spice handling areas.

Section VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

Managers of establishments should arrange for adequate and continuing training of workers in hygienic handling of spices and in personal hygiene so that they understand the precautions necessary to prevent contamination of food. Training should include relevant sections of this code.

6.2 Medical Examination

Persons who come in contact with the food in the course of their work should have a medical examination prior to their employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary because of epidemiological considerations, the nature of the food prepared in a particular establishment or the medical history of the prospective food handler. Medical examination of a food handler should also be carried out at other times when clinically or epidemiologically indicated.

6.3 Communicable Diseases

The management should take care to ensure that no person, while known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through spices or while afflicted with infected wounds, skin infections, sores or with diarrhoea, is permitted to work in any spice handling area in any
capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic micro-organisms. Any person so affected should immediately report to the management.

6.4 Injuries

Any person who has a cut or wound should not continue to handle the material until the injury is completely protected by a waterproof covering which is firmly secured, and which is conspicuous in colour. Adequate first-aid facilities should be provided for this purpose.

6.5 Washing of Hands

Any person working in a spice handling area should wash hands frequently and thoroughly with a suitable hand-cleaning preparation under running warm water which should be in accordance with the Sub-Section 7.3 of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 2-1985). Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and wherever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal Cleanliness

Every person engaged in a spice handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should be washed in an appropriate area. Where hands come into direct contact with spices, any jewellery should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in spice handling.

6.7 Personal Behaviour

Any behaviour which could result in contamination of spices, such as eating, use of tobacco, chewing (e.g. gum, sticks, betel nuts, etc.) or unhygienic practices such as spitting, should be prohibited in handling areas.

6.8 Gloves and Other Protection Equipment

Gloves and other protection equipment such as masks, if used in the handling of spices, should be maintained in a sound, clean and sanitary condition. The wearing of gloves does not exempt the operator from having thoroughly washed hands.

6.9 Visitors

Precautions should be taken to regulate the entry of visitors to handling and processing areas to avoid contamination. These precautions may include the use of protective clothing. Visitors should observe the provisions recommended in Sub-Section 5.9, 6.3, 6.4 and 6.7 of this code.

6.10 Supervision

Responsibility for ensuring compliance by all personnel with the requirements of Sub-Sections 6.1 to 6.9 should be specifically allocated to competent supervisory personnel.

Section VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

7.1.1 Acceptance Criteria

Spices should not be accepted by the plant if they are known to contain parasites, microorganisms, decomposed, toxic, or extraneous substances which will not be reduced to acceptable levels by normal plant procedures, sorting or preparation. Particular care should be taken to avoid contamination.

Plants, parts of plants or spices suspected of being contaminated with animal or human faecal material should be rejected for human consumption. Special precautions must be taken to reject spices showing signs of insect damage or mould growth because of the danger of their containing mycotoxins such as aflatoxins.

7.1.2. Inspection and Sorting

Raw materials should be inspected and sorted prior to processing and where necessary, laboratory tests should be conducted. This inspection may include:

- Visual inspection for foreign matter
- Organoleptic evaluation: odour, appearance, possibly taste
- Testing for microbiological or mycotoxin contamination: systematic monitoring for sensitive materials, periodic monitoring for less sensitive materials.

These tests should refer either to national regulations, international standards or recommendations, or established methods used in the industry.

7.1.3 Treatment

In order to control microbiological contamination or pest infestation, appropriate methods of treatment may be used in accordance with the regulations set by the official agency having jurisdiction. Whenever spices have been treated, the type of treatment must be stated explicitly in an accompanying certificate. For use of irradiation, consult the Code of Good Irradiation Practice for the Control of Pathogens and Other Microflora in Spices, Herbs and Other Vegetable Seasonings.[1]

7.1.4 Storage

Raw materials stored in the plant premises should be maintained under conditions that will protect them against contamination and infestation and minimize deterioration. Spices not scheduled for immediate use should be stored under conditions that prevent infestation and mould growth.

The warehouse should be of sound construction and well equipped so that it will provide suitable storage and adequate protection for spices. Any breaks or openings in the walls, floors, roof shall have been repaired. Any breaks or openings around doors, windows and ventilators should be repaired or screened. Screens should be used only in those areas of the building where moisture entry from precipitation cannot occur. The building should have sufficient ventilation to prevent accumulation of moisture. Provision should be made in existing storage or at the design stage in new storage for gas tightness to permit in situ fumigation of spices.

Areas with new concrete floors or walls should not be used for storage until it is absolutely certain that the new concrete is well-cured and free of excess water. It is safer to use an approved plastic cover spread over the entire new concrete floor as a moisture barrier prior to use for spices. However, other means of protecting the spices against moisture from "sweating" concrete can be used, such as stacking of containers on pallets. The plastic can be removed when the warehouse is emptied. This system will protect against moulding of the spices due to the sweating of new concrete.

Products which affect the storage life, quality or flavour of spices should not be stored in the same room or compartment as spices. For example, such items as fruits, vegetables, fish, fertilizer, gasoline or lubricating oils, etc. should not be stored along with spices.

7.2 Prevention of Cross-Contamination

7.2.1 Effective measures should be taken to prevent contamination of uncontaminated spices by direct or indirect contact with material at earlier stages of the processing.

7.2.2 Persons handling raw materials or semi-processed products capable of contaminating the end-product should not come into contact with any end-product unless and until they discard all protective clothing worn by them during the handling of the said products and have changed into clean protective clothing.

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[1] Code of Good Irradiation Practice for the Control of Pathogens and Other Microflora in Spices, Herbs and Other Vegetable Seasonings (International Consultative Group on Food Irradiation (ICGFI) Document No. 5).

7.2.3 If there is a likelihood of contamination, hands should be washed and disinfected thoroughly before handling products at different stages of processing.

7.2.4 Raw products that may present a hazard should be processed in separate rooms, or in areas physically separate from those where end-products are being prepared.

7.2.5 All equipment which has been in contact with raw or contaminated materials should be thoroughly cleaned and disinfected prior to being used for contact with end-product.

7.3 Use of Water

7.3.1 As a general principle only potable water, as defined in the latest edition of Vol. 1 of the WHO "Guidelines for Drinking Water Quality", should be used in food handling.

7.3.2 Non-potable water may be used with the acceptance of the official agency having jurisdiction for steam production, refrigeration, fire control and other similar purposes not connected with food. However, non-potable water may, with specific acceptance by the official agency having jurisdiction, be used in certain food handling areas provided this does not constitute a hazard to health.

7.3.3 Water re-circulated for re-use within an establishment should be treated and maintained in a condition so that no health hazard can result from its use. The treatment process should be kept under constant surveillance. Alternatively, re-circulated water which has received no further treatment may be used in conditions where its use would not constitute a health hazard and will not contaminate either the raw material or the end-product. Re-circulated water should have a separate distribution system which can be readily identified. The acceptance of the official agency having jurisdiction should be required for any treatment process and for the use of re-circulated water in any food process.

7.4 Processing

7.4.1 Processing should be supervised by technically competent personnel.

7.4.2 All steps in the production process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration or the development of pathogenic and spoilage micro-organisms.

7.4.3 Rough treatment of containers should be avoided to prevent the possibility of contamination of the processed product.

7.4.4 Methods of preservation and necessary controls should be such as to protect against contamination or development of a public health hazard and against deterioration within the limits of good commercial practice.

7.5 Packaging

7.5.1 All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination.

7.5.2 Containers should not have been used for any purpose which may lead to contamination of the product. Containers should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary cleaned and/or disinfected; when washed they should be well drained and dried before filling. Only packaging material required for immediate use should be kept in the packaging or filling area.

7.5.3 Packing should be done under hygienic conditions that preclude the introduction of contamination into the product.

7.6 Storage of the End-Product

7.6.1 Spices and their products should be stored at a moisture low enough so that the product can be held under normal storage conditions without development of mould or significant deterioration by oxidative or enzymatic changes. An environment with a relative humidity between 55 and 60 percent should be maintained to protect quality and prevent mould growth. Where this is not practicable, spices should be packed in water-proof and gas-proof containers and stored in a proper warehouse.

7.6.2 Finished products may be packed in gas tight containers preferably under inert gases like nitrogen, etc., or under vacuum in order to protect quality and retard possible mould growth.

7.6.3 All products should be stored in clean, dry buildings, protected from insects, mites and other arthropods, rodents, birds, or other pests, chemical or microbiological contaminants, debris and dust.

7.6.4 Control of Infestation by Insects, Mites and Other Arthropods

Spices should be stored in such a manner that infestation can be controlled by such methods as anaerobic or refrigerated storage or fumigation prior to storage. Stored spices should be inspected regularly and, if infested, fumigated by appropriate methods. If necessary, affected spices may be removed for fumigation. In this case, the storage areas should be cleaned and disinfected separately.

7.7 Transport of the End-Product

Spice products should be stored and transported under conditions that maintain the integrity of the container and the product within it. Carriers should be clean, dry, weatherproof, free from infestation and sealed to prevent water, rodents or insects from reaching the products. Spice products should be loaded, transported and unloaded in a manner that protects them from any damage or water. Well insulated carriers or refrigerated vehicles are recommended for transport when climatic conditions indicate such a need. Extreme care should be taken to prevent condensation when unloading spice products from a refrigerated vehicle or while taking out of a cold storage. In warm, humid weather, the spices should be allowed to reach ambient temperature before exposure to external conditions; this may require 1-3 days. Spices that have been spilled are vulnerable to contamination and should not be used as food.

7.8 Sampling and Laboratory Control Procedures

7.8.1 Laboratory procedures used should preferably follow recognized or standard methods in order that the results may be readily reproduced.

7.8.2 In addition to any control by the official agency having jurisdiction, it is desirable that each production plant should have its own or contracted laboratory control of the hygienic quality of the spice products processed and of the pest control procedures. The amount and type of such control will vary with

the different spice products as well as the needs of management. Such control should provide for monitoring of the quality of the finished products and rejection of all spices that are unfit for human consumption.

Section VIII - END-PRODUCT SPECIFICATIONS

8.1 When tested by appropriate methods of sampling and examination, the products:

(a) should be free from pathogenic micro-organisms in levels that may represent a hazard to health;

(b) should not contain any substances originating from micro-organisms, particularly aflatoxins, in amounts that exceed the tolerances or criteria established by the Codex Alimentarius Commission or, where these do not exist, by the official agency having jurisdiction;

(c) should not contain levels of insect, bird or rodent contamination that indicate that spices have been prepared, packed or held under unsanitary conditions;

(d) should not contain residues resulting from the treatment of spices in excess of levels established by the Codex Alimentarius Commission or, where these do not exist, by the official agency having jurisdiction; and

(e) should comply with the provisions for food additives, contaminants, and with maximum levels for pesticide residues established by the Codex Alimentarius Commission or, where these do not exist, by the official agency having jurisdiction.

8.2 Microbiological Criteria

Ready-to-eat spices and dried aromatic plants shall be free from Salmonella when ten samples of 25 g are analyzed by appropriate methods of examination
($n=10$, $c=0$).

CODEX ALIMENTARIUS GENERAL PRINCIPLES OF FOOD HYGIENE

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INTRODUCTION

People are entitled to expect the food they eat to be safe and suitable for consumption. Food borne illness and foodborne injury is at best unpleasant; at worst, it can be fatal. But there are also wider 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 trade in food, and foreign travel, are increasing, bringing important 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 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 and foodborne injury and food spoilage, wherever they occur. Everyone, farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to protect the safety of food and ensure it is suitable for consumption.

These General Principles lay a firm foundation for ensuring food hygiene. The document follows the food chain from primary production through to the final consumer, highlighting the key hygiene controls at each stage and 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 Point (HACCP) system in the Annex to this document. These controls are internationally recognised as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, industry 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 *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 should be read in conjunction with this document and the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) system (Annex 1).

2.1.2 Safety and suitability for consumption

The term "contamination" in this document refers to the contamination of food by microbial pathogens, chemicals, foreign bodies, spoilage agents, objectionable taints and unwanted or diseased matter eg sawdust, decomposed material. The document also uses the terms "food safety" and "suitability for consumption". The former refers to ensuring that food does not cause illness or injury to consumers, the latter to spoiled food or food that is otherwise not suitable for normal human consumption.

2.1.3 Roles of Governments, industry, and consumers

Governments should 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, including drink;

- provide assurance that food is suitable for normal human consumption;

- maintain confidence in internationally traded food; and

- provide health education programs which effectively 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 instructions, 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 recognize 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.

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 residues, dirt, grease or other objectionable matter.

Contamination - the occurrence of any objectionable matter in the product.

Disinfection - the reduction, without adversely affecting the food, by means of hygienically satisfactory chemical agents and/or physical methods, of the number of micro-organisms to a level that will not lead to harmful contamination of food.

Establishment - any building(s) or area(s) in which food is handled and the surroundings under the control of the same management.

Food Hygiene - all measures necessary to ensure the safety, soundness and wholesomeness of food at all stages from its growth, production or manufacture until its final consumption.

Hazard - See Appendix I.

HACCP - See Appendix I.

Food Handler - means any person who directly handles food and/or has control over the integrity, hygienic condition or safety of food.
OR - means an individual working with unpackaged food, food equipment or utensils, or food contact surfaces. [French translation]

Food Chain - means the totality of all stages of the production of food from the primary product, including all materials used in the production of the primary product, through to the final consumer.

Food Safety - See 2.1.2.

Food Suitability - See 2.1.2.

Industry -

Primary Producer -]

3. PRIMARY PRODUCTION

Objectives:

Primary production should be managed in a way that ensures that food is safe and suitable for human consumption. 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 reduce that probability.

Producers should implement measures to:

- control contamination from soil, water, feedstuffs, 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 quality assurance programs which achieve specific food safety goals are becoming an important part of primary production and should be encouraged.

3.3 Processing, handling, storage and transport

Procedures should be in place to:

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

- dispose of any rejected material in a hygienic manner.

Food and food ingredients should be protected from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during processing, 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 by other controls.

3.4 Cleaning, maintenance and personnel hygiene

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 sited, designed and constructed to ensure that:

- **food contamination is minimised;**
- **design and layout permit appropriate maintenance, cleaning and disinfection and minimise air-borne contamination;**
- **surfaces and materials, in particular those in contact with food, are non-toxic 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 siting, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

4.1 Siting

4.1.1 Establishments

Potential sources of contamination need to be considered when deciding where to site food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be sited 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 sited 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 sited 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 by foodstuffs between and during operations.

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, disinfect. 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, non-toxic materials;

- 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 and non-toxic materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

4.2.2 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. 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 be effectively controlled; 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; and
- control odours which might affect the 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 (eg by temperature and humidity control).

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 and suitability 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 shelf-life 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 system is the guidelines for the application of the Hazard Analysis Critical Control Point (HACCP) system (Appendix 1).

5.2 Key aspects of control systems

5.2.1 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 process steps which contribute to control of food hazards include:

- freezing
- pasteurizing
- irradiation
- cooking
- 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.

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 materials or gases where used in packaging 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, refrigeration, fire control and other similar purposes not connected with food; and

- in certain food processes and 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 ensure foods are not contaminated.

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 there is an immediate health hazard, products produced under similar conditions, and likely to present a similar hazard to public health, may 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, 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;**
- **ensure the absence of 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.

Industrial cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored 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 scrubbing or turbulent flow, 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; 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. General good hygiene practices should be employed to avoid creating an environment conducive to pests. Integrated pest controls can minimise the likelihood of infestation through good sanitation, inspection of incoming materials, and monitoring, thereby limiting reliance on pesticides.

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 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;**
- **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 to the management.

Medical examination of a food handler should be carried out only when clinically or epidemiologically indicated.

7.2 Illness and injuries

Examples of conditions which should be reported to management so that any need for medical examination and possible exclusion from food handling can be considered include:

- viral hepatitis A (jaundice)
- diarrhoea
- gastro-intestinal infection
- vomiting
- fever
- sore throat
- skin infections, sores, infected cuts, lesions or wounds
- discharges from the ear, eye or nose.

7.3 Personal cleanliness

Food handlers should maintain a high degree of personal cleanliness and, where necessary, 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 affect 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.

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 necessary, wear protective clothing and observe 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;
- 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 any 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, display, store, and prepare the product safely and correctly;**
- **the lot or batch can be easily identified and recalled in the event of a hazard.**

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

- **understand the importance of product information; and**
- **make informed choices appropriate to the individual.**

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) provides advice on lot identification.

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) provides advice on labelling.

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 food-borne illness.

10. TRAINING

Objective:

those engaged in food business operations who come directly or indirectly into contact with food should be trained, and/or instructed and supervised, 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 operations poses 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 in protecting food from contamination or deterioration before they commence their duties. 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

[Basic training in personal hygiene and food hygiene should be provided for foodhandlers.] 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.

GUIDELINES FOR THE APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM
(At Steps 5 and 8 of the Procedure)

PREAMBLE

The Hazard Analysis Critical Control Point (HACCP) system identifies specific hazards and preventative measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on preventative measures 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 should include appropriate experts. Examples might be agronomists, veterinarians, production personnel, microbiologists, medical experts, public health specialists, food technologists, 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 system can equally be applied to other aspects of food quality.

DEFINITIONS

HACCP: A system which identifies specific hazard(s) and preventative measures (PMs) for their control.

Hazard: The potential to cause harm. Hazards can be biological, chemical or physical.

Critical Limit: A value which separates acceptability from unacceptability.

Critical Control Point (CCP): A point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels.

Corrective Action: The actions to be taken when the results of monitoring the CCP indicate a loss of control.

Monitor: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control.

PRINCIPLES

HACCP is a system which identifies specific hazard(s) and preventative measures for their control. The system consists of the following seven principles:

PRINCIPLE 1

Identify the potential hazard(s) associated with food production at all stages, from growth, processing, manufacture and distribution, until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the preventative measures for their control.

PRINCIPLE 2

Determine the points/procedures/operational steps that can be controlled to eliminate the hazard(s) or minimize its likelihood of occurrence - (Critical Control Point (CCP)). A "step" means any stage in food production and/or manufacture including raw materials, their receipt and/or production, harvesting, transport, formulation, processing, storage, etc.

PRINCIPLE 3

Establish critical limit(s) which must be met to ensure the CCP is under control.

PRINCIPLE 4

Establish a system to monitor control of the CCP by scheduled testing or observations.

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 which include supplementary tests and procedures 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.

APPLICATION OF THE PRINCIPLES OF HACCP

During the hazard analysis 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, consumer populations at risk 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 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 requires the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. Assemble HACCP team

Assemble a multidisciplinary team that has specific knowledge and expertise appropriate to the product. Where such expertise is not available on site, expert advice should be obtained from other sources.

2. Describe product

A full description of the product should be drawn up, including 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. Each step within the specified area of operation should be analyzed for the particular part of the operation under consideration to produce the flow diagram. 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 hazards associated with each step and consider any preventative measures to control hazards (Principle 1)

The HACCP team should list all the biological, chemical or physical hazards that may be reasonably expected to occur at each step and describe the preventative measures that can be used to control these hazards.

The HACCP team next analyzes each hazard.

For inclusion in the list, hazards must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of a safe food.

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

Preventative measures are those actions and activities that are required to eliminate hazards or reduce their impact or occurrence to acceptable levels. More than one preventative measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified preventative measure.

7. Apply HACCP Decision Tree to Each Step (Principle 2)

The identification of a CCP in the HACCP system is facilitated by the application of a decision tree (Diagram 1). All hazards that may be reasonably expected to occur, or be introduced at each step, should be considered. Training in the application of the decision tree may be required.

If a hazard has been identified at a step where control is necessary for safety, and no preventative 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 preventative measure.

Application of the decision tree determines whether the step is a CCP for the identified hazard. Application of the decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other.

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

Critical limits must be specified for each preventative measure. 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, Aw, 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 for corrective action to be taken to regain control of the process before there is a need to reject the product. 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 occur 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 that the HACCP system is working correctly. Monitoring 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 validate the HACCP system. Examples of verification activities include:

Review of the HACCP system and its records.

Review of deviations and product dispositions.

Operations to determine if CCPs are 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. Documentation of HACCP procedures at all steps should be included and assembled in a manual.

Examples are records associated with:

Ingredients
Product safety
Processing
Packaging
Storage and distribution
Deviation file
Modifications to the HAACP system

An example of a HACCP worksheet is attached as Figure 2.

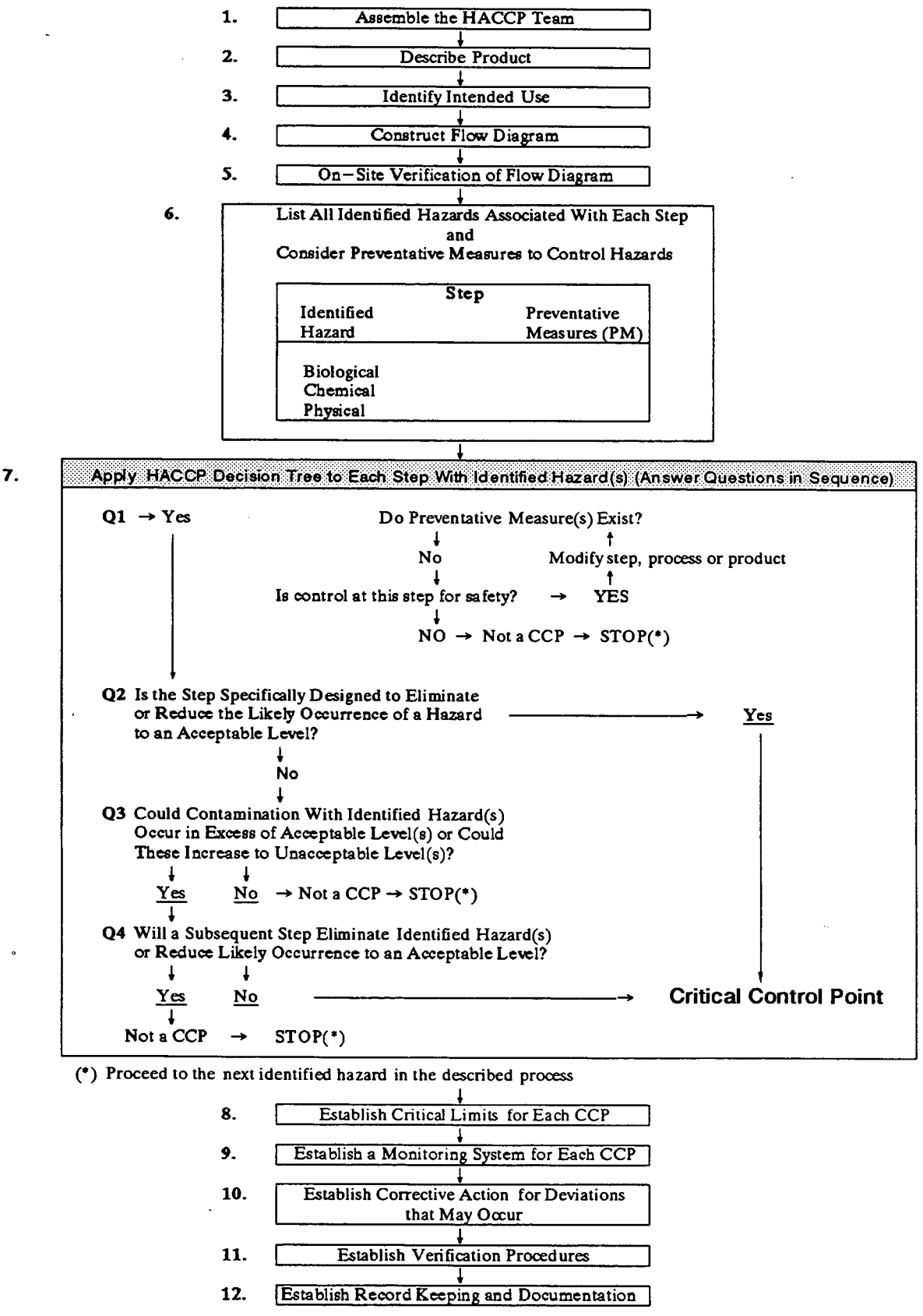
TRAINING

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. The International Commission on Microbiological Specifications for Foods (ICMSF) Monograph, "HACCP in Microbiological Safety and Quality," which describes the type of training required for various target groups, is an example of a general approach to training (Blackwell Scientific Publications, Oxford Mead, UK, 1988, reprinted 1989). The section on training (Chapter 8) in the above monograph is equally applicable as an approach to training in respect to hazards other than those of a microbiological nature.

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



APPENDIX 1: PASTEURIZING VALUES

The processor needs to know the effect of the heat treatment on the microbiological safety of his product during its shelf life. It is necessary therefore to know the thermal treatment used and the level of destruction of vegetative forms of micro organisms required. Pasteruizing values are used to carry this out.

A.1 - Definition:

The pasteurizing value is the length of time at a given temperature to obtain a specified level of destruction of a microorganism whose thermal resistance characteristics are known.

The thermal 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 microbial 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).

To obtain the desired level of reduction, it is necessary to know:

- the maximum acceptable level of microorganisms in the final product;
- the potential initial population;
- and the possible rate of proliferation of the microorganisms during the shelf life of the product.

A.2 - Reference microorganisms:

The reference microorganism chosen to calculate the pasteurizing value is related to the shelf life of the product. For example:

- for products with a short shelf life, the reference microorganism could be *Listeria monocytogenes* ($z=7.5°C$, D_{70} = 0.33 min[1].);
- for products with a long shelf life, the reference microorganism could be *Clostridium botulinum*, type E ($z=7.5$ °C below 90°C and 10°C above 90°C, D_{90} = 1.6 min.[1]);
- for products with a medium shelf life, as there is no non spore forming pathogen with a significant enough thermal resistance, one could use a micro organisms indicative of sanitary conditions such as *Enterococcus faecalis* [2] ($z=10°C$, D_{70} = 2.95 min.).

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1 CFDRA - *Food Pasteurization Treatments* - Technical Manual N° 27, April 1992. A Review - The Heat Resistance of *Listeria monocytogenes*, B.M. Machey & N. Bratchell, letters in Applied Microbiology, 1989, 9, 89-94.

2 Ecart de température (exprimé en degré Celsius) permettant de diviser ou de multiplier ce temps par 10.

CFDRA - *Food Pasteurization Treatments* - Technical Manual N° 27, April 1992. A Review - The Heat Resistance of *Listeria monocytogenes*, B.M. Machey & N. Bratchell, letters in Applied Microbiology, 1989, 9, 89-94.

Formerly named *Streptococcus faecalis*.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF LIFE
(At Step 3 of the Procedure)

TABLE OF CONTENTS

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

FOREWORD

Refrigerated prepared foods are foodstuffs that are kept refrigerated to preserve them. In general, the thermal treatment that these products receive is not sufficient to ensure their commercial sterility. Refrigeration retards food spoilage and prevents growth of most pathogens.

However, there are possibilities for thermal abuse (increase in temperature) during manufacture, storage, distribution, sale, and handling by the consumer. These thermal abuses can permit growth of pathogenic microorganisms. Moreover, refrigeration alone is not always sufficient to minimize microbial risk, because certain microorganisms are physchrotrophic, for example, certain strains of *Clostridium botulinum* which can grow at temperatures of 4°C or lower. There is therefore a risk that these certain undesirable microorganisms will proliferate at refrigeration temperatures.

There are other problems with refrigerated foods. For example, for Modified Atmosphere Packaged (MAP) foods the anaerobic environment limits growth of aerobic flora. Aerobic flora compete with pathogenic microorganisms; since these flora cannot survive in MAP, certain pathogenic microorganisms may proliferate. Aerobic flora are also often the flora that cause product spoilage. Therefore, in the absence of aerobic microorganisms MAP products may become unsafe without any visible signs of spoilage.

Thermal treatment for packaged food is not necessarily the only factor to be controlled. Microbiological risk can be controlled by a combination of inhibiting factors, called barriers. These factors will assist in retarding or preventing growth of microorganisms, including pathogenic microorganisms. The main barriers which may be used in addition to thermal treatment are: pH, a_w, salt content, preservatives, competitive microflora, modified atmosphere, etc.

The purpose of this code is to set out recommendations for processing, packaging, storage and distribution of refrigerated prepared foods. Its aim is preventing the outgrowth of pathogenic organisms and it is based on hazard analysis. This hazard analysis may draw on, for example, the principles of the HACCP method. (The HACCP method is described in detail in Supplement 1, Volume 1 Codex Alimentarius - General Requirements, 2nd. Ed).

SECTION I - SCOPE

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

- are low acid, that is, with pH $>$ 4.6 and are high water activity $a_w > 0.85$;

- are refrigerated during their shelf life;

- are heat treated to significantly reduce their original microbial population;

- may or may not use barriers in addition to heat and refrigeration to retard or prevent the proliferation of undesirable microorganisms;

- are packaged before or after heat treatment, not necessarily hermetically;

- have an extended shelf life of more than 5 days;

- may not necessarily require heating prior to consumption.

This code does not apply to canned foods, raw products, deep-frozen products, fermented meats an vegetables, dried and/or salted fish and meats, smoked fish, cured meat products with an appropriate amou of salt and preservatives, milk, creams and other dairy products, including cheeses, or to foods with pH ≤ 4.6 or $a_w \leq 0.85$.

In any case, foods containing one or more ingredients that are excluded and one or more ingredients that ar covered by this code are not excluded.

SECTION II - DEFINITIONS

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

Cooling equipment: equipment to rapidly reduce a product's temperature to a given refrigeration temperature.

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

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

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

Use-by-date: The date after which the product should not be offered for sale or consumed. It is calculated from the date of production, utilizing the product shelf life, leaving a margin of safety of at least two days.

Shelf life: maximum period between time of manufacture and date of consumption of a product. This is the period during which the product maintains its microbiological and organoleptic qualities. Shelf life considerations will be elaborated on within the examples. Also will be discussed under Section VIII (HACCP) to reflect *Listeria* and *Clostridium* risk.

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

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

Lot: all units produced in the same conditions and during the same processing period, usually not exceeding 24 hours.

Handling: any operation in manufacture of refrigerated prepared foods during which personnel has to touch food directly or with utensils.

Handling of foodstuffs: any operation involving transfer of raw materials and in-process or final products.

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

Container: any box, tin, plastic or other receptacle, wrapper or cover in direct contact with the food product.

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

Rapid cooling: lowering the temperature of the food in a way such that the critical zone for microbial proliferation (60°C-10°C) is passed through as rapidly as possible. The cooling time is established during hazard analysis.

High Risk Zone (HR): In addition to the characteristics of the 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 cross contamination by target organisms. Hazard analysis will allow the identification of HR.

Refrigerated food: Food intended to be kept at 4°C or less. Other storage temperatures may be suitable provided sufficient evidence can be presented with respect to the safety of such products.

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 and in process foods and the raw materials and waste;
- strict separation in the plant of the HR zone 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 havi 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 bei 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 an requirements, that is free from unpleasant odors, smoke, dust or other contaminants and not subject to floo 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, shoul 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 i good condition. Construction materials used should not be capable of transmitting undesirable substances t the foodstuffs. It is advisable to avoid use of materials that are difficult to clean and disinfect, unless it i certain that they are not a source of contamination. All dimensions of buildings and installations should b 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, hygrometry 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, 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 sanitation and hygiene of operations through their regular progression, from arrival of raw materials to final product, and should ensure appropriate thermal conditions suitable 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.

Respecting 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 microbes;

- ceilings should be designed, constructed and finished to prevent accumulation of filth and reduce vapor condensation, development of moulds and flaking to a minimum. 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., shou be located and constructed in such a way as not to cause contamination of foods. Chutes should b equipped with openings for inspection and cleaning.

In HR areas:

- entrances should be provided with foot baths and hand washing and sanitizing installations;

- windows should be permanently closed and not capable of being opened;

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

- if the temperature in the HR areas exceeds the prescribed temperature and adversly increases th temperature of the product, the manufacturer would be responsible for demonstrating the product' safety;

- air should be filtered and under positive pressure in locations where foodstuffs are handled in orde 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 also be insulated when necessary, and the construction should be such that dirt accumulation is prevented, development of mould and chipping reduced to a minimum, and 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 monitored.

4.3.11 Water supply

A plentiful supply of water, conforming to Vol. 1 of 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 reflux 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 sufficiently large 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, su as an alarm, to signal loss of control. These devices should be clearly visible and placed so that the maximu temperature in the refrigerated area is recorded as accurately as possible. Accuracy of the devices should verified at regular intervals, calibrated against a known source of standard, and repaired or replaced wh necessary.

4.3.13.2 Cooling

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

Rapid cooling of large quantities of food requires equipment capable of rapidly extracting heat from th maximum quantity of food likely to be produced. Ideally, the method used should ensure that the foodstuf are not kept for more than two hours at temperatures between 60°C and 10°C where feasible. Other coolin 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 specifie 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 in the HR area 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 filtered or otherwise 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 ma of materials that cannot transfer toxic substances or undesirable odors or flavors. They should be no absorbent, corrosion-resistant and strong enough to withstand repeated cleaning and disinfection operation Surfaces should be smooth and free of cavities and cracks. Some suitable materials are stainless steel ar synthetic rubber. It is best to avoid use of wood and other materials that are difficult to clean and disinfec unless it can be determined that they will not be a source of contamination. Utilize corrosion resistant meta for food contact surfaces.

Equipment and utensils are a potential source of contamination transfer and should not be use indiscriminately for raw and cooked foods. All equipment and utensils used for raw foods should b 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 are should not be authorized. Equipment leaving the product assembly area should be cleaned and disinfecte 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 treatment. If reusable trays are used, equipment needed to clean and sanitize them should be located on the same side as the HR of the processing operation.

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.

For HR areas:

Equipment and utensils for handling thermally processed products should be cleaned and disinfected at regular intervals. These cleaned and sanitized utensils and equipment should not pass through a zone where they may be cross contaminated unless they are protectively covered.

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 maintained in good working order 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 reliable temperature-monitoring and recording system that is easy to read and is calibrated regularly. The temperature sensor should be so located to measure the temperature of the refrigerated compartment. This system should be suitably located -- gauges 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 of Appendix I of the General Principles of Food Hygiene (CAC/VOL. A - Ed. 1) and to those of this code.

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

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

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

For HR areas:

- Equipment and utensils for handling products after heat treatment should be cleaned and sanitized a 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 o 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 monitoring by sampling for bacteria is strongly 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.

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 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 preparation and thermal treatment of prepared refrigerated foods, waste matter should be placed in receptacles specially designed 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 surroundi 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. The measures, including treatment with chemical, physical or biological agents, should not be implemented witho direct supervision of a staff member who is completely aware of the dangers inherent in such treatmer including possible risks from product residue. These measures should be carried out only on t recommendation of the authority concerned.

5.7.3 Pesticides should not be used unless other precautionary measures cannot be used effectively. Befo using pesticides, it is advisable to protect all food, equipment and utensils from possible contamination. Aft their use, contaminated equipment and utensils should be thoroughly cleaned 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. The should be stored in locked rooms or cupboards that are kept exclusively for this purpose. They should b distributed and handled only by authorized and duly-trained personnel. Every precaution should be taken t 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.

To this end, 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 are familiar with the precautions to be taken to avoid contamination of food.

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.

All employees should be sensitized to their responsibilities for the quality and safety of the food products produced.

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 affection 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 hou This includes wearing hair nets and beard covers, and footwear should be of construction to not contribu to poor hygiene, washable or disposable after use and should be kept as clean as is required by the nature the employee's job.

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

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

For HR areas:

Personnel working in HR areas should enter through an air-lock and should change into work uniforms in specific cloakroom. They should wear protective clothing and footwear specific to the area. These clothe should not be removed from this area and should be taken off in the cloakroom before personnel leave th production line for any reason, such as going to toilets, canteen, etc. Clothing should be changed at the en of the work day, shift or more frequently if needed, and footwear 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 should 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.

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 and/or preparation should not be accepted by the establishment.

7.1.2 Specifications for raw materials and packaging materials

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 organoleptic, physical, chemical, parasitological and microbiological characteristics of delivered goods.

Raw materials should be purchased from suppliers who observe good manufacturing practices. Manufacturers should ensure, by means of audits, for example, that suppliers have put in place a program to ensure the safety of their products.

Specifications should be determined in the product design phase (Section VIII), taking into account the intended use.

Packaging materials should be suitable for the kind of product, the conditions provided for storage and the equipment for filling, sealing and packaging.

7.1.3 Controls at receiving

Raw materials or ingredients should be inspected, sorted and if needed subjected to laboratory examinati before being introduced on the processing line. These examinations may include:

- temperature measurement;
- visual checks, in particular for foreign materials;
- organoleptic checks: odor, visual appearance, and eventually, taste;
- microbiological checks: their frequency to be determined during the hazard analysis as pa of a HACCP program.

Control measures should refer to national regulatory laws or to standards or to international recommendatio or to methods established in agreement with the supplier.

When goods are received, temperatures of raw materials and perishable ingredients, as well as temperature inside the delivery vehicle, should be measured to ensure that they are within the limits specified in th specifications manual.

Cleanliness of the vehicle should also be checked.

Periodic verifications of temperature during transit should be made to ensure that they are within the limit specified in the specifications manual.

If the required temperature limits have been exceeded when goods are delivered, a trained person should decide whether the raw materials should be used for manufacture, stored for a limited period, returned to supplier, used in another way or thrown out. Unacceptable raw materials and ingredients should be stored separately from raw materials and ingredients used for manufacture of prepared foods. Discarded raw materials should be clearly marked so as to identify them as unusable for manufacture of products.

As a result of the risk analysis microbiological quality of packaging materials and of materials from which containers are made should be checked. It may also be necessary to verify, with visual checks and physical testing, their properties as a barrier (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 as quickly as possible after delivery in a suitable area.

Raw materials should be stored so that any cross-contamination with 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 failure.

7.1.4.2 All packaging material 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 and should not pass through or remain in processing areas while they are being used.

7.1.5 Storage temperatures

Raw materials should be stored at temperatures appropriate for the product. Temperatures should be checked at least once a day and the records retained.

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 kept well away from in process goods.

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 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 on the outside of the packaging.

7.2.4 If there is a possibility of contamination, personnel should wash and disinfect hands scrupulously 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.

7.4.2 All steps in production, including packaging, should be accomplished without delays and in conditions such that any possibility of contamination, deterioration or development of microbes is prevented. In all steps

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

If there are delays in manufacture, raw materials and in-process products should quickly be placed 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 place If this is not possible, these operations should be carried out at different times, with cleaning and disinfecti being done between operations.

The preparation area for raw materials should be designed so that they can be hygienically handled.

Before use, raw materials may be decontaminated.

7.4.4 Thawing (total or partial)

When total or partial thawing is necessary apart from thermal treatment (meat products, etc.), it can be don following one of the four following methods, as long as authorization is received from the authorit concerned:

- in a refrigerated room where the temperature is lower than 4°C;
- in running, potable, non-recyclable water, kept at a maximum temperature of 15°C;
- in a microwave oven;
- in a cabinet designed especially for thawing.

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 thaw drip from the product during thawing.

After thawing, raw materials should immediately be processed or refrigerated until they are used -- temperature of 4°C should be attained. 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 perfectly clean.

7.4.5 Heat treatment

Heat treatments result in the reduction of microbial population: to quantify this, "pasteurization values" are used.

The selection of heat treatment(s) depends on the pasteurization values needed for product safety and shelf life. These values should take into consideration all factors used. The determination of the appropriate target organism of the pasteurization value and how the pasteurization value is delivered should be made by personnel specially trained in this area.

To determine pasteurization values, refer to Appendix I.

7.4.5.1 Process schedule

Each time a new product is developed, it is necessary to define a process schedule for heat treatment in terms of both time and temperature in order to obtain the pasteurizing value desired, calculated for the coldest point of the product during treatment, which should allow the hygienic qualities of the product to be maintained for its use (expiry date, storage temperature, etc.)

7.4.5.2 Heat treatment application

The heat treatment should be carried out by competent, specially trained staff. The scheduled heat treatment should be ensured:

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

Any container which contains products should be marked with a heat-sensitive indicator, or other effective means, to indicate whether the products have already been heat-treated. Indicators already used should be removed from containers before these containers are reused.

7.4.5.3 Monitoring heat treatment

It is advisable to check that the heat treatment applied conforms to the scheduled process and allows the desired pasteurization value, at least, to be reached.

The heat treatment area should be equipped with an accurate, clearly visible clock, or any other suitable device. Process time periods should be read from this clock, not from personal watches. If more than one clock is used, they should be synchronized.

Thermal treatment equipment should be equipped with devices for monitoring and recording temperature and time.

The critical factors which were taken into consideration during the development of the process (cf. 8.3.2) 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.

7.4.6 Cooling

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 microbial proliferation. This means bringing the temperature at the centre of the product to under 10°C in less than two hours if possible.

The cooling should be carried out so that the centre of the product reaches 4°C in less than 6 hours. 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 power, etc.) should be adapted to the quantities of products produced in order to allow for:

- refrigeration without delay, as soon as the internal temperature reaches 60°C after the he treatment; and

- an even temperature distribution in the batch when it is cooled.

This equipment should be provided with a system for checking and recording the temperature in the coolir area or at the centre of the product as well as a reliable system, an alarm, for example, to signal any loss control. There should be specified procedures for action to be taken in case of loss of control. Records shou 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, permi continuous recording of temperature and thus results in better control of the microbiological quality of th food and the smooth running of the processing process. The factors which were taken into consideratio during the development of the cooling procedure (c.f. 8.3.3) should be measured, checked and recorded a regular intervals.

7.5 Packaging

7.5.1 There may possibly be a need to provide a method for decontaminating containers before use especially if there is no heat treatment 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 left to dry completely before being refilled.

7.5.2 If filling and sealing is not done before the thermal treatment, it should be done except for technical constraints (slicing, assembly, etc.) as soon as possible after heat treatment and before chilling, so as to limit risk of contamination and development of microbial flora.

If filling and sealing is done after chilling, 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 and it may be necessary to check the hermetic seal of the packaging. It might be recommended that rooms or equipment be supplied with air, the quality of which is controlled.

7.5.3 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:

- "durable life" date;

- type of food;

- identify 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 official authorities, for example, the list of ingredients.

7.7 Storage, Transport, Distribution and Use of Final Product

7.7.1 General

In order to guarantee 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 respected during successive stages of transport, storage, distribution and sale.

In the course of these successive stages, there should be good 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 the cold chain:

- 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 some of the 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. 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

Putting the products out for sale is a particularly sensitive point.

Products should not be stacked higher than the maximum level indicated in display cases or in front of a ducts; there should be good circulation of cold air. Products that have reached expiry date, are spoiled or hav damaged packaging should be removed from the display case.

In case of breakdown of display case, the products should be moved to another case or to a cold room. If th breakdown takes place at night, temperature of the products should be checked. If it is acceptable, th products should be moved to a suitable area; if not, they should be removed from the case and destroyed necessary.

7.7.4 Use of product

Refrigerated prepared 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 (ALINORM 93/13, Appendix III).

SECTION VIII - HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

Risk analysis takes place in the context of design and development of products.

Product design should comprise the following steps:

- definition of requirements the product should meet. These requirements have to do with the product's performance (safety and nutritional requirements, durable-life date, use, packaging, labeling, weight, etc.) and sensory characteristics (recipe, smell, taste, etc.), the standards and regulations with which it should comply, its packaging, the controls to which it should be submitted (characteristics to be checked, criteria for acceptability);
- risk analysis and application of HACCP principles (Supplement 1, Volume 1 Codex Alimentarius, 2nd Ed.);
- creation of a prototype;
- verification of the prototype with respect to the previously defined requirements;
- industrial feasibility study;
- industrial trial processing.

8.1 General

In each production unit, it is necessary to define the particular procedures that allow optimal hygienic quality to be ensured, with consideration given to operations specific to the plant -- raw materials, environment, processing techniques, organization of labour, etc.

The process recommended for developing these procedures is part of risk analysis.

Specific risks -- 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 to control them, should be identified. Following this, 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 functioning effectively.

It is recommended that simple, quick methods be used to control operations and that they be implemented by qualified persons.

The responsibility for all measures planned to ensure optimum hygienic quality of the product should be the responsibility of a single qualified person. This person should be a permanent employee of the establishment who does not work in production.

8.2 Application of the HACCP Principles

The processor should carry out a study following the HACCP principles as described in Supplement 1, Volume 1 Codex Alimentarius, 2nd Ed., prior to any new product design or development.

8.3 Development of Product and Process

8.3.1 Design of product

The following product characteristics should be studied: existence of sensitive ingredients, physical and chemical properties, shelf life, treatments applied, packaging, distribution and sale, control of cold temperature throughout shelf life, use by the consumer.

When products are designed, a microbiological, chemical and physical risk analysis should be conducted by a competent person or organization, with particular attention being given to:

- finding the risks related to incoming materials;
- identifying those that are linked to all the operations of processing, distribution, up to consumption of the final product;
- determining procedures required to control risk;
- verifying effectiveness of these control procedures, in particular by checking a limited number of samples, with the knowledge that it is essential to carry out controls all through the processing chain, not only on the final product;

This study also serves to determine the shelf life of products, taking into account:

- heat treatment applied to product;
- type of packaging (hermetically sealed or not);
- storage temperature;
- sufficient margin for safety.

Challenge studies [1] or other scientific evidence should be carried out to validate the shelf-life of the product. Studies concerning use in product formulation of factors that inhibit or minimize multiplication of pathogens, and the synergy of these factors, should be conducted.

8.3.2 Development of heat treatment

Process development should take into account if necessary:

- composition of the product, including amounts and types of preservatives, pH, acidity, a_w;
- composition (solid to liquid ratio) and consistency affecting rate of heat penetration;
- type of product and/or container that can lead to stratification of product in the packaging or to a change in dimensions of packaging. To control this factor, packaging should be arranged in a specific way in the heat treatment equipment;
- size of packaging, type of material, weight of individual portion and maximum weight for filling;
- minimum vacuum pressure to ensure packages are sealed;
- composition of modified atmosphere;
- microbial flora and maximum number of microbes expected in raw materials;
- initial temperature of product before heat treatment begins;
- amount of heat required to bring the product being considered to the desired level of safety;
- product transport, distribution and retail system conditions.

These factors should permit identification of the microorganisms to be eliminated and the final level to be attained. It should at least destroy the vegetative cells of pathogenic bacteria.

The thermal process 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 the procedure is being developed, a program for periodic verification of the adequacy of the thermal process should be determined and planned.

When changes in the composition, processing and use of the product are carried out, the necessary changes should be established and verified by a qualified person.

8.3.3. Development of cooling method

Development of the cooling method should take into account the following:

- cooling rate of product;
- product/packaged product dimensional control;
- separation of product/package product to be cooled;

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[1] Reference to the UK Chipping Campden document.

- temperature and adequate circulation of the cooling media;
- temperature of product before cooling begins;
- timing of cooling especially for products/packaged product conveyed through chilling equipment.

8.3.4 Records maintenance

The files and records relevant to the establishment of the shelf life of the product, those establishing the process controls to maintain the microbiological safety of the product, specifically the files and calculations leading to the establishment of the thermal treatment and any modifications to the product formulation should be placed on permanent records.

8.4 Establishing Monitoring and Verification Methods

When the risk analysis is carried out during the design of the product, a number of critical control points were determined. For each critical control point, monitoring and verification procedures and corrective actikons should be established and implemented.

For monitoring and verification purposes, it will be necessary to define and implement sampling plans and evaluation methods in support of monitoring and verification procedures once the acceptance and analytical methods have been defined.

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 durable shelf life.

Documents that should be kept are for example:

- for the raw materials: suppliers' certificates of conformity of ingredients with the processor's specifications, records of processor's audits, records of temperature at delivery and during storage of ingredients with a limited shelf life;
- for processing: records of all critical points monitored, records verifying that the process continues to conform adequately to specifications;
- for packaging: records indicating conformity of packaging materials with the processor's specifications, results of the processor's audit on suppliers' premises;
- for storage and distribution: records indicating suitable storage;
- for the equipment used to control critical control points: maintenance reports;
- for deliveries: initial delivery records for each lot.

APPENDIX 1: PASTEURIZING VALUES

The processor needs to know the effect of the heat treatment on the microbiological safety of his product during its shelf life. It is necessary therefore to know the thermal treatment used and the level of destruction of vegetative forms of micro organisms required. Pasteruizing values are used to carry this out.

A.1 - Definition:

The pasteurizing value is the length of time at a given temperature to obtain a specified level of destruction of a microorganism whose thermal resistance characteristics are known.

The thermal 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 microbial 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).

To obtain the desired level of reduction, it is necessary to know:

- the maximum acceptable level of microorganisms in the final product;
- the potential initial population;
- and the possible rate of proliferation of the microorganisms during the shelf life of the product.

A.2 - Reference microorganisms:

The reference microorganism chosen to calculate the pasteurizing value is related to the shelf life of the product. For example:

- for products with a short shelf life, the reference microorganism could be *Listeria monocytogenes* ($z=7.5°C$, D_{70} = 0.33 min[1].);
- for products with a long shelf life, the reference microorganism could be *Clostridium botulinum*, type E ($z=7.5$ °C below 90°C and 10°C above 90°C, D_{90} = 1.6 min.[1]);
- for products with a medium shelf life, as there is no non spore forming pathogen with a significant enough thermal resistance, one could use a micro organisms indicative of sanitary conditions such as *Enterococcus faecalis* [2] ($z=10°C$, D_{70} = 2.95 min.).

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1 CFDRA - *Food Pasteurization Treatments* - Technical Manual N° 27, April 1992. A Review - The Heat Resistance of *Listeria monocytogenes*, B.M. Machey & N. Bratchell, letters in Applied Microbiology, 1989, 9, 89-94.

2 Ecart de température (exprimé en degré Celsius) permettant de diviser ou de multiplier ce temps par 10.

CFDRA - *Food Pasteurization Treatments* - Technical Manual N° 27, April 1992. A Review - The Heat Resistance of *Listeria monocytogenes*, B.M. Machey & N. Bratchell, letters in Applied Microbiology, 1989, 9, 89-94.

Formerly named *Streptococcus faecalis*.

A.3 - Rate of destruction (n):

The destruction rate (n) is the number of divisions by 10 (logs) of the population of the reference microorganism after the heat treatment has been applied. It can be calculated by subtracting the log of the final concentration of the reference microorganisms from the log of the original population, known or estimated, as follows:

$n = \log N_0 - \log N_1$

N_0 = initial population
N_1 = final population

The initial and final populations are determined or evaluated by the person carrying out the experiment.

For example, let us look at a case of heavy initial population in which $N_0 = 10^7$ cfu/g and, to ensure sufficient safety, N_1 has been set at a very low value, 10^{-6} cfu/g.

The destruction rate is thus equal to:

$n = \log N_0 - \log N_1 = 7 - (-6) = 13$ log reductions.

A.4 - Method for calculating pasteurizing value:

When a food is heated to a higher temperature, it passes through a series of successively increasing temperatures allowing for the partial destruction of the microbial population. At each temperature increase, the bacterial population present in the food decreases and the importance of this destruction is a function of the heat resistance of the microorganisms and the time they are exposed to each of the temperatures.

A-4.1 Calculation of partial pasteurizing value

The pasteurizing value may be calculated or estimated for the whole thermal treatment.

For each temperature over 50°C, a partial pasteurizing value, PPV, is calculated using the following formula: $PPV = \log^{-1} (T_x - T_r)/z$, where

PPV is equal to the time, expressed in minutes, the food is held at a reference temperature T_r resulting in the same rate of destruction of a given microbial population as a unit of time at temperature T_x actually applied. The value of z is explained below.

These partial pasteurizing values can be obtained more easily by consulting the tables.

In the example given, Table 1 indicates the partial pasteurizing values for 50°C to 80°C, with Enterococcus faecalis as the reference microorganism . It allows us to deduce, for example, that the partial pasteurizing value of one minute of heating at 73°C can result in the same rate of destruction of Enterococcus faecalis as heating at 70°C for 1.995 minutes.

Table 1

PASTEURIZING VALUES

°C	TENTH OF DEGRES									
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
50	0.010	0.010	0.010	0.011	0.011	0.011	0.011	0.012	0.012	0.012
51	0.013	0.013	0.013	0.013	0.014	0.014	0.014	0.015	0.015	0.015
52	0.016	0.016	0.017	0.017	0.017	0.018	0.018	0.019	0.019	0.019
53	0.020	0.020	0.021	0.021	0.022	0.022	0.023	0.023	0.02'	0.025
54	0.025	0.026	0.026	0.027	0.028	0.028	0.029	0.030	0.030	0.031
55	0.032	0.032	0.033	0.034	0.035	0.035	0.036	0.037	0.038	0.039
56	0.040	0.041	0.042	0.043	0.044	0.045	0.046	0.047	0.048	0.049
57	0.050	0.051	0.052	0.054	0.055	0.056	0.058	0.059	0.060	0.063
58	0.063	0.065	0.066	0.068	0.069	0.071	0.072	0.074	0.076	0.078
59	0.079	0.081	0.083	0.085	0.087	0.089	0.091	0.093	0.095	0.098
60	0.100	0.102	0.105	0.107	0.110	0.112	0.115	0.117	0.120	0.123
61	0.126	0.129	0.132	0.135	0.138	0.141	0.145	0.148	0.151	0.155
62	0.158	0.162	0.166	0.170	0.174	0.178	0.182	0.186	0.191	0.195
63	0.200	0.204	0.209	0.214	0.219	0.224	0.229	0.023 4	0.240	0.245
64	0.251	0.257	0.263	0.269	0.275	0.282	0.288	0.295	0.302	0.309
65	0.316	0.324	0.331	0.339	0.347	0.355	0.363	0.371	0.380	0.389
66	0.398	0.407	0.417	0.427	0.436	0.447	0.457	0.468	0.479	0.490
67	0.501	0.513	0.525	0.537	0.549	0.562	0.575	0.589	0.603	0.617
68	0.631	0.646	0.661	0.676	0.692	0.708	0.724	0.741	0.759	0.776
69	0.794	0.813	0.832	0.851	0.871	0.891	0.912	0.933	0.955	0.977
70	1.000	1.023	1.047	1.072	1.096	1.122	1.148	1.175	1.202	1.230
71	1.259	1.288	1.318	1.349	1.380	1.413	1.445	1.479	1.514	1.549
72	1.585	1.622	1.660	1.698	1.738	1.778	1.820	1.862	1.905	1.950
73	1.995	2.042	2.089	2.138	2.188	2.239	2.291	2.344	2.399	2.455
74	2.512	2.570	2.630	2.692	2.754	2.818	2.884	2.951	3.020	3.090
75	3.162	3.236	3.311	3.388	3.467	3.548	3.631	3.715	3.802	3.890
76	3.981	4.074	4.169	4.266	2.365	4.467	4.571	4.667	4.786	4.898
77	5.012	5.129	5.248	5.370	5.495	5.623	5.754	5.888	6.026	6.166
78	6.310	6.457	6.607	6.761	6.918	7.079	7.244	7.413	7.586	7.763
79	7.943	8.128	8.318	8.511	8.710	8.913	9.120	9.333	9.550	9.773

Table 2

Time of Heat Treatment (in minutes)	Product temperature (in °C)	Partial Pasteurizing Value (PPV°	PPV by period of time
10	55	0.032	0.0875
11	59.5	0.089	0.605
12	63	0.200	0.1445
13	64	0.251	0.2255
14	66	0.398	0.3245
15	56	0.040	0.2190
	Total pasteurizing value		1.0615

A.4.2 Calculating total pasteurizing value of a heat treatment

The time/temperature combination for an example of a heat treatment is shown in Figure 1.

An example of the way in which these partial pasteurizing values can be used to calculate the total reduction in a population of reference microorganisms is given in Table 2 for the time/temperature combinations in Figure 1.

Values indicated in the column headed "partial pasteurizing values" are obtained from Table 1 for each given temperature.

Calculation of total pasteurization value is more complicated. To do this, we establish a curve with partial pasteurizing values for each temperature on the y-axis and time on the x-axis. (For Table 2 values, see Figure 2.) The area below the curve thus obtained is determined.

This method has been widely used to determine the sterilizing value in heat treatment of canned foods and is called the "general method" or "graphic method".

Many methods have been used to calculate this area below the curve. A satisfactory method is as follows.

The PPV of Table 2 for the time intervals t_1 to t_6 are represented by P_1 to P_6. The partial pasteurizing value for the interval of 10 to 11 minutes can be calculated using the following formula:

By replacing P_1 and P_2 with the values from Table 1:

VP = 0.0605

This figure represents surface the area of the figure below.

Thus, the pasteurizing value achieved when time went from 10 min. to 11 min. and temperature from 55°C to 59.5°C was 0.0605 min.

This calculation can be repeated for each temperature interval. Values obtained are given in column four of Table 2.

The total pasteurizing value for the treatment shown in Table 2 is obtained by adding all the values found in column 4, which gives us 1.0615. That means the treatment is equivalent to holding the product at a temperature of 70°C for 1.0616 minutes, taking *E. faecalis* as the reference microorganism and when D_{70} = 2.95 min. and Z = 10°C.

A.4.3 Relation between total pasteurizing value and reduction of microbial population

In the preceding example (*E. faecalis*) the value of D at 70°C is 2.95. This means that it requires 2.95 minutes at 70°C to obtain a decimal reduction of this microorganism.

Thus, 1.0615 minutes at the reference temperature of 70°C will lower the initial population by 1.0615/2.95 or 0.360 log. If this population were 10^6, it would be reduced to 6 - 0.360 = 5.640 log or $4.37.10^5$ microorganisms.

A.5 - Measuring

Measurement is taken by inserting a probe into the product to be pasteurized in the slowest heating point; several readings should be taken to locate this point.

It is recommended that equipment used which permits regular measurement and recording of time-temperature combination, and also for direct calculation of the pasteurizing value.

REFERENCE TEXTS

CODEX - *Proposed Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life* (at Step 3 of the Procedure) - *ALINORM* 93/13.

AQIS - *Code of Hygienic Practice for Heat-Treated Refrigerated Foods Packaged for Extended Shelf Life* - AQIS (Australian Quarantine and Inspection Service), Department of Primary Industries and Energy - Australia, 1992. *

CFA - *Guidelines for Good Hygienic Practice in the Manufacture, Distribution and Retail Sale of Chilled Foods* - CFA (Chilled Food Association) - England, 1989. *

CFDRA - *Evaluation of Shelf Life for Chilled Foods* - Technical Manual No. 28, July 1991 (second edition) - England.

CFDRA - *Food Pasteurization Treatments* - Technical Manual No. 27, April 1992 - England.

CFDRA - *The Microbiological Safety of Sous-Vide Processing* -Technical Manual No. 39, October 1992 - England.

Canadian Code of Recommended Manufacturing Practices for Pasteurized/Modified Atmosphere Packaged/Refrigerated Food - Agri-Food Safety Division, Agriculture Canada - Canada, March 1990.

ECFF - *ECGG Guidelines, Draft 6* - Europe, April 1993. *

Food Safety Act 1990, Code of Practice No. 10, Enforcement of the Temperature Control Requirements of Food Hygiene Regulations - MAFF - England.

Guidelines for the preparation and handling of chilled foods -Institute of Food Science and Technology - England, 1989 (Revised 1990).

Guidelines on cook-chill and cook-freeze catering system - HMSO -England, 1989.

Guidelines on the Food Hygiene Regulations - Department of Health - England, 1990.

Guidelines for the Production, Distribution, Retailing and Use of Refrigerated Packaged Foods with Extended Shelf Life - Health and Welfare Canada - Canada, 1992. *

MOBERG (Lloyd) - *Good Manufacturing Practices for Refrigerated Foods* - Journal of Food Protection, 52:5, 363-367 - USA, May 1989. *

National Advising Committee on Microbiological Criteria for Foods -*Recommendations for refrigerated foods containing cooked uncured meat or poultry product that are packaged for 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.

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.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE MANUFACTURE OF UNCURED/UNRIPENED AND RIPENED SOFT CHEESES (At Step 3 of the Procedure)

TABLE OF CONTENTS

SECTION I - SCOPE

The Code of Hygienic Manufacturing Practice applies to uncured/unripened and ripened soft cheese as defined, which for the latter covers cheese ripened from the surface inwards, as well cheese ripened from the inside and smear cheese.
For convenience in the text, the terms "fresh cheese" (for the former) and "soft cheese" (for the latter) are used throughout this document.

This document describes general hygienic and technological manufacturing practices (incorporating production, processing, curing or ripening, packaging, distribution and storage), including the application of the Hazard Analysis Critical Point (HACCP) principles to insure safe and wholesome products.

- The main document contains two categories of requirements and provisions:
  * those with a general nature (HMP)
  * those specifically required for the manufacture of soft and fresh cheese.

- For convenience of the reader the latter item is marked as (**).

- Items, particularly applicable to cheese made from pasteurized milk, will be marked as "See footnote".

- Additional provisions may be required if in the same factory cheese is produced from pasteurized milk as well as from raw milk. Those requirements will be referred to in the annex on raw milk cheese.

- Hygiene requirements of a general nature (HMP) are meant as a basis for incorporating specific elements of the hygienic manufacture in each particular factory.

The HACCP principles and their implementation for the specific manufacturing processes for uncured/unripened cheese and soft ripened cheese are explained in an appendix, together with an example. It should be emphasized that is by way of an example only.
It is emphasized, that, for successful application of the HACCP principles for Good Manufacturing Practice (GMP), a fundamental investigation of every step in the food handling should be undertaken and that the subsequent establishment of critical control points and monitoring procedures be carried out for each establishment.

This Code of Hygienic practice and the microbiological criteria (guidelines) are of an advisory nature.

SECTION II - DEFINITIONS

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

2.1 Uncured/Unripened Cheese

Uncured/unripened cheese are cheeses which comply with the definition in Codex Alimentarius - General Standards for Cheese, Standard A6 (Section 2) and which are ready for consumption (shortly) after manufacture.

2.2 **Ripened Soft Cheese**

Ripened soft cheese are cheeses which comply with the definition in Section 2 of Standard A6, contain a minimum of 67% moisture on a fat free basis and which have been ripened (surface-ripened and/or interior-ripened) prior to sale.

2.3 **Adequate**

Sufficient to accomplish the intended purpose of this Code.

2.4 **Cleaning**

The removal of ingredient and food residues, and soil, dirt, grease or other objectionable matter.

2.5 **Contamination**

The presence of a contaminant in cheese at a level which renders the cheese injurious to health or unfit for human consumption. Such contaminant may be physical, chemical or microbial in nature.

(This formal definition should not be confused with the hygienic meaning)

2.6 **Disinfection**

The reduction, without adversely affecting the food by means of hygienically satisfactory chemical agents and/or physical methods, of the number of micro-organisms to a level that will not lead to contamination of food.

2.7 **Establishment**

Any building(s), area(s) or surroundings in which fresh or soft cheeses are produced, packed or stored.

2.8 **Food Handling**

Any operation in the production, curing or ripening, processing, packaging , storage of food.

2.9 **Pasteurization**

Pasteurization is a heat treatment process applied to a product with the aim of avoiding public health hazards arising from pathogenic microorganisms associated with milk. Pasteurization as a heat treatment process is intended to result in only minimal chemical, physical and organoleptic changes.

Note: Pasteurization is intended to avoid public health hazards in the sense that, although it may not destroy all the pathogenic microorganisms which may be present, it reduces the number of any harmful microorganisms that might be present to a level at which they do not constitute a significant health hazard for the intended keeping and consumer practices. Pasteurization also extends the keeping quality of some products by reducing the number of spoilage microorganisms in the product.

Minimum Temperature/Time Combinations for Pasteurization

Pasteurized milk and skimmed milk	63 °C for 30 min 72 °C for 15 s

Pasteurized cream: 10–20% fat	75 °C for 15 s
> 20% fat	80 °C for 15 s
Pasteurized concentrated milk	80 °C for 25 s

Note: The temperature/time combinations given are typical examples of many combinations of temperature and time having an equivalent and minimum bactericidal effect necessary for pasteurization. The combinations depend on such factors as the nature of the product, solid content, viscosity, etc. Temperature/time tables may be found in the following references: Enright, J.B., W.W. Sadler and R.C. Thomas: Thermal Inactivation of Coxiella burnetii in Milk Pasteurization. Publ. Hlth Service Pub. N° 517, US Supt Doc., Washington, DC, 1957; Enright, J.B.: The Pasteurization of Cream, Chocolate Milk and Ice Cream Mixes containing the Organism of Q Fever, Journal of Milk and Food Technology Vol. 24, N° 11, Nov. 1961.

2.10 End-Product

The food (fresh or soft cheese) which is ripened and/or packaged and ready for sale.

2.11 Pests

Insects, rodents and birds.

SECTION III - HYGIENE REQUIREMENTS IN THE MILK PRODUCTION AREA

Obviously it is an essential prerequisite that the requirements of hygienic handling of the raw milk are met. This subject should be dealt with in a separate code (IDF Recommendations for the hygienic manufacture of milk and milk based products, Chapter 3, draft 1992) and could be incorporated in this draft.

SECTION IV - ESTABLISHMENT: DESIGN & FACILITIES

4.1 Location

Establishments should preferably be located in areas which are free from objectionable odours, smoke, dust or other air borne contaminations and are not subject to flooding.

4.2 Roadways & Yards

Roadways and yards serving the establishment and which are within its boundaries or in its immediate vicinity should have a hard paved surface.

4.3 Buildings & Facilities

4.3.1 Buildings & Facilities should be of sound construction and maintained in good repair. All construction materials should be such that they do not transmit any undesirable substances to food.

4.3.2 Adequate working space should be provided to allow for satisfactory performance of all operations.

4.3.3 The design should be such as to permit easy and adequate cleaning and to facilitate effective supervision of food hygiene.

4.3.4 The buildings & facilities should be designed to prevent the entrance and harbourage of pests and the entry of environmental contaminants such as smoke, dust, etc.

4.3.5 Buildings & facilities should be designed to provide separation, by partition, location or other effective means, between operations in which cross-contamination should be avoided, for example,, raw milk collection and handling premises, starter propagation facilities and curing of the cheese .

4.3.6 Buildings & facilities should be designed to secure hygienic operations by means of a well-considered logical material flow in the process from the arrival of the raw ingredients at the premises to the end-product (fresh and soft cheeses), and should provide for appropriate temperature conditions at each stage of the process and for the end-product(s).

4.3.7 In food handling areas:

- Floors, where appropriate, should be of water-proof, non-absorbent, washable, non-slip and non-toxic materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should slope sufficiently for liquids to drain to trapped outlets.

- Walls, where appropriate, should be of water-proof, non-absorbent, washable and non-toxic materials. Up to a height appropriate for the operation they should be smooth and without crevices, and should be easy to clean and disinfect. Walls should be strengthened where appropriate to avoid damage from handling and indoor transportation of foods, utensils and equipment.

- Ceilings should be constructed of non-toxic, non-absorbent, non-flaking materials which are impervious to liquids and vapours. They should be designed to prevent the accumulation of dust and to minimize condensation and development of undesirable moulds, and be easy to clean.

- Windows and other openings should be so constructed as to avoid accumulation of dirt. Those which open should be fitted with screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.

- Doors should have smooth, non-absorbent surfaces, and, where appropriate, be self-closing and close fitting.

- Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes, should be so situated and constructed as not to cause contamination to ingredients or food. Chutes should be constructed with inspection and cleaning hatches.

Note (**): When there are technological justifications these requirements need not apply to traditional ripening areas, provided that no safety or health risks can result from this.

4.3.8 In food handling areas all overhead structures and fittings should be installed in such a manner as to avoid contamination directly or indirectly of food and ingredients by condensation and drip, and should not hamper cleaning operations. They should be insulated where appropriate and be so designed and finished as to prevent the accumulation of dirt and to minimize condensation, mould development and flaking. They should be easy to clean.

4.3.9 Living quarters, toilets and areas where animals are kept, should be completely separated from and should not open directly on to food handling areas.

4.3.10 Where appropriate, establishments should be so designed that access to food processing areas can be controlled.

4.3.11 The use of material which cannot be adequately cleaned and disinfected, such as wood, should be avoided unless there are convincing technological justifications.

4.4 **Sanitary Facilities**

4.4.1 Water Supply

4.4.1.1 An ample supply of water in compliance with Section 7.4 of this Code under adequate pressure and of suitable temperature should be available with adequate facilities for its storage where necessary and distribution, and with adequate protection against contamination.
The standards of potability should not be less than those contained in WHO "Guidelines for Drinking-Water Quality" (1993).

4.4.1.2 The use of non-potable water should be avoided. When non-potable water is used it should be carried in a system completely separate from the potable water system, identifiable preferably by colour, and with no cross-connection with or back-siphonage into the system carrying potable water (see also Section 7.3.2 of this Code).

It should not be possible to connect lines carrying non-potable water to any equipment or cleaning-disinfection apparatus used in handling food. The facilities for non-potable water should be approved by the official agency having jurisdiction.

4.4.2 Steam

4.4.2.1 An adequate supply of steam, or other heating medium, should be provided to ensure satisfactory operation of all heat treatment equipment during the production of fresh and soft cheese, and also provide the necessary heat for cleaning, disinfection and other operations.

4.4.2.2 Steam used in direct contact with food or food contact surfaces should contain no foreign matter (including volatile boiler water compounds) which may contaminate the food.

4.4.3 Refrigeration (**)

Sufficient refrigeration capacity should be available to chill and maintain raw and pasteurized milk and milk products at a temperature sufficiently low (5 °C or lower) to ensure no adverse effect on the hygienic quality of the product, including minimal proliferation of pathogenic micro-organisms. Condensation from refrigeration equipment should be piped directly to an enclosed drainage system. Adequate refrigeration of cheese curing rooms should be provided.

4.4.4 Air (**)

Both air circulated in the plant and compressed air which comes into contact with food or food contact surfaces should be free from oil, dirt, insects, odours and all other undesirable contamination. Circulation of air in areas which may be contaminated (the cheese ripening area included) should be maintained separately from air circulated in areas in which fresh or soft cheese is produced, cured, processed or packaged. No water must condense in the air pressure lines.

4.4.5 Effluent & Waste Disposal

Establishments should have an efficient effluent and waste disposal system which should at all times be maintained in good order and repair. All effluent lines (including sewer systems) should be large enough to carry peak loads and should be so constructed as to avoid contamination of potable water supplies. Dispersion of droplets during effluent disposal should be avoided. Sewer systems should be constructed so as to avoid reverse air flow into production areas.

4.4.6 Changing Facilities & Toilets

Adequate, suitable and conveniently located changing facilities and toilets should be provided in all establishments. Toilets should be so designed as to ensure hygienic removal of waste matter. These areas should be well lit, ventilated and where appropriate heated. They should not open directly on to food handling areas. Hand washing facilities with warm or hot and cold water, a suitable soap dispenser with suitable hygienic means of drying hands, should be provided adjacent to toilets, and in such a position that the employee must pass them when returning to the processing area. Where hot and cold water are available, mixing taps should be provided. Where paper towels are used, a sufficient number of dispenses and receptacles should be provided near to each washing facility. Taps of a non-hand operable type are desirable. Notices should be posted directing personnel to wash hands after using the toilet.

Changing facilities and toilets for personnel employed on tasks presenting a risk of cross-contamination (for example, maintenance personnel, visitors, those handling raw milk and other raw materials) should be located separately from similar facilities for staff employed in processing areas. Drainage from hand washing facilities should be piped directly to an enclosed drainage system.

4.4.7 Hand Washing Facilities in Processing Areas

Adequate and conveniently located facilities for hand washing and drying should be provided wherever the process demands. Where appropriate, facilities for hand disinfection should only be provided when risks of cross-contamination by direct hand contact are at stake. Warm or hot and cold water and a suitable hand-cleaning preparation should be provided. Where hot and cold water are available, mixing taps should be provided. There should be suitable hygienic means of drying hands. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps of non-hand operable type are desirable. The facilities should be furnished with properly tapped waste pipes leading to drains.

Drainage from hand washing should be piped directly to an enclosed drainage system.

4.4.8 Disinfection Facilities

Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. The facilities should be constructed of corrosion-resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying warm and cold water in sufficient quantities.

In those areas in which food is handled, such as curing rooms and packaging rooms, disinfectant solutions should be provided for the hands and other food contact surfaces.

4.4.9 Lighting

Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colours and the intensity should not be less than:

540 lux (50 foot candles) at all inspection points
220 lux (20 foot candles) in work rooms
110 lux (10 foot candles) in other areas

Light bulbs and fixtures suspended over food ingredients in any stage of production should be of a safety type and protected to prevent contamination of food in case of breakage.

4.4.10 Ventilation

Adequate ventilation should be provided to prevent excessive heat or cold and to remove steam, condensation or contaminated air. The air flow direction should be from areas in which food is produced or packaged to utility areas or areas in which raw milk or ingredients are received. Ventilation openings should be screened or have other enclosure devices made of non corrodible material. Screens and louvers should be easily removable for cleaning.

4.4.11 Facilities for Storage and Disposal of Waste and Inedible Material

Facilities should be provided for the storage of waste and inedible material to avoid contamination by pests of food, potable water, equipment, building or roadways. Containers used for waste or inedible materials should be used exclusively for that purpose and should be clearly marked or colour coded.

4.5 Equipment and Utensils

4.5.1 Materials

All equipment and utensils used in food handling areas and which may contact food should be made of material not containing toxic substances, odour or taste components that could migrate into the food, is non-absorbent, is resistant to corrosion and is capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices. The use of wood and other materials which can not be adequately cleaned and disinfected should be avoided unless there are convincing technological justifications. The use of different materials in such a way that contact corrosion can occur should be avoided. Utensils, materials or any mobile equipment should not be used in other than the intended sectors of the production plant, owing to risks of cross-contamination.

4.5.2 Sanitary Design, Construction & Installation

4.5.2.1 All equipment and utensils should be so designed and constructed as to prevent hygienic hazards and permit easy and thorough cleaning and disinfection and, where practicable, be visible for inspection. Stationary equipment should be installed in such a manner as to permit easy access and thorough cleaning.

Dead ends of pipework should be avoided by adequate knowledge and forethought during designing of installations.

4.5.2.2 Containers for inedible materials and waste should be leak proof, constructed of metal or other suitable impervious material which should be easy to clean, or disposable and able to be closed securely. Containers should be clearly marked or colour coded.

4.5.2.3 (**) The equipment for heat treating or pasteurizing milk & liquid milk products should be provided with thermometer and automatic temperature recorder, holding tube, flow diversion valve or pump "cut out" as well as positive pump or timing device to ensure that the proper time/temperature combination is maintained. Within heat exchangers, pasteurized milk or milk constituents should be at higher pressure than raw products or coolant (see footnote[1]). Another adequate safety system preventing the mixture of pasteurized milk with incompletely heated milk or coolant is allowed.

4.5.2.4 (**) Sensors of the temperature measuring devices should be so positioned as to measure the temperature of the milk or liquid milk products in the holding section of the heating or pasteurizing process (see footnote[1]).

4.5.2.5 (**) Facilities for the convenient withdrawal of samples for the purpose of control of effective pasteurizing or heat-treatment should be provided where necessary (see footnote[2]).

4.5.2.6 All refrigerated spaces including curing rooms should be equipped with temperature measurement or recording devices.

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[1] Footnote: requirements only for fresh and soft cheese made from pasteurized milk.

[2] Footnote: requirements only for fresh and soft cheese made from pasteurized milk.

4.5.3 Thermometers & Recording Devices

4.5.3.1 Thermometers which include glass in their construction should not be used in any application where glass may come into contact with milk or milk products.

4.5.3.2 Thermometers, temperature recorders and similar instruments should be calibrated against a reference instrument upon installation and periodically at specified intervals, to ensure effective operation.

4.5.4 Equipment Identification

Equipment and utensils used for inedible or discarded materials should be clearly marked or color coded. They should not be used for edible food or food ingredients.

SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

5.1.1 The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in good repair and in orderly condition. As far as practicable, rooms should be kept free from steam, vapour and needless water. Storage rooms should be kept dry.

5.1.2 Processing equipment should be regularly inspected for cracks and damage. Needed repair should be made promptly.

5.1.3 Critical and essential maintenance activities should be

5.2 Cleaning & Disinfection

5.2.1 Cleaning & disinfection should meet the requirements of this Code. For further information on cleaning and disinfection procedures see Section 6 of the Recommended International Code of Practice - General Principles & Food Hygiene (ALINORM 95/13, Appendix III).

5.2.2 To prevent contamination of food, all equipment and utensils should be cleaned immediately after use at least once per working day and disinfected whenever circumstances demand.

5.2.3 Metallic cleaning materials such as steel wool should not be used in the cleaning of dairy equipment or utensils.

5.2.4 Equipment and pipelines which are cleaned in place should be rinsed with water. In certain cases the use of warm water in general with a temperature not exceeding 45 °C, may be recommended.

5.2.5 Cleaned equipment and utensils should be disinfected immediately before use, by physical or chemical agents as appropriate to the equipment and the nature of the food, provided that cleaning alone could result to hygiene risks. Where chemical agents are used, the equipment should be drained and then rinsed with water that is in compliance with Section 7.4 of this Code.

5.2.6 Adequate precautions should be taken to prevent food from being contaminated during cleaning or disinfection of rooms, equipment or utensils by water and detergents or by disinfectants and their solutions. Detergents & disinfectants should be suitable for the purpose intended and should be acceptable to the official agency having jurisdiction. Any residues of these agents on a surface which may come in contact with food should be removed by thorough rinsing

with water in compliance with section 7.4 of this Code before the area or equipment is again used for handling foods.

Cleaning with water of high pressure, resulting in the formation of aerosols, should be avoided in processing areas during production.

Note: In some countries those agents are only allowed for use if officially certified.

5.2.7 Floors, including drains, auxiliary structures and walls of food handling areas should be thoroughly cleaned immediately after cessation of work for a day if appropriate. Thorough drying of production areas between production periods might be appropriate.

5.2.8 Changing facilities and toilets should be kept clean at all times.

5.2.9 Roadways and yards in the immediate vicinity of and serving the premises should be kept clean.

5.3 Hygiene Control Programme

A cleaning and disinfection schedule should be drawn up for each establishment to ensure that all areas are appropriately cleaned and that critical areas, equipment and material are designated for special attention. These activities should be carried out according to a scheduled plan and should be recorded.

A single individual who should preferably be a member of the management staff of the establishment and whose duties should be independent of production, should be appointed to be responsible for the cleanliness of the establishment. He/she should have a thorough understanding of the significance of contamination, the hazards involved, and cleaning/sanitizing technology. All cleaning personnel should be well trained in cleaning techniques.

5.4 Storage & Disposal of Waste

Waste material should be handled in such a manner as to avoid contamination of food or potable water. Care should be taken to prevent access to waste by pests. Waste should be removed from the food handling and other working areas as often as necessary and at least daily.

Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste, should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

5.5 Exclusion of Domestic Animals

Animals should be excluded from establishments.

5.6 Pest Control

5.6.1 Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard all food, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

5.6.2 There should be an effective and continuous programme for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation. Records of pest control programmes should be maintained.

5.6.3 Should pests gain entrance to the establishment, eradication should be promptly instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who are skilled in the use of these agents and who have a thorough understanding of the potential hazards to health which may arise from residues retained in the product. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

5.7 Storage of Hazardous Substances

5.7.1 Pesticides or other substances which may represent a hazard to health should be labelled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets, used only for that purpose, dispensed and handled only by authorized and properly skilled personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating food, food additives and ingredients.

5.7.2 Except when necessary for hygienic or processing purposes, no substance which could contaminate food should be used or stored in food handling areas.

5.8 Personal Effects & Clothing

Personal effects & clothing should not be deposited in processing areas. Appropriate storage facilities should be provided.

SECTION VI - PERSONNEL: HYGIENE & HEALTH REQUIREMENTS

6.1 Hygiene Training

Managers of establishments should arrange for adequate and continuing training of every food handler in hygienic handling of food and in personal hygiene so that they understand the precautions necessary to prevent contamination of food. Instruction should include relevant parts of this Code.

6.2 Medical Examination

Persons who come in contact with food in the course of their work should have a

medical examination prior to their employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, either because of epidemiological considerations, the nature of the food prepared in a particular establishment or the medical history of the prospective food handler. Medical examination of a foodhandler should be carried out at other times when clinically or epidemiologically indicated.

6.3 Communicable Disease

The management should take care to ensure that no person, while known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores or with diarrhea, is permitted to work in any food handling area in any capacity in which there is a likelihood of such a person directly or indirectly contaminating food with pathogenic micro-organisms. Any person so affected should immediately report to the management that he/she is ill. Management should seek medical advice concerning the risks posed by employee illness, including when it may be appropriate for a person who has been ill to return to work.

6.4 Injuries

Any person who has a cut or wound should not continue to handle food or food contact surfaces until the injury is completely protected by a waterproof covering which is firmly secured, and which is conspicuous in colour.
Adequate first-aid facilities should be provided for this purpose.

6.5 Washing of Hands

Every person engaged in a food handling area should wash his/her hands frequently and thoroughly **by means of a suitable soap dispenser** under running warm water in compliance with Section 7.4 of this Code while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might carry transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal Cleanliness

Every person engaged in a food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the work in which the person is engaged. They should not be worn outside production areas and should be stored in adequate facilities. Aprons and similar items should not be washed on the floor. **A scheduled plan should be followed for changing the clothings in consistency with the work.**

During periods when food is manipulated by hand, any jewellery should be banned.

6.7 Personal Behaviour

Any behaviour which could result in contamination of food, such as eating, use of tobacco, chewing (e.g. gum, sticks, betel nuts), hair combing, etc. or unhygienic practices such as spitting, should be prohibited in food handling areas.

6.8 Gloves

Gloves, if used in the handling of food, should be maintained in a sound, clean and sanitary condition or be disposable. The wearing of gloves does not exempt the operator from having thoroughly washed hands.

6.9 Visitors and Other Persons with Tasks Not Related to Daily Production

Precautions should be taken to prevent visitors to food handling areas and to personnel with tasks not related to daily production (maintenance engineers, craftsmen, electricians, etc.) from contaminating food. They (precautions) may include the use of protective clothing. Such persons should observe the provisions recommended in Sections 5.8, 6.7 and 6.8 of this Code.

6.10 Supervision

Responsibility for ensuring compliance with all requirements of Sections 5.1 - 6.9 of this Code should be specifically allocated to competent trained supervisory personnel.

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Milk Collection

Milk transporttankers and other means of transporting milk must be cleaned and disinfected at least once a day and each time before changing from transport of other food to milk.

If the same transporttankers are to be used for whey, precautions should be taken to prevent contamination of the raw milk by bacteriophases.
The unloading and cleaning area must be cleaned at least once a day.

7.2 Raw Material Requirements

This subject is extensively covered in the IDF document: Recommendations for the Hygienic Manufacture of Milk and Milk-Based Products.

7.2.1 All milk & milk products used in the manufacture of fresh and soft cheeses should have been produced under hygienic conditions in compliance with the provisions of the official agency having jurisdiction.

7.2.2 No milk should be accepted by an establishment unless it has been derived from healthy animals. Milk from animals which have been treated with antibiotics and other drugs should be excluded for a period adequate to prevent contamination of the milk.

7.2.3 Incoming milk, milk products and other ingredients should be inspected upon arrival to ensure that they are in good condition and suitable for use. Ingredient containers should be clearly labelled including batch code numbers.

7.2.4 Where necessary, representative samples should be taken and tested prior to use. Adequate laboratory test records should be maintained.

7.2.5 Raw milk & milk products, and other ingredients stored on the premises of the establishment should be maintained under conditions that will prevent spoilage, protect against contamination and minimize damage. Stocks of ingredients should be used in compliance with "first in first out".

7.3 Prevention of Cross-Contamination

7.3.1 (**) Pasteurized milk and milk constituents or other ingredients should be kept separate to prevent contamination from contaminants at an early stage in the processing (7.6.4). Effective measures must be taken to prevent direct contact. Particular attention should also be paid to contamination via air circulation (see footnote[1]).

7.3.2 (**) Persons handling raw milk or milk products or semi-processed ingredients capable of contaminating the cheese should not come into contact with any cheese unless and until they discard all protective clothing worn by them and they have changed into clean protective clothing (see footnote[1]).

7.3.3 If there is a likelihood of contamination, hands should be washed thoroughly and sanitized between handling food at different stages of processing.

7.3.4 All equipment which has been in contact with raw milk or milk products or contaminants should be thoroughly cleaned and disinfected before re-use (see footnote[1]).

7.3.5 Packaging materials should be stored separately and handled to prevent contamination.

7.3.6 (**) It is important to have a separate CIP system for raw and pasteurized milk sections.

7.4 Use of Water

7.4.1 Only potable water as defined in the latest edition of "International Standards of Drinking Water" (WHO) should be used in food handling.

7.4.2 Non-potable water may be used with acceptance of the official agency having jurisdiction for steam production, refrigeration, fire control and other similar purposes not connected with food processing. However, non-potable water may, with specific acceptance by the official agency having jurisdiction, be used in certain food handling areas provided this does not constitute a hazard to health.

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[1] Footnote: Requirements only for fresh and soft cheese made from pasteurized milk.

7.4.3 Water recirculated for re-use within an establishment should be treated and maintained in a condition so that no health hazard can result from its use. The treatment process should be kept under constant surveillance. Alternatively, recirculated water which has received no further treatment may be used in conditions where its use would not constitute a health hazard and will not contaminate either the raw milk or milk products or the cheese. Recirculated water should have a separate distribution system which can be readily identified. The acceptance of the official agency having jurisdiction should be required for any treatment process and for the use of recirculated water in any manufacturing process.

7.5 Milk Pasteurization (**)

Relevant back-ground knowledge about pasteurization technology is given in the Monograph on Pasteurized Milk - IDF Bulletin No. 200 (1986), especially in Chapters IX to XI.

7.5.1 Requirements To The Cheese Milk Pasteurizer

7.5.1.1 There must be an up-to-date test report of the cheese milk pasteurizer available, containing at least the following information:

- structure of the pasteurizer;
- presence of recording and safety equipment;
- place of the sensor of the thermometer and the sensors the safety equipment;
- inertia of sensors and recording equipment;
- phosphate limit;
- retention time (holding) and holding efficiency;
- reading accuracy of the recording equipment.

This test report must be drawn up by an expert internal or external authority.

7.5.1.2 The pasteurizer should preferentially have a minimum heat retention time of 10 seconds.

7.5.1.3 The pasteurizer must be equipped with a flow diversion valve (FDV). Once under-pasteurization happened, it is allowed to resume the production without interruption by cleaning provided that the FDV is mounted before the outgoing regenerative and the temperature sensor is mounted in or before the holding section at such a distance from the FDV that the inertia of the sensor and of the FDV cannot result in the passage of unpasteurized milk.
If this FDV is placed after the outgoing regenerative, then the pasteurizer must be cleaned and disinfected in case of underpasteurization.

7.5.1.4 The outgoing regenerative must, with respect to the incoming regenerative, have a positive pressure difference of at least 7 kPa at the place where the pressure difference is the smallest; i.e. between the holding section and the generative section. This can be achieved by placing a product pump before the outgoing regenerative.

In case of too small a pressure difference between the outgoing and incoming regenerative, the FDV must be activated after the outgoing regenerative.

7.5.1.5 The pasteurizer must be equipped with a temperature recorder located at the end of the holding section.

7.5.1.6 If the curding temperature of the cheese milk is controlled by means of milk from the heat retainer, it must occur after the FDV.

7.5.1.7 The FDV's must work in such a way that the milk is phosphatase-negative for all time after the pasteurizer.

7.5.2 Monitoring Of The Pasteurizer

7.5.2.1 The pasteurization temperature must be recorded on charts or with other adequate devices.

7.5.2.2 In the absence of another adequate safety system preventing the mixture of pasteurized milk with incompletely heated milk or coolant, the pressure difference between the outgoing and incoming regenerative must be measured at least once a day.

7.5.2.3 The milk pasteurization temperature must be checked every day on the thermograph with the calibrated mercury-in-glass thermometer or an equivalent measuring instrument.

7.5.2.4 The pasteurized milk must be checked periodically for the absence of phosphatase.

7.5.2.5 When installing new or changing existing equipment, the cheese milk pasteurizer must be inspected by an expert internal or external authority to ensure that it meets the relevant requirements. If no new equipment is installed or existing equipment changed, such an inspection must be carried out at least once every five years. The results must be entered in a test report. This report must contain at least the following information:

- structure of the pasteurizer;
- place of recording and safety equipment;
- place of the sensor of the thermometer and the sensors of the safety equipment;
- inertia of sensors and recording equipment;
- phosphatase limit;
- holding efficiency at the pasteurization temperature;
- reading accuracy of the recording equipment.

7.5.2.6 Documentation is required of:

- temperature recording disks or strips;
- temperature measurements using mercury-in-glass thermometer or an equivalent measuring instrument;
- pressure difference measurements;
- in the absence of another adequate safety system preventing the mixture of pasteurized milk with incompletely heated milk or coolant.

The relevant data must be stored for at least a year for control purposes.

7.6 Processing (**)

7.6.1 Processing should be supervised by technically competent personnel.

7.6.2 All processing steps should be performed without unnecessary delay and under conditions which will minimize microbial proliferation.
When breakdowns or unplanned discontinuities in processing occur which disrupt the normal flow of the cheese, the product implicated should not be released for human consumption unless it is of proven acceptable hygienic quality.

7.6.3 Ripened soft cheese may also be made from unpasteurized milk under conditions specified in the annex [referred to France].

7.6.4 The cheese production area, the starter preparation room and the cheese ripening location must be considered as a restricted area, i.e. access granted only to authorized persons. Authorization should be granted by the management:

- employees working outside the restricted area may not work in the cheese production room in the same work clothes;
- a restricted area must be clearly indicated; relevant documentation must be provided;
- a disinfection footbath and a hand-washing facility must be available at the entrances to the restricted area;
- the place where clothing (and if necessary, footwear) are changed must have adequate storage facilities for this purpose;
- the toilets and changing rooms must be physically separated from the cheese preparation room.

7.6.5 For safeguarding health risk the fermentation process needs to be controlled by monitoring. Appropriate tests should be conducted For this purpose to affirm that the lactic acid fermentation process is normal and that all key product characteristics are within specification. Adequate records should be compiled for each vat or lot which includes times, temperatures, ingredients used, pH or acidity determinations, etc.

7.6.6 Curd residues on the floor may not be returned in the process line. In case of draining trays, careful attention must be paid to control the cleaning performance.

7.6.7 The equipment of the salting room must be constructed in such a way as to facilitate good cleaning. Visual inspection must be conducted easily.

7.6.8 Conveyor tracks to and from the salting room must be as short as possible, their function must be limited to the conveyance to and from salting the cheese. They must be easily accessible and easy to clean.

7.7 Production Room (**)

7.7.1 Pipes in the restricted area for the transport of cold liquids must be insulated in such a way as to prevent condensation, unless adequate measures are taken to prevent contamination through condensation.

7.7.2 It should be avoided that stairs and loading platforms are sources of contaminations to the product and they should be treated in such a way as to prevent cross-contamination.

7.7.3 The starter preparation room should be considered as a restricted area and should be supplied with over pressure filtered air.

7.7.4 The cheese ripening room should be constructed as to minimize aerial recontamination of the cheese from outside and to prevent that air from this room recontaminates the environment in the production area.

7.8 Packaging (**)

7.8.1 All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the food to be packed and for the expected conditions of storage and should not transmit to the product contaminants beyond the limits acceptable to the official agency having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination.

7.8.2 Cheese packaging should be conducted in an area separate from all other plant operations. The air supply to this room should be free of contamination and should be controlled for humidity and temperature controlled.

7.8.3 Unskilled packaging personnel should be instructed and trained in Good Manufacturing Practices. They should wear clean uniforms, gloves, etc. to minimize end-product contamination.

7.8.4 Personnel not involved in food packaging should not be permitted to enter the packaging area.

7.8.5 Lot Identification

Each container should be permanently marked to identify the producing factory and the lot. A lot is a quantity of food produced under essentially identical conditions, all packages of which should bear a lot number that identifies the production during a limited time interval, and usually from a particular "line" or other processing unit.

7.8.6 Processing & Product Records

Permanent, legible and dated records of pertinent processing and production details should be kept concerning each lot. These records should be retained for a period that exceeds of at least 1 year.

7.9 (**) Storage of the End-Product (Fresh & Soft Cheeses)

7.9.1 The end-product should be stored under such conditions as will minimize contamination and/or proliferation of microorganisms and protect against deterioration of the product or damage to the container.

7.9.2 During storage, periodic inspection of the end-product should take place to ensure that only food which is free from contamination is dispatched. The product should be dispatched in the sequence of lot numbers.

7.10 (**) Sampling & Laboratory Control Procedures

7.10.1 The establishment should have access to adequate laboratory facilities to carry out routine testing needed to effect continuous control and monitoring of the production process.

7.10.2 Where appropriate, representative samples of the production should be taken to assess the safety and quality of the ingredients and end-product.

7.10.3 The following should be at least monitored:

(i) Incoming milk & milk products
(ii) Other ingredients
(iii) Packaging materials

(iv) Calibration of instruments, for example, gauges, thermometers, etc.
(v) Processing and manufacturing stages, in particular pasteurization and acid development.
(vi) Cleaning & disinfection in the plant
(vii) End products (fresh & soft cheeses)
(viii) Water quality
(ix) Air quality
(x) Steam quality
(xi) Microbiological monitoring of the environment within and immediately outside the plant.

7.10.4 Laboratory testing procedures and practices should preferably follow recognized or standard methods in order that the results may be readily interpreted. In many cases Codex or AOAC, ISO, IDF methods are available.

7.10.5 The performance of tests for pathogenic micro-organisms at the plant should be avoided unless adequate precautions have been taken to ensure that no contamination of the ingredients or end-product arising from the laboratory is possible.

7.10.6 An adequately trained, experienced individual should be designated as responsible for the proper performance of sampling and testing procedures as well as the interpretation of results. This individual should consistently monitor the testing laboratory programme and should inform management concerning deviations from normal characteristics and the actions that should be taken. The individual should act promptly whenever there is any indication that plant operations or product are not within normal limits or specifications.

7.10.7 The records of the examinations should be kept at each establishment for a period that exceeds the shelf-life of the end-product, but unless a specific need exists they need not be kept for more than 1 year. It would also be appropriate to retain the records of examination relating to the various manufacturing processes. All records should be available for inspection if so required. Means of identifying batches with samples should also be provided.

SECTION VIII - MICROBIOLOGICAL CRITERIA

8.1 Scope

This code of practice describes general hygienic and product-specific provisions that should be applied, including a quality assurance programme, to ensure the wholesomeness of the products.

It is accepted that the confidence of microbiological testing for pathogenic bacteria based on the examination of a realistic number of sample units is very low and by consequence not productive and hardly reliable.

Moreover it is recognized that the key that provides the degree of assurance expected by the consumer for safe food, is the proper control of the microbiological hazards in the operations of the food manufacture. The strategy that is being increasingly accepted to achieve this goal, is the HACCP procedure, a preventive quality assurance system which is based on the prevention of hazards by design of requirements for specific process-operation. The sequential steps in applying HACCP are considered in the appendix to this code.
One of the steps is the specification of criteria for monitoring the Critical Control Points (CCP's) which were identified before, in order to check that an operation is under control.

Although criteria of a physical nature will preferably be applied, microbiological criteria may be useful. "Coliforms" is an example of the former for monitoring the CCP's for the hazards of recontamination. Those criteria, applied for monitoring, are defined as "Guidelines" in accordance with the "General Principles for the Establishment and Applications of Microbiological Criteria for Foods", Codex Procedure Manual 8th Ed.

Because the specification of criteria for control requirements of the unique CCP's are of concern to particular operations, tolerance levels of guidelines can hardly be defined for the applications as intended within the scope of this code.
They should be restricted to the end products at the end of production or ripening.

8.2. Microbiological Guidelines

8.2.1 Specifications

The tolerance levels of microbiological guidelines, given in the following table, are intended for monitoring at the end of the **processing included ripening**. They are intended to guide the manufacture and should not be used as a microbiological standard.

When the settled monitoring criteria are surpassed, action should result in intervention in such a way that emerging hazards is sought to be eliminated.

The symbols used in this table are defined as follows:

n = numbers of samples to be tested

c = maximum allowable number of samples in which the concentration of organisms may exceed "m"

m = maximum number of test-organisms that can be exceeded in "c" samples

M = maximum allowable concentration of organisms in any of the "n" samples

GUIDELINES (end-product at the end of production)

Fresh cheese

S. aureus	n = 5	m = 100	M = 1000	c = 2
Coliforms	n = 5	m = 100	M = 1000	c = 2
Yeasts and Moulds	n = 5	m = 100	M = 1000	c = 2

Soft cheese[1]

S. aureus	n = 5	m = 100	M =1000	c = 2
Coliforms	n = 5	m = 100	M =1000	c = 2

8.2.2 Applications

Because fresh and soft cheese have a limited bacteriological shelf life under chilled distribution conditions, it is recommended that criteria should be defined

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[1] Footnote: requirements only for fresh and soft cheese made from pasteurized milk.

at the best before date, for verification purposes as part of the HACCP procedure.

Criteria for Salmonella and Listeria monocytogenes are to be defined for verification at the best before date as end product specification.

The application of guidelines and end product specifications may also be useful for the authorities to check that the hygienic provisions of this code have been met.

Annex I to Appendix V

CODE OF HYGIENIC PRACTICE FOR SOFT CHEESE MADE WITH RAW MILK

SECTION I - SCOPE

This Annex deals with the specific requirements applying to cheese made with raw milk, as defined in Section 2.2 of this Code.

SECTION II - DEFINITIONS

For the purpose of this Code of Hygienic Practice the following definitions shall apply.

1.1 Raw milk

Milk produced by the secretion of the mammary glands of one or more cows, ewes, goats or buffaloes, which has not been heated beyond 40°C.

1.2 Soft cheese made with raw milk

Cheese as defined in section 2.2 of this Code and made exclusively with raw milk as defined in paragraph 1.1 above.

1.3 Herd of bovidae or capridae officially tuberculosis-free: a herd complying with the provisions of article 3.2.3.9 of the International Zoosanitary Code of the International Office of Epizootics.

1.4 Herd of bovidae officially brucellosis-free: a herd complying with the provisions of article 3.2.1.6 of the International Zoosanitary Code of the International Office of Epizootics.

1.5 Herd of bovidae or capridae officially brucellosis-free (Brucella melitensis): a herd complying with the provisions of article 3.3.2.4 of the International Zoosanitary Code of the International Office of Epizootics.

SECTION III - HYGIENE REQUIREMENTS IN THE MILK PRODUCTION AREA

1. Scope[1]

This section lays down specific health and sanitary recommendations for the production of milk destined for the manufacture of cheese as defined in this annex, free from germs causing zoonoses, and the microbiological quality of which is not likely to cause specific risks for the consumer.

2. Requirements applying to the herd

Raw milk should originate from animals:

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[1] This annex may also apply to cheese made entirely or partly from milk which has been subject to a heat treatment less intense than pasteurization as defined in paragraph 2.9 this Code.

2.1 belonging to a herd subject to regular checks by the authority having jurisdiction to ensure that:

- the holder or owner of the herd keeps a permanent record of the animals in which all individual sanitary information is recorded, besides specific information pertaining to each animal;

- each animal is identified so as to locate it individually in its herd of origin and registered so as to trace it back to its herd of origin in any place and under any circumstances, in accordance with official regulations;

2.2 belonging:

- for cows and buffaloes, to a herd which is officially tuberculosis-free and brucellosis-free;

- for goats, to a holding which is officially tuberculosis-free and brucellosis-free;

- for sheep, to a holding which is brucellosis-free;

2.3 which do not show any symptoms of diseases communicable to human beings through milk.

2.4 Presenting no visible alteration of the general state of health and free from genitals diseases with running, diarrhoeic syndrome with fewer or inflammatory alteration of the udder, teat and/or milk.

2.5 Presenting no sore on the udder and/or teat likely to affect the milk.

2.6 Which have not been treated with hazardous substances or substances which might be hazardous to human health and might be communicated to the milk. If this should be the case, observance of the required delay should be ensured so that the maximum limit for residues of these substances is complied with.

3 SECTION IV - HYGIENE REQUIREMENTS IN THE HOLDING

3.1 Potable water

The holding should be supplied with cold and hot potable water, under pressure, and in a quantity sufficient to carry out the operations of milking, cleaning and maintenance of milking and cooling equipment.

3.2 Buildings

3.2.1 Buildings where animals are kept should be designed and maintained so as to ensure the health, welfare and cleanness of the animals. Each animal should be

provided with adequate space. The buildings should be well aired so as to avoid any condensation and preserve the quality of the surrounding air.

Cattle-sheds should be kept dry and clean, especially through renewing of litters if they are used, and through appropriate removal of excreta.

3.2.2 The buildings where animals are milked should be designed so as to be easy to clean and maintain in good order:

- washable floors and ceilings;
- effluent disposal;
- separation of all sources of contamination (cattle-dung, toilets, ...).

They should be kept clean at all times.

Equipment and utensils used for milking should be easy to wash, clean and disinfect, and kept clean.

If milking is carried out with a movable system under an open shed, the facilities should be kept clean and in good order.

Availability of potable water is mandatory.

Any accumulation of excreta and waste under the eaves and in the vicinity of the establishment should be avoided.

3.2.3 Facilities for milk storage

Milk should be cooled at 4°C immediately after milking if it is not used immediately. A higher temperature may be allowed when specific technologies are used, and when the shelf-life is short.

Milk should be stored in a closed area separated from the areas where animals are kept, reserved for the cooling of milk, and for cleaning and storage of milk equipment.

This areas should be kept clean and in good order:

- washable floors and walls;
- effluent disposal system.

Animals of all species should be kept away from this area.

A water supply should be provided outside for the cleaning of boots before entering the premises.

3.2.4 Access to the cattle-sheds and adjacent buildings should be free from accumulation of cattle- or swine-dung, mud or any other unclean or ill-smelling substances.

As a rule the vicinity of the establishment should be kept clean.

3.2.5 Measures for the control of insects, rodents, birds should be taken in all cattle-sheds and adjacent buildings.

All precautions should be taken to avoid contamination of milk by the agents used for treatment.

3.2.6 Different species should be kept separate in the holding as far as possible.

3.3 Feeding - Watering

Animals should not be fed with feed likely to make the milk toxic for human beings, or to modify its properties or its composition.

Feed should be well preserved and should especially be free from unusual fermentation.

All precautions should be taken to avoid that feed should carry microorganisms which are pathogen for human beings or animals.

Watering and feeding troughs, feeding areas should be cleaned regularly and cleared of waste. Feed should be protected from contamination by excreta, rain water or running water, and protected against insects, rodents, birds, etc..

Watering troughs should be located and designed to prevent contamination and kept clean.

Pastures and grazing-grounds should be safe, and should not be soiled by effluent of cattle or swine-manure or contaminated by infected animals. When cattle or swine-manure is spread on the grass, a delay of at least four weeks should be observed before grazing is resumed.

Where appropriate, ensilage should be prepared and kept with particular care and under strict control, especially through pH measurement and the use of preservatives.

4 SECTION V - MILKING HYGIENE REQUIREMENTS

4.1 Milking of healthy animals

Animals showing clinical symptoms of diseases communicable to human beings through milk (see par. 2.2, 2.3, 2.4) should be milked last, or with a separate milking equipment, or by hand until the last drop, and the milk should not be used.

4.2 Milking clean animals

Animals intended for milking should have clean udders and teats, as well as the area of the groin, the thigh and the abdomen.

4.3 Operations likely to affect the quality or hygiene of milking.

Any operation which might cause damage with regard to milking should be avoided during the preceding hour.

4.4 Checking and maintenance of milking equipment

Mechanical milking equipment, when it is used, should be checked every year by competent services; repairs or adjustments which have been prescribed should be implemented. Between checks, the equipment should be kept in good order.

4.5 Milking personnel

Milking personnel should wear clean clothes and head covering. They should wash their hands and arms before milking and keep them clean as far as possible throughout the milking. For this purpose, near the place of milking, suitable facilities should be provided to enable persons performing milking or handling milk to wash their hands and arms.

Scratches and cuts should be covered by waterproof dressings.

4.6 Visual inspection of milk

Milking personnel should check the aspect of milk from each teat before milking. If any anomaly should occur, the milk from the concerned animal should not be used.

4.7 Control of udder health

The holder should implement all measures judged necessary by the authority having jurisdiction to ensure adequate prevention of udder infections.

4.8 Hygiene of equipment and utensils

Equipment and utensils used for milking and all their elements thereof should be kept clean and in good order at all times.

4.9 Rinsing of equipment after milking

After cleaning and disinfection, equipment and utensils used for milking, handling, storage and transport of milk should be rinsed with potable water, dried and should remain dry until the next milking operation. Utensils and milking brushes should be stored hygienically.

5 Approval of the establishment producing raw milk

5.1 Official services certify that the state of health and condition of the animals complies with the provisions of point 2, the buildings and their annexes with point 3, and the establishment with point 4, through regular inspection.

5.2 Moreover, approval is given to the holder for the production of raw milk intended for the manufacture of raw milk products in so far as:

- the holder is able to substantiate that his knowledge of hygiene enables him to comply with the provisions in points 2, 3 and 4;
- he is committed to implement the Hazard Analysis Critical Control Point System (HACCP) as mentioned in the annex.

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.2 Raw materials

7.2.1 Milk and milk products used in the manufacture of soft cheese made with raw milk should have been produced under conditions of hygiene complying with the provisions of section III of this annex and their microbiological quality should be such as to comply with microbiological specifications set in point 8.2.

7.2.2 During storage on the farm, cooled milk intended for the manufacture of soft cheese made with raw milk should comply with the following bacteriological and sanitary guidelines, when sampled for analysis:

-	Total microflora	at 30 °C	< 100 000/ml
-	Somatic cells		< 250 000/ml (1)
-	Staphylococcus coagulase +		< 500/ml
-	Escherichia coli		< 100/ml

(1) This provision applies only to cow milk; for milk from other species, it has no significance.

7.2.4 Add 2nd paragraph.

"Lots of milk originating from areas where the most recent analyses have shown an insufficient hygienic quality should not be used for processing until the responsible producer(s) has (have) been identified and withdrawn from the collection list".

7.2.5 Mixed raw milk used for processing should be analyzed to check that its condition will ensure a normal growth of lactic starters and an acidification compatible with the required processing. The records of laboratory tests should be kept for a sufficient time, and at least equivalent to the shelf-life of the cheese.

7.2.6 Raw milk and milk products and other ingredients kept on the premises should be kept in conditions such as to prevent alteration, to protect them from contamination and to reduce damage at the minimum.

The operator or manager of the processing establishment should take all necessary measures to ensure that raw milk is processed in the 36 hours following its reception if the temperature of the milk does not exceed +6°C, or in the 48 hours following its reception if the milk is kept at a temperature of 4°C or below.

7.2.7 The activity of lactic starters used for the ripening and manufacture should be checked, before their use, by a test of acidification.

7.3 Prevention of cross-contamination

7.3.1 The following basic principles should be applied in all circumstances:

1 - Principle of the flow forward: the flow of the product and of the ingredients should move in the same direction, without going backward.

2 - Principle of the absence of crossing: the flow of contaminating materials should not cross the flow of materials which should not be contaminated.

For example, the flux of the following materials should be carefully studied: water, air, effluent. The same principle should be applied to the circulation of personnel.

3 - Principle of partition: adequate partitions should separate areas where the levels of risk are different as regards contamination. When applied to the personnel, this principle means that rooms should be provided between areas to allow a change of clothes.

7.3.2 When a risk of contamination exists, hands should be washed and disinfected carefully between food handling operations at different stages of the process.

7.3.3 All equipment should be scrupulously cleaned and disinfected before being used again.

7.3.4 Packaging materials should be stored and handled so as to prevent contamination.

7.9 Storage and distribution of the end-product

7.9.1 The end-product should be stored and distributed in conditions such as to exclude contamination by microorganisms and/or the multiplication of microorganisms, and to ensure protection against any alteration of the product or the container.

7.9.2 After ripening in the processing unit, cheese should be kept refrigerated during distribution, the temperature not exceeding +6°C. An indication of the shelf-life should appear in the labelling.

SECTION VIII - LABELLING*

SECTION IX - MICROBIOLOGICAL CRITERIA

The following recommendations apply to microbiological criteria:

a) microbiological specifications concerning the end-product so as to ensure that the hygiene requirements of the Code have been followed;

b) microbiological guidelines applying to the production establishment during processing so as to control compliance with hygiene requirements:

(1) Sampling program: see the General Code.
(2) Microbiological levels: see the General Code.

8.1 Guidelines

Listeria monocytogenes: $m = 0$, $n = 5$, $c = 0$ (25 g: resulting of 5 sample units taken in the same sample of the same product in different spots) at the end of the process, and according to a plan of control to be defined.

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* The labelling must clearly show the words 'made with raw milk'.

8.2 Microbiological specifications

a) Bacteria indicating poor hygiene

Staphylococcus aureus/g	$m = 10^3$, $M = 10^4$, $n = 5$, $c = 2$
Escherichia coli/g	$m = 10^4$, $M = 10^5$, $n = 5$, $c = 2$

at the end of the manufacturing process and according to a control plan to be defined.

b) For pathogen bacteria (Listeria monocytogenes and Salmonella), criteria should be defined. Checks should be carried out in the processing unit to ensure that at the end of its shelf-life, the product does not reach the limits set in these criteria, as the operator should monitor keeping conditions.

Annexes: Application of the Hazard Analysis Critical Control Point (HACCP) to the production of soft cheese made with raw milk.

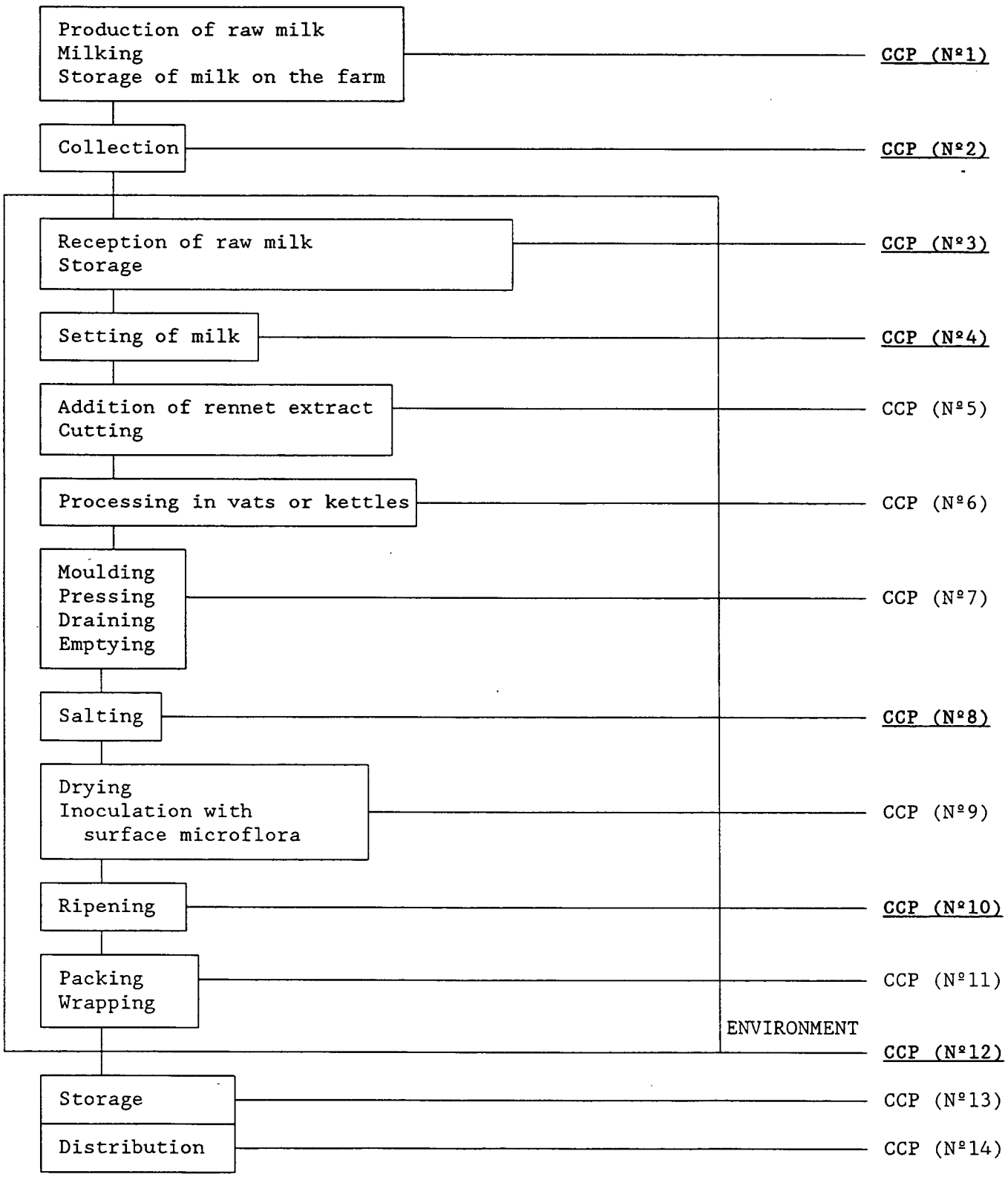
1. Production diagram (cf. table).

2. HACCP checklist specific to soft cheese made with raw milk.

ANNEX: Application of the HACCP system to the production of soft cheese made with raw milk

Note: All the critical control points (CCP) are common to soft cheese in general. Only CCP 1, 2, 3, 4, 8, 10 and 12 of particular importance in the production of cheese made with raw milk, are detailed in this annex.

PRODUCTION DIAGRAM



HACCP CHECKLIST

STEP	HAZARD	PREVENTION	CCP	TARGET LEVELS	MONITORING	CORRECTIVE ACTION
Production of raw milk Milking	Contamination by: - pathogen microorganisms	• Health and hygiene of herd • Hygiene of the holding • Hygiene of milking • Feeding-watering of herd	Nº1 cf C C P N O T E 1	Milk for processing/ml: • MAF < 10^5 • S. aureus < 500 • E. coli < 100 • Leucocytes < $2,5.10^5$ • pH of ensilage	• Sanitary control, monitoring by competent authorities (Brucellosis) and approved laboratories • Microbiological analysis of water • Sampling of milk to ensure compliance with target levels • Approval of holdings fit for milk production • Keeping of records in each holding	• Isolation of sick animals y treatment • Possible slaughtering • Revision of sanitary practices • Revision of hygiene practices • Revision of milking practices
	Presence of inhibitors and residues	• Sampling plan • Observance of delays for the use of veterinary drugs • Elimination of residues of agents used to clean the equipment		Absence of inhibitors and residues	• Plan for monitoring contaminants (feeding, environment, etc.) • Monitoring inhibitors and residues	• Sorting of milk, non-use or rejection
Storage of milk on the farm	Proliferation of microorganisms	• Keeping constant temperature		t < +4°C	• Temperature measurement	• Sorting • Checking of cooling equipment

STEP	HAZARD	PREVENTION	CCP	TARGET LEVELS	MONITORING	CORRECTIVE ACTION
Collection	Contamination spoilage	• Identification of milk • Training of driver • Adequate frequency of collection • Hygiene and adaptation of equipment	Nº2	t < 10°C during transportation	• Labelling • Collection Records • Records of cleaning • Monitoring cleaning techniques	• Review of collection, maintenance and cleaning practices • Use of more adequate equipment
Reception Storage	Contamination Proliferation Spoilage	• External washing of tankers before emptying • Provisions to avoid any contact with milk of another quality • Physical or timing separation • Reduced storage time • Temperature checks	Nº3	CF POINT 7.2.6	Reception documents and records	• Downgrading in case of tank error or inadequate temperature • Review of procedures

STEP	HAZARD	PREVENTION	CCP	TARGET LEVELS	MONITORING	CORRECTIVE ACTION
Setting of milk Rennetting	Proliferation of undesirable microorganisms	• Control of acidification • Checking of the absence of inhibitors • Cleaning procedures	N°4	According to production	• Measurement and recording of the amount of starter added (mass or volume) • Measure of activity of starter (acidification, pH) • Measurement and recording of milk temperature during maturing • Monitoring of cleaning, disinfection and rinsing procedures	• Sorting of milks: rejection of non acceptable milk • Change of starter • Monitoring of process
Salting	• Contamination • Lack of inhibitation of undesirable microorganisms	• Quality of dry salt (physical characteristics, water contents) • Brine: regularly renewed; filtration or other permitted treatment • Level of salting • T°C and time in brine • Cleaning and maintenance of salting equipment • Monitoring plan	N°8	According to production In brine: absence of pathogens. L. monocytogenes: absence in 25 ml	• Measurement of – salt level – humidity and physical characteristics of salt – titre of brine • Measurement and recording of T°C and time in brine • Checking of cleaning efficiency	• Downgrading of cheese towards distribution with a short shelf life (expiry date) or melting • Revision of salting procedures • Control of brine

STEP	HAZARD	PREVENTION	CCP	TARGET LEVELS	MONITORING	CORRECTIVE ACTION
Ripening	• Undesirable microbiological growth • Contamination	• Design of buildings and equipment • Loading of ripening areas • Temperature - Hygrometry • Ripening time • Quality of air • Cleaning and disinfection between all cycles • Hygiene of rubbing and/or of rubbing machines for cheese where the surface is rubbed or requires a specific treatment • Machine cleaning procedures	Nº10	According to production	• Measurement and recording T°C, humidity, ripening time • pH measurement • Microbiological analyses (floors, walls, equipment, personnel, products) • Checking of cleaning procedures • Recording of results	• Analyses and where necessary, downgrading of cheese • Revision of ripening procedures

STEP	HAZARD	PREVENTION	CCP	TARGET LEVELS	MONITORING	CORRECTIVE ACTION
Environment	• Contamination • Proliferation and resistance of undesirable microorganisms	• Limit or forbid access of undesirable micro-organisms • Monitoring of flow: materials, liquids, personnel • Identify then reduce or eliminate contamination risks (assessment of good manufacturing practices, equipment, procedures for cleaning and disinfection)	N°1 2		• Monitoring compliance with requirements and procedures ensuring effectiveness of operations bearing on hygienic quality (e.g. washing machines) • Cleaning on site • Training, inspection assessment of hygiene	• Review and modification of procedures • Training of personnel

CCP note 1: Production of raw milk, Milking, Storage of milk on the farm

a) During the production of milk and milking, the hazard associated with this stage originates in pathogen bacteria in raw milk, especially Mycobacterium tuberculosis, Brucellosis spp., Listeria monocytogenes and Salmonella.

Adequate plans of inspection should be implemented through sanitary monitoring of the herd (tuberculosis, brucellosis) under the control of the agency having jurisdiction (cf Section III).

Raw milk should be checked regularly in each holding through random sampling to ensure that target levels are met:

- for pathogen bacteria (Listeria monocytogenes and Salmonella): criteria to be defined so that the guidelines referred to in 9.2 are met;
- for somatic cells (cf 7.2.2);
- for bacteria indicating hygiene: total microflora at 30°C, S. aureus, E. coli (cf. 7.2.2).

The milk which does not meet these target levels should not be used for the manufacture of cheese made with raw milk. It should be set aside from other milk in order to be either eliminated, or directed towards a heat treatment at least equivalent to pasteurization.

b) During storage of milk on the farm, hazards originate in proliferation of undesirable micro-organisms.

In order to control this hazard, milk temperature should be kept below +4°C, when milk is collected daily; milk temperature should be below +6°C.

This temperature should be measured as often as possible and the results should be recorded.

Deviations should have as a consequence the sorting of milk and the adjustment of the cooling system.

CCP note 2: Collection

The hazard at this stage originates in milk contamination and spoilage. In order to control this hazard, milks should be identified so as to avoid mixing contaminated milk with safe milk, an appropriate frequency of collection should be chosen, hygiene of the equipment and conditions of collection should be checked.

During transportation to processing establishments, milk temperature should not exceed 10°C.

CCP note 3: Reception of raw milk - Storage

The hazard at this stage originates in milk contamination, proliferation and survival of microorganisms.

All precautions should be taken to keep the quality of raw milk, especially by avoiding mixing with milks of a different quality.

On reception of raw milk in the processing establishment, measures mentioned in 7.2.6 should be applied.

CCP note 4: Setting of milk - Rennetting

The hazard originates in proliferation of undesirable microorganisms (pathogen psychrotrophs) due to insufficient acidification.

Cheese processing operations should be carried out by a personnel trained in the science and art of cheese-making so as to achieve a monitoring of the process from the milk storage before processing to the draining of the curd.

Frequent records should be made on processing criteria, especially milk and curd acidification before rennetting, so as to check that lactic fermentation proceeds normally and all characteristics of the product meet the specifications defined according to the type of cheese. Adequate records should be kept for each vat or lot, indicating especially time, temperature, ingredients used, pH or acidity, etc..

CCP note 12: Environment

The hazard related to this stage, concerning the processing plant, originates in contamination and survival of microorganisms.

In order to control this hazard, the following approach could be followed along three main principles:

- reducing or eliminating potential access of undesirable microorganisms from the outside to the processing units;

- managing flows of products, personnel, materials so as to limit the possibilities for cross contamination, having special regard to the principle of the "flow forward" (cf. 7.3);

- identify, then reduce or eliminate risks of contamination in processing units through assessment of hygiene rules, good manufacturing practices, equipment used, procedures for cleaning/disinfection on site, and adjusting them if necessary.

MICROBIAL CRITERIA PROPOSED BY DELEGATIONS DURING THE SESSION FOR FRESH AND SOFT CHEESE *

1. European Community (EC Directive 92/46)

- fresh and soft cheese, made from raw, thermized or pasteurized milk
  - L. monocytogenes Absent in 25 g, n=5, c=0
  - Salmonella Absent in 25 g, n=5, c=0
- fresh cheese
  - made from raw, thermized or pasteurized milk
    - S. aureus m=10, M=100, n=5, c=2
  - made from raw/thermized milk
    - E. coli m=10 000, M=100 000, n=5, c=2
- soft cheese
  - made from pasteurized milk
    - S. aureus m=100, M=1000, n=5, c=2
    - E. coli m=100, M=1000, n=5, c=2
    - coliforms (30°C) m=10 000, M=100 000, n=5, c=2
  - made from raw/thermized milk
    - S. aureus m=1000, M=10 000, n=5, c=2
    - E. coli m=10 000, M=100 000, n=5, c=2

2. Canada

- Standards for cheese from pasteurized milk
  - S. aureus m=100, M=10 000, n=5, c=2
  - E. coli m=100, M=2000, n=5, c=2

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* See para. 62.

3. Switzerland*

	Maximum
- fresh cheese	
- total bacterial flora not belonging to the fermentation organisms	10^6/g
- Enterobacteriaceae	10^3/g
- S. aureus	10^2/g
- moulds	10^3/g
- soft cheese (inclusive rind which is eaten)	
- Enterobacteriaceae	10^6/g (no signs of blowing)
- S. aureus	10^3/g
- fresh and soft cheese	non-pathogenic organisms detectable in 25 g of cheese

* no differentiation between soft cheese from raw or pasteurized milk

4. South Africa

- specifications
  - may not be sold if in 5 samples of cheese exceeds the MPN of 1000 coliform bacteria in 1.0 g

    in 2 of the 5 samples exceeds 5000 coliform bacteria in 1.0 g
  - E. coli should be absent in all samples

REVISION OF THE SECTION ON HYGIENE IN ALL STANDARDS FOR TROPICAL FRESH FRUITS AND VEGETABLES
(Endorsed by the Committee)

8. HYGIENE

8.1 It is recommended that the produce ~~product~~ covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969 Rev. 2-1985), and other Codes of Practice recommended by the Codex Alimentarius Commission which are relevant to this produce ~~product~~.

8.2 To the extent possible in good packaging and handling ~~manufacturing~~ practice, the product shall be free from objectionable matter.

8.3 When tested by appropriate methods of sampling and examination, the produce ~~product~~:

- shall be free from microorganisms in amount which may represent a hazard to health;
- shall be free from parasites which may represent a hazard to health; and
- shall not contain any substance originating from microorganisms in amounts which may represent hazards to health.